



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

August 29, 2006

Covance Clinical Research Unit, Inc.  
ATTN: Mark Jacobs, PharmD  
Site Director  
401 Kamakee Street  
Honolulu, HI 96814

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 01 to NRC License No. 53-27775-01 **changing Item 1 of the license.**

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). 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.

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;
  - 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. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
  - a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);

- b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
  - c. The licensee's mailing address changes;
  - d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
  - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.
5. 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, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
  - d. Change the name or ownership of your organization.
6. 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 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 Enforcement Policy is available on the following internet address:  
<http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>.

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](http://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.

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,

A handwritten signature in black ink, appearing to read "Jacqueline D. Cook". The signature is fluid and cursive, with the first name being the most prominent.

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

Docket: 030-36585  
License: 53-27775-01  
Control: 471001

Enclosures: As stated

**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. Covance Clinical Research Unit, Inc.</p> <p>2. 401 Kamakee Street Honolulu, Hawaii 96814</p>	<p>In accordance with letter dated May 23, 2006</p> <p>3. License number 53-27775-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date July 31, 2014</p> <p>5. Docket No. 030-36585 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Any tagged byproduct material</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any, except generators</p> <p>C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 50 millicuries</p>
<p>9. Authorized Use</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> <p>C. For phase one in vivo research studies in humans to explore the pharmacokinetics of uptake, excretion, and distribution of pharmaceuticals.</p>		

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 401 Kamakee Street, Honolulu, Hawaii.
11. The Radiation Safety Officer for this license is Richard D. Wasnich, M.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

53-27775-01

Docket or Reference Number

030-36585

Amendment No. 01

12. Licensed material is only authorized for use by, or under the supervision of:

- A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- C. The following individual is an authorized user for the materials and uses indicated:

Authorized UsersMaterial and Use

Richard D. Wasnich, M.D.

35.100, 35.200, and any tagged byproduct material

13. 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 financial assurance for decommissioning.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 April 12, 2004
  - B. Letter dated April 23, 2004
  - C. Letter dated May 17, 2004
  - D. Letter dated May 31, 2006

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date August 29, 2006

By



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