UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. STE 210
LISLE, IL 60532-4352

AUG 17 2015

Yinghui Zhang, Ph.D.
Radiation Safety Officer
Good Samaritan Hospital
520 South 7th Street
Vincennes, IN 47591

Dear Dr. Zhang:

This refers to your letter ("the letter") dated February 20, 2015, requesting renewal of your NRC byproduct material License No. 13-01787-01. This also refers to the telephone discussion of these items on August 17, 2015, between your consulting physicist, Mark Beanblossom, and me.

Although this letter is addressed to you, Dr. Zhang, the application attached to your renewal letter directs us to contact Mr. Beanblossom for additional information. Therefore, this letter will be sent via regular mail to you, Dr. Zhang, and transmitted to Mr. Beanblossom as a scanned PDF attachment to an email I will send.

We have reviewed your letter dated February 20, 2015, and the attached application dated February 20, 2015, and find that we need the information below in order to continue our review.

Please provide only one complete, written response that is currently dated and signed by a senior management official, or by Michael R. Dixon, Nuclear Medicine Department Manager, or by Mr. Beanblossom, as directed in your letter. This will help ensure that your response is processed correctly in our offices.

Please submit your response no later than close of business on August 24, 2015, or contact me to make alternative arrangements.

Your written response should be addressed to my attention at the above address, as "additional information to control number 586158." We will then continue our review. I can be reached at (630) 829-9841 directly. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

In preparing your response, 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."

1. Subitem Nos. 6. – 9.G. of your license authorizes a strontium-90 sealed source, as it appears on Amendment No. 79.

However, your letter was silent with respect to continuing or removing this authorization. We cannot remove an authorized material simply because it was omitted in the renewal. Depending on what your intentions are with this material, please contact me directly to determine what additional information we will need to either continue the authorization or delete it.

Please note that this material was authorized "for storage only, incident to disposal." However, since its half-life exceeds 120 days, it may not be disposed of under the "decay-in-storage" provisions in 10 CFR 35.92.

2. Subitem Nos. 6. and 8. I. authorize up to 60 microcuries of "Cerium-139" sealed sources on your license, as it appears on Amendment No. 79. However, your letter requests "60 mCi" of "Cesium-139." Please correct this radionuclide and the total possession limit requested.

3. On page 5-1 of your letter, we encountered the following issues:

   a. Your authorization request for materials in 10 CFR 31.11 is a new request, and "as needed" possession is requested. Please specify a finite possession limit and please name at least one proposed authorized user for this material. A typical possession limit of 3 millicuries may be considered.

   b. In addition to specific radionuclides requested individually under 10 CFR 35.400, you also requested an unspecified "Any material per 10 CFR 35.400" in "as needed" quantities, etc. This is no longer an acceptable authorization. Please withdraw this request in your response.

   c. You have requested germanium-68 rod sources in quantities of "231 MBq each," without providing a finite number of sources to be possessed. Please adjust your request for maximum activity to traditional units of curies and specify the maximum number of sources you wish to have possession of. Your requested number of sources should be realistic for your needs and may accommodate reasonable growth.

      Please also provide the Sealed Source and Device Registry (SSDR) number for this material, as it is new to your license and our research into the manufacturer and model numbers given indicates that several different registration certificates may correlate with your request. However, each different certificate shows a different activity permitted, which does not match up exactly with your requested possession.

   d. You requested "Depleted Uranium" also, in "as needed" quantities. Please submit a finite possession limit for this material.

   e. Your request for the germanium-68 source above indicates that it is for use in a PET scanner for Positron Emission Tomography (PET) imaging. The rest of your renewal request failed to provide the information we need to renew your authorization for PET under 10 CFR 35.200.

Please also see NUREG 1556, Vol. 9, Rev. 2 for an overview of information we need to continue this authorization, including, but not limited to, appropriate shielding information for your facility.

Due to placement concerns, we have located the information needed for PET renewal at the end of this letter. Please see below.

We are also aware that Mr. Beanblossom was not entirely certain as to whether PET authorization was needed for your license, or if you used an outside contracted licensee for such studies. Please clarify the status of your PET usage in response and provide appropriate supporting information.

4. Your letter was silent with respect to continuing authorization for five previously approved authorized users, Drs. Michael M. Moss, Garry Malnar, Enrique Burszten, Joseph B. Lee and Robert Cirillo.

As we did not know if this was an oversight or intentional omission, please be reminded that absence of a commitment in your correspondence to us does not constitute an explicit instruction, i.e., we can only act upon specifically stated requests. Licensees are required to notify us within 30 days when an Authorized User permanently discontinues duties under the license, in accordance with 10 CFR 35.13 and 35.14.

If it is your intention to delete these physicians from your license, you must explicitly direct us to do so in writing, in accordance with 10 CFR 35.14(b)(1). Simply omitting mention of them in the renewal request is unacceptable. Please specifically describe your intentions with respect to these physicians.

In addition, Amendment No. 79 shows authorization in Condition No. 12.B. for "Roger Robison, M.D." However, your letter requests authorization for "Roger Robinson, M.D." Please clarify the correct spelling of this name.

5. We noted that much of your letter made references to two out-of-date versions of our medical licensing guidance document, "NUREG 1556, Vol. 9" and its "Rev. 1.," NUREG 1556, Vol 9, Rev. 2, dated January 2008 is the only version that should be in use for medical licensing correspondence. Also, many of the Appendices referenced in your letter for particular sections in the NUREG are incorrect, mainly because they are directed toward an obsolete document.

During our review of your renewal letter and attachments, we noted that your renewal request was only partially prepared in accordance with NUREG 1556, Vol. 9, Rev. 2 , although the abstract in NUREG 1556, Vol. 9, Rev. 2, states, in part, "NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance about Materials Licenses: Program –Specific Guidance about Medical Use License," is the third version of the ninth program-specific guidance document developed for the new process; it is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States."

Full use of this document for all of your licensing correspondence will greatly reduce your regulatory burden, simplify your license and enhance safety by providing for more comprehensive, updated safety procedures and a complete renewal application.

Please see the additional information and suggestions regarding renewal of licenses near the end of this letter.

6. HDR Authorization

This is in addition to, and may overlap some of, the HDR guidance contained in NUREG 1556, Vol. 9, Rev. 2.

Many of the details and commitments needed to continue the HDR authorization were missing from the application, including diagrams that contain the information we need, procedures required by 10 CFR 35.610 and 35.643, detailed shielding calculations to demonstrate compliance with the radiation limits in 10 CFR Part 20, etc.

Please clarify whether there have been any changes in the design, shielding, function, or functional identity for each of the locations and areas of use authorized by this license, especially with respect to the high dose rate remote (HDR) afterloading brachytherapy rooms and all of the surrounding adjacent areas, including the spaces above and below each HDR room.

If there have been no changes to the HDR storage/usage room, or to any of the contiguous spaces immediately surrounding it, including above and below, then you may be able to "recycle" the diagrams, shielding calculations, and procedural commitments requested.

Please provide current diagrams (simple, hand-drawn diagrams are good) that clearly show the HDR treatment room and the location and functional identity of all contiguous rooms, areas and/or spaces surrounding it, especially the area above it. No blueprints or copies of blueprints should be submitted as they show a great deal of information that we do not need and very little of what we do need.

None of this information was included in your letter's attachments.

Your diagrams should be either drawn to scale or show actual dimensions;

*provide correct room numbers for all spaces (if none, please so state or identify the room by another means);

*show the direction of north;

*show the functional identity of each room, space or area immediately surrounding the HDR room and whether they are restricted (R) or unrestricted areas (U);

*show the elevation/grade clearly described and what spaces are above and beneath the HDR room, their functional identity and whether they are restricted (R) or unrestricted areas (U);

*indicate clearly on the diagram where you anticipate the patient/" exposed source" to be located within the room;

*for each barrier in each direction, including ceiling:

**the specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);

**thicknesses (individually and total, expressed in inches, feet or centimeters); and,

**the distances from the patient/"exposed source" to the opposite, occupiable places for barriers/walls/ceilings/floors in all directions.

Please indicate clearly whether persons may gain access to any area adjacent to, or above the proposed HDR treatment room.

If areas may be occupied during treatment, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, closed circuit television surveillance, lock-out, key control, etc.) that will be put in place to prevent occupation during HDR treatments or source exposures.

Please provide simple and complete shielding calculations, using traditional units (preferred), showing your work, barrier transmission factors (and calculation of them), detailed assumptions, defined terms, equations, constants, substitutions and parameters to demonstrate that radiation levels in all adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

Please include the following details in your calculations:

(1) expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum installed source activity;

(2) all parameters used to perform the calculations, including: distance to each area of concern, the type and thickness of material(s) used as shields, especially if portable shields will be used;

(3) the maximum "beam-on time" per hour and per week; the number of patients/treatments/exposures expected per week(i.e., workload);

(4) occupancy factors used for all adjacent areas, including areas above and below;

(5) demonstrate by calculation that the dose received by an individual member of the public likely to receive the highest dose from HDR procedures when present in unrestricted area (in mrem/hr and mrem/yr) will not exceed the limits specified in 10 CFR 20.1301(a);

(6) sufficient information, in a readily understandable format, to permit us to independently evaluate the adequacy of shielding in your proposed room.

7. Renewal suggestions, based upon NUREG 1556, Vol. 9, Rev. 2:

Please note that using the NUREG 1556 series documents will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner.

In preparing your response, and for future licensing correspondence, please focus on providing the information requested in Appendix C to NUREG 1556, Volume 9, Rev. 2. Follow the "Suggested Format.." provided in this Appendix and use the suggested responses and model procedure/appendix references whenever possible, appending descriptive information as appropriate. It is strongly advisable to read the corresponding text in the front of each NUREG to ensure a complete understanding of the commitments that you make.

For an incumbent RSO and incumbent Authorized Users, whose authorization you are not seeking to expand, you only need to provide their names and authorizations. The RSO will need to submit a currently dated, management and RSO - signed "Delegation of Authority" from Appendix I in NUREG 1556, Vol. 9, Rev. 2. Note: except as noted above for AU discrepancies, this section does not need to be responded to as your letter was sufficient for the RSO and AU's named within it.

Please do not submit resumes, curricula vitae, college transcripts, any personal, proprietary information, blueprint diagrams, or copies of blueprint diagram and any extraneous, prescriptive information and procedures, unless we specifically request it, which is unlikely.

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" from previous documents only so long as 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 only provide those commitments, statements, representations and procedures, in a clear and explicit manner, that we require to issue your license. These documents will form the basis for the license in the last condition of the license, called the "tie-down" condition.

You will realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Vol. 9, Rev. 2, Appendix C, especially Tables C.2 and C.3 to your copy machine and copy it out directly. Read the text in the front of the NUREG that corresponds to each section and simply fill in the checkmarks and blanks on the copied checklist, thereby making your license commitments. Note: except as noted above, table C.2 does not need to be responded to as your letter was sufficient.

Please refrain from re-typing the checklist as errors and omissions are typically introduced.

As you need to append certain information or provide an alternative procedure, please be sure to incorporate the information in the NUREG, at a minimum, to ensure completeness. You may "recycle" previously approved diagrams, documents containing procedures, etc., provided they do not contain extraneous details and that they are current and accurate in all material respects.

Please refrain from submitting procedures and commitments that exceed the scope of the guidance in Table C.2 and especially Table C.3. Note: your letter contained several procedures and commitments that were beyond the scope of the guidance in Table C.3.

Please see the Tables C.2 and C.3, NUREG 1556, Vol. 9, Rev. 2, Appendix C. A hard copy of this document should have been sent to you already. It is also available on our website at:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/

8. PET Guidance:

This is in addition to, and may overlap some of, the the PET guidance contained in NUREG 1556, Vol. 9, Rev. 2.

Please include a copy of your facility diagrams and shielding calculations that show compliance with 10 CFR Part 20.1101, "Radiation Protection Programs," 20.1301 and 20.1302, "Radiation Dose Limits for Individual Members of the Public," and 20.1501, "Surveys and Monitoring."

In providing this information, please include the following, as appropriate:

The following is a listing of some peer reviewed literature that addresses PET/CT design and shielding considerations and factors. It may be used to assist you in preparing your PET and PET/CT facility design and shielding calculations.

It is our understanding that PET use is commonly combined with CT use. So when we refer to "PET" we are also referring to "PET/CT," even if not explicitly stated.

This is not intended to be an exhaustive, all-inclusive list:

http://www.aapm.org/pubs/reports/RPT_108.pdf

http://www.crcpd.org/Pubs/PET-CT-Fusion/02-18-04_1330-Martin.pdf

http://www.radsafe.com/Papers/PETpaper.pdf"

Please provide shielding evaluations based on the "worst case scenario" for your proposed facility. For example, maximum activity used per patient, maximum number of patients injected and in queue at about the same time, distance assumptions, maximum potential exposure rates, etc.

F-18 will be the bounding isotope for any shielding evaluations provided.

Exposure results should be shown in units of millirem per hour and traditional units should be used throughout, but may be provided "in addition to" SI units.

A. Diagrams

If your PET room diagrams consist, even in part, of copies of blueprints, which we strongly discourage submitting (blueprints show a lot of information we do not need and very little of what we do need and they are often illegible), we will be unable to gain a full understanding of your PET facilities. Kindly refrain from submitting blueprint diagrams or copies of them.

Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the entire PET usage stream, from the receipt and survey of incoming packages/doses to the injection areas, prep/quiet rooms, patient rest rooms, PET console/control area, PET and/or PET/CT scanning rooms, "post-dosed" or "post prepped" patient waiting rooms (should be separate from "pre-dose" waiting room where non-injected patients wait), and waste storage facilities.

Please clearly show the location and functional identity of all contiguous rooms, areas and/or spaces surrounding the PET facilities, especially the areas above and below the afore-mentioned rooms where the PET materials will be used in patients.

Your diagrams should be either drawn to scale or show actual dimensions and should:

*provide room numbers (if none, please so state or identify the room by another means);

*show the direction of north;

*show the functional identity of each room, space or area immediately surrounding all of the PET facility rooms and indicate clearly whether they are restricted (R) or unrestricted areas (U);

*show the elevation/grade clearly described and what spaces are above and beneath the PET rooms, their functional identity and whether they are restricted (R) or unrestricted areas (U); please include whether the roof will be restricted or unrestricted;

*indicate the expected path for a typical patient, such as waiting room, changing area, injection room, quiet area, rest room, PET scanner room, waiting room and/or changing room;

*describe for each barrier in each direction, including ceiling and floor:

**the specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);

**thicknesses of each barrier (individually and total, expressed in inches, feet or centimeters); and,

*the distances from the patient/"exposed source" to the opposite, occupiable places for barriers/walls/ceilings/floors in all directions.

Please indicate clearly whether persons may gain access to an area above or below the proposed PET facilities. If these areas may be occupied during PET studies, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, closed circuit television surveillance, lock-out, etc.) that will be put in place to prevent occupation during PET use.

B. Shielding Calculations

Please provide simple and complete shielding calculations, using traditional units (preferred), showing all of your work, barrier transmission factors (and calculation of them), appropriately detailed assumptions, defined terms, equations, constants, substitutions and parameters to demonstrate that radiation levels in all

adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

It should be clearly shown what the anticipated worst case dose rates from PET/CT use are expected to be in each area *before* shielding is applied and then, *after* the specifically described shielding is factored in, what the shielded dose rates will be.

Please include the following details in your calculations:

(1) expected radiation levels for each under the most adverse and typical source term usage and workload;

(2) all parameters used to perform the calculations, including: dose rate constant values; typical dosage and expected worst case dosages amounts in millicuries; whether syringe shields, L-blocks, remote handling tools, portable shields, etc. will be used; distance to each area of concern, the type and thickness of material(s) used as shields, especially if portable shields will be used;

(3) the number of patients expected per week(i.e., workload);

(4) occupancy factors used for all adjacent areas, including areas above and below;

(5) demonstrate by calculation that the dose received by an individual member of the public likely to receive the highest dose from PET procedures when present in unrestricted area (in mrem/hr and mrem/yr) will not exceed the limits specified in 10 CFR 20.1301(a);

(6) sufficient information, in a readily understandable format to permit us to independently evaluate the adequacy of shielding in your proposed PET facilities.

Please describe the equipment (remote handling tools, syringe shields, portable shields, etc.) you will have available to keep exposures to all personnel, workers and patients, under the limits specified in 10 CFR Part 20.

If you have any specific questions concerning this letter or the information we are requesting, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

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 http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-01787-01
Docket No. 030-01600
Control No. 586158