6 PAGES

# CONVERSATION RECORD


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
EMAIL: COLLEEN.CASEY@NRC.GOV


| | TIME | DATE |
|---|---|---|
| ACTUALLY FAXED/(EMAILED)? YES. | | April 16, 2012 |

**Fax No.: 269-783-3056**

**Email address: pjursinic@wmcc.org**

| NAME OF PERSON(S) CONTACTED | ORGANIZATION | TELEPHONE NO. |
|---|---|---|
| Paul Jursinic, Ph.D., RSO and Tom Mushett | | 269-373-7407 (PJ)<br>269-226-4833 (TM) |

SUBJECT: 21-12275-02 BMC amdmt 030-02115 576076 BMC amdmt.
21-18912-01 HCE term 030-17349 576077 HCE term.
21-32287-01 LMH term. 030-35603 576074 LMH term.

License No.: 21-12275-02 **Control No.: 575210 (Borgess renewal)**

SUMMARY

**We have reviewed your letters dated September 16, 2011 (three of them), as well as 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).**
**In addition you requested an amendment/renewal of your byproduct materials license for BMC and find that we need additional information as follows:**

1. **Your letter dated April 29, 2011, indicates that you now wish to downgrade your broad scope license for Borgess Medical Center (BMC) to a limited scope medical license. However, some of the information we will need in order to accomplish this was not provided in the letter dated April 29, 2011. This information is addressed and responses are requested below.**

2. **In addition, you are requesting the merger into the Borgess Medical Center license of the licenses for Heart Center for Excellence (HCE) (C/N 576077, L/N 21-18912-01) and Lee Memorial Hospital (LMH) (C/N 576074, L/N 21-32287-01).**

These mergers are intended to be concurrent with the termination of each of these respective licenses for HCE and LMH. Some of the information we will need in order to accomplish this was not provided in the letter dated April 29, 2011. This information is addressed and responses are requested below.

With respect to the requested downgrade of the broad scope components of your license for BMC, please note that we cannot remove any authorization from your license on the basis of statements made in your letter dated April 29, 2011, that you are no longer using certain materials, such as phosphorus-32 in the Isostent, sealed iridium-192 sources, and the materials covered under the broad scope authorization.

You must explicitly direct us to remove each authorization you no longer wish to continue and provide appropriate supporting information, such as waste disposal records, final leak tests, etc. as appropriate.

Please demonstrate that no residual radiation sources, including waste streams, remain in the facilities where materials you will be requesting the deletion of were received, possessed, used or stored.

3. Since much of it applies to the current situation and we wanted to be sure to capture the "animal research" component of your past broad scope activities, the following information is repeated and paraphrased from my letter to you dated October 23, 2008, concerning your letter dated July 7, 2008, in which you requested the deletion of the authorization for "animal research" from your license because such activities had ceased.

   In order for us to approve the deletion of the broad scope materials from this license we will need all of this information provided to cover the period from December 7, 1998 (when the broad scope authority was first approved), to the present.

   We are unable to approve the deletion of these authorizations because the information submitted in your letters dated July 7, 2008, (animal research) and April 29, 2011, (broad scope) was insufficient to complete our review.

   A. Please provide a complete historical review of your broad scope activities, including but not necessarily limited to, medical and animal research activities, both "in vitro" and "in vivo."

   B. Please specify which broad scope radioisotopes were used, where, when, how much and which chemical and physical forms were used.

   C. What types of studies, experiments, procedures, etc. were conducted under the broad scope license authorization, including but not necessarily limited to, medical and animal activities?

   D. Please also specify which kinds of animals were used for the research activities (mice, rats, dogs, etc.)

E. Please also provide copies of the final records showing a description of the disposition of animal tissues/carcasses, P-32 Isostent sources and devices, Ir-192 sealed sources and all broad scope authorization sources, unsealed and sealed, including radioactive waste streams and final disposition records associated with that program's use over the years.

Please include the final leak tests for sealed sources (if they were held less than 6 months, then the incoming leak test copy should suffice), acknowledgments of receipt from vendors or waste disposal brokers (and proof of their appropriate licensure to receive your materials if not the vendor of origin), records showing decay-in-storage and final disposal, etc. Please contact me if you have any questions about these matters.

4. Regarding your facilities diagram for 1521 Gull Road, Kalamazoo, Michigan:

   A. Please identify what is located on the west side adjacent to the hot lab.

   B. Please identify where the injection area(s) is located.

   C. Please identify where the hot lab is located in relation to the imaging rooms.

   D. For all future facility diagrams, please follow the exhibit in NUREG 1556, Vol. 9, Rev. 2, Figure 8.1, to ensure completeness.

5. It appears that your authorization for americium-241 in Subitem Nos. 6. through 9. J., inclusive, may be captured by the authorization in 10 CFR 35.65. If it is, please advise me in your response, request its deletion and it will not be necessary to list this as a line item authorization. You will still be able to use and obtain the source under 10 CFR 35.65.

6. Please describe the emergency response equipment you will have available for brachytherapy use. "Remote handling tools" only were mentioned in your letter dated April 29, 2011, which appears to be insufficient.

7. Item 1 in the September 16, 2011, letter for the BMC amendment, (C/N 576076) stated that the "RSO acceptance" document was attached. It was not attached. We did not find it attached to any of the documents submitted for the other licensing actions related to this merger/renewal/termination either. Therefore, please provide the Delegation of Authority as requested in my record to you dated August 16 and 17, 2011, and as follows:

   Your letters, all dated September 16, 2011, for BMC (C/N 576076, amendment); for HCE (C/N 576077, termination); and LMH (C/N 576074, termination) state that upon the termination of the HCE and LMH licenses and concurrent with their merger into the BMC license, Dr. Jursinic will "automatically" become the RSO for all three facilities.

   This is not necessarily true. First, you must explicitly request that Dr. Jursinic be appointed RSO for the other two licensed programs and complete a Delegation of Authority, signed by both Dr. Jursinic and senior management for BMC/LMH/HCE.

A sample Delegation of Authority is provided in Appendix I, NUREG 1556, Vol. 9, Rev. 2, "Program-Specific Guidance About Medical Use Licenses."

NRC's regulations in 10 CFR 35.24(b) require that the proposed RSO consent in writing to serving as the RSO for the licensed facilities and programs and that he acknowledges the duties and responsibilities associated with the position.

Please provide the requested Delegation of Authority, signed by Dr. Jursinic and senior management and currently dated, for Dr. Jursinic to be named RSO for all licensed institutions covered by the merger of the HCE and LMH licenses into BMC.

8. Please be reminded that, pursuant to 10 CFR 30.35(g), you must keep records important to safe and effective decommissioning, especially since at least some of the areas of use covered by your soon-to-be former broad scope authority will be considered released for unrestricted use by your Radiation Safety Committee. These close-out surveys and the RSC's disposition of these areas must be retained for the eventual resolution of this license at some future point.

   To help facilitate the completeness of your records, please include in your records the last date(s) when licensed materials were used in each location of use and area of use. Records of spills and cleanup activities are especially important.

   It is also important to note that these areas of use are not considered released for unrestricted use (even by other members of your staff) until your RSC has received and approved close-out survey information for each location/area of use where the broad scope activities were conducted.

   Your Radiation Safety Committee may have evaluated and approved/disapproved of the release for unrestricted use for your facilities internally under the broad scope components of your license.

   In response, please acknowledge your understanding of and commitment to this reminder.

9. Item 8.12 Item 7 lists the authorized users proposed for your limited scope license and states that your RSC has already approved these AU's.

   Please note that limited scope licenses are no longer able to express limitations on the NRC Form 374 License itself for the use of materials in 10 CFR 35.200, such as a limitation to cardiovascular clinical procedures. This is a change that took place when new 10 CFR Part 35 became final in April 2002.

   NRC can list the AU's for 10 CFR 35.200 and the limitation will not be expressed on the license except for the inclusion of the letter dated April 29, 2011, in the last condition of your license, also called the "tie-down condition." So the AUs' authorizations will be expressed and restricted in this manner.

   In addition, I noted that Dr. Linda Grossheim was listed for use of materials in 10 CFR 35.1000. However, it appears that you will be requesting removal of the only

material listed on your license under 10 CFR 35.1000, i.e., P-32 in the Isostent. Please adjust your requested authorization for Dr. Grossheim accordingly.

We compared your list of proposed AUs against the existing licenses for HCE and LMH and noted a common discrepancy for three physicians that appears to be the result of the complete revision of 10 CFR Part 35 in April 2002.

For Drs. Michael S. Pawlik, D.O, Christopher Rogers, D.O., and Robert A. Williams, D.O., their proposed authorization for materials in 10 CFR 35.200 excludes generators, xenon-133 and aerosols.

NRC can no longer continue to exclude generators, xenon-133 and aerosols from 10 CFR 35.200 authorization. All authorized users for 10 CFR 35.200 must be fully qualified for all of the materials in 10 CFR 35.200, including generators, xenon-133 and aerosols.

Please confirm that Drs. Michael S. Pawlik, D.O, Christopher Rogers, D.O., and Robert A. Williams, D.O. are qualified for all of the materials in 10 CFR 35.200, including generators, xenon-133 and aerosols.

We noted that none of the proposed AUs were named to use materials in 10 CFR 31.11. In response, please name at least one AU for the use of materials in 10 CFR 31.11.

10. In the letter dated September 16, 2011, for the BMC amendment request under control no. 570076, there are 14 pages of documents that begin with "Leased Employee Agreement" and appears to pertain to West Michigan Cancer Center.

    We do not understand what these documents are or their relevance to the amendments currently under consideration by us. Please withdraw these documents as they appear to be extraneous.

11. Item 7 in your letter dated September 16, 2011, for the BMC amendment states that the requested "last decay in storage, waste disposal records for Pipp are attached." Please note that these records were not attached to either this document or any of the others submitted for the related licensing actions.

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

---

13. The letter dated April 29, 2011, for the renewal of the BMC license that downgrades it from a broad scope license to a limited scope license states in section 8.3 Item 3 the locations of use, including the location for HCE. However, it appears that the location of use proposed for Lee Memorial Hospital, at 420 W. High Street, Dowagiac, Michigan was not included. It also appears from your letter dated September 16, 2011, for the LMH termination request, C/N 576074, that it was your intention to merge this location into the BMC license. Your letter dated September 16, 2011, for the BMC amendment also indicates that merging LMH into the BMC

license was your intention. Please clearly state your intentions regarding LMH's license and confirm whether it should be added to BMC as a location of use.

14. We noted that there were extraneous documents printed on the reverse-side of certain pages of your letters to us dated September 16, 2011, for the termination requests for HCE and LMH. We do not understand what these documents are or why they were included. Please explain and withdraw them.

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.

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."

ACTION REQUIRED

Since the above issues crosscut and overlap with each other in various respects, it may be easiest for you to respond with one letter that addresses each item above in order, adding attachments, as appropriate. This one letter may be used for all four of the control numbers given below and in the text of this document. One copy of that response letter should be provided for each of the control numbers given below. NRC no longer requires duplicate copies so only one copy of this letter for each control number will suffice. If you have questions about this, please contact me.

Submit the requested information within 30 calendar days (by May 18, 2012) by referencing control numbers **576074 (LMH termination), 576077 (HCE termination), 576076 (BMC amendment) and 575210 (BMC renewal)** to facilitate proper handling in our office. Please contact me if you need to make alternative response arrangements.

Upon receipt of your response we will resume our review. Address your written response, via an appropriately dated and signed (by management) cover letter, to my attention at the above address.
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 | Colleen Carol Casey | April 16 , 2012 |