

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

21-00998-01

Docket or Reference number

030-08290

Amendment No. 22

Mt. Carmel Mercy Hospital  
6071 W. Outer Drive  
Detroit, MI 48235

In accordance with letter dated June 26, 1985, License Number 21-00998-01 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 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. 6 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. 3 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withdrawn or terminated)  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withdrawn, terminated  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. 500 millicuries

G. Any byproduct material  
with Atomic Numbers  
between 3 and 83, —  
inclusive, except as  
noted below:

G. Any

G. 25 millicuries of  
each byproduct  
material with Atomic  
Numbers between  
3 and 83, inclusive.  
Total possession  
limit for Item A.  
is 1 curie.

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. To be used for in vitro research and development studies, including animal studies.

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Conditions 12., 13., and 19. are amended to read:

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, K.D. McGinnis, M.D., Chairman.
- B. Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980.
- C. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).
- D. The Radiation Protection Officer for the activities authorized by this license is Lloyd A. Smith.
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.
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 application dated January 1, 1983; and letters dated June 16, 1983, July 22, 1983, June 26, 1985 and September 6, 1985. 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

OCT 2 1985

Original Signed

By George M. McCann

Materials Licensing Section, Region III

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