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

James M. Forde, M.D.
Radiation Safety Officer
Porter Regional Hospital
85 East U.S. Highway 6
Valparaiso, IN 46383

JAN 16 2018

Dear Dr. Forde:

We have reviewed your letters dated June 22, 2016, August 18, 2016, February 20, 2017, April 26, 2017, June 28, 2017 and October 9, 2017, requesting authorization for a new high dose rate (HDR) remote afterloading brachytherapy device program, as permitted by 10 CFR 35.600 for your NRC license number 13-17073-01.

We have determined that we need the additional information below in order to continue our review.

This is a separate letter from the letter transmitting Amendment No. 50. We are sending this letter in regular mail to you, Dr. Forde, and we are faxing it to your designated point of contact for the HDR program request, Gary Dillon, M.S., your proposed authorized medical physicist, at 219-983-6011.

If you wish to pursue this matter, please provide only one complete, written response that is currently dated and signed by a senior management official for this license. This will help ensure that your response is processed correctly in our offices.

Your written response should be addressed to my attention at the above address, as "additional information to control number 600102." We will then continue our review.

1. In the six letters above, we noted that an unusually large amount of extraneous documents and information was submitted that we did not and do not request when considering applications for new HDR programs, as well as repetitious copies of identical or similar information that failed to meet the requirements for a new HDR program and its authorized users.

   In response, please do not send us the following:

   a. A Radiation Alert Monitor manual;
   b. The HDR treatment protocol for patients;
   c. The Varian Medical Systems, Inc. Linear Accelerator Checklist;
   d. The Linear Accelerator Information Sheet;
   e. The Isotronics Calibration Laboratory Certificate of Calibration;
   f. The University of Wisconsin – Madison Accredited Dosimetry Calibration Laboratory (ADCL) certificate and report of calibration for HDR Well-type Ionization Chamber;
   g. The QSA Global Type A Package Evaluation for Model 98207 HDR Shield Container;
   h. The Nucletron microSelectron Digital 106.990 User Manual;

i. The Nucletron Oncentra External Beam v4.3 Oncentra Brachy v4.3 User Manual;

j. The complete Sealed Source and Device Registry Certificate NR-0497-S-107-S (just the certificate number is sufficient); and,

k. The Nucletron microSelectron HDR Emergency Procedures Manual – we only need certain emergency procedures, not the entire manual.

2. Also, in the six letters listed above, we have several copies of NRC Forms 313a (AUS) for each of two proposed AUs, Drs. Jon Quackenbush and Koppolu Sarma.

   Some of the forms indicate that each has received a medical specialty board certification that NRC accepts. In fact, NRC does not accept the specialty board certification for either proposed AU, as shown on our website at: https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.

   Information demonstrating compliance with 10 CFR 35.690 and 35.59 with an "alternate pathway" and "recentness of training" was not provided for either physician either.

   Some of the other forms indicate that each physician is already listed on an NRC license for a modality in 10 CFR 35.600 and that each is seeking additional authorization under 10 CFR 35.600, instead of indicating that each has received a medical specialty board certification that NRC accepts. In researching this issue, we could not find any NRC license showing either physician as an AU for a modality under 10 CFR 35.600.

   Please do not send us additional requests to consider Drs. Jon Quackenbush and Koppolu Sarma as authorized users (AUs) for the HDR program unless you are able to support their applications with clear evidence that each meets the training and experience requirements in 10 CFR 35.13; 35.14; 35.57; 35.59; and 35.690, as applicable.

   In addition, we noted that Dr. Sarma's first name is spelled differently among the six letters listed above. In some letters, it is spelled "Koppolu" and in others it is spelled "Koppula." If you request that Dr. Sarma become an AU again, please state which spelling is correct and use only that spelling throughout your application.

   Although neither proposed AU's request was able to be considered thoroughly, because we encountered problems with the reviews before reaching the end of each application, please note that it also appeared that the preceptor physicians signing each form may not have been appropriate. If you decide to pursue AU status for these physicians again, please review the information in NUREG 1556, Vol. 9, Rev. 2, including, but not limited to, the information in Appendix D, especially as it relates to preceptor physician's qualifications, being on Agreement State licenses, being on Type A broad scope licenses, etc.

3. Please advise us as to whether you wish to have Gurbachan S. Kapoor, M.D. become an AU for the proposed HDR program. If you do, please so state explicitly and confirm the correct spelling of his name, advising us if it merits correction.

4. Please state explicitly which sealed source you want authorization for in the HDR device you are requesting. This device can accommodate several different sources and it was not clear to us which one you wanted authorization for.

5. Please also clearly state the maximum activity per source and the total activity you want to have authorization for, which cannot exceed the maximum specified in the Sealed Source and Device Registry Certificate for this sealed source and device.

   Please also clarify which model HDR device you want, as it appears that there are several different models that accommodate the sealed source(s).

   Please be mindful of the requirements in 10 CFR 37 when determining how much total activity you want authorization for as the thresholds requiring implementation of 10 CFR 37 are relatively low for the radionuclide you are seeking authorization for in the HDR device.

6. As your HDR room diagrams showed relatively little of what we need in order to evaluate them, we were unable to gain a full understanding of your proposed new HDR facilities.

   Please provide revised 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.

   Some of this information was included in your application's attachments but much of it was not, or was difficult to decipher.

   Please clearly state and mark the street address for the HDR room on one of the diagrams and include with your response.

   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 space is above the HDR room, its functional identity and whether it is restricted (R) or unrestricted area (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/roof:

**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:

a. expected radiation exposure rates, in traditional units, for each adjacent area, under the most adverse and typical source orientations and maximum installed source activity, both without shielding and distance factored in and with shielding and distance factored in;

b. 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;

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

d. occupancy factors used for all adjacent areas, including areas above and below;

e. 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);

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

We were unable to identify the procedures ("how you are going to do something") in 10 CFR 35.610 and 35.643 as being present in your letter. Commitments ("statements that you are going to do something and, as appropriate, how, briefly") required by 10 CFR 35.615 are also needed.

It appeared that some language alluding to some of these requirements and procedures was in your six letters above but the language was often incomplete and contained in a document intended for patients.

Please also note that submitting either a blank or sample data collection sheet instead of actual, explicit commitments and procedures is not acceptable. To complete your application for this amendment, please submit these procedures, briefly and concisely, keyed to each regulatory requirement.

7. Please confirm that the postings required by 10 CFR 20.1902, based upon definitions in 10 CFR 20.1003, will be placed, for the new HDR room, the roof above it and for any immediately adjacent spaces where it may be necessary.

8. Your diagrams and letter dated June 22, 2016, use the terms "controlled" and "uncontrolled" areas. These terms are not appropriate for the new HDR room as they are not defined according to expected radiation levels. The more appropriate terminology is "restricted area" and "unrestricted area," which are terms defined in 10 CFR 20.1003. Please incorporate the correct terminology in your revised amendment request.

9. The following is some general information, compiled from deficiency correspondence I've prepared over the years, to assist you in preparing not only this response, but also any future licensing actions, to minimize or eliminate requests we must make for additional information. This can greatly lessen the workload for you and for us and permit us to serve you better.

Please be reminded that USNRC is an independent and objective federal government regulator.

This is not intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

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."

What this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved.

Only after the request has been thoroughly vetted and corrected by the applicant/licensee should the licensing correspondence be transmitted to NRC.

This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

For HDR licensing specifically:

Please refrain from submitting copies of "off the shelf" licensing packages prepared by other licensees, vendors or consultants. We understand that these packages may seem to be convenient but HDR authorizations are not "one size fits all," considering that 37 Agreement States each have their own requirements and guidance, in addition to that of the NRC.

Experience has shown that these documents are not crafted to address current NRC regulations and guidance.

On the contrary, such documents are often based upon "guidance" that NRC used from 1993 – 2002. NRC discontinued that "guidance" when 10 CFR Part 35 was revised completely in April 2002 and HDR regulations were first promulgated.

Using such documents now may "over-commit" your HDR program in several areas and "under-commit" your program in most others. This creates the need to contact you for additional information resulting in mutual delays and extra work.

In addition, please do not send us vendor's operations manuals, vendor's emergency procedures manuals, dosimetry equipment calibration information, lengthy procedure details, patient instructions and explanations, Department of Transportation (DOT) test results for the sealed source packaging to be used by the vendor for shipment of your source, patient records, resumes, college transcripts, and any personally identifiable information.

We never need or ask for such information but it is often submitted to us instead of briefly and concisely providing the information specifically called for in our regulations and our guidance. Your current application and subsequent letters contained multiple copies of such information so please refrain from doing so again.

When submitting the procedures required by 10 CFR 35.610 and 35.643, please include a brief description of the procedure/check itself.

In other words, the procedure should describe "how" you will do the particular task to meet the requirement. Simply stating that you "will" meet the requirement or perform the task is not a procedure.

Further, providing a copy of a checklist that you use to record the results of procedures/tests/tasks, etc. is not an acceptable substitute for providing commitments to perform procedures/tests/tasks, etc. and a description of how each will be done.

It is acceptable to describe how you will perform a procedure and to also state that you reserve the right to change the procedure so long as the regulatory requirement is met and safety is not degraded. Please see 10 CFR 35.26, for additional regulatory assistance in this matter.

It will be helpful for you to refer to 10 CFR 35.600-35.657 (Subpart H) and corresponding sections in NUREG 1556, Vol. 9, Rev. 2 available on our website in the "Medical Licensing Toolkit" at https://www.nrc.gov/materials/miau/med-use-toolkit.html for assistance.

The technical quality, accuracy and completeness of your submission are primary factors that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Please note that your submission should not include extraneous documentation, which only serves to delay the review process.

Please only submit information that our regulations and guidance specifically address. Please completely and concisely answer questions that we ask and provide information that we specifically request.

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.

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.

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.

If you have any questions concerning this amendment, or the additional information requested below, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841.

My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-17073-01
Docket No. 030-12150
Control No. 600102