



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

JAN 27 2011

James C. Hatten  
Radiation Safety Officer  
LaPorte Hospital and Health Services  
Department of Nuclear Medicine  
1007 Lincolnway  
LaPorte, IN 46350-0250

Dear Mr. Hatten:

Enclosed is Amendment No. 45 to your NRC Material License No. 13-15151-01 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.

**In correspondence dated October 27, 2010, and January 27, 2011, you indicated that you wished to release your former brachytherapy source area for unrestricted use. The NRC staff has reviewed your final status surveys.**

**Based on its review, the staff has concluded that all licensable radioactive material has been removed from your former brachytherapy source area and residual radioactive material attributable to licensed activities does not exceed current NRC criteria. Based on these conclusions no further remediation or actions with respect to NRC regulated material is required for this area of use and it is suitable for unrestricted use.**

**At this time I removed your authorization for materials in 10 CFR 35.400, as requested in your letters dated October 27, 2010, and January 27, 2011. This resulted in a re-ordering of your remaining Subitem Nos. so please examine your amended license carefully.**

**This also refers to the telephone conversation between you and me on January 27, 2011, concerning a typo related to the "10 CFR 35.500" reference in the October 27, 2010, letter and my inability to approve your requests to authorize Drs. Krishna Pillai, Syed Ali and Irfan Ahmad because the information in the October 27, 2010, letter was insufficient to complete my review.**

**If you wish to pursue these requests please provide the information requested below and submit it to my attention as "additional information to control number 573828." We will then continue our review.**

**The three doctors named above were not approved as authorized users for the use of materials in 10 CFR 35.300 because none provided complete, accurate and acceptable NRC Forms 313a, or the equivalent, in support of their applications, as required by 10 CFR 35.390(b)(1). The abbreviated, initialed notes provided offered no useful information to support their applications.**

**It is also not clear whether Drs. Pillai, Ali and Ahmad have each completed the required**



200 hours of didactic training in the subjects specified in 10 CFR 35.390(b)(1) and especially "in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive" (emphasis added.).

Please note that this classroom and laboratory training is different from that required in 10 CFR 35.290(b)(1) because the training in 10 CFR 35.290(b)(1) is specific for imaging and localization diagnostic studies, or in other words, non-therapeutic unsealed byproduct materials work that does not require a written directive.

In addition, Dr. Ahmad presented information from Ohio State University's (OSU) training program. The information as presented is unacceptable in several ways. OSU is a broad scope licensee located in an Agreement State where we do not have access to the licenses to verify preceptors. Further, as a broad scope licensee, OSU does not name individual users on its license because its Radiation Safety Committee (RSC) evaluates and approves/disapproves of authorized users internally.

Please see Appendix D in NUREG 1556, Vol. 9, Rev. 2, section V. for further information on how to correctly respond in such situations. Appendix D also contains excellent guidance for completion of the NRC Forms 313a which you should find useful.

Drs. Ali and Ahmad also need to present preceptor attestations (included in the Forms NRC 313a) to document their training in 10 CFR 35.290(c)(2), as each is appropriately certified by a specialty board that we accept, but only for uses in 10 CFR 35.100 and 35.200.

Please resubmit complete and accurate Forms NRC 313a, as appropriate, for each proposed authorized user that encompasses the proposed uses each doctor wishes to have (but does not already have, as the case may be.)

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, Revision 2, for assistance in preparing your response. NRC's regulations and the Guidance document referenced, NUREG 1556, Vol. 9, Rev. 2, are available on our website through <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>.

Please do not submit resumes, CV's, or personal, proprietary information that we must protect, in accordance with 10 CFR 2.790, such as social security numbers, dates of birth, home addresses or phone numbers, patient records, college transcripts, etc.

Please be reminded of the recentness of training regulations in 10 CFR 35.59. 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."

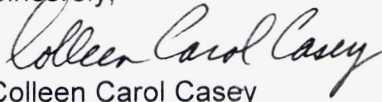
If you have any questions, please call me at (630) 829-9841. My fax number is (630) 515-1078.

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

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  
Materials Licensing Branch

License No. 13-15151-01  
Docket No. 030-08653

Enclosure: Amendment No. 45