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

MAR 21 2011

Dale J. Schippers, M.S.
Radiation Safety Officer
Saint Mary's Health Care
200 Jefferson, S.E.
Grand Rapids, MI 49503

Dear Mr. Schippers:

Enclosed is Amendment No. 81 to your NRC Material License No. 21-01078-01 in accordance with your request. Please note that the major changes made to your license are printed in **bold** font.

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.

Please note that, at this time, I was unable to approve Gilbert Padula, M.D. as an authorized user for use of yttrium-90 in the Theraspheres dose delivery system and I was unable to approve the use of twelve curies of iridium-192 in your high dose rate remote afterloading brachytherapy device (HDR). These requests were not approved because the information in your letter dated December 16, 2010, was insufficient to complete our review.

If you wish to pursue these request please provide the information below, addressed to my attention, as "additional information to control number 574190." We will then continue our review.

Dr. Padula was not approved as an authorized user for use of yttrium-90 in the Theraspheres dose delivery system because it was not clear that the training and experience presented for him complied with the guidance on our website for this device, which is available at :

http://adamswebsearch2.nrc.gov/idmws/DocContent.dll?library=PU_ADAMS^pbntad01&LogonID=a975ebf233554f6c1956cb2228c8a6b7&id=110390168

Further, your letter dated December 16, 2010, stated that "this documentation should complete the training requirements for authorized users: Francis Verde, Charles Wilkinson and Gilbert Padula." However, only Drs. Verde and Wilkinson needed to have their training completed as a carryover from the initial authorization for the Theraspheres dose delivery system. The third physician who initiated training in the Theraspheres dose delivery system was Dr. James Kane, based upon your previous letter dated February 11, 2010. Dr. Padula did not begin training in February 2010 and it is unclear whether his training is equivalent to that described in our guidance.

Please provide additional, explicit information describing the training and experience Dr. Padula has completed to demonstrate that he meets the criteria in our guidance.

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

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As Dr. Kane's training appears to be incomplete, because he did not complete the remainder of the requisite training and experience, please advise us as to whether his authorization for the use of the Theraspheres dose delivery system should be continued, as it appears to us that his authorization may not be completely valid at this point.

In addition we could not approve the increase in activity for your HDR device because you failed to provide revised shielding calculations demonstrating that the room your HDR device is located in can accommodate the higher activity without exceeding the exposure limits in 10 CFR Part 20.

In order to consider your request, please provide complete, clear and concise diagrams and information describing the expected radiation profiles in all six areas surrounding your HDR room. The following information describes what will be needed:

Please provide diagrams 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.

Your diagrams should be either drawn to scale or actual dimensions given; room numbers provided; show the direction of north; the functional identity of each room, space or area; the elevation/grade clearly described; indicate where you anticipate the patient to be located; the composition and thickness of each barrier in each direction; whether each area is restricted or unrestricted; and the distances from the source to the barriers/walls in all directions.

Please do not submit blueprints or copies of blueprints for HDR facilities. Simple hand-drawn diagrams containing only the information requested in NUREG 1556, Vol. 9, Rev. 2, sections for HDR are best. (Note Rev. 2 is on our website for Pt. 35 medical licensing.)

Please indicate clearly whether persons may gain access to an area above or below the proposed HDR treatment room. If these areas may be occupied or accessed 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, lock-out, etc.) that will be put in place to prevent occupation during HDR treatment.

Please provide revised and simple shielding calculations, showing all of your work, detailed assumptions, defined terms, equations, constants, substitutions, parameters, and diagrams 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 your calculations for the barrier transmission factors and indicate whether poured concrete or any other shielding material, or combination of materials, will be the only barrier(s) employed.

Please indicate the thinnest wall/barrier.

Please indicate the elevation of your facility.

Include the following details in your submission:

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a. expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum 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, and the transmission factor of the shields;

c. the maximum "beam-on time" per hour and per week; the number of patients/treatments (i.e., workload) per week; and occupancy factors used for all adjacent areas; and

d. demonstrate by calculation the dose received by the 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). These calculations must demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded.

e. Please include in your shielding calculations sufficient information, in a simple, readily understandable format using traditional units (preferred) to permit us to independently evaluate the adequacy of shielding in your proposed room.

It may 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 for assistance.

Please note that we no longer use the HDR licensing guidance that was in place from ~1993 to April 2002 because 10 CFR 35 Subpart H and NUREG 1556, Vol. 9, Final superseded it. (This information is provided only in case you were unaware of it.)

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.

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 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

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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.

Sincerely,

Colleen Card Casey

Materials Licensing Branch

License No. 21-01078-01
Docket No. 030-08291

Enclosure:

Amendment No. 81