

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

18-07561-01

Docket or Reference number

030-01765

Amendment No. 21

V.A. Medical Center  
Nuclear Medicine Service  
Togus, Maine 04330

In accordance with letter dated January 14, 1986, License Number 18-07561-01 is amended as follows:

Items 6., 7., 8., and 9. are amended to read:

- |                                                                                                |                                                                                                                                                                                                                                                                                                                   |                                                                                |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 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 6.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. 1,000 millicuries total for sources authorized in Subitem 6.E.              |
| 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. Xenon 133                                                                                   | G. 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 | G. 300 millicuries                                                             |

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## 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. 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. In vitro studies.
- G. Blood flow and pulmonary function studies.

Conditions 12. and 19. are amended to read:

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:

Jay F. Rowe, M.D.

Group VI

Victor Skorapa, Jr., M.D.

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

Richard D. Baldwin, M.D.

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

19. 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 ALARA Program dated August 17, 1982; and letters dated June 24, 1983, July 27, 1983, July 10, 1984, August 13, 1984, December 6, 1984, September 17, 1985, November 5, 1985 and January 14, 1986. 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. Johansen

By

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

FEB 10 1986

Date \_\_\_\_\_