

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

06-19661-01MD

Docket or Reference number

030-19066

Amendment No. 17

Syncor International
Medical Service Group
228 Murphy Road
Hartford, Connecticut 06114

In accordance with letter dated July 17, 1985, License Number 06-19661-01MD is amended as follows:

- | | | |
|--|--|--|
| 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. Molybdenum 99 | A. Any Molybdenum 99/
Technetium 99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations | A. 50 curies |
| B. Any byproduct material listed in Section 31.11(a) of 10 CFR 31 | B. Prepackaged <u>in vitro</u> diagnostic test kits | B. 50 millicuries total possession limit |
| C. Any byproduct material authorized under Section 35.14(d)(4) of 10 CFR Part 35 | C. Any sealed source listed in Section 35.14(d)(4) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations | C. 50 millicuries total for all sources authorized under Subitem 6.C. |
| D. Cobalt 60 | D. Sealed source | D. 2 millicuries |
| E. Barium 133 | E. Sealed source | E. 250 microcuries |
| F. Cesium 137 | F. Sealed source | F. 2 millicuries |

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(6., 7. 8 continued)

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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 |
| G. Xenon 133 | G. Unit dose containers of Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA | G. 2 curies |
| H. Iodine 131 | H. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR 35 | H. 375 millicuries |
| I. Technetium 99m | I. Any form listed in Groups I through II of Schedule A, Section 35.100 of 10 CFR 35 | I. 50 curies |
| J. Any byproduct material, except Iodine 131 and Technetium 99m, listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 | J. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR 35 | J. 10 millicuries total possession limit |
| K. Any byproduct material, except Iodine 131 and Technetium 99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 | K. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35 | K. 50 millicuries total possession limit |
| L. Any byproduct material, except Iodine 131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 | L. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35 | L. 50 millicuries total possession limit |
| M. Uranium (Depleted in Uranium 235 | M. Metal encased in stainless steel | M. 180 kilograms |

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(continued)

9. Authorized use

- A. Production of technetium 99m pertechnetate; Redistribution of unopened generators, as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved package insert, to authorized recipients.
- B. Redistribution to general and specific licenses in accordance with statements, representations, and procedures contained in letter received August 30, 1984.
- C. Instrument calibration; Redistribution of sources of specifically authorized recipients. Pursuant to Section 32.74, 10 CFR 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR 35, or under equivalent licenses of Agreement States.
- D., E., and F. Instrument calibration.
- G. Distribution to authorized recipients.
- H. Dispensing and/or distribution to authorized recipients.
- I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate of processing with reagent kits in the preparation of radiopharmaceuticals.
- J. through L. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
- M. As shielding of molybdenum 99/technetium 99m generators.

Pursuant to Sections 32.72 and 32.73, 10 CFR 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR Part 35, or under equivalent licenses of Agreement States, for the Groups indicated below:

- A. Molybdenum 99/technetium 99m generators may be redistributed to persons licensed pursuant to Group III.
- H. through L. Any form listed in each Group, Groups I, II, IV or V of Schedule A, Section 35.100 of 10 CFR 35, may be redistributed to persons licensed pursuant to that Group.

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(continued)

Condition 22. is amended to read:

22. Except as specifically provided otherwise by this license, the licensee shall possess, use, package, label, and distribute licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated January 8, 1981; letters dated March 20, 1981, July 15, 1981, and March 18, 1982; letter received May 12, 1983; letter dated November 14, 1983; letter received August 30, 1984; and letters dated October 30, 1984, November 6, 1984, December 5, 1984, January 4, 1985, January 25, 1985, March 5, 1985, and July 17, 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.

SEP 30 1985

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

Date _____