

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

REGION III
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CONVERSATION RECORD	TIME	DATE
ACTUALLY FAXED OR		8/16/11
TRANSMITTED VIA SCANNED/SIGNED PDF? <i>yes</i>		8/17/11

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Paul Jursinic, Ph.D. presumed RSO for Lee Memorial Hospital and Heart Center for Excellence, incumbent RSO for Borgess Memorial Hospital; also Tom Mushett, Director of Radiology For Borgess Memorial Hospital		269-373-7407

SUBJECT
License No.: 21-32287-01 for Lee Memorial Hospital Control No.: 575218, Lee Mem. Hosp.
License No.: 21-18912-01 for Heart Cntr for Excellence, C/N: 575220, HCE
License No.: 21-12275-02 for Borgess Memorial Hosp, C/N: 575223, BMH

SUMMARY

This refers to your letters dated May 17, 2011 (one letter), and April 29, 2011 (several letters), in which a series of changes to the above licenses, (Lee Memorial Hospital ("Lee"), "Heart Center for Excellence" ("HCE") and Borgess Memorial Hospital ("BMH")) were requested, including termination of the Lee and HCE licenses concurrent with their merger into license no. 21-12275-02 for Borgess Memorial Hospital (BMH).

This also refers to the telephone conversations on August 16, 2011, between Tom Mushett, Director of Radiology and Paul Jursinic, Ph.D. and me, as well as followup telephone discussions on August 17, 2011, between Dr. Jursinic and me.

These conversations helped to clarify the situations and requests made in the correspondence above.

Based on these discussions it is my understanding that the following sequence of events is probably what transpired:

It appears that BMH acquired Lee and HCE on January 1, 2011, via an unspecified change of ownership/control transaction and wanted termination of their licenses to become effective on April 29, 2011, concurrent with their merger into the BMH license.

However, in accordance with 10 CFR 30.34(b) and Section 1.3.3 and Appendix G from NUREG 1556 Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses," Lee and HCE were required to have obtained NRC's written consent prior to the date when the transaction occurred, January 1, 2011.

This means that an amendment request/change of ownership – control/request for consent should have been received by NRC approximately 90 days before the January 1, 2011 date, in order for us to consider the requests and, as appropriate, provide the written consent letters!

This was apparently not done.

Subsequently, on April 29, 2011, a series of letters requesting changes to the three licenses above, all bearing that date, were prepared and attached to a single cover letter dated May 17, 2011, received in our offices on May 19, 2011. The attached letters dated April 29, 2011, were not segregated and all appeared to be a part of the May 17, 2011, letter as attachments. This led to an inappropriate “processing in” of these requests, which I finally got straightened out on Aug. 16, 2011 and Aug. 17, 2011.

Dr. Jursinic and Mr. Mushett helped to clarify the individuality of the letters and your intentions with them on Aug. 16, 2011, in our phone calls.

For future reference, please ensure that all licensing correspondence for different licenses is clearly marked and segregated to facilitate proper handling in our offices. Your cooperation in such matters is greatly appreciated.

When a license is acquired by a different entity and its merger/termination is requested, it is usually best to contact the NRC to arrange the details of the licensing issues as these types of cases are usually not “one size fits all” and they can get complicated.

For example, we would usually ask the licensee to select a date in the near future when use of materials under the license would cease and close-out surveys would be conducted. The affected licensees involved in the termination requests and merger into a different license would submit their requests at least several weeks prior to the selected date, as per a pre-arrangement with the reviewer, by mutual agreement.

Then, on that date(s), the required closeout surveys would be submitted to NRC and the amendments finalizing the license terminations and merger into the other license would be concluded and transmitted to the affected licenses. Hence, patient care would not be adversely impacted and a clear transition would be made from each terminated license to the license absorbing the merging programs/facilities, etc.

This was apparently not done.

Your letters dated April 29, 2011, appear to indicate that the transition of terminated licenses to BMH should take place on that date, but a cover letter sending these letters to us was dated May 17, 2011, and received May 19, 2011, as noted above. So compliance beforehand was not possible due to the late involvement of NRC.

For the Lee Memorial Hospital license termination request and portion of the BMH merger amendment:

Please submit all of the information requested in Appendix G to the NUREG 1556, Vol. 9, Rev. 2 above. Please do not consolidate/abbreviate your responses as they appear in the April 29, 2011 letter.

Please clarify whether the RSO will change as a result of this transaction. The letter dated April 29, 2011, states that no personnel will change but Dr. Jursinic indicated that he expected to become the RSO when the terminations/merger were complete.

10 CFR 35.24 only permits each human use licensee to have one Radiation Safety Officer, which presumably will be Dr. Jursinic, as he is already RSO for BMH. Toward this end, please have Dr. Jursinic sign and date a written acceptance of the position as RSO for the Lee license, including a management delegation of authority extended from BMH to Dr. Jursinic. Please see Section 8.11, Item 7 and Appendix I in the aforementioned NUREG 1556, Vol. 9, Rev. 2 for assistance and guidance in preparing these documents.

Please specify how often Dr. Jursinic will be on campus at Lee and how much time will he have, at a minimum, to devote to the RSO duties there?

If you wish to select a future transition date for the Lee closeout survey information, please see the Enclosure for additional detailed information that we will need. Note that this is the preferred pathway. OR,

If you want to make a direct transfer of the license without a closeout survey, please clearly state that BMH will accept full responsibility for the Lee Memorial Hospital licensed program, including any residual radioactive contamination, all sealed and unsealed radioactive materials, and radioactive waste streams.

If appropriate, please prepare an updated, signed and dated Form NRC 314 for each license, HCE and Lee.

I noted that, contrary to the assertions made in your letter dated May 17, 2011, neither consultant appeared to provide surveys for Lee or HCE. Instead, a copy of each consultant's quarterly visit report was provided, which does not constitute a closeout survey (see enclosure.) The visit reports provide some information but not everything that a closeout survey does for a license termination.

For the HCE license termination request and portion of the BMH merger amendment:

Please submit all of the information requested in Appendix G to the NUREG 1556, Vol. 9, Rev. 2 above. Please do not consolidate/abbreviate your responses as they appear in the April 29, 2011 letter.

Please clarify whether the RSO will change as a result of this transaction. The letter dated April 29, 2011, states that no personnel will change but Dr. Jursinic indicated that he expected to become the RSO when the terminations/merger were complete.

10 CFR 35.24 only permits each human use licensee to have one Radiation Safety Officer, which presumably will be Dr. Jursinic, as he is already RSO for BMH. Toward this end, please have Dr. Jursinic sign and date a written acceptance of the position as RSO for the HCE license, including a management delegation of authority extended from BMH to Dr. Jursinic. Please see Section 8.11, Item 7 and Appendix I in the aforementioned NUREG 1556, Vol. 9, Rev. 2 for assistance and guidance in preparing these documents.

Please specify how often Dr. Jursinic will be onsite at HCE and how much time will he have, at a minimum, to devote to the RSO duties there?

If you wish to select a future transition date for the HCE closeout survey information, please see the Enclosure for additional detailed information that we will need. Note that this is the preferred pathway. OR,

If you want to make a direct transfer of the license without a closeout survey, please clearly state that BMH will accept full responsibility for the HCE licensed program, including any residual radioactive contamination, all sealed and unsealed radioactive materials, and radioactive waste streams.

If appropriate, please prepare an updated, signed and dated Form NRC 314 for each license, HCE and Lee.

I noted that, contrary to the assertions made in your letter dated May 17, 2011, neither consultant appeared to provide surveys for Lee or HCE. Instead, a copy of each consultant's quarterly visit report was provided, which does not constitute a closeout survey (see enclosure.) The visit reports provide some information but not everything that a closeout survey does for a license termination.

For the BMH amendments merging the Lee Memorial Hospital and HCE sites into it and the review of the Naomi Street location of use that was requested to be deleted:

Please address the RSO issues as noted above. Dr. Jursinic needs to explicitly state that he accepts the position as RSO for Lee Memorial Hospital and Heart Center for Excellence and that he understands the duties and responsibilities associated with that position. He and senior management officials for Lee, HCE and BMH should sign your responses to this letter and the delegations of authority.

Please stipulate that all of the radiation safety program elements currently in place for the BMH license will be extended to the programs at Lee Memorial Hospital and Heart Center for Excellence when the licenses have been terminated and merged into the BMH license.

Please provide copies of any/all documents that currently appear in the last, "tie-down" condition of each of the licenses for Lee Memorial Hospital and Heart Center for Excellence that should, after the termination of each license, become incorporated into the BMH license.

Please examine this carefully to ensure that the BMH license addresses each licensed program at Lee and HCE completely. It is possible that only the facility diagrams and descriptions, which should be prepared completely in accordance with NUREG 1556, Vol. 9, Rev. 2, Section 8.6, Item 9 and Attachment 9.1, a sample diagram in the guidance.

For the Naomi Street location, "Pipp," please clarify the actual historical use of licensed materials at this site. This is unclear because, on the license, all licensed materials were apparently authorized for use at this site but only materials in 10 CFR 35.200 were asserted to have been used. If this was the case, then the license should have been amended accordingly and the discrepancy brought to our attention.

Also, on the "Sealed Source Inventory Record" page, at the bottom, under "Sealed Source Ambient Exposure Record Survey" it says "Bicron at flood." A measurement is given. I noted that more than one flood source appears on the inventory. Please explain and clarify what this means and which flood source is referred to.

Please submit a copy of the last decay-in-storage waste disposal record for this location. Only the last record is needed to establish cessation of activities and complete disposition of licensed materials.

Also, please always include the telephone number and fax number/email address of at least one person who serves as a point of contact for all future licensing requests. Ensure that a management representative signs the amendment request, in accordance with 10 CFR 35.12(a).

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."

In accordance with 10 CFR 2.390 of the NRC's "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's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

ACTION REQUIRED

As we cannot issue the license terminations or the amendments to the BMH license at this time, we are voiding these requests, i.e., removing them from our active database. This action is taken without prejudice to resubmission at a later date.

Please submit written responses to the above items by referencing the appropriate license nos. and control numbers to facilitate proper handling in our offices.

Please address your written responses to my attention as "additional information to control number _____ (fill in the blank appropriately for each)" and ensure that each is currently dated and signed by a senior management representative and the RSO, as indicated above.

We will then continue our review.

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



August 17, 2011

ENCLOSURE – CLOSEOUT SURVEYS

We normally cannot authorize licensees to release the areas (excepting areas covered by 10 CFR 35.13(e) and 35.14(b)(4)) or locations of use from licenses for unrestricted use (even by other members of their staff) and/or subsequent license termination until we have received and reviewed a copy of the results of decommissioning and close-out surveys for the facilities.

The final status survey must include a complete historical review of all actual licensed materials used, including sealed and unsealed sources, spills, and contamination. It should specify when and where the materials were used and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred (may be a future date).

Please respond by stating exactly which licensed materials were used at this location historically and please submit final status survey information covering those radioactive materials.

The final status survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored.

Please submit the following information with your close-out survey:

- a. Diagrams of each facility with exposure rate survey and wipe test results keyed to specific locations, as appropriate. Meaningful units must be specified, i.e., "counts per minute" are inappropriate. "Disintegrations per minute," "millirem per hour," etc. are appropriate.
- b. The name of the person performing the survey.
- c. The date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- e. Background readings and each instruments' efficiency or correction factor and which radionuclides/energy ranges apply to the efficiency or correction factor(s). The radionuclide(s) being surveyed for should be within the energy range of the instrument used.
- f. The date(s) that the survey instruments were last calibrated.
- g. The action levels for both exposure rate measurements and wipe tests. Include the identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken.
- h. A copy of the final decay-in-storage waste disposal record, per 10 CFR 35.92 and 35.2092. Only the last decay-in-storage waste disposal record is necessary.
- i. A copy of the most recent leak tests on all sealed sources authorized by the license and by 10 CFR 35.65. Again, only the last and most recent leak tests are necessary.