



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

January 28, 2000

Central Pharmacy Services, Inc.  
d/b/a Great Western Radiopharmaceutics  
ATTN: Daniel D. Cariddi, R.Ph.  
Radiation Safety Officer  
1603 C Avenue  
Sioux Falls, South Dakota

SUBJECT: LICENSE AMENDMENT NO. 01

Please find enclosed Amendment No. 01 to License No. 40-27598-01 changing the name of your license. You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact me at (817) .

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.
3. By 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license; or
  - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material more than the amount or form authorized on the license;
  - c. Add or change the areas or address(es) of use identified in the license application or on the license; or
  - d. Change the name or ownership of your organization.
  
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600.

Thank you for your cooperation.

Sincerely,

*/RA/*

Jack E. Whitten  
Senior Health Physicist  
Nuclear Materials Licensing Branch

Docket: 030-34813  
License: 40-27598-01  
Control: 467666

Enclosures: As stated

**MATERIALS LICENSE**

**Amendment No. 01**

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, 36, 39, 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). 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.

<p style="text-align: center;">Licensee</p> <p>1. Central Pharmacy Services, Inc. d/b/a Great Western Radiopharmaceutics</p> <p>2. 1603 "C" Avenue Sioux Falls, South Dakota 57104</p>	<p>In accordance with letter dated December 29, 1999</p> <p>3. License number 40-27598-01 is amendment in it entirety to read:</p> <hr/> <p>4. Expiration date November 30, 2008</p> <hr/> <p>5. Docket No. 030-34813 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations</p> <p>B. Iodine-131</p> <p>C. Technetium-99m</p> <p>D. Any byproduct material listed in 10 CFR 31.11(a)</p> <p>E. Any byproduct material authorized under 10 CFR 35.57(a)</p> <p>F. Any byproduct material listed in Sections 35.400 and 35.500 of 10 CFR Part 35</p>	<p>7. Chemical and/or physical form</p> <p>A. Unsealed</p> <p>B. Unsealed</p> <p>C. Unsealed</p> <p>D. Prepackaged units for <u>in vitro</u> diagnostic tests</p> <p>E. Any sealed source listed in 10 CFR 35.57(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations</p> <p>F. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <table border="0"> <tr> <td>A. Molybdenum-99</td> <td>200 Ci</td> </tr> <tr> <td>Xenon-133</td> <td>1 Ci</td> </tr> <tr> <td>Technetium-99m</td> <td>200 Ci</td> </tr> <tr> <td>Iodine-131</td> <td>4 Ci</td> </tr> <tr> <td>Strontium-89</td> <td>50 mCi</td> </tr> <tr> <td>Samarium-153</td> <td>50 mCi</td> </tr> <tr> <td>Phosphorus-32</td> <td>50 mCi</td> </tr> <tr> <td>Rhenium-186</td> <td>100 mCi</td> </tr> <tr> <td>Chromium-51</td> <td>50 mCi</td> </tr> </table> <p>B. 4 curies</p> <p>C. 200 curies</p> <p>D. 50 millicuries</p> <p>E. 50 millicuries</p> <p>F. 4 curies</p>	A. Molybdenum-99	200 Ci	Xenon-133	1 Ci	Technetium-99m	200 Ci	Iodine-131	4 Ci	Strontium-89	50 mCi	Samarium-153	50 mCi	Phosphorus-32	50 mCi	Rhenium-186	100 mCi	Chromium-51	50 mCi
A. Molybdenum-99	200 Ci																			
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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
40-27598-01

Docket or Reference Number  
030-34813

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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. Uranium (depleted in the isotope Uranium 235)      | G. Metal encased in stainless steel | G. 400 kilograms   |

9. Authorized use:

- A. through C. Preparation and distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.
- D. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- E. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.57(a) or under equivalent licenses of Agreement States.
- F. 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 to authorized recipients for use and storage.
- G. Shielding for Mo99/Tc99m generators.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through E. of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1603 "C" Avenue, Sioux Falls, South Dakota.
11. A. Licensed material shall be used by, or under the supervision of:
- 1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) and (4), or
  - 2) authorized nuclear pharmacists: Daniel Cariddi, Walter Adiche, Jill Twehues, Clyde Cole, James Pancy, Peter Iverslei, Janet Reuther, and John Carr.
- B. The Radiation Safety Officer for this license is Daniel Cariddi.

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12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen-3; or
  - (ii) they contain only a radioactive gas; or
  - (iii) the half-life of the isotope is 30 days or less; or
  - (iv) they contain not more than 100 micro curies of beta and/or gamma emitting material or not more than 10 micro curies of alpha emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 micro curie of radioactive material on the test sample. If the test reveals the presence of 0.005 micro curie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.
13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
15. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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 10 half-lives.
  - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall 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.
17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in application dated July 27, 1998, and letter dated October 12, 1998.
18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

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19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 27, 1998
  - B. Letter dated October 12, 1998
  - C. Letter dated November 19, 1998
  - D. Letter dated December 29, 1999



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 28, 2000By     /RA/      
Jack E. Whitten, Senior Health Physicist  
Nuclear Materials Licensing Branch  
Region IV  
Arlington, Texas 76011