



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 7/6/09 NUMBER OF PAGES: 4
(including this page)

SEND TO: Dr. Robert D. Brock

LOCATION: Saint Margaret Mercy Healthcare Centers

FAX NUMBER: 219-933-2634 **VERIFY BY CALLING SENDER**

FROM: Colleen Carol Casey
(SENDER)

TELEPHONE NUMBER: 630-827-9241 FAX NUMBER: 630-515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

*Please call me if you have questions,
Thank you,
Colleen Carol Casey*

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

**COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 515-1078**

CONVERSATION RECORD

|TIME

|DATE

ACTUALLY FAXED? YES.

July 6, 2009

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Robert D. Prock, M.D., RSO for Saint Margaret Mercy
Healthcare Centers

219-933-2130
Fax: 219-933-2634

SUBJECT

License No.: 13-02047-01

Control No.: **318120**

SUMMARY

We have reviewed your letter March 20, 2009, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. **Please note that I was unable to approve Dr. Harish A. Shah as an authorized user for materials in 10 CFR 35.100 and 35.200 at this time because the information in your letter dated March 20, 2009, was insufficient to complete my review.**

If you wish to pursue this request, please submit the information requested below and address it to my attention as "additional information to control number 318120." We will then continue our review.

Dr. Shah was not approved for the use of materials in 10 CFR 35.100 and 35.200 because the paperwork supporting his/her application was incomplete, i.e., no information demonstrating compliance with the regulatory requirements in 10 CFR 35.290(c)(1)(ii) and 35.290(c)(2) was submitted. The application cannot be reviewed without this information.

I noted that various correspondence pertaining to Continuing Education training and numbers of patients studied at a different clinic were provided, none of which is relevant to Dr. Shah's application. Please focus on completing the appropriate 313a (AUD) form only and kindly refrain from submitting extraneous documents.

Please submit completed 313a AUD forms for Dr. Shah.

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.

As Forms 313a should be used in support of your response, please use the newly 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)

In addition, 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."

Please also be reminded that a senior hospital management official should sign all correspondence to us as the license is issued to the hospital, in accordance with 10 CFR 35.12:

"35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management."

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

ACTION REQUIRED

As we cannot issue an amendment at this time we are voiding this request in order to enable you to prepare a quality application without time constraints. This is done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A "GOOD THING."

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9841 or (800) 522-3025.

NAME OF PERSON DOCUMENTING CONVERSATION

Colleen Carol Casey

SIGNATURE

Colleen Carol Casey

DATE

July 6, 2009
