

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

37-19586-01MD

Docket or Reference number

030-18920

CORRECTED COPY

Amendment No. 10

"OFFICIAL RECORD COPY"

Nuclear Pharmacy, Inc.
dba Elfreth's Alley Apothecary
7446 Derry Street
Harrisburg, Pennsylvania 17111

In accordance with letter dated December 10, 1984, License Number 37-19586-01MD 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. 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 the manufacturer by an
Agreement State pursuant
to equivalent State
regulations

A. 80 curies

B. Barium 133

B. Sealed source

B. 500 microcuries

C. Cesium 137

C. Sealed source

C. 2 millicuries

D. Xenon 133

D. 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withdrawn or terminated)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withdrawn, terminated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
FDA

D. 800 millicuries

E. Iodine 131

E. Any form listed in
Groups I through V
of Schedule A, Section
35.100 of 10 CFR 35

E. 375 millicuries

F. Technetium 99m

F. Any form listed in
Groups I and II of
Schedule A, Section
35.100 of 10 CFR 35

F. 80 curies

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REG1 LIC30
37-19586-01MD PDR

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(6., 7. and 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. Any byproduct material, except Iodine 131 and Technetium 99m listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 | G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR 35 | G. 10 millicuries total possession limit |
| H. Any byproduct material, except Iodine 131 and Technetium 99m listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 | H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35 | H. 50 millicuries total possession limit |
| I. Any byproduct material, except Iodine 131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 | I. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35 | I. 50 millicuries total possession limit |
| J. Any byproduct material, except Iodine 131, listed in Group V of Schedule A, Section 35.100 of 10 CFR Part 35 | J. Any form listed in Group V of Schedule A, Section 35.100 of 10 CFR 35 | J. 50 millicuries total possession limit |
| K. Uranium (Depleted in Uranium 235) | K. Metal encased in stainless steel | K. 101 kilograms |
| L. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR Part 35 | L. Any sealed source 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 | L. 500 millicuries |

9. Authorized use

- A. Production of technetium 99m pertechnetate.
- B. and C. Instrument calibration.
- D. Distribution to authorized recipients.
- E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

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(9. continued)

- F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium 99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals and for calibration of the licensee's and his customer's survey instruments.
- G. through J. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.
- K. As shielding of molybdenum-99m/technetium-99m generators.
- L. Redistribution of sealed sources, as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions for use and storage, to authorized recipients.

Pursuant to Sections 32.72 and 32.74, 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.

- E. through J. Any form listed in each Group, Groups I, II, IV or V or Schedule A, Section 35.100 of 10 CFR 35, may be distributed to persons licensed pursuant to the Group.
- L. Sealed sources may be redistributed to persons licensed pursuant to Group VI.

Condition 24. is amended to read:

- 24. 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 October 24, 1980; and letters dated December 5, 1980, February 10, 1981, March 6, 1981, May 24, 1983, November 16, 1983, December 9, 1983, January 3, 1984, letter with attachments dated February 21, 1984, and letters dated November 27, 1984 and December 10, 1984. 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 and Safeguards Branch
Region I

King of Prussia, Pennsylvania 19406

Date

MAR 07 1985