

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)-829-9841~~ ~~(630)-545-1289~~

630-515-1078 FAX

CONVERSATION RECORD

TIME

DATE

ACTUALLY FAXED?

10/5/07

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Laura Lung, Consultant for Cardiovascular Consultants

734-662-3197

SUBJECT

License No.: 21-32424-01 Control No.: 316402

(Fax: 734-662-9224)

SUMMARY

We have reviewed your letter ^{received 7/24/07} ~~dated~~ requesting an amendment to your byproduct materials license and find that we need additional information as follows:

① 10 CFR 35.24(b) requires, in part, that a licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program.

Please submit a letter, currently dated and signed by your management and your proposed RSO, Dr. Mohsin Alam stating that she/he accepts the position as RSO for this license and that she/he understands the duties and responsibilities associated with this position.

In addition please submit a currently signed and dated delegation of authority for

Dr. Alam. A sample delegation of authority may be found in NUREG 1556, Vol. 9, Rev.1, copy attached and available on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/>

⊗ Also see attachment for additional deficiencies.

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."

②

ATTACHMENT

Dr. Alam's request to become the RSO for this license depends, in large part, upon his status as an authorized user under the Henry Ford Hospital license, 21-04109-16. However, the referenced license, 24-04109-16, is a broad scope license that does not include the names of specific authorized users.

The Radiation Safety Committee for that license evaluates and approves/disapproves of authorized users internally. No other relevant and descriptive information (such as a specific license of limited scope naming Dr. Alam as an AU, etc.) was provided for Dr. Alam to support his application.

Please refer to the regulatory requirements in 10 CFR 35.50, 35.290, 35.57, 35.13 and 35.59, as well as section 8.11, item 7 and Appendices B, D and E in NUREG 1556, Vol. 9, Rev. 1, for assistance in preparing your written response to demonstrate that Dr. Alam's training and experience meet the appropriate regulatory requirements to become the RSO.

Note that it is recommended that Forms 313a be used to resubmit Dr. Alam's application and document his training and experience. If Forms 313a will 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) (or use the 313a for RSO)

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.

If Dr. Alam was an authorized user under license no. 24-04109-16 please obtain a letter currently signed and dated by either the RSO or the RSC Chairperson attesting that Dr. Alam was or is an authorized user for (specify which materials in 10 CFR Part 35) under license no. 24-04109-16, including the beginning and, if appropriate, ending date(s) of his authorization.

Also, the letter received July 24, 2007, states that "A copy of the RSO/Executive Management letter of agreement and his preceptor letter to become an RSO is enclosed."

Note that no copy of the RSO/Executive Management letter of agreement was enclosed with this letter.

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

1. Submit the requested information within ²⁰⁰⁷10 calendar days (by ~~Oct. 15, 2006~~ ^{Oct. 15, 2007}) by referencing control number ~~316402~~ to facilitate proper handling. If we do not receive an adequate response by this date, we ~~will~~ **VOID** the current action ~~without~~ attempting to contact you further and without prejudice to resubmission of your request at a later date. Upon receipt of your response we will reactivate placement of your request in our database and 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

- ~~2. 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.**~~

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey

Colleen Carol Casey

Oct. 5, 2007

APPENDIX I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. Typically, these duties and responsibilities include ensuring the following:

- Stopping unsafe activities involving licensed material;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;

APPENDIX I

- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

Signature of Management Representative

Signature of Radiation Safety Officer

Date

Date

cc: Affected department heads



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2443 Warrenville Road, Suite 210
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TELEFAX TRANSMITTAL

DATE: 10/5/07

NUMBER OF PAGES: 7
(including this page)

SEND TO: LAURA LUNA

LOCATION: MPC for Cardiovascular Consultants

FAX NUMBER: 734 - 662 - 9224 **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 but note I will be out of the office from Oct. 8th - 12th. If you need to discuss an alternate response date, leave a voicemail message for me please.

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.

TRANSMISSION VERIFICATION REPORT

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