

## ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Radiant Research

License No.: 53-27775-01

Docket No.: 030-36585

Mail Control No.: 471001

Type of Action: Amend

Date of Requested Action: 05-31-06

Reviewer Assigned:

ARM reviewer(s): Torres

Response	Deficiencies Noted During Acceptance Review
1.	<input type="checkbox"/> Open ended possession limits. Submit inventory. Limit possession. <input type="checkbox"/> Inform licensee that we are limiting possession limits. <input type="checkbox"/> Ask the licensee if they have any type-amount of EPAct Material.
2.	
3.	

Reviewer's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

<input type="checkbox"/> Yes <input type="checkbox"/> No	Request for unrestricted use for Group 2 or higher category should be transferred by memo to FCDB within 10 days of receipt.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Decommissioning notification should be completed within 30 days.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes <input type="checkbox"/> No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
<input type="checkbox"/> Yes <input type="checkbox"/> No	TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: \_\_\_\_\_ Date: \_\_\_\_\_

**SUNSI Screening according to RIS 2005-31**

Yes  No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- Exact location of RAM (whether = or > than Category 3 or not)
- Design of structure and/or equipment (site specific)
- Information on nearby facilities
- Detailed design drawings and/or performance information
- Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- RAM quantities and inventory
- Manufacturer's name and model number of sealed sources & devices
- Site drawings with exact location of RAM, description of facility
- RAM security program information (locks, alarms, etc.)
- Emergency Plan specifics (routes to/from RAM, response to security events)
- Vulnerability/security assessment/accident-safety analysis/risk assess
- Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RJT Date: 5/21/06



May 31, 2006

Jacqueline D. Cook, Senior Health Physicist  
Materials Licensing, Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011-8064  
Phone: (817) 860-8132  
Fax Number: (817) 860-8263

Re: Radiant Research  
NRC License No. 53-27775-01  
Docket No. 030-36585

Subject: Amendment to our Materials License for Name Change, follow-up information

Dear Ms. Cook:

Thank for your response to our fax dated 23 May 2006 that informed you of the name change for our research facility. I have completed the requested additional information and have indicated that the specific name change for our clinical facility will be "Covance Clinical Research Unit, Inc."

I am available at the same phone numbers (tel 808.441.6312, fax 808.592.2638) and my email address is [markjacobs@radiantresearch.com](mailto:markjacobs@radiantresearch.com). I will continue to receive email at my Radiant email account; I do not have at this time have a Covance email account. All other contact information and operational processes remain unchanged.

Please review the additional information provided and let me know if you require anything further, or please call me if you have any questions.

Please direct any questions to Elizabeth Rodenbeck, our ongoing consultant on Radiation Safety Compliance, available by phone at (808) 922-7743, or facsimile at (808) 373-3139, or email at [beth808@hawaii.rr.com](mailto:beth808@hawaii.rr.com) or myself.

Sincerely,

Mark Jacobs, PharmD  
Site Director  
Radiant Research  
401 Kamakee Street  
Honolulu, HI 96814



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8004

FACSIMILE FORM

DATE: May 24, 2008

MESSAGE TO: Elizabeth Rodenbeck  
Radiant Research

Docket: 030-38585  
License: 35-27775-01

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

Telephone number 817-860-8132  
Facsimile number 817-860-8263

NUMBER OF PAGES: 3

FACSIMILE NUMBER: 808-373-3139 VERIFICATION NUMBER: 808-922-7743

Elizabeth Rodenbeck:

10 CFR 30.34(b) states that "no license issued or granted pursuant to the regulations...nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing. Although not specifically addressed by 10 CFR 30.34, licensees undergoing a name change may also be affected by this regulation.

Control over licensed activities can be construed as the authority to decide when and how a license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control. The central issue is whether the authority over the license has changed. In all cases, determining whether a change of control has taken place or whether a change is in name only is the Commission's responsibility.

Licensees must notify the Commission when they are undergoing a possible change of control and/or a change of name. While this notification is not required within a certain time frame, NRC needs adequate time to review the submittal to ensure that the transfer is in accordance with the regulations. Please respond to this fax no later than close of business Thursday, June 15, 2006.

In order to process your request for a change of control/ownership and/or a name change, the information on the following pages is required. Our fax number is (817) 860-8263. If you have any questions regarding our discussion or this fax, please contact me. When responding to this fax, please include the license, docket, and mail control numbers, located at the top of this page as well as the following pages. Thank you.

A handwritten signature in cursive script that reads "Jacqueline D. Cook".

Jacqueline D. Cook, Senior Health Physicist

Re: *Radiant Research*  
*NRC License No. 53-27775-01*  
*Docket No. 030-36585*

Information Required for Change of Control and/or Change of Ownership  
(to include a name change)

source: Appendix F of NUREG-1556, Volume 15 (Date Published: November 2000)

Please provide the following information concerning changes of control (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (i.e., transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

- A. Description of the transaction: *Radiant Research Phase I units are being purchased in total by Covance Incorporated. No changes in site personnel are expected. The new site director Mark Jacobs was hired by Radiant Research. Arlin Blood continues on staff as a consultant for own ADME studies.*
- B.  No name change  
 New name of licensed organization: *Covance Clinical Research Unit, Inc.*
- C.  No change in contact  
 New contact: *Mark Jacobs, PharmD*  
 New telephone number \_\_\_\_\_

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

- A.  No changes in personnel having control over licensed activities.  
 Changes in personnel having control over licensed activities (e.g. officers of a corporation):
- B.  No changes in personnel named in the license.  
 Changes in personnel named in the license (e.g. RSO, AUs) - including training, experience and responsibilities:

3. Describe, in detail, any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

- Organization:  Equipment:  
 Location:  Procedures:  
 Facility:  Not applicable - *No changes*

Re: Radiant Research  
NRC License No. 53-27775-01  
Docket No. 030-36585

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4. Describe the status of the surveillance program (i.e., surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

- A. Description of the status of all surveillance program: *Some surveillance program and RSO remain in effect. Annual review, inspection and education program by outside consultant on radiation safety compliance (Elizabeth Bodenbeck) is planned for June 2006*
- B. Surveillance Items & Records: calibrations, leak tests, surveys, inventories, and accountability requirements will be current at the time of transfer

Yes     [ ] No (explain)

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Records transferred to:

[ ] New licensee     [ ] NRC for license termination      Not applicable

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

[ ] Description of proposed licensed program attached

OR

\_\_\_\_\_ will abide by all constraints, conditions,  
(transferee)  
requirements and commitments of \_\_\_\_\_  
(transferor)

\_\_\_\_\_  
Signature/Title  
Transferee  
  
\_\_\_\_\_  
date

\_\_\_\_\_  
Signature/Title  
Transferor  
  
\_\_\_\_\_  
date

OR

Not applicable (name change only)

Mark Jacobs, PharmD  
Certifying Officer - Signature

25 MAY 2006  
Date

Mark Jacobs, PharmD Honolulu Site Director  
Certifying Officer - Typed name and title



May 23, 2006

Materials Licensing, Nuclear Materials Safety Branch  
U.S. Nuclear Regulatory Commission, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011-8064  
Phone: (800) 952-9677  
Fax Number: (817) 860-8263

Re: Radiant Research  
NRC License No. 53-27775-01  
Docket No. 030-36585

Subject: Amendment to our Materials License for Transfer of Control

Dear Sir or Madam:

We wish to notify you that Radiant Research is being acquired by Covance, Incorporated. We wish to amend our licensee name to Covance, Incorporated. There are no changes to the personnel or the operations. We will continue to operate from the same location using the same radiation safety procedures submitted by Radiant Research and under the supervision of our current Radiation Safety Officer, Dr. Richard D. Wasnich.

I, Mark Jacobs, PharmD was hired by Radiant Research to taken over as site clinical director for Arlin Blood, PhD. Please use me as the site contact person. I am available at the same phone numbers (tel 808.441.6312, fax 808.592.2638) and my email address is [markjacobs@radiantresearch.com](mailto:markjacobs@radiantresearch.com).

We ask that you please expedite this license amendment.

Please direct any questions to Elizabeth Rodenbeck, our ongoing consultant on Radiation Safety Compliance, available by phone at (808) 922-7743, or facsimile at (808) 373-3139, or email at [beth808@hawaii.rr.com](mailto:beth808@hawaii.rr.com) or myself.

Sincerely,

Mark Jacobs, PharmD  
Site Director  
Radiant Research  
401 Kama'ee Street  
Honolulu, HI 96814



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

FACSIMILE FORM

DATE: May 24, 2006

MESSAGE TO: Elizabeth Rodenbeck                      Docket: 030-36585  
                    Radiant Research                              License: 35-27775-01

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

Telephone number    817-860-8132  
Facsimile number    817-860-8263

NUMBER OF PAGES: 3

FACSIMILE NUMBER: 808-373-3139    VERIFICATION NUMBER: 808-922-7743

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Elizabeth Rodenbeck:

10 CFR 30.34(b) states that "no license issued or granted pursuant to the regulations...nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing. Although not specifically addressed by 10 CFR 30.34, licensees undergoing a name change may also be affected by this regulation.

Control over licensed activities can be construed as the authority to decide when and how a license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control. The central issue is whether the authority over the license has changed. In all cases, determining whether a change of control has taken place or whether a change is in name only is the Commission's responsibility.

Licensees must notify the Commission when they are undergoing a possible change of control and/or a change of name. While this notification is not required within a certain time frame, NRC needs adequate time to review the submittal to ensure that the transfer is in accordance with the regulations. Please respond to this fax no later than close of business Thursday, June 15, 2006.

In order to process your request for a change of control/ownership and/or a name change, the information on the following pages is required. Our fax number is (817) 860-8263. If you have any questions regarding our discussion or this fax, please contact me. When responding to this fax, please include the license, docket, and mail control numbers, located at the top of this page as well as the following pages. Thank you.

A handwritten signature in cursive script that reads "Jacqueline D. Cook".

Jacqueline D. Cook, Senior Health Physicist

11061421

Information Required for Change of Control and/or Change of Ownership  
(to include a name change)  
source: Appendix F of NUREG-1556, Volume 15 (Date Published: November 2000)

**Please provide the following information concerning changes of control (transferor and/or transferee, as appropriate). If any items are not applicable, so state.**

1. Provide a complete description of the transaction (i.e., transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

A. Description of the transaction:

B.  No name change

New name of licensed organization: \_\_\_\_\_

C.  No change in contact

New contact: \_\_\_\_\_

New telephone number: \_\_\_\_\_

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

A.  No changes in personnel having control over licensed activities.

Changes in personnel having control over licensed activities (e.g. officers of a corporation):

B.  No changes in personnel named in the license.

Changes in personnel named in the license (e.g. RSO, AUs) - including training, experience and responsibilities:

3. Describe, in detail, any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

Organization:

Equipment:

Location:

Procedures:

Facility:

Not applicable



4. Describe the status of the surveillance program (i.e., surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

A. Description of the status of all surveillance program:

B. Surveillance Items & Records: calibrations, leak tests, surveys, inventories, and accountability requirements will be current at the time of transfer

Yes       No (explain)

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Records transferred to:

New licensee       NRC for license termination       Not applicable

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Description of proposed licensed program attached

**OR**

\_\_\_\_\_ will abide by all constraints, conditions,  
(transferee)  
requirements and commitments of \_\_\_\_\_  
(transferor)

\_\_\_\_\_  
Signature/Title  
Transferee

\_\_\_\_\_  
Signature/Title  
Transferor

\_\_\_\_\_  
date

\_\_\_\_\_  
date

**OR**

Not applicable (name change only)

\_\_\_\_\_  
Certifying Officer - Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Certifying Officer - Typed name and title

JUN 21 2006

DATE

This is to acknowledge the receipt of your letter/application dated 5-31-06, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 471001.  
When calling to inquire about this action, please refer to this mail control number.  
You may call me at 817-860-8103.

Sincerely,



Licensing Assistant

RETURN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LEMS USE)  
INFORMATION FROM ITS  
.....  
Program Code: 02201  
Status Code: 0  
Fee Category: 70  
EXP. Date: 20140731  
Fee Comments:  
Detcom Fin Assur Regdt: N  
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED  
Applicant/Licensee: RADIANT RESEARCH  
Received Date: 20060601  
Docket No: 3036585  
Control No.: 471001  
License No.: 53-27775-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: \_\_\_\_\_  
Check No.:       /      

3. COMMENTS

Signed William J. Anderson  
Date 6/21/06

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: \_\_\_\_\_

2. Correct Fee Paid. Application may be processed for:  
Amendment  
Renewal  
License

3. OTHER

Signed \_\_\_\_\_  
Date \_\_\_\_\_