



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

RESENT 6/13/09

(SUNSI Paragraph was
missing on original)

TELEFAX TRANSMITTAL

DATE:

6/13/09

NUMBER OF PAGES:
(including this page)

7

SEND TO:

NICK BATES

LOCATION:

3M COMPANY

FAX NUMBER:

651-736-2285

VERIFY BY CALLING SENDER

FROM:
(SENDER)

Colleen Carol Casey

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, preferably Mon. afternoon to discuss this 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? (Y) (N)

June 13, 2009

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Nick Bates, CHP, Corporate HP Office 3M Company

651-737-1019

SUBJECT

License No.: 22-00057-61

Control No.: 318049

SUMMARY

We have reviewed your letter dated March 16, 2009, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. Please submit a written statement, currently signed and dated by Bill Flynn, stating that he accepts the position as Alternate RSO and that he understands the duties and responsibilities associated with being an Alternate RSO for this license.

Please also provide, in accordance with Appendix H below, a description of the duties and responsibilities Mr. Flynn will assume when he serves as Alternate RSO. Every element in Appendix H should be addressed, as appropriate.

2. It appears that Mr. Flynn may be qualified to become an Alternate RSO for this license. As an Alternate RSO, it is expected that he is equivalently and fully qualified as RSO.

However, his training and experience qualifications were not presented in a manner than readily enabled me to directly correlate his credentials with NUREG 1556, Vol. 6, Appendix G (and Appendix H) copied below from the subject document as it appears on our website. Every element in Appendix G should be addressed, as appropriate.

Specifically, please submit an outline of the training course that Mr. Flynn took on April 28 – May 2, 2008. How many contact hours of training were covered by this course, what topics were covered (see "Course Content" section topics below), and was there a written and/or practical and/or oral examination of Mr. Flynn at the completion of the course? How many questions were on the exam and what was Mr. Flynn's score? Was it a closed-book exam? Were the correct answers to missed questions reviewed with Mr. Flynn?

Who is “Guy Desroches”? What are his qualifications as an instructor, as related to “Course Instructor Qualifications” excerpted below OR what is his position/title? Does Mr. Desroches work for MDS Nordion directly or is he a contractor?

Was Mr. Flynn trained by Nordion in all of the topics listed in Appendix G for both the S-8 and S-10 irradiators and did his training and experience include non-routine operations authorized for your irradiators (irradiation of flammable materials and troubleshooting)?

A certificate from 3M is included with your letter regarding Mr. Flynn’s completion of an “RSO Training Program” on September 18 -19, 2006. No details about this course were provided. Please describe what this course consisted of, as well as the examination, using context from Appendix G, below. Were the correct answers to missed questions reviewed with Mr. Flynn?

General advice for preparing all licensing correspondence is offered as follows: it is always best to closely follow the format and content in our guidance whenever possible.

Please also be reminded of the provisions in 10 CFR 30.9(a), “Completeness and accuracy of information,” which states in part that...(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 (emphasis added).”

From Appendix G: “Course Content

Instruction may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of irradiators:

Radiation Safety:

- External radiation vs. radioactive contamination
- Internal vs. external exposure
- Biological effects of radiation (e.g., why large radiation doses must be avoided)
- Units of radiation dose
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure (e.g., how shielding and access controls prevent large doses)
- Proper use of survey meters and personnel dosimeters.

Regulatory Requirements:

- Applicable regulations
- NRC dose limits
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials

- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Record keeping
- Case histories of accidents or problems involving irradiators
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by regulatory agency
- Need for complete and accurate information (10 CFR 30.9)
- Employee protection (10 CFR 30.7)
- Deliberate misconduct (10 CFR 30.10).

Practical Explanation of the Theory and Operation for Irradiators:

- Basic function of the irradiator
- Radiation safety features of an irradiator
- Operating and emergency procedures which the individual is responsible for performing
- Routine vs. non-routine maintenance
- Lock-out procedures
- How an irradiator is designed to prevent contamination.

On-the-job or simulator training must be done under the supervision of a qualified irradiator operator:

Supervised Hands-on Experience Performing:

- Operating procedures which the individual is responsible for performing
- Test runs of emergency procedures which the individual is responsible for performing
- Routine maintenance
- Lock-out procedures.

Training for an RSO should include at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

Course Examination

Written examination designed to verify an individual's competency and understanding of the subject matter (e.g., 25 to 50 question, closed-book written test with 70% as passing grade. Emphasis on radiation safety of irradiator operations and maintenance, licensee operating and emergency procedures that the individual will be responsible for performing, and other operations necessary to safely operate the irradiator without supervision

Review of correct answers to missed questions with prospective irradiator operators immediately following the scoring of the test.

Training Assessment

Management will ensure that potential RSOs and authorized operators are qualified to work independently with irradiators. This must be demonstrated by written examination and by direct observations.

Course Instructor Qualifications

Instructor should have either:

Bachelor's degree in a physical or life science or engineering
Successful completion of an irradiator manufacturer's course for users (or equivalent)
Successful completion of an 8 hour radiation safety course AND
8 hours hands-on experience with irradiators

OR

Successful completion of an irradiator manufacturer's course for users (or equivalent)
Successful completion of 40 hour radiation safety course; and
30 hours of hands-on experience with irradiators.

Note:

Licensees must maintain records of training (10 CFR 36.81(b)).
Additional training is required for those applicants intending to perform non-routine operations such as source loading and unloading. See Appendix I, "Non-Routine Operations."

Appendix H : Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with both NRC regulations and the conditions of the license. Typically, the RSO's duties and responsibilities include:

Stopping activities that the RSO considers unsafe

Keeping exposures ALARA

Developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures

Ensuring that individuals associated with irradiator operations are properly trained and evaluated

Ensuring that non-routine operations (See Appendix I) for irradiators are consistent with the limitations in the license, the Sealed Source and Device Registration Certificate(s), and the manufacturer's written recommendations and instructions

Analyzing potential safety consequences of non-routine operations before conducting any such activities that have not been previously analyzed

Ensuring non-routine operations are performed by the manufacturer or person specifically authorized by the NRC or an Agreement State to perform those operations

Ensuring that personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained by the licensee

Maintaining documentation that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or provide personnel monitoring devices

Notifying proper authorities of incidents such as damage to or malfunction of irradiators, fire, loss or theft of licensed materials (See also Appendix O)

Investigating emergencies and abnormal events involving the irradiators (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s)

Performing radiation safety program audits at least every 12 months and developing, implementing, and documenting timely corrective actions

Ensuring transport of licensed material according to all applicable DOT requirements

Ensuring proper disposal of licensed material

Maintaining appropriate records associated with irradiator operations

Maintaining an up-to-date license and timely submission of amendment and renewal requests

Ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented"

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.

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection 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> (the Public Electronic Reading Room).

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from original fax*

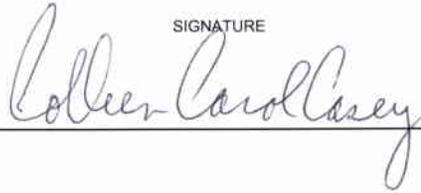
ACTION REQUIRED

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

NAME OF PERSON DOCUMENTING CONVERSATION

Colleen Carol Casey

SIGNATURE

A handwritten signature in cursive script that reads "Colleen Carol Casey". The signature is written in black ink and is positioned between the "SIGNATURE" label and the "DATE" label.

DATE

June 13, 2009

TRANSMISSION VERIFICATION REPORT

TIME : 06/13/2009 18:16
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER. # : 000A7J925774

DATE, TIME : 06/13 18:15
FAX NO./NAME : 86517362285
DURATION : 00:01:16
PAGE(S) : 07
RESULT : OK
MODE : STANDARD
ECM

NRC FORM 386 (RIII)
(4-2004)



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

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Colleen Carol Casey

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DATE

June 13, 2009

TRANSMISSION VERIFICATION REPORT

TIME : 06/13/2009 17:05
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER. # : 000A7J925774

DATE, TIME : 06/13 17:04
FAX NO./NAME : 86517362285
DURATION : 00:01:01
PAGE(S) : 07
RESULT : OK
MODE : STANDARD
ECM

NRC FORM 386 (RIII)
(4-2004)



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

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MESSAGE