



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

July 27, 2006

Hematech, Inc.
ATTN: Zhongde Wang, Ph.D.
Radiation Safety Officer
4401 South Technology Drive
Sioux Falls, South Dakota 57106

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 05 to License No. 40-27743-01, **recognizing the name change from Hematech, LLC, to Hematech, Inc.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(v). You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact me at 817-860-8189.

NRC's Regulatory Issue Summary (RIS) 2005-31, provides criteria to identify security-related sensitive information and guidance for handling and marking such documents. This ensures that potentially sensitive information is not made publicly available through NRC's electronic document system (ADAMS). The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. Pursuant to NRC's RIS 2005-31, the enclosed materials license will be made publicly available.

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(d) 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 whether at the entire site or any separate building or outdoor area; or
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.

4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, radionuclide 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. Since the NRC also accepts a letter requesting amendment or renewal 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 NRC Enforcement Policy.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. 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.

Hematech, Inc.

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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>.

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-36160
License: 40-27743-01
Control: 471011

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.

<p>Licensee</p> <p>1. Hematech, Inc.</p> <p>2. 4401 South Technology Drive Sioux Falls, South Dakota 57106</p>	<p>In accordance with application and facsimile dated June 12, 2006, and July 27, 2006, respectively</p> <p>3. License number 40-27743-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 2013</p> <p>5. Docket No. 030-36160 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Phosphorus-32</p> <p>B. Phosphorus-33</p> <p>C. Sulfur-35</p> <p>D. Hydrogen-3</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any, except sealed sources</p> <p>C. Any, except sealed sources</p> <p>D. Any bound/nonvolatile, except sealed sources</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 20 millicuries</p> <p>B. 20 millicuries</p> <p>C. 30 millicuries</p> <p>D. 100 millicuries</p>
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9. Authorized use
- A. through D. Research and development as defined in 10 CFR 30.4

CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located at:
- A. 4401 South Technology Drive, Sioux Falls, South Dakota, and
- B. 3904 West Technology Circle, Suite 102, Sioux Falls, South Dakota
11. A. The Radiation Safety Officer for this license is Zhongde Wang, Ph.D.
- B. Licensed material shall be used by, or under the supervision of Zhongde Wang, Ph.D., Eddie Sullivan, Ph.D., Yoshimi Kuroiwa, Ph.D., Keith Haffer, Ph.D., Hiroaki Matsushita, M.S., Melanie Nichols, B.S., Melissa Bien, B.S., and Thillainayagam Sathiyaseelan, Ph.D.
12. Licensed material shall not be used in or on human beings except as provided otherwise by specific condition of this license.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
40-27743-01Docket or Reference Number
030-36160

Amendment No. 05

13. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
14. 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 January 3, 2003
 - B. Facsimile dated May 16, 2003
 - C. Application dated December 16, 2003
 - C. Application dated April 28, 2005
 - D. Application dated November 2, 2005
 - E. Emails dated February 1, 2006
 - F. Application dated June 12, 2006
 - G. Facsimile dated July 27, 2006

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date July 27, 2006By: /RA/

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011