



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

SEP 13 2000

George Kreick
Safety Manager
Parke-Davis Company
2800 Plymouth Road
Ann Arbor, MI 48106-1047

Dear Mr. Kreick:

Enclosed is Amendment No. 52 to your NRC Material License No. 21-01443-06 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Sincerely,

A handwritten signature in cursive script, appearing to read "Cassandra F. Frazier".

Cassandra F. Frazier, Senior Health Physicist
Materials Licensing Branch

License No. 21-01443-06
Docket No. 030-04794

Enclosure: Amendment No. 52

306686

MATERIALS LICENSE

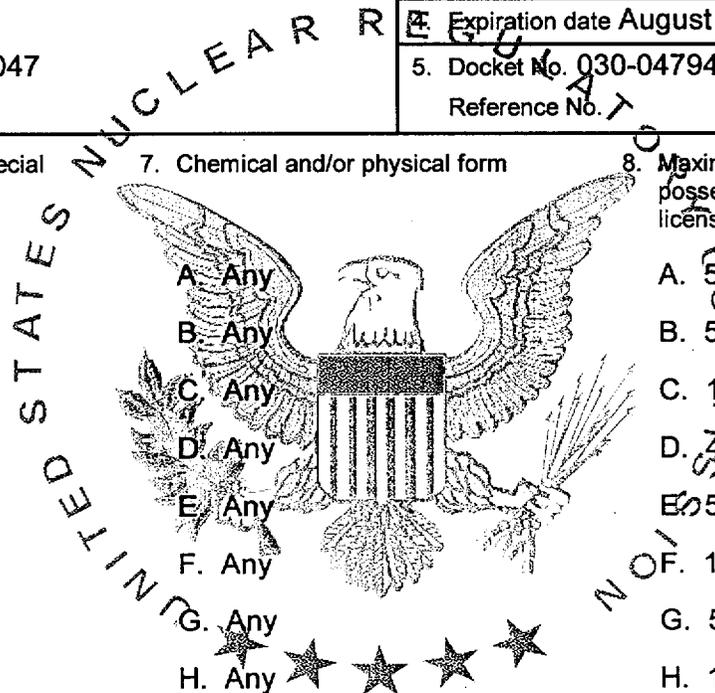
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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.

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<p>Licensee</p> <p>1. Parke-Davis Company</p> <p>2. 2800 Plymouth Road Ann Arbor, MI 48106-1047</p>	<p>In accordance with the letter dated April 4, 2000</p> <p>3. License number 21-01443-06 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date August 31, 2004</p> <hr/> <p>5. Docket No. 030-04794 Reference No. 7</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen-3</p> <p>B. Carbon-14</p> <p>C. Sodium-22</p> <p>D. Phosphorus-32</p> <p>E. Phosphorus-33</p> <p>F. Sulfur-35</p> <p>G. Calcium-45</p> <p>H. Scandium-46</p> <p>I. Chromium-51</p> <p>J. Iron-59</p> <p>K. Strontium-85</p> <p>L. Rubidium-86</p> <p>M. Niobium-95</p> <p>N. Ruthenium-103</p> <p>O. Iodine-125</p> <p>P. Iodine-131</p> <p>Q. Cerium-141</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>L. Any</p> <p>M. Any</p> <p>N. Any</p> <p>O. Any</p> <p>P. Any</p> <p>Q. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 50 curies</p> <p>B. 50 curies</p> <p>C. 100 millicuries</p> <p>D. 400 millicuries</p> <p>E. 500 millicuries</p> <p>F. 1 curie</p> <p>G. 500 millicuries</p> <p>H. 100 millicuries</p> <p>I. 250 millicuries</p> <p>J. 100 millicuries</p> <p>K. 150 millicuries</p> <p>L. 500 millicuries</p> <p>M. 100 millicuries</p> <p>N. 100 millicuries</p> <p>O. 500 millicuries</p> <p>P. 15 millicuries</p> <p>Q. 150 millicuries</p>
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
21-01443-06

Docket or Reference Number
030-04794

Amendment No. 52

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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 |
| R. Hydrogen-3 | R. Foils in detector cells | R. Not to exceed 1 curie per foil |
| S. Strontium-90 | S. Foils in detector cells | S. Not to exceed 40 millicuries per cell |
| T. Nickel-63 | T. Foils or plated detector cells | T. Not to exceed sources in 15 millicuries per foil or cell |
| U. Any byproduct material listed in subitems 6.A. through 6.Q. above | U. Solid and/or liquid waste | U. See Item 9.U below |

9. Authorized Use:

- A. and B. To be used for sample analysis in research and development, as described in letter dated July 12, 1999.
- A. through Q. To be used for research and development as described in application dated December 14, 1993, including animal studies.
- R. through T. To be used in gas chromatographs.
- U. Possession incident to interim storage of waste in accordance with statements, representations and procedures contained in letter dated March 26, 1991 and June 8, 1993.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at 2800 Plymouth Road, Ann Arbor, Michigan, 24 Frank Lloyd Wright Drive, Ann Arbor, Michigan, and 2900 Huron Parkway, Ann Arbor, Michigan..
- B. License material in Subitem Nos. 6.A. and 6.B. may be used at the licensee's facilities located at Parke-Davis Plymouth Township, 46701 Commerce Center Drive, Plymouth, Michigan.
11. The Radiation Safety Officer for this license is George Kreick.
12. Licensed material shall be used by or under the supervision of individuals who meet the requirements stated in 10 CFR 33.15(b) and have successfully completed the training described in application dated December 14, 1993 and have been designated by the radiation safety officer. The licensee shall maintain records of the individuals designated as authorized users.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
21-01443-06

Docket or Reference Number
030-04794

Amendment No. 52

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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 survey 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. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
14. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
15. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by NRC.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
16. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
17. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
18. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
19. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
20. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
21-01443-06

Docket or Reference Number
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Amendment No. 52

- 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.
- E. 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 microcuries of beta and/or gamma emitting material or not more than 10 microcuries 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.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie 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 III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.
- G. 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.
21. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
22. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
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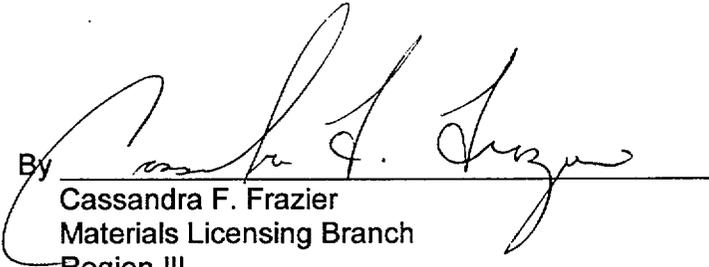
23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated December 14, 1993;
 - B. Letters dated July 28, 1994, July 12, 1999 and April 4, 2000 ; and
 - C. Radiation Safety Manual dated December 14, 1993.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 13 2000

By


Cassandra F. Frazier
Materials Licensing Branch
Region III