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

JUN 28 2012

Paul Jursinic, Ph.D.
Radiation Safety Officer
Borgess Medical Center
1521 Gull Road
Kalamazoo, MI 49001

Dear Dr. Jursinic:

Enclosed is Amendment No. 93 renewing your NRC Material License No. 21-12275-02 in accordance with your request. Bold font is added in this letter to facilitate readability and selective sections are underlined for emphasis.

Please note that your license has been renewed for a two year term as a Type A medical broad scope license and will not expire until June 30, 2014.

Please check the license and, if there are any errors or questions, notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

You may contact me directly at (630) 829-9841 and my fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

In a letter dated September 15, 2010, with attached application dated September 30, 2010, you requested renewal of License No. 21-12275-02 as a Type A medical broad scope, which is the type of license it has been since December 7, 1998.

In Amendment No. 90 dated April 6, 2011, we issued a one year limited term renewal of your license because most of the information pertaining to the broad scope elements of your licensed program were not provided in the renewal request documents.

In letters dated May 17, 2011, September 16, 2011, and April 27, 2012, you requested, in part, the renewal of License No. 21-12275-02, as a limited scope license, instead of as a Type A medical broad scope license. You provided the names of authorized users and most of the elements of a limited scope medical license program.

However, contrary to our requests in conversation records and letters dated April 6, 2011, August 17, 2011, April 16, 2012, June 8, 2012, your correspondence has thus far failed to address the final disposition of all radioactive materials possessed and used under the Type A medical broad scope authorization.

P. Jursinic

This also refers to the telephone discussion between me and you and Tom Mushett on May 10, 2012, regarding the requested downgrade of the broad scope components of License No. 21-12275-02, several matters related to it and the license's renewal.

On June 8, 2012, we issued Amendment No. 92 which authorized, in part, the merger into your license of several new locations of use. Our letter to you on that date also reiterated and augmented previous requests for additional information pertaining to your renewal request and downgrade of the license.

Until now, we were unable to issue the renewal of License No. 21-12275-02 because the information in your letters dated May 17, 2011 (including attachments and letters dated April 29, 2011), September 16, 2011 (with attachments and letters), and April 27, 2012 (with attachments and letters) was insufficient to complete our review.

As we haven't heard from you since May 10, 2012, and as it appears that you will need additional time to prepare an appropriate, high quality response to completely account for all of the broad scope materials, we decided to issue another limited term renewal of your license as a Type A medical broad scope.

We have temporarily continued all of the documents forming the basis of your Type A medical broad scope license that are shown in the last condition of your license, called the "tie-down condition," Condition No. 21.

These are the same documents incorporated into your license during its last full term renewal on November 30, 2000, in Amendment No. 82.

Please provide the information discussed previously in the telephone call on May 10, 2012, that was also described in my correspondence to you dated August 17, 2011, and April 16, 2012, and in telephone calls on August 16, 2011, and August 17, 2011.

In preparing your written responses to the information requests, please address your responses to my attention as "additional information to control number 575210," in order to facilitate proper handling in our offices.

In our letter to you dated October 23, 2008, responding to your request to delete animal research authorization from the license, we provided extensive, specific guidance to facilitate your ability to produce an appropriate and complete response. We also stated, in part, "Please note that, in order to delete any authorization from your license, you must support each request by demonstrating that no residual contamination or radiation sources, including waste streams, remain in the facilities where materials were used/stored.

The information still needed to complete the downgrade of the broad scope components of the license, and make the other related changes requested, consists of:

1. Please ensure that your possession limits for all materials are sufficient, since the one license will capture use at several different locations. In particular, the possession limit authorized in Subitem Nos. 8.C. is currently 800 millicuries.

P. Jursinic

Please be reminded that, for iodine-131 only, your total possession must be less than ten curies total including waste streams.

Please advise us if you need to adjust any of your current possession limits.

2. Your letter dated May 17, 2011, with attached letters dated April 29, 2011, application was confusing with respect to continuing the authorization in Subitem Nos. 6. through 9.F, inclusive, for the IsoStent Investigational Device Exemption.

Your authorization for the iridium-192 sealed sources in Subitem Nos. 6. through 9. H., inclusive, was also confusing me as it is my understanding that intravascular brachytherapy is no longer in common practice and that is what this authorization is for.

Please note that, in order for us to remove any authorization from your license, you must explicitly direct us to remove each authorization you no longer wish to continue and provide all appropriate supporting information, such as final waste disposal records, close-out surveys, final leak test record copies, license copies from transferees, and so on.

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.

10 CFR 30.41 and 30.51 may assist you.

It appeared that you wanted these authorizations removed from your license but no supporting information was provided that would enable us to do so.

3. Your letters dated May 17, 2011, including letters dated April 29, 2011, September 16, 2011, and April 12, 2012, indicate that your wish to downgrade your broad scope license to a limited scope medical license.

However, much of the information needed in order to accomplish this was not provided to us previously. The needed information was communicated to you in my conversation records dated August 17, 2011, and April 16, 2012. Please refer to these communications and to the reminder information below, derived from my prior communications to you.

That information, and other information that was incompletely addressed in your renewal applications and letters, follows:

A. Certain elements for your intended "limited scope" medical radiation safety program were missing or incomplete also.

Please make appropriate commitments for your dose calibrator and other equipment used to measure dosages of unsealed byproduct material (section 8.18, item 9) and spill/contamination procedures (section 8.26, item 9). The

appropriate sections in NUREG 1556, Vol. 9, Rev. 2 are referenced to assist you.

B. In order for us to approve the deletion of the broad scope materials from this license, please submit the following information to cover the period from December 7, 1998, (when the broad scope authority was first approved), to the present.

C. Please provide a complete historical review of your broad scope activities, including, but not necessarily limited to, human/medical diagnostic, therapeutic and research activities, whether conducted "in vivo" or "in vitro."

As noted above, in order for us to remove any authorization from your license, including materials in 10 CFR 31.11, you must explicitly direct us to remove each authorization you no longer wish to continue and provide all appropriate supporting information, such as final waste disposal records, close-out surveys, final leak test record copies, license copies from transferees, and so on.

D. Please specify which radioisotopes were possessed, used or stored, under the broad scope authorization, including where they were used, when, activities used and which chemical and physical forms were used. This information is necessary to characterize the actual scope and content of your broad scope license activities.

E. Please briefly summarize the types of studies, experiments, and procedures, etc. that were conducted under the broad scope license authorization, building upon the details in your response to item 4.D. above.

F. Please demonstrate that no residual radiation sources, including waste streams, remain in any of the facilities where materials you will be requesting the deletion of were received, possessed, used or stored. If your Radiation Safety Committee has evaluated and approved the release of former "areas of use" for unrestricted use, please describe the status of those facilities in response.

G. Please include the final leak tests for sealed sources (if they were held less than 6 months, then the incoming leak test record copy should suffice), acknowledgments of receipt from vendors or waste disposal broker (and proof of their appropriate licensure to receive your materials if they were 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.

H. We were unable to specifically list your proposed Authorized Users in Condition 12 of the license at this time because the downgrade of your broad license is not yet complete. When it is complete, Condition 12 will change to a specific list of your authorized users. This is a "no response" item.

P. Jursinic

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

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.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-rc/regulatory/enforcement/safety-culture.html.

P. Jursinic

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

Colleen Carol Casey

Materials Licensing Branch

License No. 21-12275-02
Docket No. 030-02115

Enclosure:

Amendment No. 93