



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

NOV 21 2008

Donald J. Peck, Ph.D.
Radiation Safety Officer
Henry Ford Macomb Hospital – Warren Campus
13355 East Ten Mile Road
Warren, MI 48089

Dear Dr. Peck:

Enclosed is Amendment No. 110 to your NRC Material License No. 21-04082-01 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 concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

This also refers to your letter dated August 20, 2008, concerning a request for amendment to your byproduct materials license no. 21-04082-01.

Please note that I was unable to approve Ishani Dalal, M.D. and Sami M. Fakir, M.D. as Authorized Users (AUs) at this time because the information in your correspondence above was insufficient to complete my review.

If you wish to pursue these requests, please submit the information requested below and address it to my attention as “additional information to control number 317427.” We will then continue our review.

Dr. Dalal wasn't approved as an AU for the use of materials in 10 CFR35.100, 35.200 and 35.300 because we were unable to verify the preceptor's qualifications. The preceptor references William Beaumont Hospital's license, which is a broad scope license, i.e., it does not name AU's on its license document directly; rather, its Radiation Safety Committee evaluates and approves/disapproves of AU's internally.

Please submit a letter currently signed and dated by the Chair of the RSC for William Beaumont Hospital stating which modalities Dr. Helena Balon was authorized for under the license and specifying which timeframes she held said authorization.

Please do NOT submit copies of minutes from the licensee's RSC meetings or other documents from the licensee, esp. patient records, or extraneous documentation that we must protect, per 10 CFR 2.390.

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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, Rev. 2, for assistance in preparing your response.

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

[http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(aud\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(aud).pdf)

The following links may be useful as they include the revised Forms 313a Series as well as Guidance for the completion of the forms:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627.pdf>

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/ri200627sup1.pdf>

In addition, if, you may find the guidance in RIS 2003-17 helpful, found at this link on our website:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2003/ri200317.pdf>

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."

Dr. Fakir was not approved as an AU for the use of materials in 10 CFR 35.100, 35.200 and 35.300 because neither of the two specialty certification boards s/he presented were acceptable to NRC. Please see the following link:

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

Dr. Fakir's ABNM certification was obtained prior to the 2005 date for recognition by NRC and the words "AU Eligible" do not appear above the seal for Dr. Fakir's ABR certification, rendering it unacceptable.

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 (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

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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. 21-04082-01
Docket No. 030-02042