

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

ACTUALLY FAXED? (Y) (N)

TIME: *C 3:15 PM msg for Andrea C. 5:09 PM CT*

DATE: **March 11, 2009**

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Andrea Carpenter, CNMT Center for Diagnostic Imaging
Patrick Byrne, consultant for licensee

317-846-0717
877-317-5811
Fax: 317-846-0557

SUBJECT

License No.: 13-32194-01

Control No.: 317771

SUMMARY

We have reviewed your letter dated December 11, 2008, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

Your letter requests that the authorization for iodine-131 in quantities greater than, less than or equal to 33 millicuries be added to your license, and the expansion of Dr. Michael Hofstetter's authorization to include this material and use.

Dr. Hofstetter's preceptor forms 313 AUT rely upon a specialty board certification to demonstrate his training and experience, which was not submitted with this letter. I checked our records for Dr. Hofstetter's original application and no specialty board certification was used at that time.

Please submit a copy of Dr. Hofstetter's specialty board certification, provided it is a board certification that we accept for these modalities of use.

The specialty board certifications that we accept can be found on our website at:

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

In the alternative, please submit appropriate information demonstrating that Dr. Hofstetter possesses the training and experience described in 10 CFR 35.392 and 35.394.

Additionally, Dr. Hofstetter's clinical experience, as submitted, does not document his participation in at least 3 cases involving the administration of I-131 requiring a written directive in quantities less than or equal to 33 millicuries, as required by 10 CFR 35.392(c)(2)(vi).

We will be unable to continue processing your request until we receive this information.

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."

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>.

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 SUBMISSION OF 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.

ACTION REQUIRED

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

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



March 11, 2009

TRANSMISSION VERIFICATION REPORT

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

TELEFAX TRANSMITTAL

DATE: 3/11/09 NUMBER OF PAGES: 3
(including this page)

SEND TO: Andrea Carpenter, RSO

LOCATION: Center for Diagnostic Imaging

FAX NUMBER: 317-846-0557 **VERIFY BY CALLING SENDER**

FROM: Colleen Carol Casey
(SENDER)

TELEPHONE NUMBER: 630-829-9841 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



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

TELEFAX TRANSMITTAL

DATE:

3/11/09

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3

SEND TO:

Andrea Carpenter, RSO

LOCATION:

Center for Diagnostic Imaging

FAX NUMBER:

317-846-0537

VERIFY BY CALLING SENDER

FROM:
(SENDER)

Colleen Carol Casey

TELEPHONE NUMBER:

630-829-9241

FAX NUMBER:

630-515-1078

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MESSAGE

Please call me if you have questions.
I did not have a fax # for Patrick
Kyras so I faxed this directly to you.

Thank,
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.