



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

**FEB 04 2020**

James Duce M.S.  
Radiation Safety Officer  
Evansville Cancer Center/Vantage Oncology  
700 N. Burkhardt Rd.  
Evansville, IN 47715

Dear Mr. Duce:

Enclosed is Amendment No. 42 to your NRC Material License No. 13-25945-01 in accordance with your request.

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.

- A. In Amendment No. 41, you requested that we update the name of one of your high dose rate (HDR) remote afterloading brachytherapy source vendors from "Mallinckrodt Medical B.V." to "Curium Netherlands B.V.", but we were unable to do so at the time, without including the former company name. In this amendment, we have deleted the former company name for this vendor and only the new name appears.
- B. The following request for additional information is being repeated from our letter dated July 8, 2019, but please note that we are only including it in this letter because we still need specific information, including shielding thicknesses, distances, exposures with and without shielding and distances for the roof.

Although your letter dated November 6, 2019, stated that no access is made to the roof, and although this may be true most of the time, it may still be possible for the roof to be accessed for some kind of maintenance or other purpose during an HDR treatment.

Therefore, please submit the information requested below, limited to the roof area.

In addition, your response letter dated November 6, 2019, did not address our request concerning appropriate postings. That section from the November 6, 2019 letter is extracted and repeated as follows:

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

Please respond to our request about postings, as shown above.

J. Duce

- 2 -

Please do not resubmit the information from your November 6, 2019, letter again. We only need the information for the roof areas and posting commitments.

If you have questions about these requests, please email me at [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov) to arrange a telephone discussion at a mutually convenient date and time.

"In the course of our review and in checking your last renewal application and subsequent amendment requests, it became apparent that we do not have a current facility diagram and shielding calculations incorporated into your license. Apparently a previous reviewer misunderstood this issue but we must correct it at this time.

Please provide diagrams (simple, hand-drawn diagrams are good) that clearly show the HDR treatment room and, if applicable, associated source storage room(s) and the location and functional identity of all contiguous rooms, areas and/or spaces surrounding it, especially the areas above and beneath it.

Please clearly state and mark the street address for these rooms on the diagrams and include with your response.

1. Your diagrams should be either drawn to scale or show actual dimensions;
2. provide correct room numbers for all spaces (if none, please so state or identify the room by another means);
3. show the direction of north;
4. 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);
5. 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);
6. indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room;
7. for each barrier in each direction, including ceiling/roof:
  - a. the specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);
  - b. thicknesses (individually and total, expressed in inches, feet or centimeters); and,
  - c. the distances from the patient/"exposed source" to the opposite, occupiable places for barriers/walls/ceilings/floors in all directions.
8. Please indicate clearly whether persons may gain access to any area adjacent to, or above the rooms.

J. Duce

- 3 -

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.

9. 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.
10. 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.

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

8. We have noted that many HDR licensees use the terms "controlled" and "uncontrolled" areas. These terms are not appropriate for the HDR rooms 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 response."

C. Please provide the written responses above, limited to the roof areas and postings, within 30 days of the date of this letter (by March 9, 2020). Please provide only one response to the item

J. Duce

- 4 -

above. If an alternative response time is needed, please contact me directly first at either [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov) (preferred) or (630) 829-9841.

Please only send us one complete, written, currently dated and legibly, physically signed (by an appropriate senior management official) correspondence document, such as either an NRC Form 313 or a business-style letter containing the same information as an NRC Form 313a.

Please ensure that the requested information above is answered completely and accurately and is attached to your transmittal letter.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us. If you resubmit such information for the sake of adding context and other details to enhance its meaning, that is acceptable.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail.

Sending only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors, although emailing a PDF document is the least efficient mechanism for responding to me.

The most reliable and fastest way to respond is to send a fax of one complete copy only to me at (630) 515-1078.

Please address your written response to my attention as "additional information to control number 616912" to facilitate proper handling in our offices. Please note that this is a different control number than the one you were directed to use in our July 8, 2019, letter.

Please always provide the name, direct telephone number, fax number and email address for at least one individual knowledgeable in the amendment being requested.

If you have any questions about the items in this letter, please schedule a telephone call with me to discuss them. Arranging the call by email is preferable.

Please also note that 10 CFR 30.41 and 30.51 may be of assistance to you, in addition to the regulations mentioned below.

Please be reminded that 10 CFR 30.9(a) requires: "(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."

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

J. Duce

- 5 -

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document and this letter are exempt from public disclosure because their disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system "Agencywide Documents Access and Management System" (ADAMS).

The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011.

While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at:

<http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

J. Duce

- 6 -

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey  
Materials Licensing Branch

License No. 13-25945-01  
Docket No. 030-30712

Enclosure: \*

Amendment No. 42