Form NRC-374

U. S. NUCLEAR REGULATORY COMMISSION
MATERIALS LICENSE

Amendment No. 01

THIS COPY IS FOR YOUR FILES

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 9 438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 40 and 70, and in reliance o statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee t receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use suc material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorize to receive it in accordance with the regulations of the applicable part(s); and to import such byproduct and sourc material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 195 as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now hereafter in effect and to any conditions specified below.

Licensee	
1. Washington University School of Medicine Radiology Department (Box 8131) 2. 660 South Euclid St. Louis, Missouri 63110	In accordance with letters dated December 28, 1979 and March 16, 1981 3. License number 24-00063-08 is amended in its entirety to read as follows:
	4. Expiration date May 31, 1986
	5. Docket or Reference No. 30-10094

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Teletherapy sealed sources (AECL Model C-146 or C-151 or Neutron Products, Inc. Model NPI-20-6000W)	A. 13,400 curies (2 source of not more than 6,700 curies each)

9. Authorized use

A. One source to be used in an AECL Eldorado 8 teletherapy unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary to the replacement of the source in the teletherapy unit only.

CONDITIONS

10. Licensed material shall be used only at Washington University School of Medicine, Basement Level of the Mallinckrodt Institute of Radiology, 510 South Kingshighway, St. Louis, Missouri.

11. 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."

12. Licensed material shall be used by, or under the supervision of, physicians (as defined in 10 CFR 35.3(b)) who are certified by the American Board of Radiology in Radiology or therapeutic Radiology and who have been approved by the licensee's Radiation Hazards Committee.

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13. The teletherapy facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room, during patient irradiation.

14. A. Teletherapy sources shall be tested for leakage at intervals not to exceed six months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Commission. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the source shall not be used until tested for leakage.

B. The test shall be sufficiently sensitive to detect 0.05 microcurie of contamination on the test sample.

C. The test sample shall be taken from selected accessible surfaces of the teletherapy head. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cones or beam collimating device. The test sample shall be taken with the source in the "off" position.

D. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall promptly take action to prevent spread of contamination and shall file a report within five days of the test with the Materials Branch, Division of Materials and Fuel Cycle Facility Licensing, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, describing the test results and the corrective action taken. A copy of such report shall also be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

15. Prior to initiation of a treatment program, each teletherapy unit shall be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to assure compliance with § 20.105(b) of 10 CFR 20, "Standards for Protection Against Radiation," as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with Condition No. 18.

16. A set of written emergency instructions shall be posted at the teletherapy machine control. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room.

17. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.

B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation off immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.

C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of any door interlock, the teletherapy machine control shall be locked in the "off" condition and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

18. Prior to initiation of a treatment program, and subsequent to each installation of a teletherapy source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(i) The teletherapy source housing, with the teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.

(ii) All areas adjacent to the treatment room, with the teletherapy source in the "on" position. The survey, except Item (c), shall be performed with a phantom in the primary beam of radiation and shall clearly establish:

(a) The radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in § 20.105(b), 10 CFR 20.

(c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

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18. B. Tests shall be made to determine proper operation of:

(i) Electrical interlocks on entrance doors to the teletherapy treatment room.

(ii) The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.

(iii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism).

(iv) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Materials Branch, Division of Materials and Fuel Cycle Facility Licensing, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, not later than thirty (30) days following each installation of a teletherapy source. A copy of such report shall be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

19. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the teletherapy unit that could result in increased radiation levels in areas outside the teletherapy treatment room shall be evaluated by a radiation survey made in accordance with Condition 18., and reported to the Commission within thirty (30) days following completion of the change(s).

B. Relocation of the teletherapy unit to a new facility is not permitted without prior approval of the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 18., and reported to the Commission within thirty (30) days after completion of the move.

20. Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State and a report of the inspection and servicing must be kept on file for review by the Commission's Office of Inspection and Enforcement.

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(continued)

21. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import the uranium contained as shielding material in the teletherapy units authorized by this license.

22. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

    A. Installation, relocation, or removal of teletherapy units containing sources.

    B. Source exchange.

    C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

23. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

    (a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

    (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

    The licensee shall maintain for inspection by the Commission, copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

24. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.

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4. continued

B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.

5. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in letter with enclosures dated December 28, 1979 signed by John Eichling, Ph.D.; letter with enclosures received August 5, 1980 signed by John Eichling, Ph.D.; and letters dated March 16, 1981 and April 1, 1981 signed by Glenn P. Glasgow, Ph.D. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

Date MAY 11 1981

For the U. S. Nuclear Regulatory Commission

by Material Licensing Branch

Division of Fuel Cycle and

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
AT WASHINGTON UNIVERSITY MEDICAL CENTER

DIVISION OF
RADIATION SAFETY

April 2, 1985

James E. Marks, M.D.
Radiation Oncology

Dear Dr. Marks:

You have been authorized to use US Nuclear Regulatory Commission licensed materials in 2 different clinical activities while at Washington University School of Medicine. The 2 categories are as follows:

(1) You have been approved by our institutional radioisotope committee, the Radiation Safety Committee, to use USNRC-licensed materials for Groups IV, V & VI applications under the institutional medical broad scope license - USNRC 24-00167-11. In addition, statements specifying your training and experience were submitted to the NRC at the time of our last renewal of the broad-scope license in 1981. Copies of these statements are enclosed.

(2) You have been approved by the Radiation Safety Committee to use our two ^{60}Co teletherapy devices authorized by USNRC license #24-00063-08 (Mallinckrodt Institute of Radiology) and USNRC license 24-00063-10 (Jewish Hospital).

If you ever need additional information please call me at (314) 362-2988. Best wishes at Loyola University.

Sincerely,

John Eichling, Ph.D.
Institutional RSO

JE:fiw

enclosures

Box 8053
724 S. Euclid Avenue
St. Louis, Missouri 63110
(314) 362-3476

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
James E. Marks, M.D.	Missouri, Illinois

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiation Oncology - American Board of Radiology		June, 1972

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. of Chicago Hosp. & Clinics- Argonne Cancer Research Hosp. April, 1969 to June, 1972	2 courses on basic physics 40 hours	10 hours
b. RADIATION PROTECTION	Univ. of Chicago Hosp. & Clinics- Argonne Cancer Research Hosp. April, 1969 to June, 1972	3 hours	1 hour
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. of Chicago Hosp. & Clinics- Argonne Cancer Research Hosp. April, 1969 to June, 1972	3 hours	none
d. RADIATION BIOLOGY	Univ. of Chicago Hosp. & Clinics- Argonne Cancer Research Hosp. April, 1969 to June, 1972	20 hours	none
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Radium	30-40 mg	Univ. of Chicago	5 years	intracavitary and interstitial.
Gold 198	150 millicuries	Univ. of Chicago	5 years	intracavitary.
Radon	5 millicuries	Univ. of Chicago	5 years	interstitial.
Iridium 192	10 millicuries	Mallinckrodt Inst. of Radiology	5 years	interstitial.
I 131	100 millicuries	Mallinckrodt Inst. of Radiology	5 years	oral

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

James E. Marks, M.D.

STREET ADDRESS

510 S. Kingshighway

CITY	STATE	ZIP CODE
St. Louis	MO	63110

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		I had 3 months training in Nuclear Medicine as a resident and am not qualified in the diagnostic use of isotopes.
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		

CONTROL NO. 7952

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

SOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	0	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	5	
I-131	TREATMENT OF THYROID CARCINOMA	25	
	TREATMENT OF HYPERTHYROIDISM	0	
Au-198	INTRACAVITARY TREATMENT	10	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	80	
Co-60 or Cs-137	TELETHERAPY TREATMENT	600	
Sr-90	TREATMENT OF EYE DISEASE	2	
	RADIOPHARMACEUTICAL PREPARATION		I had 3 months training at [illegible] Medicine as a resident and am [illegible] qualified in the diagnostic use of isotopes.
Mo-99/ Tc-99m	GENERATOR	10	
Sn-113/ In-113m	GENERATOR	0	
o-99m	REAGENT KITS	0	
ner		0	

DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

1969 to 1974 total number of hours 100.

THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

Melvin L. Griem, M.D.

b. NAME OF INSTITUTION

University of Chicago

c. MAILING ADDRESS

950 East 59th Street

d. CITY

icago, IL 60637

e. MATERIALS LICENSE NUMBER(S)

5. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

RM NRC-313M SUPPLEMENT B
78)

CONTROL NO. 7 952 7