



**ST. JOHN'S MERCY
MEDICAL CENTER**



August 25, 2010

Nuclear Material Licensing Branch
Region III, U.S.N.R.C.
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Acquisition of Nuclear Cardiology Facility

To Whom It May Concern:

This letter is a follow up to previous letters requesting an amendment to St. John's Mercy Medical Center material license 24-00794-03. Letters dated April 27, 2010 were sent to the NRC via certified mail requesting an amendment to material license 24-00794-03 regarding the acquisition of The Heart Health Center, material license 24-26530-01. I received the verification of receipt via the "green card" from certified mail. On about August 10, I phoned Bill Reichhold of the NRC to request a status update. Mr. Reichhold was kind enough to check his desk and other places for hard copy mail as well as the NRC database for documents that would have been scanned into the NRC system, but was unable to locate any of the documentation previously sent from this facility concerning this transaction.

I am including copies of those letters dated April 27, 2010 and I am again requesting an amendment to material license 24-00794-03 and some clarification of the request as made in the letter of April, 27, 2010. St. John's Mercy Medical Center plans to terminate material license 24-26530-01 when the amendment to add the materials and new locations of use is approved by the NRC. All necessary closeout surveys will be performed as discussed in the letters of April 27.

For additional information or questions please contact me at 314-251-6657 or 314-251-6844.

Sincerely,

Robert F. Turco, Ph.D.
Radiation Safety Officer



**ST. JOHN'S MERCY
MEDICAL CENTER**



April 27, 2010

Nuclear Material Licensing Branch
Region III, U.S.N.R.C.
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Acquisition of Nuclear Cardiology Facility

To Whom It May Concern:

This letter is documentation that St. John's Mercy Medical Center (STJMMC), material license 24-00794-03, agrees to the transfer of ownership and control of the licensed material and activity of The Heart Health Center, material license 24-26530-01, with facilities located at 450 North New Ballas Road Suite 170, West Wing, St. Louis, MO and at 620 Maple Valley Drive, Farmington, MO.

We are requesting an amendment to the STJMMC license to add the facilities and assets of The Heart Health Center upon the NRC's approval of the asset transfer. We hope you will consider expedition of this request. In order to allow clinical services to continue to be provided to these patients with cardiac health issues the transfer of ownership and control of The Heart Health Center license material will not occur until the requested amendment to the STJMMC license is approved by the NRC. I, the Radiation Safety Officer for STJMMC and Dr. Allen Soffer, the Radiation Safety Officer for The Heart Health Center or his designee will be available to coordinate all required closeout activities and transfer of records to STJMMC and facsimile of all closeout records to the NRC upon written approval of the transfer from the NRC.

We are providing the following information in accordance with NUREG 1556, Vol. 9, Revision 2, Appendix G:

1. The STJMMC/Heart Health Center transaction will include a transfer of assets and personnel in an "asset transfer" to occur on June 1, 2010. As described above, the transfer of ownership and control of The Heart Health Center license material will not occur until the requested amendment to the STJMMC license is approved by the NRC. After June 1 and prior to the NRC's approval of the requested amendment to the STJMMC license The Heart Health Center and Dr. Allen Soffer, the Radiation Safety Officer for The Heart Health Center, will continue to be responsible for all licensed material and shall continue to serve as the RSO for the NRC regulated activities at the then former Heart Health Center locations. After June 1 the former Heart Health Center facilities will operate under a new name "St. John's Mercy Heart and Vascular". The NRC may contact Robert F. Turco, Radiation Safety Officer at 314-251-6657 or Ken Andrews, M.S., 314- 251-7258 if Dr. Turco is not available.

2. Once the amendment to the STJMMC license is approved the only change in personnel and duties as it relates to NRC regulated activities at the former Heart Health Center facilities will be that of the Radiation Safety Officer (RSO). These duties will be performed by Robert F. Turco, Ph.D., who is the RSO for STJMMC. Allen D. Soffer, M.D. is the current RSO for The Heart Health Center and will assist Dr. Turco with this transaction.

Once the amendment to the STJMMC license is approved the personnel and duties as they relate to NRC regulated activities of all other Staff specifically the Authorized User (AU) and technologists, at the facilities will remain unchanged. The current AU for The Heart Health Center, Allen D. Soffer, M.D., will be issued a user's permit through the Radiation Safety Committee of STJMMC for authorized use of any radioactive material and for any imaging and localization use permitted by 10 CFR 35.100 and 10 CFR.200, but specifically limited to cardiovascular clinical procedures.

3. There will not be any changes, other than what has been previously described above, in the organization, locations, facilities, equipment, or procedures as they relate to NRC regulated activities at these facilities.
4. The status of the surveillance program as it relates to NRC regulated activities will not change as a result of this asset transfer. All surveys wipe tests, and other quality assurance control procedures outlined in the material license application for The Heart Health Center shall continue as such. All required surveillance has been performed, documented, reviewed and is up to date.
5. All decommissioning records will be transferred from The Heart Health Center to STJMMC or the NRC as appropriate, including documentation of ambient radiation survey results and/or removable radiation contamination results with a description of all the methods used and their corresponding sensitivity. In addition, once the amendment to the STJMMC license is approved, STJMMC will accept The Heart Health Center's inventory of sealed sources located at each facility. Dr. Turco or his representative will be present during the leak testing of these sealed sources and STJMMC will obtain these leak test records as required by 10 CFR 35.2067. STJMMC shall provide written attestation of receipt of these sealed sources to the NRC by facsimile following their transfer if required.
6. STJMMC will abide by all constraints, conditions, requirements and commitments of the current material license of The Heart Health Center facilities.

We are providing the following additional information pertaining to the Availability of the Radiation Safety Officer, as outlined in a facsimile (enclosed) dated April 1, 2010 from William Reichhold:

- a. I will not spend time each week at each of the facilities as a routine, unless there is an emergency or urgency for my oversight or consultation. Each location has CNMTs available to oversee routine operation of NRC regulated activities. I will have a radiation safety assistant available on May 1, 2010 who will be able to assist me with oversight of these facilities. Either I or my designee will perform audits in a timely fashion at these locations and will engage the local CNMTs to coordinate maintenance of surveillance records. Personnel monitoring reports will be mailed directly to me for review from the vendor once the transfer of control and purchase of The Heart Health Center is completed.
- b. I am available by cell phone at any time other than when out for vacation or out of town meetings. On those occasions either my assistant or Ken Andrews, M.S. will be available to respond to an emergency. I will be available by phone when out of town. Otherwise, I can be on sight at the 450 North New Ballas facility usually within 10 minutes and at the facility in Farmington within 2 hours.
- c. My commitments as RSO are to St. John's Mercy Medical Center and its satellites most of which are within 30 minutes of St. John's Mercy Medical Center. St. John's Mercy Hospital, located in Washington Missouri is approximately 50 miles west of St. John's Mercy Medical Center. As previously mentioned I will have a physics assistant to help with coordination of NRC regulated activities at these facilities. I am also the RSO for material license 24-24392-01. However, this will not impact duties as RSO at the new facilities. Activities related to material license 22-24392-01 are limited to instrument checks and calibrations. There are no clinical activities related to this license.
- d. NRC regulated activities at the new facilities will eventually come under the control of St. John's Mercy Medical Center and NRC regulated activities will be coordinated through the radiation safety program at St. John's Mercy Medical Center. With the help of an assistant and communications with the on-site CNMTs there should not be an adverse impact on my duties.
- e. A majority of the facilities are either located on or within 30 minutes of the main campus of STJMMC. Two of the facilities, St. John's Mercy Hospital and the new facility in Farmington are 1 hour and 2 hours respectively from STJMMC or any other facility. The majority of my time will be spent at STJMMC which is the hub for NRC regulated activities. The majority of patient activities related to licensed material occur at STJMMC. However, either I or my designee will visit the other sites to perform activities related to radiation safety and NRC licensed activities.

If you have any additional questions or require additional information regarding this letter, please contact me at 314-251-6657

Sincerely,



Robert F. Turco, Ph.D.
Radiation Safety Officer



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE April 1, 2010

NUMBER OF PAGES 4

SEND TO Bob Turcho, Radiation Safety Officer

LOCATION St. John Hosptial

FAX NUMBER (314) 251-4337

☐ VERIFY BY CALLING

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839

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 Bob, I had a similar question from a licensee last month, so I was able to get this information together for you quickly. See accompanying documents.

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 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.

As we discussed on the telephone, the following are typical questions we ask for change of ownership/control and availability of the Radiation Safety Officer. Your circumstances may be different and may need additional information and/or clarification.

Change of Ownership/Control Information

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's prior written consent **before transferring control of the license**. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (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.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

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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.

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.

7. Provide documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

NUREG-1556, Volume 15 discusses change of control (and other topics). You can find a copy of NUREG-1556, Volume 15 on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/>. Also see 10 CFR 30.34(b), and other references in NUREG-1556, Volume 15, Section 5, "Change of Control".

Availability of the Radiation Safety Officer

Please describe the availability of the Radiation Safety Officer (RSO):

a. Please describe the amount of time each week Bob Turcillo will spend at the "new" facilities.

b. Please indicate the amount of time it will take for Bob Turcillo to respond to an emergency involving radioactive materials when he is not at the "new" facilities.

c. Please describe any previous commitments Bob Turcillo has as the RSO and/or authorized user at any other NRC licensed facility and describe the impact this will have on his duties as the RSO at the new facilities.

d. Since Bob Turcillo will be the RSO for at least three or more facilities, please describe any adverse impact this will have on his duties as the RSO at the "new" facilities. If there will be no adverse impact, please state so, and why.

e. Please describe how Bob Turcillo will divide his time between all facilities so that he will be able to adequately perform his duties as the Radiation Safety Officer

Please call me at 630-829-9839 if you have any questions.

From the desk of:

Bill Reichhold
Bill Reichhold

THE HEART HEALTH CENTER



April 27, 2010

DAVID L. COLE, M.D., F.A.C.C.
JACKIE L. CHONKLO, M.D., F.A.C.C.
ROBERT G. KOPPEL, M.D., F.A.C.C.
CLARK R. MCKENZIE, M.D., F.A.C.C.
STEPHEN L. HOFFER, M.D., F.A.C.C.
PAUL A. ROBBIOLO, M.D., F.A.C.C.
J. ALBERTO SANCHEZ, M.D., F.A.C.C.
ALLEN D. SOFFER, M.D., F.A.C.C.
WILLIAM E. SOUTHWORTH, M.D., F.A.C.C.

Nuclear Materials Licensing Branch
Region III, U.S.N.R.C.
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Asset Transfer of Nuclear Cardiac Facility

To Whom it May Concern:

This letter is notification that The Heart Health Center, material license 24-26530-01, agrees to transfer all assets of its nuclear cardiology facilities, located at 450 North New Ballas Road, Suite 170 West Wing, St. Louis, MO and 620 Maple Valley Drive, Farmington, MO, to St. John's Mercy Medical Center (STJMMC), material license 24-00794-03. This transfer would be effective upon the NRC's approval of the requested amendment to the STJMMC license. This transfer is being made in connection with a broader transaction involving The Heart Health Center and STJMMC as described below.

We ask that the NRC consider this request while allowing us to continue, as described below, clinical operations uninterrupted at these facilities. Dr. Soffer, the Radiation Safety Officer for The Heart Health Center will coordinate all required closeout activities and transfer of records to STJMMC and facsimile of all closeout records to the NRC as required.

The STJMMC/Heart Health Center transaction will include a transfer of assets and personnel in an "asset transfer" to occur on June 1, 2010. The transfer of ownership and control of The Heart Health Center license material will not occur until the requested amendment to the STJMMC license is approved by the NRC. After June 1 and prior to the NRC's approval of the requested amendment to the STJMMC license The Heart Health Center and Dr. Allen Soffer, the Radiation Safety Officer for The Heart Health Center, will continue to be responsible for all licensed material and shall continue to serve as the RSO for the NRC regulated activities at the then former Heart Health Center locations. After June 1 the former Heart Health Center facilities will operate under a new name "St. John's Mercy Heart and Vascular".

We are providing the following information in accordance with NUREG 1757, Volume 1, Revision 2, Section 8.2:

1. Once the amendment to the SJMMC license is approved the Heart Health Center would transfer its entire inventory of sealed sources to STJMMC, which they have been confirmed as being authorized to receive. Leak tests shall be performed on all sealed sources upon approval of transfer by the NRC in writing, prior to their transfer to STJMMC. The results of these leak tests shall be provided to STJMMC (and the NRC via fax) to demonstrate there is no leakage.

450 NORTH NEW BALLAS ROAD
SUITE 170 WEST WING
ST. LOUIS, MO 63141
PHONE: 314-993-6969
FAX: 314-993-6792

620 MAPLE VALLEY DRIVE
FARMINGTON, MO 64425
PHONE: 573-769-0111
FAX: 573-769-0790

2. Prior to the transfer of the licensed materials at these facilities, a radiation safety closeout survey will be performed to demonstrate that the facility is suitable for release in accordance with the decommissioning criteria as stated in 10 CFR 20 Subpart E. The results of this radiation safety closeout survey will be submitted to STJMMC (and the NRC via fax) in accordance with 10 CFR 30.36(j) and NRC Form 314.
3. All records pertaining to NRC regulated activities at this facility shall be retained by the management of The Heart Health Center in accordance with 10 CFR Parts 30 and 35 with copies being provided to STJMMC as appropriate.
4. NRC form 314, "Certification of Disposition of Materials" has not been enclosed. Following approval from the NRC of the amendment of the STJMMC license, The Heart Health Center will fax to the NRC written confirmation from STJMMC including the inventory of sealed sources and that the sealed source inventory has been transferred and received.

In addition to the agreement to transfer assets, and upon approval of the NRC to the amendment to the STJMMC license, we will subsequently terminate our material license. If you have any additional questions or require additional information regarding this letter, please contact our office at 314-993-6969.

Sincerely,



Allen D. Soffer, M.D., F.A.C.C.
Radiation Safety Officer

St. Johns Mercy Medical Center
615 South New Ballas Road
St. Louis, MO 63141

CERTIFIED MAIL



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Mailed From: 63045

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Nuclear Material Licensing Branch
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