NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 39

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). 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 Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Iowa Methodist Medical Center	In accordance with application dated May 24, 1985
2. 1200 Pleasant Street Des Moines, IA 50308	3. License number 14-01908-01 is amended in its entirety to read as follows:
	4. Expiration date: June 30, 1990
	5. Docket or Reference No.: 030-01685

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. 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. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 2 curies of each byproduct material authorized in Subitem 6.B
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 2 curies total for all sources authorized in Subitem 6.E

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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
F. Xenon-133	F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	F. 1 curie
G. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	G. Prepackaged kits	G. 3 millicuries of each byproduct material authorized in Subitem 6.G
H. Uranium (Depleted in Uranium 235)	H. Cadmium plated metal	H. 205 kilograms
I. Gadolinium-153	I. Sealed sources (Gulf Nuclear, Inc. Model GD-1 contained in a Lunar Radiation Corp. source holder)	I. 2 sources not to exceed 1.5 curies each

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. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

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9. Authorized Use (cont'd)

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. In vitro studies.

H. For use as shielding in a linear accelerator.

I. For use in a Lunar Radiation Corp. Model DP3 "Spine Scanner" for analysis of human bone mineral content.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1200 Pleasant Street, Des Moines, Iowa.

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. A. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Terrance J. Allen, M.D.	Groups I, II, III, IV, V and VI Xenon-133 In vitro studies
Alexander Ervanian, M.D.	Groups I, II, III, IV and V Xenon-133 In vitro studies Gadolinium-153 contained in a bone mineral analyzer
Thomas E. Murphy, M.D.	Groups I, II and III Iodine-131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma Xenon-133 In vitro studies
Jeffrey B. Watters, M.D.	Groups I, II and III Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction Xenon-133 In vitro studies

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Edward F. Loeb, M.D.	Groups I, II and III Xenon-133 In vitro studies Gadolinium-153 contained in a bone mineral analyzer
Russell H. Mahoney, M.D.	Groups I, II and III Xenon-133 In vitro studies Gadolinium-153 contained in a bone mineral analyzer
John W. Green, Jr., M.D.	Groups I, II and III Xenon-133 In vitro studies
Gordon L. Grado, M.D.	Groups IV, V and VI
Louis L. Maher, M.D.	Groups IV and VI
William L. McGinnis, M.D.	Group VI
Richard R. Hankenson, M.D.	Chromium-51 and hydrogen-3 for non-human studies

B. The Radiation Protection Officer for the activities authorized by this license is Charles Bischof, Ph.D.

13. 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.

14. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

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15. A. (1) Each sealed source containing licensed 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, a sealed source received from another person 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.

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 five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

16. 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.

17. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.

B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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18. Individuals who work in or whose duties may require them to work in restricted areas or in the vicinity of licensed materials, shall be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

19. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

20. Sealed sources contained in bone mineral analyzers shall not be opended or removed from their respective source holders.

21. The licensee shall have available and follow the instructions contained in the manufacturer's manual for the bone densitometer.

22. The licensee shall incorporate into their contamination survey program the "Recommended Action Levels For Removable Surface Contamination in Medical Institutions," outlined in Table 2 of Regulatory Guide 8.23, January, 1981.

23. 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 application dated May 24, 1985; letter dated May 18, 1985; and Model ALARA Program as contained in Appendix O of Regulatory Guide 10.8, October 1980. 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.

For the U.S. Nuclear Regulatory Commission

Date June 19, 1985

Original Signed
By George M. McCann
Materials Licensing Section, Region III

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CONVERSATION RECORD

TIME: 8:18 am | DATE: 6 June 1985

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Steve Kuhn Chief Tech Nuc Med	Iowa Methodist Med Ctr Des Moines, Iowa	(515) 283 6458

SUBJECT: C/N16377

ROUTING	
NAME/SYMBOL	INT

SUMMARY

1) Call and discussed training program with licensee. That all person must be trained and informed to the level specified in 19.12. Will put in training condition.

2) Discussed action points for decon 2x background does not specify a minimum level. Will condition 8.23 limits. ALARA

3) Discussed their bioassay program. Action points not correct, no specified levels at which bioassay will be performed. Will condition 8.20

4) Discussed xenon use regarding the trap. Is the resalent used to determine trap efficiency, if so need specify frequency at which periodic calibration will be done. Dedicated room used only, don't use moniter for trap saturation. System designed to handle direct exhaust.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME | DATE

TYPE ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.

ROUTING

NAME/SYMBOL	INT

SUBJECT

SUMMARY

5) Discussed license authorization for following doctors

a) Dr. Ervanian presently diagnosis only could be expanded Groups I-V (he's board certified NuM page 1566)

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
mike McCann	Lieut M. McCann	11 June 1985

ACTION TAKEN

SIGNATURE	TITLE	DATE