



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

APR 13 2011

Gregory M. Sutliff, M.D.
Radiation Safety Officer
Premier Health care, LLC
550 Landmark Avenue
Bloomington, IN 47403

Dear :Dr. Sutliff

Enclosed is Amendment No. 10 to your NRC Material License No. 13-32020-01 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.

If you have any questions about this amendment please contact me at (630) 829-9841 and my fax number is (630) 515-1078.

Please note that this amendment represents my best guess as to the exact sealed source and device that you intended to have authorized in Subitem Nos. 6. through 9.C. of the license, inclusive.

This is because your letters dated January 5, 2011, and April 13, 2011, and several emails sent to me on April 13, 2011, from Dawn Kirchner and Erin Bell did not contain the specific vendor/manufacture's name and sealed source/device model number for the gadolinium-153 sources you wanted.

Finally, using the "CardioMD" clue, I searched in several different sections of the NRC's Sealed Source and Device Registry and located what I thought you were trying to add authorization for under "ADAC Laboratories" and "Isotope Products Laboratories" for an attenuation correction device. But neither of these vendors were mentioned in any of the above correspondence.

As I previously communicated to your consultant, Ms. Bell, we can only consider licensing specifically what you ask us for. With respect to sealed sources and devices, we must have the vendor/manufacturers' names and model numbers in order to verify that the sealed sources and devices requested meet the requirements in 10 CFR 35.49 and, in this instance, 35.500. The vendors/manufacturers know this and should have this information readily available to provide to their customers in order to enable them to obtain the appropriate licensure for their products.

G. Sutliff

In the course of this review we received confusing vendor information, parts numbers, sales information and serial numbers, most of which was not useful in conducting the licensing review.

We also received a request to expand Andrew Ferguson, M.D.'s authorization to include this new sealed source and device but the supporting information for his application was inaccurate and incomplete as apparently a misunderstanding had occurred..

Dr. Ferguson's specialty board certification is not recognized as proof of training for 10 CFR 35.590 because no specialty board applied to NRC to have its certification exam evaluated and approved for 35.590.

Therefore Dr. Ferguson will either have to demonstrate that he is already an authorized user for materials in 10 CFR 35.590 or complete the 313a (AUD) forms for the alternate pathway, including a preceptor attestation.

Although you now have authorization for materials in 10 CFR 35.590, the material cannot be used on humans until you have a qualified physician approved for this use. Please see 10 CFR 35.13, 35.14, 35.57, 35.59 and 35.590 for assistance with this. Also, Appendices B, D and E to NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses," may be helpful. Appendix C and the corresponding sections that precede the Appendices in this NUREG may also be helpful, for preparing an authorized user's application and for future amendments.

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."

It is noted that your consultant, Ms. Bell, took issue with the perceived delay involved with this review. However, because we receive many deficient applications that involve a great deal of correspondence and research that such casework "delays" become unavoidable. We are doing our very best to afford each case an appropriate level of health and safety review and that process is optimized when applications are complete and accurate. Your assistance and patience in this endeavor is greatly appreciated.

In accordance with 10 Code of Federal Regulations 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

G. Sutliff

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,

A handwritten signature in cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 13-32020-01
Docket No. 030-34523

Enclosure: Amendment No. 10