



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. STE 210
LISLE, IL 60532-4352

David E. Sieffert, M.S.
Radiation Safety Officer
Lakeland Medical Center, St. Joseph
1234 Napier Avenue
St. Joseph, MI 49085

JUL 01 2015

Dear Mr. Sieffert:

This refers to your application dated January 19, 2015, requesting renewal of your NRC Material License No. 21-04177-01.

We have reviewed your application dated January 19, 2015, and the attachments that accompanied it 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, within 14 days from the date of this letter (by July 15, 2015).

If an alternate timeframe to respond is needed, please contact me to make other arrangements. These details will help to 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 585785." Your complete, signed and dated response may be submitted as a PDF file sent to my email at colleen.casey@nrc.gov. We will then continue our review.

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. Sections 8.5 and 8.6, Item 5 and section 8.9, Item 6 refer to your authorization of gadolinium-153 under 10 CFR 35.500. You have requested continued authorization of two sources not to exceed one microcurie each for the purpose of possession and storage only with the intent to dispose.**

Please be reminded that the provisions in 10 CFR 35.92 do not apply to these sealed sources because the half-life of gadolinium-153 exceeds 120 days. Please clarify what your specific intentions are for these sources with respect to disposing of them. Please include a timeframe when you expect to be able to dispose of them to an appropriately licensed entity and please specify when these sources were placed into storage with the intention of disposing of them.

2. **We noted that you requested continued authorization for your high dose rate remote afterloading brachytherapy device (HDR).**

Some of the information needed to continue this authorization was not included, especially with respect to the room diagram for the HDR device and related details for the shielding evaluation.

You submitted one very minimal diagram of the HDR room and only one shielding calculation, without specifying at which point on the diagram the shielding calculation was prepared for.

In order to complete your application to renew this authorization, please respond to all of the following:

Have there been any changes to your HDR room, or any of the immediately adjacent spaces surrounding it, including above it, including the mechanical room?

Have your shielding calculations for this room, or any of the immediately adjacent spaces surrounding it, including above it, changed at all since the most recent time it was approved?

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.

Please also identify the HDR treatment room with a room number or another, similar identifier. The address for the HDR treatment room should also be clearly stated and marked on at least the first diagram in your resubmission, if you submit more than one diagram in response.

Some of this information was included in your letter but most of it was not.

- A. Your diagrams should be either drawn to scale or show actual dimensions;**
- B. Provide correct room numbers for all spaces (if none, please so state or identify the room by another means);**
- C. Show the direction of north;**
- D. 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);**
- E. Show the elevation/grade clearly described and what spaces are above the HDR room, their functional identity and whether they are restricted (R) or unrestricted areas (U);**

- F. Indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room;
- G. For each barrier in each direction, including the floor and ceiling:
- H. The specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);
- I. Thicknesses (individually and total, expressed in inches, feet or centimeters, consistently); and,
- J. 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 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.

- 3. 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 levels for each adjacent area, under the most adverse and typical source orientations and maximum installed source activity;
- 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

D. Sieffert

- 4 -

- f. 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.

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
Materials Licensing Branch

License No. 21-04177-01
Docket No. 030-02049
Control No. 585785