

# UNITED STATES NUCLEAR REGULATORY COMMISSION

#### REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-4005

December 27, 2004

Blood Systems, Inc. dba United Blood Services ATTN: David Switzer, M.S. Radiation Safety Officer P.O. Box 1672 Billings, MT 59103-1672

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 02 to NRC License No. 25-29078-01. Your license was amended to release property located at 3000 7<sup>th</sup> Avenue North, Billings, Montana, for unrestricted use. An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(vii). You should review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or if you have any questions, contact me at 817-860-8132.

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. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also 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.

The NRC no longer publishes the <u>NRC Rules and Regulations</u> loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at <u>www.nrc.gov</u>. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room"; choose "All Document Types" on the drop down menu; scroll down to "NUREG-Series Publications"; and select "Publications Prepared by the NRC Staff". Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Jacqueline D. Cook, Senior Health Physicist Nuclear Materials Licensing Branch

Docket: 030-33682 License: 25-29078-01 Control: 470314

Enclosures: As stated

NRC FORM 374

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## **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.

	Licensee

- Blood Systems, Inc. dba United Blood Services
- 2. P.O. Box 1672

Billings, Montana 59103

In accordance with letter received

December 20, 2004

- 3. License number 25-29078-01 is amended in its entirety to read as follows:
- 4. Expiration date November 30, 2004
- 5. Docket No. 030-33682 Reference No.

- 6. Byproduct, source, and/or special nuclear material
- 7. Chemical and/or physical form

CLEAR

 Maximum amount that licensee may possess at any one time under this license

A. Cobalt-60

- A. Sealed Source (J.L. Shepherd & Associates Model 7810)
- A. 4500 curies

### 9. Authorized Use

A. To be used in a J.L. Shepherd & Associates Model 109-C Irradiator for human blood component irradiation.

# CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1444 Grand Avenue, Billings, Montana.
- 11. The Radiation Safety Officer for this license is David Switzer, M.S.
- 12. Licensed material is only authorized for use by or under the supervision of David Switzer, Brenda Heiman, Colleen Stott, or Stacy Purcell.
- 13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
  - B. In the absence of a certificate from a transferor indicating that a leak test has been made, within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

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- C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- D. Sealed sources need not be tested if they 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 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 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- F. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by NRC or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
- 14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
- 15. The procedures contained in the J.L. Shepherd & Associates Operation Manual for the Model 109 Laboraory Irradiator shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

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- 16. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall Application dated September 26, 1994

  The dated September 8, 2004

  The dated September 20, 2004 govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - Α.
  - B.
  - C.



By

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date December 27, 2004

/RA/

Jacqueline D. Cook, Senior Health Physicist Nuclear Materials Licensing Branch Region IV Arlington, Texas 76011