From: Weidner, Tara
To: newmann@ors.od.nih.gov
Subject: Request for additional information concerning NIH renewal
Date: Thursday, May 16, 2013 2:33:00 PM

License No.: 19-00296-10
Docket No.: 03001786
Control No.: 577840

********** PLEASE CONFIRM RECEIPT OF THIS E-MAIL **********

Dear Ms. Newman,

This is in reference to your renewal application dated June 28, 2012. In order to continue with our review of your application, we will need the following additional information:

Pertaining to the Radiation Safety Committee (RSC) and Radaition Safety Officer (RSO)

In your application you stated that:

1. the RSC is responsible for the establishment of minimum training and experience qualifications for Authorized Users (AU). Describe the minimum qualifications established by the RSC for the approval of AUs.
2. the RSC is responsible for the approval of radiation safety laboratory protocols. Please confirm that the review/approval of the radiation safety laboratory protocols includes the review and approval of the AUs training and experience, and
3. the RSC is responsible for the review of the comprehensive annual report on the radiation safety program. Confirm that the review includes the analysis of any possible trends, suggestions for corrective actions, and evaluation of corrective action effectiveness.

Submit a description of the RSC's program for review of permits issued to authorized users for renewal or re-issue of the permits, and state the frequency at which this review will be required. The program for renewal of permits should include a review of the authorized users' safety and compliance history, types and quantities of materials requested, facilities and equipment, and training and supervision of radiation workers in the users' laboratory.

In your application you stated that the Radiation Safety Officer has the authority to authorize the start of protocol work pending the final approval by the RSC. 10 CFR 33.13(c)(3)(iii) requires, in part, that the RSC review, approve and record safety evaluations of proposed uses prior to the use of the byproduct material. 10 CFR 33.17(b) requires, in part, that byproduct material may only be used by, or under the supervision of, individuals approved by the licensee's RSC. Your procedures give the RSO these responsibilities, which is contrary to the regulations. Please review the following list of acceptable alternatives, and submit the information for the alternative which will allow work at your facility to continue:

1. The Radiation Safety Committee may approve new users and uses between meetings by distributing the information about the proposed activities and/or users by mail or other available means, and gathering comments for approval from the members, or
2. Proposed users may work under the supervision of someone who is currently authorized by the Radiation Safety Committee to use licensed materials, until such time as the Radiation Safety Committee grants authorization to the proposed user.

NRC will provide even greater flexibility to Type A Broad Scope licensees to make programs changes and changes to procedures specifically identified in documents which were previously approved by the Commission and incorporated into the license, without prior Commission approval. If you would like authorization for this flexibility, please provide the following statements.

1. Changes to your program and procedures will be limited to the following areas: training; audit program; radiation monitoring instruments; material receipt and accountability; safe use of radionuclides and emergency procedures; and radiation surveys. In addition, state that you will apply for, and receive an amendment to your license prior to implementing any other programmatic or procedural changes.

2. The proposed revision will be documented, reviewed, and approved by your Radiation Safety Committee in accordance with established procedures prior to implementation.

3. The revised program will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.

4. Your staff will be trained in the revised procedures prior to implementation.

5. Your audit program will evaluate the effectiveness of the change and its implementation.

Describe the process for procedure and program review and approval, including documentation of the specific change. At a minimum, the documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to the approval of the change.

Confirm that the RSC will consider the guidance on NRC's website when reviewing and approving medical emerging technologies.

Provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material. Appendix J of NUREG-1556, Volume 11 contains a model delegation of authority and may be helpful to you in developing your response.

Pertaining to the Training Program, you stated that specialized courses are for ancillary staff who require training per 10 CFR 19.12(a) or 10 CFR 35.310(a). Confirm that specialized training will also be provided to ancillary staff that may be involved in the care of patients who are receiving brachytherapy and cannot be released under 10 CFR 35.75.

Pertaining to Facilities and Equipment

In your application you provided diagrams/pictures of area designed or established for special uses (radiopharmacy, therapy treatment room, waste management/storage areas). We also require
diagrams of the PET radiopharmacy (including transfer tubes), iodination facilities using greater than 10 millicuries per experiment, compactors, instrument calibration facilities, areas of use of unsealed
alpha emitters, and brachytherapy source storage areas. Please provide diagrams, including room numbers, of these areas, if applicable.

Describe the criteria used by the RSC to review and approve new facilities (research laboratories, decay-in-storage facilities, iodination/tritiation laboratories, unsealed alpha laboratories). Address the
following:

1. Provide sample diagrams for each classification scheme that take in to consideration shielding requirements, the proximity of radiation sources to unrestricted areas, ventilation systems, and other radiation safety related items.
2. Describe your procedures for control, review, and approval of significant facility or equipment modifications.

In your application you stated that licensed materials are used in animals, please submit:

a. a diagram and description of the animal housing facilities,

b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and

c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

Appendix H of NUREG-1556, Volume 7 addresses considerations for laboratory animal uses and may be helpful in developing a response.

In your application you provided a photo of the I-131 inpatient therapy room. Describe the shielding that is contained within the walls/doors and confirm that additional shielding is available if needed to reduce exposure levels to below the regulatory limits.

Describe the surveys you will require and the criteria you will use for release of facilities and equipment for unrestricted use. Confirm that for radionuclides with a half-life greater than 120 days, you will use the criteria described in NUREG 1557 for release of facilities and equipment and that facilities and equipment will not be released until the results of surveys are reviewed and approved by the Radiation Safety Officer.

Describe how Radiation Safety assures that instruments are calibrated at the prescribed frequency.

In your application you stated that calibration of designated instruments for exposure or dose equivalent rate measurement will be done by qualified in-house personnel. Please specify the instruments to be calibrated by NIH staff and describe the procedures used. In addition, describe what qualifies a staff member to perform the instrument calibrations.

Specify the types of instruments that will be required for surveys and monitoring by authorized users in laboratories at your facility. Describe the criteria you will use to determine the types, uses, and calibration of users' instruments.

Submit your procedures for transfer and transportation of licensed material between authorized users at your facility, and your procedures for transfer and transportation of licensed material to other licensees. Describe your program to control such transfers, including update of material inventory and audits of users' procedures.

In your application you stated that contamination surveys of unrestricted areas abutting restricted areas would be performed periodically. Define periodically and under what circumstances would these surveys be performed.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 577840. If you have any technical questions regarding this deficiency letter, please contact me via e-mail.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

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-nrc/regulatory/enforcement/safety-culture.html. 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.

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U.S. Nuclear Regulatory Commission