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

MAY 18 2012

Stephen T. Slack, Ph.D.
Radiation Safety Officer
Midwest Division – RMS, LLC
d/b/a Research Medical Center
2316 East Meyer Blvd.
Nuclear Medicine/Radiation Oncology
Kansas City, MO 64132

Dear Dr. Slack:

Enclosed is Amendment No. 56 to your NRC Material License No. 24-18625-01 in accordance with your request.

Please note that significant changes to your license may appear in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. As a result of our deletion of your previous depleted uranium authorization in this amendment, the remaining authorizations in Subitem Nos. 6 through 9 were reordered.

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 or require clarification on any of the information stated above, you may contact me at (630) 829-9841 or you may reach our administrative support staff at (630) 829-9887. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

I acted upon the requests made in your letters dated February 15, 2012, May 1, 2012, and May 11, 2012.

In correspondence dated February 15, 2012, you indicated that you wished to release your former area of use where a Clinac 4 accelerator, containing depleted uranium shielding, had been used many years ago, for unrestricted use. The NRC staff has reviewed your final status surveys. Based on its review, the staff has concluded that all licensable radioactive material has been removed from your former area of use noted above and residual radioactive material attributable to licensed activities does not exceed current NRC criteria. Based on these conclusions no further remediation or actions with respect to NRC regulated material is required for this location and it is suitable for unrestricted use.

This also refers to the telephone conversation between you and me on May 17, 2012, concerning the remaining issues with the cesium-137 sealed sources, the continued authorization of a strontium-90 ophthalmic applicator (that you no longer have possession of) and the advice that we do not list Authorized Medical Physicists (AMPs) for "low dose rate brachytherapy," i.e., materials in 10 CFR 35.400.

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The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

S. Slack

On occasion, we may list an AMP on a license for the calibration of a strontium-90 ophthalmic applicator but that is a rare occurrence.

We were unable to approve the deletion of your cesium-137 sources at this time, as well as the approval of your "newer" HDR program shielding calculations. This is because the information provided in your letter dated February 15, 2012, was insufficient to complete our review.

In our telephone discussion on May 17, 2012, you agreed to furnish us with a copy of the license for the recipient of the cesium-137 sources, as well as a copy of the final leak tests performed on those sources.

In addition, since no possession limit was listed in Subitem No. 8.D. for the strontium-90 eye applicator, and since its authorization had to be continued temporarily until appropriate information is provided to us to delete it, we authorized a possession limit for it based upon its registration. As discussed with you, it is our understanding that your intention is to request deletion of this source as soon as possible. In order to support that request, please submit a copy of its last leak test, acknowledgement of receipt from the party who took possession of it and a copy of the license for the party who took possession of the source.

Please also be reminded that submitting a "bill of lading" only tells us that something was prepared for shipment; it does not prove that the shipment was successful and the material was appropriately transferred to an authorized recipient. 10 CFR 30.41 and 30.51 may assist you regarding transfers of licensed material.

In order to resume our review and replace the old documents in the last condition of your license, known as the "tie-down" condition, it will be necessary to have a complete and clear submission of all elements for your HDR program.

Please submit a written response within 30 days of the date of this letter, referencing it to my attention at the above address as "additional information to control number 576974," to facilitate proper handling in our office. If this timeframe cannot be met, please contact me to arrange an alternative response date.

Upon receipt of this letter, please contact me to discuss these items, as we have attempted to resolve them before and we do not appear to be making appropriate progress with them as of yet.

We understand your HDR program is pre-existing but in order to continue it into the renewed license and delete the "old" documents in your "tie-down" condition, all elements of the HDR program must be resubmitted in a license renewal.

Most of this information was missing in your renewal application and from the letter dated February 15, 2012.

In addition, the information presented in the letter dated February 15, 2012, was extremely

confusing and unclear. We could not associate which calculations belonged to which room and which data correlated with the room or space referenced. Therefore we could not perform our own independent calculations using your data.

The diagrams of the floor were illegible and could not be deciphered. Only one diagram of an HDR room was submitted but it contained insufficient information and it was not clear which HDR room it represented.

As your HDR room diagrams consisted 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 were unable to gain a full understanding of your 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 areas above and below the room. Some of this information was included in your application's attachments but some of it was not, or was very difficult to decipher.

Your diagrams should be either drawn to scale or show actual dimensions;

***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 the HDR room and whether they are restricted (R) or unrestricted areas (U);**

***show the elevation/grade clearly described and what spaces are above and beneath the HDR room, their functional identity and whether they are restricted (R) or unrestricted areas (U);**

***indicate where you anticipate the patient/"exposed source" to be located within the room;**

***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 (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 HDR treatment room.

If this area 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, 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 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 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.**

Your renewal application and your letter dated February 15, 2012, were missing most of the procedures and commitments for continuation of your HDR program, as specified in 10 CFR 35.610 and 35.643.

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.

S. Slack

Further, providing a copy of a checklist that you use to record the results of procedures/tests/tasks, etc. is not a 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 at:

http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0026.html

for additional regulatory assistance in this matter.

It may be helpful for you to refer to 10 CFR 35.600-35.657 (Subpart H) and the corresponding sections for HDR use in NUREG 1556, Vol. 9, Rev. 2, especially in Appendix C.3, for assistance.

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."

Please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

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.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

S. Slack

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.

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.

You will be periodically inspected by NRC. 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.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 24-18625-01
Docket No. 030-13959

Enclosure:

Amendment No. 56