



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

MAY 18 2010

Garry Malnar, D.O.
Radiation Safety Officer
Good Samaritan Hospital
520 South Seventh Street
Vincennes, IN 47591

Dear Dr. Malnar:

Enclosed is Amendment No. 69 to your NRC Material License No. 13-01787-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

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.

At this time we were unable to approve Dr. Enrique Bursztyn as an Authorized User (AU) for the use of materials in 10 CFR 35.100, 35.200 and 35.300, because the information in your letter dated February 5, 2010, was insufficient to complete our review.

If you wish to pursue this request, please submit the information requested below and address it to my attention as "additional information to control number 318850." We will then continue our review.

The letter dated February 5, 2010, stated that "documentation of training" for Dr. Bursztyn was attached. However, no documentation of any sort was attached.

Subsequently, in the course of our review several conversations were conducted on various dates in May 2010 between representatives of your hospital, including you, Michael Dixon and Mark Beanblossom; representatives of the NRC Region III Materials Licensing staff, Colleen Carol Casey and Michael Herr; and Michael Harmon of the State of New York Department of Health (NYDOH).

To date, we have received a total of five different submissions pertaining to Dr. Bursztyn's application to become an AU. As noted above, his application is still incomplete and we were unable to approve him as an AU.

Also, we were unable to completely verify his authorization status on a referenced license, Little Falls Hospital, in Little Falls, New York, because the Little Falls Hospital holds an Agreement State license that we do not have access to.

We attempted to obtain appropriate copies of the Little Falls Hospital license to support Dr. Bursztyn's application, which is actually the responsibility of the

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applicant physician. NYDOH sent us copies of the Little Falls Hospital license amendments, including Amendment No. 14, which authorized Dr. Bursztyn for the use of materials on the license, but this amendment did not list the materials or modalities for the license.

We subsequently received a copy of Amendment Nos. 17 through 21, inclusive, for the Little Falls Hospital license. A list of AU's is provided on Amendment Nos. 18, 19, 20 and 21 and Dr. Bursztyn is not on these lists.

In order for us to approve Dr. Bursztyn as an AU using the notification pathway in 10 CFR 35.13 and 35.14, as you have been attempting to do, please contact NYDOH to obtain a copy of the most recent amendment for Little Falls Hospital prior to Amendment No. 14 that includes a complete list of the materials and modalities authorized by the license.

This amendment copy should be accompanied by a signed and dated transmittal letter, as described above. Please also refer to 10 CFR 35.12(a) for assistance.

Please also note that Little Falls Hospital was not authorized for the possession and use of materials in 10 CFR 35.300, "diagnostic studies and therapeutic procedures" utilizing unsealed byproduct materials permitted by 10 CFR 35.300.

Therefore, even if you are successful in supporting Dr. Bursztyn's application by providing appropriate amendments from Little Falls Hospital, we would only be able to authorize him for the use of materials in 10 CFR 35.100, uptake, dilution and excretion studies and 35.200, imaging and localization studies.

If Dr. Bursztyn wishes to pursue authorization for the use of materials in 10 CFR 35.300, please follow the procedure above and provide documentation of his training and experience that meets the requirements in one or more of the following regulations: 10 CFR 35.13, 35.14, 35.57, 35.59 and 35.390.

Please do not submit other documents from the Agreement State licensee, especially patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, college transcripts, etc.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 2, for assistance in preparing your response.

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If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

In addition, if you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

In addition, if Dr. Bursztyn is certified by a medical specialty board, please note that NRC may not recognize certain medical specialty board certifications. Please see this link on our Medical Licensing Toolkit page for a list of the medical specialty board certifications that we recognize:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.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."

As stated in our facsimile dated May 12, 2010, at this time we must obtain finite possession limits for the authorization of materials in 10 CFR 35.300, which is in Subitem No. 8.C. of your license.

Please respond to this request within 45 days of the date of this letter, following the response procedure described above. If this is not sufficient time for you to prepare a response for possession limits for 10 CFR 35.300 materials, please contact either Michael Herr at (630) 829-9752 or Colleen Carol Casey at (630) 829-9841. Our fax number is (630) 515-1078.

Please specify a possession limit for iodine-131, authorized by 10 CFR 35.300 and an additional possession limit for any other materials you may use that are authorized under 10 CFR 35.300.

Your possession limits must be realistic for your needs and include waste stream activities as well. Many licensees typically request one curie of iodine-131 for this purpose and a total possession of two curies for all materials in 10 CFR 35.300.

Lastly, as noted in our fax dated February 12, 2010, we removed Edward Johnston III as an Authorized Medical Physicist (AMP) in Condition No. 12.C.

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Your license does not authorize any material that requires having an AMP on your license. Your license does authorize strontium-90 in Subitem Nos. 6. through 9. E, inclusive, but only for storage, incident to disposal.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

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,



Michael G. Herr, CHP
Materials Licensing Branch

License No. 13-01787-01
Docket No. 030-01600

Enclosure:

Amendment No. 69