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

DEC 13 2004

William N. Salk, M.S.
Radiation Safety Officer
St. Cloud Hospital Imaging Services
1406 Sixth Avenue North
St. Cloud, MN 56303

Dear Mr. Salk:

Enclosed is Amendment No. 50 to your NRC Material License No. 22-10258-01 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.

A. Please note that I could not approve Jody A. Bolton-Smith, M.D., as an authorized user for the use of material in 10 CFR 35.300 (for iodine-131 only) or Dr. Barbi Kaplan Frenkel as an authorized user for the use of material in 10 CFR 35.300 and 35.400 because the information provided in the letter dated September 1, 2004, was insufficient to complete our review.

If you wish to pursue these requests, please submit evidence that each doctor's training and experience clearly meets the regulatory requirements in 10 CFR 35, Subparts E, F and/or J, as appropriate. Please send your response to my attention at the above address as "additional information to control number 313724." You may refer to NUREG 1556, Vol. 9, Section 8.7, Item 11, and Appendices B, D and E for assistance.

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.

Please also be reminded of the requirements in 10 CFR 30.9, which states, in part, that "(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 (emphasis added)." A copy of 10 CFR Part 30 is enclosed for your use.

1. Specifically, Dr. Bolton-Smith was not approved for the use of materials in 10 CFR 35.300 (for iodine-131 only), because her preceptor forms were incomplete.

   Her forms were unsigned and undated by the preceptor physician. Please submit currently signed and dated preceptor forms.

   Her medical degree was not designated, i.e., does she have an "M.D." or a "D.O.?" Please advise us in response. For the purposes of issuing this amendment I assumed her degree was an "M.D." by default.

   Section 11.b. of the preceptor forms was not completed. This section should be

completed and should correlate with the balance of the preceptor forms' content in order to serve as an acceptable application.

In order for Dr. Bolton-Smith to qualify for the use of materials in 10 CFR 35.300, she must demonstrate personal participation in clinically supervised training in at least three cases involving the oral administration of less than or equal to 33 millicuries of sodium iodide I-131, per 10 CFR 35.390(b)(1)(ii)(G) or ten cases of hyperthyroidism, per 10 CFR 35.930(b)(2)(I). Please submit evidence of this training.

Please also note that I was unable to verify Dr. Bolton-Smith's preceptor, Dr. Michael Graham, because Dr. Graham lists an Agreement State's broad scope license at the University of Iowa as the license under which he conducted Dr. Bolton-Smith's training. Broad scope licenses do not list Authorized Users on the license itself and the NRC does not have access to Agreement State licenses, even if this license did name authorized users directly on the license. The University of Iowa's Radiation Safety Committee evaluates and approves/disapproves Authorized Users internally.

Please provide a letter, currently signed and dated by the Chairman of the Radiation Safety Committee at the University of Iowa, attesting that Dr. Graham was an authorized user for the use of materials in 10 CFR 35.390 and/or 35.930 during the timeframes when Dr. Bolton-Smith was being trained by him.

2. Specifically, Dr. Kaplan Frenkel was not approved as an authorized user because no credible supporting documentation of her training and experience was included. The e-mail message provided is unacceptable as a substitute for the documentation required by 10 CFR 35, Subparts E, F and/or J. Please provide appropriate documentation in support of Dr. Kaplan Frenkel's application and please also indicate whether her medical degree is an "M.D." or a "D.O."

3. Your request concerning the gadolinium-153 line sources was too vague for the completion of this review. On December 6, 2004, when I spoke with you by telephone about this issue and the proposed authorized user issues above, you indicated uncertainty about this request also.

   Please clarify exactly what you want the license to be amended for. Do you want to add vendors, delete vendors, etc.? Please be specific in your response.

B. Your amendment has been prepared in accordance with newly revised 10 CFR Part 35, including several new standard license conditions and updated reformatting for several other Conditions. Since revised 10 CFR Part 35 has become effective and NUREG 1556, Vol. 9 has been issued, please use this new document to prepare future licensing correspondence. 10 CFR Part 35 and NUREG 1556, Vol. 9 should have been sent to you automatically and are available, respectively, on our website at:

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

and"http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/nureg-1556-9.pdf "

Using the above regulation and guidance, especially the NUREG 1556 series documents, will help ensure that your licensing correspondence is prepared more completely and in a less burdensome manner. You may realize the benefit of a reduced regulatory burden while enhancing safety and maintaining compliance and efficiency if you establish your license in this manner.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

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.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Sincerely,

Colleen Carol Casey
Materials Licensing Branch

License No. 22-10258-01
Docket No. 030-02241

Enclosures:

1. Amendment No. 50
2. 10 CFR Part 30