

## UNITED STATES NUCLEAR REGULATORY COMMISSION

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

JAN 0 3 2011

Timothy M. Quinton, R.Ph. Radiation Safety Officer Radiopharmacy Incorporated 1409 East Virginia Street Evansville, IN 47711

Dear Mr. Quinton:

This refers to the telephone conversation between you and me on November 24, 2010, regarding the renewal of your NRC byproduct material license no. 13-26246-01MD and the need for you to submit a complete renewal in entirety.

This also refers to your letter and application both dated November 15, 2010, for renewal of your license. These two brief documents are all that you submitted.

As it is our practice to remove all of the documents in the last, "tie-down" condition of your license during a license renewal, we cannot do this until we have received and reviewed a completely new application in entirety.

Since your license will not expire until February 28, 2011, and since we cannot continue processing of the "renewal application" you submitted, we must void your application at this time. "Void" means that we will take it out of our active database. This action is taken without prejudice to future resubmission of your license amendment request for renewal.

Upon receipt of your response, we will resume our review.

Please address your written response to my attention at the above address and please be sure to reference <u>Control No. 573958</u> to facilitate proper handling in our office.

As a reminder, please provide the information requested in writing, accompanied by a transmittal letter or Form NRC 313 that is <u>currently dated and signed by a senior management official.</u>

To facilitate the renewal application, it is in your best interests to prepare it in accordance with the guidance in NUREG 1556, Vol. 13, Rev. 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Commercial Radiopharmacy Licenses," which was published and a hard copy sent to you in November 2007.

The NUREG previously mentioned should be reviewed carefully to ensure you understand the commitments that you will be making in your responses, as discussed below, to Appendix C of this NUREG.

Using Appendix C (simply copying it out of the book or printing it from the website

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and filling it in, adding descriptive information as attachments) is the simplest way to prepare your renewal and helps to ensure a more complete application.

Please refer to NUREG 1556, Vol.13, Rev. 1 available at our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/r1/

In order to save time and effort, Appendix C can be used to capture the information required in Item 5-11 of NRC Form 313, focusing on the responses and commitments in Appendix C.

Full use of the NUREG 1556 Vol.13, Rev.1 document will greatly reduce your regulatory burden and enhance safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

Follow the "Suggested Format" provided in Appendix C and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

Please do <u>not</u> submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, and any extraneous, detailed information, procedures and retyped sections from advisory text in the NUREG-series documents.

It is also <u>not</u> necessary to resubmit training and experience information for incumbent Radiation Safety staff, Authorized Nuclear Pharmacists and any other authorized users named on the license, whose licensed functions are not changing. You may simply reference each appropriate person's position and name and state that his/her training and experience documents are already on file in the license.

If you must deviate from a model procedure or suggested response, it may be possible to simply indicate what the deviation is and still use the model procedure/ suggested response as a "basic" commitment. Descriptive information may be "recycled" directly from previous documents only to the extent that it is current, complete information, equivalent to the model procedure (as appropriate) and does not contain extraneous material.

It is in your best interests to <u>only provide those commitments</u>, <u>statements</u>, <u>representations and procedures</u>, in a clear and <u>explicit manner</u>, that <u>we</u>

<u>require to issue your license.</u> These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

As noted above, please do not re-type the checklists as errors and omissions may be introduced. If you need to append certain information or provide an alternative

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procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness.

Also, please check your current license to ensure that you have not omitted anything that you wish to continue authorization for, such as locations of use, line items, etc. On the other hand, if you wish to delete an authorization that you currently have, be sure to specifically request the deletion, state why, and support each request with appropriate information that justifies granting the request (such as leak tests, final surveys, acknowledgments of receipt from vendors, etc.)

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."

If you have any questions or require clarification on any of the information stated above, you may contact me directly at (630) 829-9841. My fax number is (630) 515-1078.

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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

Sincerely,

Colleen Carol Casey
Materials Licensing Branch

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License No. 13-26246-01MD

Docket No. 030-31910