

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

APR 0 6 2011

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

Dear Dr. Jursinic:

Enclosed is Amendment No. 90 renewing your NRC Material License No. 21-12275-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please note that <u>your license has been renewed for only one</u> year and will expire on April 30, 2012. This is because the letter dated September 15, 2010, and the application dated September 30, 2010, with attachments, was insufficient to complete our review in order to approve your license for the more customary ten year renewal.

Some of the information requested below must be submitted within 30 days of the date of this letter due to NRC policy changes pertaining to possession limits becoming necessary for almost all authorizations now.

The information pertaining to completion of your renewal application may be submitted later than 30 days from the date of this letter but must be submitted at least 30 days before the license expires.

In preparing your written responses to both the near-term and renewal information requests, please address your responses to my attention as "additional information to control number 573695," in order to facilitate proper handling in our offices.

To keep your license in force until these issues are resolved, I continued all of your current authorizations and retained all of the documents currently supporting your license in the last condition of your license, called the "tie-down" condition.

Normally, the renewal process enables us to delete all of your previous documents in the tie-down condition and replace them with updated and current documents. That is one of the goals we will be seeking to achieve in renewing your license within the coming year.

The information needed within 30 days of the date of this letter consists of:

1. Please provide definite possession limits for materials authorized in Subitem Nos. 8.C. (for iodine-131 only, must be less than ten curies total including waste

The enclosed document contains sensitive security-related information. When separated from this cover letter this letter is uncontrolled.

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streams); and 8.E. for materials authorized under 10 CFR 31.11; 8.F. for phosphorus-32.

The information needed in order to renew your license in its entirety consists of:

1. None of the radiation safety program elements address in NUREGs 1556, Volumes 7 for research and 11 for broad scopes were included in your renewal application. Your license is currently a Type A broad scope medical and research license. In order to retain the broad scope and research authorizations you must provide complete information for all of these program elements.

You may use the checklists in each NUREG document found in Appendix C to assist you in preparing a complete application. It is necessary that you read the corresponding text in the first half of each NUREG in order to complete the checklists correctly and provide appropriate descriptive information as attachments.

Please provide the information requested.

2. Your application was silent with respect to continuing the authorization in Subitem Nos. 6. through 9.F, inclusive, for the IsoStent Investigational Device Exemption. Therefore I considered it to be an oversight.

Please note that we cannot remove any authorization from your license on the basis of your not mentioning it during the renewal process. 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, close-out surveys, and so on.

Please describe your intentions with respect to this authorization.

3. Your authorization for the iridium-192 in Subitem No. 6. through 9. H., inclusive has confused me as it is my understanding that intravascular brachytherapy is no longer in common practice and that is what this authorization is for.

Please describe your intention with respect to this authorization, including appropriate supporting information.

- 4. it appears to me that your authorization for americium 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 and I can delete that as a line item authorization. You will still be able to use and obtain the source under 10 CFR 35.65, if appropriate.
- It was not clear from your application whether you are using positron emission tomography (PET) materials. If you are, please provide the appropriate facilities, equipment, shielding descriptions and shielding calculation information, as NUREG 1556, Vol. 9, Rev. 2 requests in Item 9, sections 8.15, 8.16 and 8.20. If you are not, please so state in your response.

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6. Certain elements for your 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); other equipment and facilities for manual brachytherapy, such as emergency response equipment (for Ir-192 use and/or therapy authorized by your broad scope line item in Subitem No. 6. through 9. G, inclusive, and/or PET materials (section 8.20, item 9); and spill/contamination procedures (section 8.26, item 9). The appropriate sections in NUREG 1556, Vol. 9, Rev. 2 are referenced above to assist you.

- 7. Please note that, when preparing the renewal using NUREGs 1556, Volumes 7, 11 and 9, Rev. 2, it may appear to you that some of these procedures will overlap. Depending on the authorization under consideration, that may or may not be true. It is always best to complete each application in its entirety to ensure that nothing is missed, especially when continuing a program that is a medical Type A broad scope.
- 8. If you decide to discontinue the Type A broad scope authorization and the research and other components associated with it, please contact me to discuss the types of information that will be required to make such an adjustment to your license.

You may contact me directly at (630) 829-9841 and my fax number is (630) 515-1078.

Copies of all three NUREG 1556 documents referenced above may be found on our website at http://www.nrc.gov and it should also be mentioned that you should already have at least one hard copy of each that was sent to you when these documents were first published in final form. If you have "draft" versions, please dispose of them and do not use them to prepare your renewal.

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.

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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.

Sincerely,

Materials Licensing Branch

ollen Carol Casey

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

Enclosure:

Amendment No. 90