

Covance Clinical Research Unit Inc. Global Clinical Pharmacology Covance - Evansville 800 St. Mary's Drive Evansville, IN 47714 Tel: 812-474-6530 Fax: 812-474-6539

16 February 2015

NRC License Reviewer Materials Licensing Branch US Nuclear Regulatory Commission-Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4351

Request to Decommission License No. 13-26640-01 Re:

Dear NRC License Reviewer:

Covance CRU requests that the above-referenced medical use license be decommissioned; this license was in the Specific Use Type 7C category and pertains to "uptake, dilution, and excretion studies permitted by 10 CFR 35.100", involving administration of only <sup>14</sup>C- or <sup>3</sup>H-radiolabeled drug materials. Since 24 Apr 2013, per Amendment No. 15, this license has been "in standby" status. As part of the historical record for the above-referenced license, Covance CRU has decommissioned the 2 previously "active" clinical sites, i.e., decommissioned the 800 St. Mary's Drive, Evansville, IN clinical site in 2008 (see license amendment No. 12) and decommissioned the One Waterfront Plaza, 500 Ala Moana Blvd., Suite 400, Honolulu, HI clinical site in 2013 (see license amendment No. 15). Since the time that the current 617 Oakley St., Evansville, IN clinical site was newly built and added in 2008 to this license (see license amendment No. 12) no radioactive material was received, possessed, or used at this specific clinical site; hence, its "in standby" status. Covance has made the corporate decision to no longer maintain this license, since all currently "active" medical use licensee activities are located at the Covance clinical site in Madison, WI (DHS License No. 025-1075-01).

We have included a completed NRC Form 314; however, since no radioactive materials have ever been procured or possessed for this remaining clinical site and since the only sealed sources ( $\approx 20$  $\mu C \mathbf{i}^{133}$ Ba source for calibrating liquid scintillation counter and  $\approx 1 \mu C \mathbf{i}^{137}$ Cs source for calibrating survey meter) do not require leak test and have never leaked, there is no supportive documents needed/attached. It is our understanding that there is no accompanying fee required for NRC evaluation of this license decommissioning request; if we are incorrect, please just let us know ASAP what the fee is so that we can forward you a check for the appropriate amount. Thank you in advance for your timely evaluation of this license amendment request.

Sincerely, Theodore D. Broering, MBA

Covance Clinical Research Unit, Inc.

She & Kochan

Robert G. Kochan, PhD Executive Director, Clinical Pharmacology Services Covance US Clinical Pharmacology RSO Covance Clinical Research Unit, Inc.

Enclosure: Completed/signed Form NRC 314 (02-2014).

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NRC FORM 314 U.S. NUCLEAR REGULATORY COMMISS			
(02-2014) 10 CFR 30.36(j)(1);	Estimated burden per response to comply with the used by NRC as part of the basis for its determ	Estimated burden per response to comply with this mandatory collection request. 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send	
40.42(j)(1); 70.38(j)(1); and 72.54(k)(5)(1)(1) CERTIFICATE OF DISPOSITIO	comments regarding burden estimate to the FO	A, Privacy, and Information Collections Branch (T-5 F53), U.S. , DC 20555-0001, or by internet e-mail to Infocollects.	
3 × 10	Resource@nrc.gov, and to the Desk Officer,	Office of Information and Regulatory Affairs, NEOB-10202,	
<sup>*</sup> ***** OF MATERIALS		et, Washington, DC 20503. If a means used to impose an thy valid OMB control number, the NRC may not conduct or	
	sponsor, and a person is not required to respond	to, the information collection.	
LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER	
Covance Clinical Research Unit, Inc.	13-26640-01		
Global Clinical Pharmacology	13-20040-01		
617 Oakley Street	LICENSE EXPIRATION DATE		
Evansville, IN 47710	0	/31/2016	
A. LICENSE STATUS (Check the appropriate box)			
This license has expired.  This license has not yet expired; please terminate it.			
B. DISPOSAL OF RADIOACTIVE MATERIAL			
(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)			
The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:			
1. No radioactive materials have ever been procured or possessed by the licensee under this license.			
2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee			
under this license number cited above have been disposed of in the following manner.			
a. Transfer of radioactive materials to the licensee listed below:			
b. Disposal of radioactive materials:			
1. Directly by the licensee:			
2. By licensed disposal site:			
3. By waste contractor:			
c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.			
C. SURVEYS PERFORMED AND REPORTED			
1. A radiation survey was conducted by the licensee. The survey confirms:			
a. the absence of licensed radioactive materials			
b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.			
2. A copy of the radiation survey results:			
a. is attached; or b. is not attached (Provide explanation); or c. was forwarded to NRC on:			
3. A radiation survey is not required as only sealed sources were ever possessed under this license, and			
a. The results of the latest leak test are attached; and/or			
The person to be contacted regarding the information provided on this form:			
NAME TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS	
Robert G. Kochan, PhD RSO	608-210-7668	robert.kochan@covance.com	
Mail all future correspondence regarding this license to:			
Robert G. Kochan, PhD (RSO); Covance Clinical Research Unit, Inc.; Global Clinical Pharmacology; Covance - Madison Clinical Research			
Unit; 3402 Kinsman Boulevard; Madison, WI 53704			
C. CERTIFYING OFFICIAL			
I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT			
PRINTED NAME AND TITLE SIGNATURE		DATE	
Theodore D. Broering, MBA; Executive Director, Clinical		02/16/2015	
Pharmacology Services; Covance Clinical Development Services	(1)		
WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT			
SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.			
NRC FORM 314 (02-2014)			

