

## MATERIALS LICENSE

Amendment No. 43

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		In accordance with letter dated November 27, 1984
1. St. Elizabeth Hospital Medical Center		3. License number 34-01131-01 is amended in its entirety to read as follows:
2. 1044 Belmont Avenue Youngstown, OH 44501		4. Expiration date June 30, 1990
		5. Docket or Reference No. 030-02670
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. 3 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E. Xenon-133	E. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed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	E. 800 millicuries

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SUPPLEMENTARY SHEET**

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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. Any byproduct material  
listed in Section  
31.11(a) of 10 CFR 31

F. Prepackaged kits

F. 3 millicuries  
of each byproduct  
material authorized  
in Subitem 6.F

G. Cobalt-60

G. Encased in needles  
and/or applicator cells  
(Nuclear Consultants  
Corporation Model No. 623)

G. 100 millicuries

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.
- E. Blood flow studies. Pulmonary function studies.
- F. In vitro studies.
- G. For storage only.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1044 Belmont Avenue, Youngstown, Ohio.
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."

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12. 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:

Clayton A. Hixson, M.D.

Groups I, II, III, IV and V  
Xenon-133  
In vitro studies

William R. Torok, M.D.

Groups I, II, III, IV and V  
Xenon-133  
In vitro studies

William L. Crawford, M.D.

Groups I, II and III  
Xenon-133  
In vitro studies

George L. Altman, M.D.

Groups I, II, III and IV  
Iodine-131 as iodide for treatment  
of thyroid carcinoma  
Xenon-133  
In vitro studies

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.
15. 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.

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16. 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.
17. 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.
18. 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 September 4, 1979; letters dated June 15, 1977, December 4, 1979, October 12, 1983, and November 27, 1984; 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

Original Signed

By James Mullauer

Materials Licensing Section, Region III

Date May 31, 1985

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