



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

JAN 10 2005

Spencer D. Feldt, CNMT
Radiation Safety Officer
Central Minnesota Diagnostic, Inc.
P.O. Box 158
150 10th Street
Milaca, MN 56353

Dear Mr. Feldt:

This refers to the application dated October 6, 2004, signed by Glenn Erickson, requesting an amendment to your license number 22-32014-01 to expand Dr. Kevin Leach's authorization to include iodine-131 for the treatment of hyperthyroidism and thyroid carcinoma.

The information provided by this application was insufficient to complete my review. As I cannot continue to process your request, I have voided your request at this time. This action is without prejudice to resubmission. If you resubmit your request please state that the resubmission is additional information to Control Number 313801 and reference it to my attention at the above address.

Dr. Leach was not approved as an authorized user for the use of iodine-131 for the treatment of hyperthyroidism and thyroid carcinoma. because his preceptor statement did not adequately support his application for this type of use and his training and experience did not appear to completely meet the requirements in 10 CFR 35.390 or 35.930.

Specifically, the preceptor statement for Dr. Leach was incomplete. Part 1, sections 4, 5a and 9 were left blank - please complete these sections. Part II, sections 11a, 11b, and 12, including A and B, were either blank or incomplete - please complete these sections. Please submit a revised preceptor statement, currently signed and dated by Dr. Lund, documenting Dr. Leach's training and experience for the use of iodine-131 for the treatment of hyperthyroidism and thyroid carcinoma.

Please refer to the above regulatory requirements as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Final, for assistance in preparing your response.

Please refer to NUREG 1556, Vol. 9, and 10 CFR Part 35 if you have questions about these matters. 10 CFR 35 and NUREG 1556, Vol. 9 are available on our website at <http://www.nrc.gov>. Then click on the "Nuclear Materials" toolbar key and the "Medical Use Licensing/Part 35" option on the Quick List.

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 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 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

If you have any questions or require clarification on any of the information stated above, you may contact me at (630) 829-9841.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 22-32014-01
Docket No. 030-34509