

TRANSMISSION VERIFICATION REPORT

TIME : 10/20/2009 17:50  
NAME : USNRC RIII  
FAX : 6308299782  
TEL :  
SER. # : 000A7J925774

DATE, TIME 10/20 17:48  
FAX NO./NAME 87346629224  
DURATION 00:02:13  
PAGE(S) 07  
RESULT OK  
MODE STANDARD  
ECM

NRC FORM 386 (R111)  
6-784



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 10/20/09 NUMBER OF PAGES: 7  
(including this page)

SEND TO: TOM KUMPVUS

LOCATION: MPC

FAX NUMBER: 734-662-9229  VERIFY BY CALLING SENDER

FROM: Colleen Carol Cysig  
(SENDER)

TELEPHONE NUMBER: 630-827-9241 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE PD - no ...



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 10/19/09

NUMBER OF PAGES: 7  
(including this page)

SEND TO: TOM KUMPUKUS

LOCATION: MPC

FAX NUMBER: 734-662-9229  VERIFY BY CALLING SENDER

FROM: Colleen Carol Casey  
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE Please call me if you have questions, Tom.

Thanks!

Colleen Carol Casey

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

**COLLEEN CAROL CASEY  
MATERIALS LICENSING BRANCH  
UNITED STATES NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE ROAD STE 210  
LISLE, ILLINOIS 60532-4352  
OFFICE: (630)-829-9841 FAX: (630) 515-1078

---

**CONVERSATION RECORD**

|TIME

|DATE

**ACTUALLY FAXED? Yes.**

*~ 5:20 pm CT on*

**Oct. 19, 2009**

---

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Tom Kumpuris, consultant for QHG Indiana, Inc.

800-321-2207

Fax: 734-662-9224

---

SUBJECT

License No.: 13-01535-01

Control No.: 318354

---

SUMMARY

We have reviewed your letters dated July 13, 2009, and July 14, 2009, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. **The letters above were both submitted on "Lutheran Hospital" letterhead but this license is under the name "QHG of Indiana, Inc." Now you are requesting a change of ownership/control, a merger/termination involving license no. 13-32106-01 and a name change to "Lutheran Medical Group" also.**

**Please briefly explain in clearer detail what has happened, especially why this request was made more than two months after the transaction took place. Please be reminded that 10 CFR 30.34(b) requires, in part, that NRC provide its consent, in writing, prior to changes of ownership and/or control involving its byproduct material licensees, as noticed in Information Notices issued in 1989 and 1994, at these links,**  
<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1989/in89025.html>  
and,

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1989/in89025r1.html> .

**Does the name "Lutheran Medical Group" now apply to all licensed activities under 13-01535- 01?**

2. **A separate termination request is needed for license no. 13-32106-01, to be completed concurrently with the merger of this location, etc. into lic. No. 13-01535-01. Use of a Form NRC 314 is preferred but a letter, signed and dated by that licensee's senior management, will suffice. Normally we require a close-out survey of the terminating license's facilities **PRIOR** to licensing the merger into the surviving license.**

**Please provide a copy of the most recent leak tests for sealed sources possessed under lic. No. 13-32106-01 and account for all radioactive waste streams and exposure rate/contamination surveys as of the date of the transaction above.**

3. Please confirm that all radiation safety program elements currently in place under license no. 13-01535-01 will be extended to the radiation safety program at the new location of use.
4. Your letter dated July 13, 2009, requested the addition of two new authorized physician users (AUs), Dr. Ryan Buss, M.D. and Dr. Jeffrey Freeman, M.D., both for the use of materials in 10 CFR 35.100, 35.200 and 35.300.

Please note that I was unable to approve Drs. Buss and Freeman as AUs for materials in 10 CFR 35.100, 35.200 and 35.300 at this time because the information in your letter dated July 13, 2009, was insufficient to complete my review.

If you wish to pursue these requests, please submit the information requested below and address it to my attention as "additional information to control number 318354." We will then continue our review.

A. Dr. Buss was not approved for the use of materials in 10 CFR 35.100, 35.200 and 35.300, in part because his specialty board certification is not recognized by NRC, i.e., the words "AU eligible" do not appear above the seal on his certificate. Please see this link on our Medical Licensing Toolkit page for a list of the medical specialty board certifications that we recognize:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

In addition, his preceptor attestation forms are incomplete and contain blank spaces and incomplete or incorrect information.

Please carefully prepare and submit the required preceptor attestation forms in accordance with 10 CFR 35.190, 35.290 and 35.390. A copy of these forms can be found at:

<http://www.nrc.gov/materials/miau/med-use-toolkit.html#forms>

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response.

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

Please do not submit resumes, CV's, copies of Radiation Safety Committee meeting minutes or applications or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

If Forms 313a will be used in support of your response, please use the

**newly revised Forms found on our website at:**

**[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)**

**Also, please note that we will have to verify Dr. Buss' preceptor when you resubmit his application. If Dr. Buss received his training at a broad scope medical institution and as the medical institution is located in an Agreement State, we will be unable to verify his preceptor's qualifications. This is because we do not have access to Agreement State licenses and broad scope licenses do not name Authorized Users (AU's) on the license document directly. Rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.**

**As appropriate, please submit a copy of the license for Dr. Buss' preceptor, as he trained at a medical institution in an Agreement State License. If Dr. Buss' preceptor AU is a permit-holder on a broad scope license, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities the preceptor AU was authorized for under the license and which timeframes he held said authorization.**

**Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."**

**B. Dr. Freeman was not approved for the use of materials in 10 CFR 35.100, 35.200 and 35.300, in part, because it appears he did not participate in the required 3 cases involving sodium iodide I-131 in quantities greater than 33 millicuries, in accordance with 10 CFR 35.390.**

**Also, please note that we will have to verify Dr. Freeman's preceptor when you resubmit his application. If Dr. Freeman received his training at a broad scope medical institution and as the medical institution is located in an Agreement State, we will be unable to verify his preceptor's qualifications. This is because we do not have access to Agreement State licenses and broad scope licenses do not name Authorized Users (AU's) on the license document directly. Rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.**

**As appropriate, please submit a copy of the license for Dr. Freeman's preceptor, as he trained at a medical institution in an Agreement State License. If Dr. Freeman's preceptor AU is a permit-holder on a broad scope license, please also submit a letter currently signed and dated by the Chair of the Radiation Safety Committee stating which modalities the preceptor AU was authorized for under the license**

and which timeframes he held said authorization.

Please also be reminded of the provisions in 10 CFR 30.9(a), “Completeness and accuracy of information,”...”(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission’s regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.”

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response.

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

Please do not submit resumes, CV’s, copies of Radiation Safety Committee meeting minutes or applications or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

5. The letter dated July 14, 2009, also included requests to add certain radioactive materials. It appears that the Sr-82/Rb-82 and Str-85 generators are authorized by the change in our definition of “byproduct material” in 10 CFR 30.4 and 10 CFR 35.200. Therefore, it does not appear to be necessary to create additional line items for these materials on your license. If you disagree, please advise me in response.
6. Further, this letter requests the addition of Yttrium-90 Theraspheres. The guidance for this modality is found on our website under 10 CFR 35.1000 at:

[http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU\\_ADAMS^PBNTAD01&ID=082620098](http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?library=PU_ADAMS^PBNTAD01&ID=082620098)

It appears that parts of this guidance were not committed to in your letter as follows:

Please provide a finite possession limit for this material, including potential waste streams, as we cannot authorize “as needed” quantities.

Please confirm that, for individuals obtaining clinical use experience under pathway 2, you will submit documentation to the NRC Region III Office within 30 days of when these three patient cases have been completed.

Please confirm that you will follow all the requirements in 10 CFR Part 35 for

**brachytherapy sources and manual brachytherapy use, except where replaced by the license commitments contained in the July 14, 2009, letter and this response letter.**

**Please confirm that you will commit to reporting any event, except for an event that results from intervention of a patient or human research subject, in which:**

**1) the administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or**

**2) the administration of Y-90 microspheres results in a dose:**

**that differs from the prescribed dose, as documented in the pre-administration written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the pre-administration written directive, by 20 percent or more; or**

**3) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the pre-administration portion of the written directive.**

**• Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).**

**These commitments immediately above were not explicitly made in the July 14, 2009, letter; instead, a blanket statement referenced them, which is not acceptable.**

**In the section of your request pertaining to future changes in your Y-90 Microsphere radiation safety program to conform to changes in NRC's licensing guidance, please confirm that you will include in your record of changes made the effective date of each change.**

**Your letter did not specifically address the potential problem of radioactive contaminants and subsequent disposal issues. Please confirm that you are familiar with these issues and that you will, as necessary, hold remaining microspheres longer for decay-in-storage in accordance with 10 CFR 35.92; or return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or transfer the microspheres to an authorized recipient.**

---

**We will be unable to continue processing your request until we receive this information.**

**In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available**

Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

---

ACTION REQUIRED

**As we cannot issue an amendment at this time we are voiding this request in order to enable you to prepare a quality application without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address using the control number 318354 to facilitate proper handling.**

**PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA SUBMISSION OF A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A "GOOD THING."**

**PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025, ext. 9841.**

---

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey		Oct. 19, 2009 <i>8/10/20/09</i>

---