

DCD

October 30, 1996

CAL No. 3-96-015

Dr. F. J. Palensky
Division Vice President
Medical Products Technology Division
3M Center
Building 275-4W-02
P.O. Box 33283
St. Paul, MN 55133-3283

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Dr. Palensky:

This confirms the conversation on October 29, 1996, between Mr. Roy J. Caniano, Deputy Director, Division of Nuclear Materials Safety, you, and others of our respective staffs, related to the NRC materials inspection conducted on October 7, 1996, and the submission of 3M's October 25, 1996, audit summary to our office. With respect to the matters discussed, we understand that you have performed or will perform the following actions:

1. The Authorized User onsite during each shift will be required to physically hand off the control room access key to an Authorized User who will be onsite during the subsequent shift, or shut down the irradiator if the hand-off does not take place. Each hand-off will be certified by the Authorized Users in writing by indicating the date, and time of the hand-off, and the signature of the Authorized Users involved.
2. Training documents and exams will be reviewed to ensure that all regulatory requirements are effectively covered and understood during annual refresher training.
3. A review will be performed on a weekly basis by someone other than an Authorized User or their immediate supervisor, to ensure that an Authorized User was onsite at all times the irradiator was operating during the previous week.
4. The staffing of Authorized Users for the irradiator will be reviewed, based on 100 percent availability, to determine the number of Authorized Users required to meet desired staffing levels without the use of excessive overtime and taking into account planned periods of vacation or leave. Additional employees will be trained and certified as Authorized Users to meet the needs identified by this review.
5. Pending completion of item 4, two additional employees will be trained and certified as Authorized Users by December 1, 1996.

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Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to notify me immediately if your understanding differs from that set forth above; notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee; nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

Original signed by W. L. Axelson for

A. Bill Beach
Regional Administrator

Docket No. 030-14999
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cc: D. Hall, 3M-St. Paul, MN
R. Stangeland, 3M-Brookings, SD
State of Minnesota

bcc: Office of Enforcement
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