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

Tom Dickinson
Consultant
c/o Edward Downey, Jr., D.O.
Phelps County Regional Medical Center
1000 West Tenth Street
Rolla, MO 65401

SEP 0 1 2015

Dear Mr. Dickinson and Dr. Downey:

This refers to your application ("the application") dated March 18, 2015, requesting renewal of your NRC byproduct material License No. 24-18295-01.

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

We have reviewed your application dated March 18, 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 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 September 14, 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 586332." 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. Page 19 of your application states that you are not requesting any 10 CFR 35.400 material on the renewed license and you are not in possession of any of these materials. Please note, however, that this information is insufficient for us to delete these authorizations from your license, which currently authorizes an inventory of iridium-192 and a variety of iodine-125 and palladium-103 seeds.

Before we can consider removing these authorizations, you must demonstrate that none of these materials remain at your facility in any form or waste stream, including residual contamination in any area where they were previously used and/or stored. This will require the submission of final leak tests on sealed sources and close out surveys for the usage and storage areas.

You must account for the disposal of these materials to an appropriately licensed entity and provide us with a copy of an acknowledgment of receipt from the recipient and a copy of the recipient's license.

Please see the requirements in 10 CFR 30.41, 30.51 and the attachment I've prepared which details a more thorough list of issues to be satisfied before we can revisit the removal of these authorizations.

2. Your application was silent with respect to continuing authorization for two previously approved authorized users, Drs. William W. Cottingham and Mary V. Graham.

   As we did not know if this was an oversight or intentional omission, please be reminded that the 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.

3. Page 22 of your application states that Brandon Morgan, M.S. is listed as an Authorized Medical Physicist (AMP) on this license for the HDR program. Please be advised that he is not an AMP on this license.

   If you wish to add him as an AMP under this license, please provide evidence of appropriate training and experience or other qualifying information, in accordance with 10 CFR Part 35. This information need not be submitted in order to complete the renewal; it may be submitted at a later date that may be more convenient for you.

4. On page 22 of your application, only one incumbent AMP is listed and your application is silent with respect to continuing authorization for five AMPs: Yuri Ellis, M.S., Amy Ettling, M.S., David Nelson, Ph.D., Kenneth Wohlt, M.S., and Jeffery Scott Wyler, M.S.

   As we did not know if this was an oversight or intentional omission, please be reminded that the 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 Medical Physicist permanently discontinues duties under the license, in accordance with 10 CFR 35.13 and 35.14.

If it is your intention to delete these physicists 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 physicists.

5. Please describe 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.

6. PET Program

   This is in addition to, and may overlap some of, 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

As your PET room diagrams consist 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 are unable to gain a full understanding of your PET facilities.

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.

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. 24-18295-01
Docket No. 030-14804
Control No. 586332

ATTACHMENT

We cannot authorize licensees to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all *actual licensed materials possessed, used, stored, etc.,* including sealed sources and unsealed materials, spills, and contamination.

If sealed sources were transferred or disposed of as part of the close-out of this location of use, area of use or license, please provide a copy of the final leak test result for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials were transferred or disposed of as part of the close-out of this license, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

An assumption of decay for relatively short-lived materials is insufficient to support a termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; 10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities," (if you have a medical program; check the "Termination of Activities" section in other volume(s) in the NUREG 1556 series for other than medical programs at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/); "NRC Form 314" at http://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf; and NUREG 1757, Vol. 1, Rev. 2 at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/.

Your complete historical review should specify when and where all licensed materials, including materials in 10 CFR 31.11 (only if appropriate), *were actually possessed* under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

If your license historically authorized radioactive materials and/or modalities that you never used, then please so state specifically. Please be mindful that NRC will review your inspection history.

For licensed materials and waste that were "decayed - in – storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license.

For other licensed material waste streams (only if appropriate), such as incineration (volume reduction), animal carcasses, shipment for burial, compaction, vial disposal, and so on, provide copies of appropriate records to demonstrate "cradle to grave accountability."

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present. Please only submit the last, or final, records for leak tests, DIS disposal, etc.

If you have any questions, please contact me directly.

Alternately, you may contact a staff reviewer by calling USNRC, Region III, the Materials Licensing Branch, (630) 829-9887 during normal business hours and asking to speak with the "Materials Reviewer on call."

Please respond by stating exactly which licensed materials were used at each authorized location historically and please submit final status survey information covering those radioactive materials.

The final status surveys should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/

Please submit the following information with your close-out survey:

a. Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

   Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately.

b. The name of the person(s) performing the survey.

c. The date(s) the survey was performed.

d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. It is expected that instruments used will be appropriate for the types of radiation being detected.

e. Background readings and each instruments' efficiency or correction factor.

f. The date(s) that the survey instrument(s) were last calibrated. Please *do not* state when the instrument(s) are "due" to be calibrated in the future. Please *do* state when the instrument(s) were last calibrated.

g. The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.

h. If sealed sources were used in the affected areas/locations, please include a copy of the most recent leak test results for each source. If sources were transferred please provide the license number (if a current Region III NRC licensee) or a copy of the license for the transferee, or a copy of the license and/or permit for the broad scope licensee who took possession of the sources. Appropriate acknowledgment(s) of receipt should be submitted for "cradle to grave" accountability.

Please always include the telephone number and fax number of at least one person who serves as a point of contact for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.

Please ensure that a senior management representative signs the amendment request. Please ensure that a management representative signs the amendment request, in accordance with 10 CFR 35.12(a), as appropriate, for medical programs.