

## MATERIALS LICENSE

Amendment No. 12

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); and to import such byproduct and source material. 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. Papastavros Associates, P.A.  
Professional Building IV
2. Suit 100, Augustine Cut-off  
Wilmington, Delaware 19803

In accordance with application dated  
April 10, 1985

3. License number 07-16529-01 is amended in its  
entirety to read as follows:

4. Expiration date August 31, 1990

5. Docket or  
Reference No. 030-11379

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
- B. Any byproduct material  
listed in Group III of  
Schedule A, Section  
35.100 of 10 CFR 35
- C. Xenon 133

- A. Any radiopharmaceutical  
listed in Groups I and  
II 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

- C. 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withdrawn or terminated)  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withdrawn, terminated or  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 In-  
vestigational Exemption  
for a New Drug" (IND)  
that has been accepted  
by FDA

- D. Any iodide that has been  
manufactured, labeled,  
packaged and distributed  
in accordance with a  
specific license issued  
pursuant to Section 32.72  
of 10 CFR Part 32 or a  
specific license issued  
to the manufacturer by an  
Agreement State pursuant  
to equivalent State  
regulations

- A. As necessary for uses  
authorized in Subitem  
9.A.
- B. 2 curies of each  
byproduct material  
authorized in Subitem 6.B.
- C. 40 millicuries

- D. 50 millicuries

- D. Iodine 131

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

U/-16529-01

Docket or Reference number

030-11379

Amendment No. 12

**9. Authorized use**

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, 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. Blood flow and pulmonary function studies.
- D. For treatment of hyperthyroidism or cardiac dysfunction.

**CONDITIONS**

- 10. Licensed material shall be used only at the licensee's facilities, Professional Building IV, Suite 100, Augustine Cut-off, Wilmington, Delaware.
- 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 Garth A Koniver M.D., Robert M. Kurtz, M.D., or Thomas W. Fiss, Jr., M.D.
- 13. 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.
- 14. 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.
- 15. 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 April 10, 1985; and Model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (Rev. 1), "Guide for the Preparation of Applications for Medical Programs", 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:

Jenny M. Johanson

Date AUG 15 1985

By

Nuclear Materials Safety and  
Safeguards Branch, Region I  
King of Prussia, Pennsylvania 19406