3M Health Physics Services

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February 4, 1997

U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Attention: Mr. James Lieberman, Director
Office of Enforcement

Dear Mr. Lieberman:

Subject: Reply to a Notice of Violation
Docket No. 030-14999
License No. 22-00057-61
EA 96-403

This letter is submitted in response to your "Notice of Violation and Proposed Imposition of Civil Penalty" and associated cover letter dated January 7, 1997.

I. Violation Assessed a Civil Penalty

Violation

3M concurs that the alleged violation did occur and is not contesting the civil penalty. A check in the amount of $8,000 is enclosed with this letter.

Reasons for Violation

The alleged violation occurred because: (1) the authorized user (operator) training program did not effectively address the authorized user attendance requirement; (2) operating procedures did not adequately emphasize the explicit requirement for authorized user attendance; and (3) neither the plant or corporate audit programs contained specific provisions for determining compliance with the authorized user attendance requirement.

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Corrective Actions

The following corrective actions have been completed with full compliance being achieved as of the dates indicated:

1. The authorized user training program has been reviewed, the section on regulatory requirements has been revised to include more detailed information on the applicable requirements of 10CFR Parts 19, 20 and 36, including the authorized user attendance requirement, and the exam has been revised to specifically test authorized users on this requirement. The revised program and exam were completed and used to train additional authorized users during the week of November 15, 1996. It will be used for the 1997 annual refresher training program and for all future authorized user training. The overall training program and exam will be reviewed during 1997 and revised as appropriate to further improve effectiveness.

2. The standard operating procedures have been revised to more explicitly address the authorized user attendance requirement and have been reviewed with all authorized users. Procedure revision and authorized user review were completed on November 20, 1996. Formal publication of the procedure was completed on December 20, 1996.

3. The standard operating procedures have also been revised to require that whenever the current onsite authorized user departs the facility, the sterilizer control room door key must be transferred to the next onsite authorized user. If the key cannot be transferred to another onsite authorized user, the sterilizer is shut down and the key must be transferred to an onsite plant security person. The security person then confirms sterilizer shutdown and retains the sterilizer operations logbook and the control room door key until it can be transferred to another onsite authorized user. All key transfers are documented in the sterilizer operations logbook and both the transferor and transferee certify the transfer with full signatures. The procedure was put into practice using authorized user initials on October 10, 1996. The use of authorized user full signatures was begun on November 4, 1996. Formal publication of the procedure was completed on December 20, 1996.

4. The operating procedures have also been revised to require a weekly audit of the sterilizer operations logbook by the Sterilizer Radiation Safety Officer (RSO) or his designated alternate to determine compliance with the authorized user attendance requirement. The RSO's designated alternate is someone other than an authorized user or their immediate supervisor. The audit is documented in the logbook with the full signature of the auditor. This procedure was put into practice on November 7, 1996. Formal publication of the procedure was completed on December 20, 1996. Weekly audits have been performed since November 7, 1996 confirming that the authorized user attendance requirement has been complied with.

5. Two additional authorized users have been trained to operate the sterilizer. Classroom and on the job training was completed on November 15, 1996. Final testing was completed on November 26, 1996. Based on 100 percent availability of the sterilizer, it

was determined that these two additional authorized users satisfy staffing needs without the use of excessive overtime.

6. Forms for the quarterly audits performed by the Sterilizer RSO have been revised to include the requirement to determine compliance with the authorized user attendance requirement. These forms have been used for the 1996 fourth quarter audit. A random audit for compliance with the attendance requirement was begun in January 1997 for weekday evening and weekend shifts and will be continued on a quarterly basis.

7. Forms for the semiannual audits performed by 3M's Corporate Health Physics Services staff have been revised to determine compliance with the authorized user attendance requirement. These forms will first be used when Health Physics Services Staff conducts its audit during the first quarter of 1997, now scheduled for March 1997. Audits for compliance with the attendance requirement will be conducted randomly for all three weekday operating shifts and for weekend shifts. In the review of the Sterilizer RSO's quarterly audits, Health Physics Services staff will determine that random shift audits are being performed. This review will begin with review of the Sterilizer RSO's 1997 first quarter audit.

8. The "Fix-It Ticket" procedure has been replaced with the formal Brookings Plant "Safety Incident Report" system. The system is used for potential hazards, near misses, injury/illness, spills and fire/property damage and was revised on November 22, 1996 so that it can be used to address regulatory compliance items. Copies of all forms initiated for the gamma sterilizer are forwarded to the Sterilizer RSO, the plant manager, the department manager, the supervisor/facilitator, the plant safety supervisor and safety department staff.

Safety Significance of Violation

3M concurs that the authorized user attendance requirement of 10CFR36.65(a)(1) was not complied with and we have taken extensive corrective actions as outlined above to ensure future compliance.

In the Notice of Violation and Proposed Imposition of Civil Penalty, the Nuclear Regulatory Commission categorized the failure to assure authorized user attendance during sterilizer use as a Severity Level II. 3M believes that this violation should have been categorized as a Severity Level III because we do not believe that "a system designed to prevent or mitigate a serious safety event" was inoperable. Indeed, the system functioned as designed to preclude any radiological exposure to 3M personnel or any hazard to public health and safety.

Safety Systems

The sterilizer design incorporates many safety systems to ensure safe operation. 3M has an extensive testing and preventive maintenance program to ensure that all these systems remain functional. The sterilizer is designed to shut itself down if any abnormal operating parameter is experienced. For example, tote jams which occurred during unattended operations did shut down the sterilizer resulting in the source rack being returned to its shielded storage position in the storage pool as designed. Shutdown is also initiated by situations such as loss of electrical power to the facility, loss of air pressure to the source rack hoist, fire in the sterilization room, inadvertent access to the sterilization room, etc. Manual shutdown of the facility can be initiated by any 3M employee through an emergency shutdown button located external to the sterilizer control room. All facility security and emergency response personnel are trained on how to respond to sterilizer emergencies and to manually shutdown the facility. This training is repeated on an annual basis.

Sterilizer Room Access

There are only three access points to the sterilization room, (1) an opening on the roof of the building filled with massive concrete plugs, (2) a personnel access door which can only be accessed from the interior of the manufacturing facility and (3) adjacent product tote access doors which can also only be accessed from the interior of the manufacturing facility.

To gain access through the roof opening , a crane is needed to remove the concrete plugs filling the opening. Therefore, access to the interior of the building through the roof is not a concern. To protect against this possibility, however, microswitches are installed to initiate sterilizer shutdown and return the source rack to the storage pool if the roof plugs are moved even just a quarter of an inch.

The personnel and product tote access doors can only be accessed from the interior of 3M's manufacturing facility. Normal public access to the manufacturing facility is restricted to (1) the front office reception area which is only accessible and staffed during the normal work day or to (2) the facility employee entrance which is controlled and staffed by security staff on a 24 hour a day, seven day a week basis. Any member of the general public must be escorted by a 3M employee. Therefore, a general public member would not have unauthorized access to the sterilizer.

Access to the sterilization room through the personnel access door must be done with the source rack in the storage pool and in a prescribed sequence which requires special training. The normally locked personnel access door can only be opened with the sterilizer

control console key. It unlocks the door only after (1)the sterilizer console key has been turned to the "off" position (returning the source rack to the storage position) and removed from the keyswitch and (2) the sterilization room radiation monitor has been turned on, is operational and registers only a background radiation level. Once inside the door, a chain must be disconnected which terminates air supply to the source rack hoist, further ensuring that the source rack is in the storage position. In addition, a photoelectric eye backup access control system would also initiate return of the source rack to the storage pool. Thus, any unauthorized personnel trying to make entry through the personnel access door would be prevented from doing so by the locked door. In addition, automatic shutdown of the sterilizer would be initiated by the backup access control system if access was somehow gained.

Any unauthorized personnel trying to make entry through the product tote entrance and exit doors would be prevented from doing so by the doors which are closed except when individual totes pass through them. There is also a photoelectric eye backup access control system which would shutdown the sterilizer if someone attempted to gain access to these doors.

Sterilizer Building

3M's sterilizer building is constructed of six foot thick dense concrete walls within its Brookings, SD manufacturing facility. The Cobalt-60 is doubly encapsulated in stainless steel pencils contained in a source rack which is confined to the sterilization room inside the sterilizer building. Since the source pencils remain inside the sterilizer building and no one enters the sterilization room until the source rack is returned to its shielded position in the storage pool, there is no potential for significant radiation exposure to 3M personnel.

Source Rack

Although the source modules are designed with a locking mechanism and are further secured in the source rack frame, in the unlikely event that a pencil were to fall out of the source rack, it would fall into a safe shielded position in the storage pool since the source rack is enclosed on all vertical sides by a stainless steel shroud which prohibits interaction of the product totes with the source rack. Therefore, it is not possible for a source pencil to fall into a product tote and be conveyed to the outside of the sterilization room. As a backup, a radiation monitor located in the maze leading from the sterilization room to areas outside the sterilizer building will automatically prevent conveyance of any sources outside from the sterilization room by shutting down the conveyor. In addition, it activates an alarm to alert personnel to the presence of increased radiation levels in the maze and returns the source rack to the storage pool.

Fire Protection

The sterilizer is constructed of fire resistant materials and the Cobalt-60 sources are designed and constructed to prevent release of Cobalt-60 even if exposed to fire. The facility is designed to sense the presence of fire with both temperature sensors and smoke detection systems and automatically return the source to the storage pool. As a backup, a fire suppression system is automatically activated if a fire is detected. It sprays pool water into the area occupied by the source rack in the sterilize position to cool the sources should the source rack not be returned for some reason to the storage pool. The fire suppression system can also be manually activated. If the source rack does not return to the storage pool, entry cannot be made to the sterilization room. Emergency procedures specify that no one is to attempt entry to the sterilization room until the fire has been extinguished.

All of the systems described above remained operable during periods when an authorized user was not in attendance. As a result, the likelihood that anyone would have received a radiation exposure should an abnormal operating parameter have been experienced was very low.

Notwithstanding the above, 3M is committed to complying with all NRC regulations and through the corrective actions listed above we have improved and strengthened the managerial control system to ensure that all future sterilizer operations will be conducted in full accordance with the authorized user attendance requirement.

II. <u>Violation Not Assessed a Civil Penalty</u>

Violation

3M concurs that the in-line Cobalt-60 radiation monitoring system annual calibration had not been performed since February 1994.

Reasons for Violation

The commitment for conducting the annual calibration of the in-line Cobalt-60 radiation monitoring system was inadvertently omitted from the preventive maintenance program which contains an automatic reminder feature. As a result, the calibration requirement was not included on the Sterilizer RSO quarterly audit forms or the Corporate Health Physics Services semiannual audit forms.

Corrective Actions

The in-line Cobalt-60 radiation monitoring system was calibrated on October 23, 1996. The annual calibration procedure was entered into the preventive maintenance program on October 25, 1996. When the 1997 and subsequent annual calibrations are due to be performed, an automatic reminder will be generated prompting the calibrations. To audit this, the annual calibration requirement has been added to the Sterilizer RSO's quarterly audit forms and the Corporate Health Physics Services semiannual audit forms. These audit forms will be used for 1997 audits.

I have read this response to the January 7, 1997 Notice of Violation. I am informed and believe the response stated herein to be true and accurate.

Fred J Palensky

Dr. F.J. Palensky
Division Vice President
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