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

NOV 1 3 2018

Stephen M. Rose, M.S.
Radiation Safety Officer
James E. Cary Cancer Center
P.O. Box 551
Hannibal, MO 63401

Dear Mr. Rose:

During our review of your letter received May 29, 2018, requesting to renew U.S. Nuclear Regulatory Commission (NRC) License no. 24-32681-01, we noted that the renewal was only partially prepared in accordance with NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses."

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

Further, upon receipt of this letter requesting additional information (RFAI), please contact us to arrange a conference call to discuss this information to resolve the remaining issues.

Please contact Magdalena Gryglak at (630) 829-9875 and Magdalena.gryglak@nrc.gov, and Colleen Carol Casey at (630) 829-9841 and colleen.casey@nrc.gov.

Please provide only one complete, written response that is physically and legibly hand signed and currently dated by close of business on November 9, 2018. If an alternative response date is needed, please contact us first to make other arrangements.

You may submit your response as a pdf document and send it via email to Magdalena.Gryglak@nrc.gov. Or, you may fax it directly to 630-515-1078 and specify its recipient as Colleen Carol Casey.

However, do not, under any circumstances, do both; only one means of transmission is best to facilitate correct processing of your response.

Please reference your response to the attention of either Magdalena Gryglak or Colleen Carol Casey as "additional information to control number 608930." We will resume our review upon receipt of the requested information.

Many of the details and commitments needed to continue the High Dose Rate (HDR) remote afterloading brachytherapy device authorization were missing in your original submittal, including diagrams that contain the necessary information, procedures (brief "how to do" certain checks and tests, not merely restating regulations) required by Title 10 of the *Code of Federal Regulations* (CFR) 35.610 and 35.643, and detailed shielding calculations to demonstrate compliance with the radiation limits in 10 CFR Part 20.

Full use of NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses," for your response and future 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 response. The document can be found at https://www.nrc.gov/docs/ML0734/ML073400289.pdf.

In preparing your response and any future correspondence, please focus on providing the information requested in Appendix C to NUREG 1556, Volume 9, Revision 2. Follow the Matrix in Appendix C.1 and in Tables C.2 and C.3, follow the "Suggested Format" provided 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 the NUREG to ensure a complete understanding of the commitments that you make.

In fact, the easiest way to prepare a renewal, for example, is to take a copy of NUREG 1556, Volume 9, Revision 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.

Please do not re-type the checklist as errors and omissions may be 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.

Where the Matrix and Appendix state that you do not need to submit certain items, information, and procedures, please refrain from doing so.

For example, do not submit a training program, package ordering procedures and package receipt and opening procedures, among others. Submitting unnecessary documents delays the progress of the review while adding to the work that you and we must do without an offsetting safety benefit.

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 the information.

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.

This advice is particularly relevant to your high dose rate (HDR) remote afterloading brachytherapy program and the significant quantity of procedures, diagrams, commitments, etc. that we need to continue this authorization.

Please provide the following information:

A. We noted that there were extraneous documents submitted in your letter that we did not and do not request when renewing your authorization for the HDR program.

In your response, please do not send us the following (no other written response is being requested):

1. Copy of your NRC License;
2. Resume and Curricula vitae for the Radiation Safety Officer (RSO) and each of the Authorized Users (AUs);
3. Taxpayer Identification Number (the instructions state to fax the information to the NRC Fee Department);
4. The procedure, "Radiation Protection Policy for Occupationally Exposed Pregnant Workers;"
5. The procedure, "Performance of HDR Brachytherapy (Cylinder and Mammosite);"
6. "Source Activity Calibration" information;
7. Copy of Appendix M, NUREG 1556, Volume 9, Revision 2, "Model Procedures for an Occupational Dose Program" (the information does not provide any information specific to your program);
8. Copy of Appendix O, NUREG 1556, Volume 9, Revision 2, "Model Procedures for Ordering and Receiving Packages," (the information is not required in the licensing process);
9. Copy of Appendix P, NUREG 1556, Volume 9, Revision 2, "Model Procedures for Safely Opening Packages Containing Radioactive Material" (the information is not required in the licensing process);
10. Copy of Appendix W, NUREG 1556, Volume 9, Revision 2, "Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return;"
11. The procedure "Source Handling Procedure for microSelectron HDR and microSelectron PDR."

B. Please provide the RSO Delegation of Authority Letter. A model letter can be found in Appendix I of NUREG 1556, Volume 9, Revision 2. Please ensure that the RSO and a senior management official date and sign the letter.

C. Please name an Authorized Medical Physicist (AMP) on your license who is qualified in accordance with Title 10 Code of Federal Regulations (CFR) 35.51.

D. Facility diagram:

1. Please provide diagrams (simple, hand-drawn diagrams are sufficient) that clearly show the proposed HDR treatment room and the location and functional identity of all adjacent rooms, areas and/or spaces surrounding it, especially the areas above it and beneath it.

   As blueprints and copies of blueprints typically show much information that we do not need, and they show very little information that we do need, please do not submit these documents in support of your request to renew your license.

2. Please clearly state and mark the street address for the HDR room on one of the diagrams.

3. Please identify the proposed HDR treatment room with a room number or label the room.

4. Your diagrams should be either drawn to scale or show actual dimensions of the HDR treatment room.

5. Show the direction of north.

6. Describe all rooms and provide room numbers for all spaces/rooms adjacent to the HDR treatment room including spaces/rooms above and below the HDR treatment room.

7. 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) (see 10 CFR 20.1003 for definitions).

8. Show the elevation/grade clearly described and what space is above and below the HDR room; its functional identity and whether it is restricted (R) restricted (R) or unrestricted areas (U).

9. Indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room.

10. Clearly show the location in the room where the HDR device will be stored and where it will be used and exposed for patient treatments and physics tests.

11. For each barrier in each direction, including the floor and ceiling:

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

    b. Thicknesses of barriers (individually and total, expressed in inches, feet or centimeters, consistently); and,

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

12. Please indicate clearly whether persons may gain access to any area adjacent to, above and below the HDR treatment room.

    Are administrative controls in place to prevent access to the roof and/or any other potentially unrestricted areas during HDR exposures and treatments? Please describe.

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.

E. Shielding Evaluation:

1. 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.

2. 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 areas (in mrem/hr and mrem/yr) will not exceed the limits specified in 10 CFR 20.1301(a).

   Please clearly correlate all points for which dose levels are calculated with points on the diagram so corroboration is possible.

3. Please include the following details in your calculations:

   a. expected radiation levels 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. realistic, meaningful occupancy factors used for all adjacent areas, including areas above and below;

   e. calculation of your transmission factor;

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

F. Radiation Monitoring Instruments:

Please provide required commitments for Radiation Monitoring Instruments as described in NUREG 1556, Volume 9, Revision 2, Section 8.17, Appendix K, and Table C.3.

G. Other Equipment and Facilities:

1. Please provide a description of the emergency response equipment available near the treatment room to respond to a source lodged within the patient following completion of the treatment in accordance with 10 CFR 35.615(g)(2).

2. In your documentation received May 29, 2018, on page 25, you stated that "an electrical interlock shall be installed at the (or each) entrance to the room." Please describe the number of entrances to the room.

H. Safety Procedures and Instructions in accordance with 10 CFR 35.610:

1. Please provide your emergency procedures and instructions to respond to abnormal situations associated with the use of the HDR unit. Please refer to NUREG 1556, Volume 9, Revision 2, Section 8.22 for guidance regarding the content of the procedures.

2. Please, ensure that you address all regulations in 10 CFR 35.610:

a. Describe how you will secure the console and the treatment room when not in use or unattended in accordance with 10 CFR 35.610(a)(1);

b. In your documentation received May 29, 2018, on page 25, you stated that "only trained personnel shall be allowed to access the device." Please define "trained personnel;"

c. In your documentation received May 29, 2018, on page 25, you stated that "when the HDR unit is either not in use or unattended, the treatment console key shall be removed from the unit and secured by an authorized individual." Please define "authorized individual;"

d. Describe how you will permit only individuals approved by the AU, RSO, or AMP to be present in the treatment room during treatment with the sources in accordance with 10 CFR 35.610(a)(2);

e. Name individuals responsible for implementing corrective actions in accordance with 10 CFR 35.610(4)(i);

f. Name and provide the telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally in accordance with 10 CFR 35.610(4)(iii);

g. Describe how you will provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to individual's assigned duties, in the operating and emergency procedures as required in 10 CFR 610(d).

h. Describe how you will ensure that operators, AMPs, and AUs will participate in drills of the emergency procedures, initially and at least annually, in accordance with 10 CFR 35.610(e).

i. Confirm that you will retain a record of individuals receiving instruction required by 10 CFR 35.610(d) in accordance with 10 CFR 35.2310.

j. Confirm that you will retain a copy of the procedures required by 10 CFR 35.610(a)(4) and (d)(2) in accordance with 10 CFR 35.2610.

k. In your documentation received May 29, 2018, on page 25, you stated that your treatment room is equipped to house an accelerator. Please be reminded that you must request an amendment to your license before adding an accelerator in accordance with 10 CFR 35.13(e).

I. Safety Procedures and Instructions in accordance with 10 CFR 35.643:

1. Please confirm that you will perform the spot checks as required in 10 CFR 35.643 after each source installation.

2. Please confirm that an AMP will review the results of the spot checks within 15 days and notify the licensee of the results in accordance with 10 CFR 35.643(c).

3. In your letter received May 29, 2018, you provided a list of the spot checks that you will perform before the first use on a given day. Please provide your procedures which describe "how" you will perform each spot check element to meet the requirement.

4. Please confirm that "if the results of the checks required in 10 CFR 35.643(d) indicate the malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system."

5. Please confirm that you will retain a record of each check required by 10 CFR 35.642(d) and a copy of the procedures required by 10 CFR 35.643 (b) in accordance with 10 CFR 35.2643.

J. Area Surveys:

Please provide the required commitment for Area Surveys as described in NUREG 1556, Volume 9, Revision 2. Section 8.24, Appendix R, and Table C.3.

Please be reminded that 10 CFR 30.9 (a), states, "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."

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Magdalena R. Gryglak

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 24-32681-01
Docket No. 030-37750
Control No. 608930