



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
612 EAST LAMAR BLVD, SUITE 400  
ARLINGTON, TEXAS 76011-4125

October 29, 2009

Rapid City Regional Hospital, Inc.  
ATTN: Richard J. Crilly, Ph.D.  
Radiation Safety Officer  
353 Fairmont Blvd.  
Rapid City, SD 57701

SUBJECT: RESPONSE TO TELEPHONE CONFERENCE DATED JULY 23, 2009

This letter responds to Mr. Lowell Husman's, Nuclear Medicine Supervisor, Rapid City Regional Hospital, request during a telephone conference on July 23, 2009, with members of the NRC Region IV staff which included Ms. Latischa Hanson, Ms. Rachel S. Browder, and myself. The telephone conference was to discuss several questions that Mr. Husman raised during a recent NRC inspection.

The regulations under 10 CFR 35.200 provides the criteria under which a licensee may obtain unsealed byproduct material prepared for medical use for imaging and localization studies. The material may be obtained from a manufacturer or preparer licensed under §32.72, an authorized nuclear pharmacist, or a physician who is authorized and who meets the requirements specified in this Part, or an individual under the supervision of the authorized nuclear pharmacists or authorized user, as specified in this Part. However, the licensee may not obtain PET materials from an authorized nuclear pharmacist or an authorized user, as specified in this Part. Therefore, since byproduct material for use under 10 CFR 35.200 may be obtained from an authorized user, then the licensee may transfer byproduct material to another licensee for use under 10 CFR 35.200.

The term distribution has the same meaning as in 10 CFR Part 32, i.e., the routine transfer of licensed materials to others. For organizations licensed in accordance with 10 CFR 32.72 and 32.74, these transfers of licensed material are to specific licensees in accordance with the requirements of 10 CFR 30.41. However, for a licensee such as a hospital, that does not routinely transfer licensed materials to others in a broad sense of the word, but performs transfers for one to three other hospitals within the local area, then the Commission does not consider the transfer to meet the meaning of distribution.

Secondly, the NRC issues a license to a person, where the definition of person means (1) *any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission.* Therefore, the NRC licenses the lowest level of incorporation for authority over the use of radioactive material. If Rapid City Regional Hospital (RCRH) is going to have ownership, control and authority over another entity, then the control of licensed activities is considered the authority to make decisions regarding possession, storage, or use of licensed materials. The entity can not be a separate incorporated business. It appears that any one of the 3 proposals under the "Second Situation" presented by RCRH in the facsimile dated

October 22, 2009, may work; however, there is not enough information regarding Queen City Regional Hospital's level of incorporation that adequately allows us to make a determination.

10 CFR 30.34(b) states in part *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 or 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.

Licensees must notify the Commission when they are undergoing a possible change of control or planning to purchase another entity in a merger or acquisition. Please review the enclosed form for Change of Control or Name Change, which should be submitted as an amendment request for any acquisition that the licensee may be considering. Additional information is available in Appendix D of NUREG-1556, Volume 15, *Program Specific Guidance about Changes of Control and about Bankruptcy involving Byproduct, Source, or Special Nuclear Material.*

We hope this letter serves to answer the questions raised by Mr. Husman regarding distribution of byproduct material and the information necessary for change of control and what constitutes the level of incorporation for licensing an entity. If there are further questions, please contact me at (817) 860-8132.

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

Sincerely,



Rachel S. Browder, Health Physicist  
Nuclear Materials Safety Branch B

Docket: 030-03231  
License: 40-00238-04

Enclosure: As stated

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 (ie., 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 a complete description of the transaction:



B.  name change

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

C.  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) - include 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 (e.g., 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. (Complete one of the following three items.)

A. \_\_\_\_\_ will abide by all constraints, conditions,  
(transferee company)

requirements and commitments of \_\_\_\_\_  
(transferor company)

\_\_\_\_\_  
Signature Title  
Transferee Official

\_\_\_\_\_  
Signature Title  
Transferor Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**OR**

B.  Description of proposed licensed program from transferee with signature, attached.

**OR**



C.  Not applicable (name change only)

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

\_\_\_\_\_  
Date

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