



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

TELEFAX TRANSMITTAL

DATE: 12/16/09

NUMBER OF PAGES: 3  
(including this page)

SEND TO: NICK BATES

LOCATION: 3M

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

*Thank you!*

*Colleen Carol Casey*

NOTICE

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**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? YES.**

|TIME

|DATE

**December 7, 2009**

NAME OF PERSON(S) CONTACTED

ORGANIZATION

TELEPHONE NO.

Nick Bates, of Corporate HP for 3M Company

651-737-1019

FAX: 651-736-2285

SUBJECT

License No.: **22-00057-61**

Control No.: **318560**

SUMMARY

This refers to your letter dated October 9, 2009, requesting an amendment to your NRC byproduct materials license and to the telephone discussions on December 1, 2009, and December 16, 2009, between you and me. We find that we need additional information as follows:

1. Please explain briefly and in clear, explicit terms which specific 3M entity (-ies) will hereafter be responsible for the development, implementation, maintenance, testing and auditing of a formal process to identify changes in formulation recipes that affect the irradiation of greater than small quantities of flammable materials, in both the S-8 and the S-10 irradiators.

What we are looking for is a "forest," so to speak, that covers all the "trees," i.e., the twelve commitments made in your letter above. Please describe your plan for a formal, comprehensive, structured process that includes an audit function and a periodic testing function (to see if the process and the previously submitted twelve commitments and subsequent structure work as designed to ensure that changes in formulation recipes cannot be initiated and implemented without a Small Quantity Volume calculation analysis and comparison to current license restrictions.

Please include, but do not be limited by, the following suggested elements in the process:

Please describe in clear, explicit terms how each affected 3M entity "stakeholder" in this situation will participate in the new formal process to prevent recurrence of this problem.

Please define this process, identify each "participant-stakeholder-3M entity (by position only and not by name)" and briefly describe how the process should work to prevent recurrence of this problem.

Specifically, among the Brookings and Corporate HP staff, please collaboratively look for weaknesses in your current program structure that need to be strengthened and describe how that strengthening will occur and its integrity will be maintained.

Please briefly describe, in clear, explicit terms how you will "test" this formal process/system to detect any future errors in the irradiation of greater than small quantity flammable products program. Please describe what the "testing" will consist of, who will conduct it, how often it will be conducted and what the consequences will be for failure of the testing process.

Please describe in clear, explicit terms how you will internally audit this formal process and train all personnel who may be involved in this process to be sensitive to this issue and its repercussions.

Please describe in clear, explicit terms whether 3M sterilization engineers will be trained to use "Lab 020" if there are any changes in formulation recipes that could affect the irradiation of greater than small quantity flammable products program.

2. This also refers to the telephone discussion between you and me on December 1, 2009, in which I advised you that it appeared that an error in your equations in Attachment 1 had been made. It appeared that a division symbol was used when a multiplication symbol was used in the substitution of actual values for equation terms, as shown on the excerpt attached. You subsequently confirmed this error's presence telephonically and via email but please respond to it and submit a corrected version as an official, signed response, included with your responses to the above items.

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 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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ACTION REQUIRED

Submit the requested information at a future date by referencing control number **318560** to facilitate proper handling. We will continue our review upon receipt of your response. Address your written response to my attention (Colleen Carol Casey) at the above address, (2443 Warrenville Road, Lisle, Illinois, 60532, etc.)

**PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.**

If I am not available, you may leave a voicemail message for me.

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NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen Carol Casey



December 16, 2009