

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 35

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 application received March 5, 1985
1. Fort Hamilton-Hughes Hospital		3. License number 34-02091-03 is amended in its entirety to read as follows:
2. 630 Eaton Avenue Hamilton, OH 45013		4. Expiration date July 31, 1990
		5. Docket or Reference No. 030-02698
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. 1 curie total for all sources authorized in Subitem 6.E

8509110076 850828
REG3 LIC30
34-02091-03 PDR

COPY

2
ml30

85 8/29/85

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

34-02091-03

Docket or Reference number

030-02698

CORRECTED COPY

Amendment No. 35

6. Byproduct, source,
and/or special nuclear
material

F. Xenon-133

7. Chemical and/or
physical form

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

8. Maximum amount that
licensee may possess
at any one time
under this license

F. 500 millicuries

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

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. 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.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 630 Eaton Avenue, Hamilton, Ohio.

COPY

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

34-02091-03

Docket or Reference number

030-02698

Amendment No. 35

CORRECTED COPY

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 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:

Stanley B. Ignatow, M.D.

Groups I, II and III

Xenon-133

In vitro studies

David L. Katz, M.D.

Groups I, II and III

Xenon-133

In vitro studies

Marcus Oswald, M.D.

Groups I, II and III

Xenon-133

Harry Horwitz, M.D.

Groups IV, V and VI

Kenneth E. Murdock, M.D.

Groups IV, V and VI

Sudha B. Mahalingam, M.D.

Group VI

Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions

James M. Thomson, Jr., M.D.

Group VI

Lowell Millburn, M.D.

Group VI

Richard Levy, M.D.

Group VI

Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions

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.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

34-02091-03

Docket or Reference number

030-02698

Amendment No. 35

CORRECTED COPY

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 Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.
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.
18. The licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.
19. The licensee shall designate an individual responsible for overseeing inventory control of Group VI sealed sources.
20. The licensee shall follow the procedures contained in Appendix I "Area Survey Procedures" of Regulatory Guide 10.8, October 1980.
21. 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 received March 5, 1985; letter dated July 1, 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

Original Signed

By James Mullauer

Materials Licensing Section, Region III

COPY

Date August 28, 1985