

## 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, 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.

Licensee		In accordance with letter received September 8, 1992	
1. Department of Health & Human Services Food and Drug Administration		3. License number 15-26421-01 is amended in its entirety to read as follows:	
2. 11630 W. 80th Street Lenexa, Kansas 66214		4. Expiration date April 30, 1994	
		5. Docket or Reference No 030-32815	
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. Nickel-63	A. Foil source (Tracor, Inc. Detector Cell Model 111019-0001)	A. No single cell to exceed 15 millicuries	
B. Nickel-63	B. Foil source (Hewlett-Packard Cell Models No. 18803A or 19303)	B. No single cell to exceed 15 millicuries	
C. Nickel-63	C. Foil source (Variac Associates Detector Cell Models No. 02-001972-01 or 03-908377-01)	C. No single cell to exceed 8 millicuries	
9. Authorized use			
A., B., and C. For use in gas chromatographs for sample analysis.			

## CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 11630 W. 80th Street, Lenexa, Kansas.
11. A. Licensed material shall be used by, or under the supervision of, Donald C. Kendall, Marvin L. Hopper, Kenneth R. Griffitt, James L. Daft or Edmond J. Baratta.
- B. The Radiation Safety Officer for this license is Donald C. Kendall.

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

15-26421-01

Docket or Reference number

030-32815

Amendment No. 01

12. A. (1) The sources specified in 7.A. through 7.C. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.
- C. The 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, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A 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 Radiation Safety and Safeguards. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. The licensee is authorized to collect leak test samples for analysis by FDA/Winchester Engineering and Analytical Center, or tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
13. Sealed sources containing licensed material shall not be opened.
14. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
15. Detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.

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16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.
17. 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.
18. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities described in Condition 10 of this license, per the provision of 10 CFR 30.35(g) until this license is terminated by the Commission.
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 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 7, 1988
  - B. Letter dated June 1, 1992
  - C. Letter received September 8, 1992

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Original Signed By  
Jacqueline D. Burks

By

Nuclear Materials Licensing Section  
Region IV  
Arlington, Texas 76011

Date OCT 6 1992



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

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

OCT 6 1992

Department of Health & Human Services  
Food and Drug Administration  
ATTN: Donald C. Kendall  
Radiation Safety Officer  
11630 W. 80th Street  
Lenexa, Kansas 66214

Gentlemen:

Please find enclosed Amendment No. 01 to your NRC material license. You should review this amendment carefully and be sure that you understand all conditions. If you have any questions, you may contact the reviewer who signed your license amendment at 817/860-8100.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).
5. Request and obtain written NRC consent before transferring your license or any right thereunder, either voluntarily or involuntarily, directly or indirectly, through transfer of control of your license to any person or entity. A transfer of control of your license includes not only a total change of ownership, but also a change in the controlling interest in your company whether it is a corporation, partnership, or other entity. In addition, appropriate license amendments must be requested and obtained for any other planned changes in your facility or program that are contrary to your license or contrary to representations made in your license application, as well as supplemental correspondence thereto, which are incorporated into your license. A license fee may be charged for the amendments if you are not in a fee-exempt category.



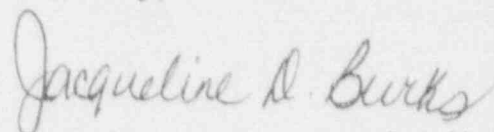
Department of Health & Human Services -2-  
Food and Drug Administration

6. Submit a complete renewal application with proper fee, 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.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will 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 Policy and Procedures for NRC Enforcement Action, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,



Jacqueline D. Burks, Health Physicist  
Nuclear Materials Licensing Section

Enclosure:  
As stated

RIV:NMLS  
JDBurks *JDBurks*  
10/05/92



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Kansas City District  
11630 West 80th Street  
Lenexa, KS 66214-3340

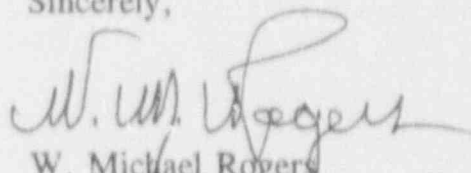
U.S. Nuclear Regulatory Commission  
Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011-8064

Dear Ms. Billie Gruszynski:

Regarding our Nuclear Materials License, this letter is to inform you that Donald C. Kendall, Director Laboratory Branch is now our Radiation Safety Officer. Please make the necessary changes.

If you have any questions please call me or Donald C. Kendall at 913 752-2100.

Sincerely,

  
W. Michael Rogers  
District Director

FEE EXEMPT  
170.11(a)(5)

464382



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
Arlington, Texas 76011-8064

JUL 27 1992

SEP 8 1992

Department of Health & Human Services  
Food and Drug Administration  
ATTN: Garrett D. Salmon  
Radiation Safety Officer  
11630 W. 80th Street  
Lenexa, Kansas 66214

Gentlemen:

Enclosed is corrected copy to License No. 15-26421-01, dated June 29, 1992, changing Conditions 11 to add 11.B.; 12.C to show Region IV as the NRC region which has oversight of your license; and 19.A. to list the proper backup documentation for your license. You should review this document for correctness and completeness.

If you have any questions concerning this action, please feel free to contact us at (817)860-8100.

Sincerely,

A handwritten signature in cursive script that reads "Billie Gruszynski".

Billie Gruszynski (Ms.)  
Nuclear Materials Licensing Section

Enclosures:  
As stated



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