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

AUG 2 0 2007

Sidney D. Machefsky, M.D.
Radiation Safety Officer
St. Joseph Health Center
300 First Capitol Drive
St. Charles, MO 63301

Dear Dr. Machefsky:

Enclosed is Amendment No. 55 to your NRC Material License No. 24-15159-01 in accordance with your request. Please note that the 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 could not approve your requests for the addition of iridium-192 in a high dose rate remote afterloading brachytherapy device and authorization for Gregg Dickerson, M.D. for the use of materials in 10 CFR 35.300 because the information in your letters dated May 12, 2006 (received May 22, 2007) and June 17, 2007, was insufficient to complete my review.

If you wish to pursue these requests please submit the information below, addressed to my attention, as "additional information to control number 316270." We will then continue our review.

1. **Dr. Dickerson was approved for the use of materials in 10 CFR 35.400 and, should the high dose rate remote afterloading brachytherapy program be approved in the future, he can be approved for that modality as well, based upon the information submitted in your letter dated June 17, 2007.**

   However, the information submitted in your letter dated June 17, 2007, did not support Dr. Dickerson's authorization for the use of materials in 10 CFR 35.300.

   Please submit appropriate documentation demonstrating that Dr. Dickerson meets the training and experience requirements in 10 CFR 35.390, 35.13, 35.14, 35.57 and/or 35.59, as appropriate.

   Please refer to the regulatory requirements in 10 CFR 35. 35.390, 35.57, 35.13 and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your written response to demonstrate that Dr. Dickerson's training and experience meet the appropriate regulatory requirements for the use of materials in 10 CFR 35.300.

   If Forms 313a will be used in support of your response, please use the newly revised Forms found on our website at:

   http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aut).pdf

   In addition, I noted that Dr. Dickerson is certified by a medical specialty board that we no longer accept - please check this link:

http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

I also noted that Dr. Dickerson submitted a curriculum vitae in support of his application to become an authorized user. Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.390, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

2. Regarding your request for new HDR authorization:

   a. Please confirm that all current HDR radiation safety program elements will be followed for this new modality. Specifically please address the information from NUREG 1556, Vol. 9, Rev. 1, table C.3, Item 9, "Other Equipment and Facilities," excerpt attached.

   b. I could not determine exactly which room you were proposing to locate the HDR device in for treatments and storage. Please provide revised diagrams that clearly show the HDR treatment room and the location 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 letter but much of it was not. Please complete and revise your diagrams and the descriptive information for them.

      Your diagrams should be drawn to scale or actual dimensions given; room numbers provided; show the direction of north; the functional identity of each room, space or area; indicate where you anticipate the patient to be located; the composition and thickness of each barrier in each direction; 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. 1, sections for HDR are best.

      Please indicate clearly whether persons may gain access to the area above 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, lock-out, etc.) that will be put in place to prevent occupation during HDR treatment.

      Please note that your submission of the report "Shielding Analysis for IMRT" was inappropriate and not useable for the purpose of evaluating the shielding of your proposed HDR storage and treatment room. In addition, the letter from Peter D. Situ, Ph.D. was unsigned.

      Further, it is my understanding that you will not be permitted to install a sealed source containing greater than 10 curies of iridium-192. Please explain and justify your request to install greater than 10 curies of iridium-192

in the HDR device.

Please provide revised shielding calculations, showing your work, detailed assumptions, 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.

Include the following details in your submission:

i. expected radiation levels for each adjacent area, under the most adverse and typical source orientations and maximum source activity;

ii. 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;

iii. 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

iv. 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.

v. 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. 1 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.

3. Please describe the following for your proposed HDR program:

a. Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for the proposed HDR treatment room;

b. area radiation monitoring equipment;

c. viewing and intercom systems;

d. steps that will be taken to ensure that no two units can be operated

simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine, etc.) are in the proposed HDR treatment room; and,

e. Methods to ensure that whenever the HDR device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

4. Please provide the procedures required by 10 CFR 35.643, "Periodic spot-checks for remote afterloader units." Please do not submit a data collection form in lieu of an actual set of procedures.

5. Please provide the procedures required by 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units....." Please do not submit a data collection form in lieu of an actual set of procedures.

If you have any questions concerning this amendment or the information above please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is (630) 515-1078.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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 (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).

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. 24-15159-01
Docket No. 030-08664

Enclosure:

Amendment No. 55