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REGION III

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Report No.: 030-14999/96001(DNMS)

Licensee: Minnesota Mining and Manufacturing (3M)  
Health Physics Services  
3M Center Bldg. 224-2E-06  
St. Paul, MN 55144-1000

Location: 3M Medical Product Technologies Division  
Gamma Sterilization Facility  
601 22nd Avenue  
Brookings, South Dakota 57006

Dates of Inspection: October 7 through 31, 1996

Inspectors: Jamnes L. Cameron, Senior Radiation Specialist  
Andrea Kock, Radiation Specialist

Approved By: Monte Phillips, Chief  
Nuclear Materials Inspection Branch 2  
Division of Nuclear Materials Safety

## EXECUTIVE SUMMARY

3M Gamma Sterilization Facility  
NRC Inspection Report 030-14999/96001(DNMS)

This was a routine, unannounced inspection to review the adequacy of the licensee's implementation of its NRC-licensed radiation safety program for a commercial irradiator operation. The inspection identified two apparent violations. The first apparent violation concerned the licensee's failure to assure that an operator was on site at all times when the irradiator was in operation. The inspection identified two instances, during the same weekend, in which the irradiator was in operation for several hours and an operator was not on site. Following the October 7, 1996, onsite inspection, the licensee conducted an audit of operator attendance and identified two additional dates on which an operator was not on site for several hours while the irradiator was in operation. The root and contributing causes of the apparent violation appeared to be deficiencies identified in the licensee's operator training program and the licensee's relatively small number of authorized users compared to the amount of time that the irradiator was in operation. The apparent violation and the root and contributing causes are discussed further in Section 3 of this inspection report. The licensee's followup actions in response to the identification of this apparent violation are discussed in Section 5 of this inspection report.

The second apparent violation concerned the licensee's failure to calibrate an in-line pool water radiation monitor at least annually, in accordance with licensee commitments. This failure appeared to be due to the lack of specific knowledge on the part of the facility Radiation Safety Officer and the licensee's Corporate Radiation Safety Organization that the calibration was required to be performed. Based on the licensee's performance of monthly instrument operability checks, it appears that the in-line pool water radiation monitor had been functioning properly. This apparent violation is discussed in Section 4 of this inspection report.

## Report Details

### 1. Organization and Scope of Program

NRC Byproduct Material License No. 22-00059-61 authorized Minnesota Mining and Manufacturing (3M) to possess and use up to 3.0 megacuries (MCI) (111 petabecquerels (PBq)) of cobalt-60 in a wet source storage irradiator for the sterilization of medical products. During this inspection, the licensee possessed approximately 1.29 MCI (48 PBq) of cobalt-60. The irradiator operates in an automatic product conveyor system. The system steps metal boxes, or totes, loaded with the prepackaged products through the irradiator on a conveyor system. In addition, the licensee was authorized to irradiate research samples for other entities, including a local university. Research samples were transported through the radiation room in a small tote suspended from an overhead track.

The licensee operated the facility seven days a week, three shifts each day. Based on information supplied by the licensee during the inspection, the irradiator was in operation approximately 95 percent of the available time. The licensee employed 6 full-time operators who typically worked two-person shifts on weekdays and single-person shifts on weekends. In addition, the licensee employed an operator supervisor, who was an authorized operator, and another person who was also an authorized operator. The second individual worked as a "float" operator who filled in when the other six operators were not available. The licensee's Radiation Safety Officer (RSO) was also an authorized operator; however, the RSO and operator supervisor did not routinely act as irradiator operators.

### 2. Training, Retraining, and Instructions to Workers

#### 2.1 Inspection Scope

The inspectors reviewed the licensee's program for providing initial qualification and annual refresher training to operators and instructions to other workers who may be required to either enter the radiation room or respond to irradiator alarms. The inspectors conducted interviews of each of the operators, the operators' supervisor, the "float" operator, and the licensee's RSO. The review included the manuals used to provide initial and refresher training information to authorized users.

#### 2.2 Observations and Findings

Interviews of the operators, the "float" operator, and the operators' supervisor and review of selected training records indicated that all current irradiator operators had received their initial operator training at least three years ago. In addition, each operator participated in annual refresher training and in drills on the irradiator emergency procedures.

Interviews of the "float" operator indicated that she received her initial operator certification training in 1988 and that prior to 1995, her involvement in the irradiator facility was limited to operation of the research loop. During the years from 1989 through 1994, she participated in the annual instruction provided to auxiliary personnel and never acted as an operator of the irradiator during that time period. In 1995, she participated in the operator refresher training, and has worked as an operator part time since then, mainly on weekend shifts. The full-time operators had all received their initial certification training more than three years ago. Each had successfully completed the annual recertification training.

The inspectors reviewed the content of the initial and refresher training provided to the operators with the operators, the operators' supervisor and the RSO. The manual used for initial and annual refresher training contains nine units, or chapters. Units one through nine were included during a 40-hour classroom instruction provided to individuals in order to initially qualify them as operators. Units four through nine were used for the refresher, or recertification, training. The recertification training consisted mainly of individual self-study of the training information and the successful completion of an examination.

10 CFR 36.51 requires, in part, that the initial training provided to operators include the requirements of 10 CFR Part 36 that are relevant to the irradiator. 10 CFR 36.51 also requires, in part, that the licensee perform an annual safety review with each operator and include any changes in the regulations, to the extent appropriate, since the last review. In order to satisfy these requirements, the licensee included a one page summary of 10 CFR Part 36 in Unit nine of the manual. That page listed the title of each of the major paragraphs of the regulation, but did not provide any details of the specific requirements. For instance, with regard to the requirement in 10 CFR 36.65, which requires, in part, that an operator be onsite at all times when the irradiator was in operation, the manual states "attendance required during operation," without further explanation or clarification. The inspectors interviewed each of the operators, the operators' supervisor, and the "float" operator in order to determine the level of significance that the licensee had placed on the requirement that an operator be onsite during irradiator operation. None of the individuals interviewed could recall the requirement being addressed during initial or recertification training, nor did they recall a specific question regarding irradiator attendance appearing on any examination they had taken.

The inspectors also interviewed the operators, the "float" operator, and the operators' supervisor in order to determine their previous understanding of the attendance requirements for irradiator operation. Of the eight individuals interviewed, four, including the supervisor, did not know that an operator was required to be onsite when the irradiator was in operation. Those that stated that they understood the attendance requirements, did so mainly due to intuition and not anything specifically stressed by the licensee during training. Based on that review, the inspectors determined that the licensee's operator training program was deficient, in that the program provided little information with regard to the requirements in 10 CFR Part 36 in general, and specifically, it did not adequately address the requirement that an operator be onsite at all times while the irradiator

was in operation. The licensee's followup actions to this finding are addressed in Section 5 of this report.

The licensee's training program also included instruction for ancillary personnel. These personnel, including maintenance and security staff, receive basic instructions regarding entering the irradiator room, precautions to observe, and the proper response to irradiator alarms. The licensee had provided these instructions to approximately 80 plant personnel. The inspectors did not identify any specific problems or weaknesses with regard to the licensee's instructions to auxiliary personnel.

## 2.3 Conclusions

The licensee's operator training program was weak regarding the level of detail provided with respect to the requirements in 10 CFR Part 36. The inspectors identified one specific deficiency in the content of the training provided to operators, both initially and annually. The deficiency may have contributed to an apparent violation that is addressed in Section 3 of this inspection report.

## 3. Operations

### 3.1 Inspection Scope

The inspectors reviewed the licensee's routine operation of the irradiator. The review included source movement, interlocks and irradiator console operation. The inspectors interviewed each of the operators, the "float" operator, the operators' supervisor, and the RSO. The inspectors reviewed also the operators' log and other licensee documents in order to verify operator attendance during irradiator operation.

### 3.2 Observations and Findings

The inspectors reviewed the operators' log located at the console of the irradiator. The operators used that log to note source movement, in-line pool water radiation monitor level, and reasons for any shutdowns that may have occurred. All log entries included, but were not limited to, date, time of day, reason for log entry, source up frequency number (number of times source had been exposed and shielded), and source up clock reading. The source up clock reading indicates the cumulative number of hours that the source had been exposed since the irradiator was put into operation.

By comparing the time of day entries with the source up clock reading entries, the inspectors noted two discrepancies. The first occurred on August 17, 1996. Two sequential log entries were made at 1:00 p.m. and 11:57 p.m. The entries were made by two separate operators. Inspector review of the source up clock reading indicated that the irradiator source had been exposed for 9.5 hours between the two log entries. The earlier entry indicated that the source was in the exposed position, while the latter entry indicated that the source had cycled to the shielded



position. This indicated that the source returned to the shielded position at approximately 10:30 p.m. on August 17, 1996, but that an operator did not note that fact in the log for approximately 1.5 hours.

The inspectors noted a second example had occurred on August 18, 1996. On that day, an operator's log entry indicated that the source was in the exposed position at 6:42 p.m. The next log entry, at 12:12 a.m. on August 19, 1996, indicated that the source was in the shielded position. Again, the source up clock reading did not match the elapsed time of day. The source up clock reading indicated that for the 5.5 hours between log entries, the source was exposed for 4 hours. Based on review of other log entries and interview of licensee personnel, when the source returns to the shielded position, it activates a local alarm, which is acknowledged by the operator and noted within minutes in the operators' log. However, on each of those two occasions the source movement was not noted for approximately 1.5 hours. In each case, the source movement alarms were acknowledged by security personnel.

The inspectors requested to review the employer's time sheets for the operators for August 17 through 19, 1996, in order to determine when the operators arrived for work and left the facility. From the review of the time sheets, the inspectors determined that on August 17, 1996, the operator left the facility at 6:31 p.m. At that time, the irradiator was in operation and continued to operate until approximately 10:30 p.m., based on the source up clock reading. The licensee indicated that only one operator worked that shift. The next operator reported for work at 11:49 p.m. Further review of the operators' time sheets indicated that on August 18, 1996, the operator left the facility at 8:07 p.m. Also at that time, the irradiator was in operation and continued to operate until approximately 10:42 p.m., based on the source up clock reading. According to licensee personnel, only one operator worked that shift and the next operator reported for work at midnight. That operator noted the source return to the shielded position at 12:12 a.m. on August 19, 1996, an hour and a half after the source returned to that position.

Interviews of the operator who left the facility each time that the irradiator was in operation confirmed that she had done so. When questioned, she indicated that the facility did not have available operators to staff the irradiator on both nights. She further indicated that the irradiator had been left unattended in the past, with the supervisor's knowledge and consent. The operators' supervisor confirmed that the irradiator had been left unattended in the past, with his consent. As described in Section 2 of this report, the operators' supervisor did not understand the requirements regarding operator attendance during irradiator operation.

Following the weekend of August 17 and 18, 1996, another operator noted that the irradiator had been left unattended and issued an internal licensee problem identification report to the supervisor. During an operators' meeting held a few days later, the group discussed the attendance requirements informally. The supervisor, in answer to a question from an operator, indicated that operators could leave the facility with the irradiator in operation. The RSO, who also attended the meeting, immediately corrected the supervisor by stating that an operator must be

onsite during irradiator operation. The supervisor requested that the RSO show him the requirement. The RSO subsequently provided the supervisor with the information contained in 10 CFR 36.65. 10 CFR 36.65(a) requires that both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, be present onsite whenever the irradiator is operated using an automatic product conveyor system. **The licensee's failure to have an irradiator operator onsite while the irradiator was in operation using an automatic product conveyor system, on August 17 and 18, 1996, appears to constitute a violation of 10 CFR 36.65(a).** During a subsequent internal audit, the licensee identified two additional examples of this apparent violation. Those examples are discussed in Section 5 of this report.

The supervisor issued a memorandum to all operators on September 5, 1996, indicating that one of them must be onsite during irradiator operation. However, at no time during any discussion of this issue did anyone inform the RSO that the facility, in fact, had been in operation without an operator onsite. The RSO was unaware of the occurrences until the inspectors brought them to his attention during the inspection. For reasons unknown, the operator supervisor failed to inform the RSO that the irradiator had been operated without an operator onsite on several occasions.

As noted above, the licensee's training program for operators failed to include specific discussion of the requirement to have an operator onsite during irradiator operation. The licensee committed to incorporate the requirement that an operator be onsite whenever the irradiator is in operation as part of its training program. This requirement would also be immediately readdressed with all of the operators.

### 3.3 Conclusions

The inspection identified an apparent violation regarding the licensee's failure to have an operator onsite on several occasions when the irradiator was in operation. The root cause appeared to be lack of knowledge of the requirement by several of the operators and the operators' supervisor. The lack of specific knowledge appeared to be due to the deficiency in the licensee's operator training program to address attendance during irradiator operation. The significance of these instances was exacerbated by the fact that the supervisor failed to inform the RSO, or licensee management, that they had occurred after the RSO informed him of the specific requirement that an operator must be onsite when the irradiator was in operation.

#### 4. Inspection and Maintenance

##### 4.1 Inspection Scope

The inspectors reviewed selected routine inspection and maintenance activities for the irradiator. The review included interviews of selected licensee personnel, examination of inspection and maintenance procedures, and examination of the results of those activities.

##### 4.2 Observations and Findings

The licensee had established an extensive preventative maintenance (PM) program for the irradiator. Routine inspection and maintenance activities had been proceduralized and frequencies for each of the activities had been established. The inspectors reviewed the following specific routine inspection and maintenance activities:

- i. operability of each aspect of the access control system
- ii. functioning of the source position indicator
- iii. operability of the product exit radiation monitor
- iv. operability of the emergency source return control
- v. operability of the high and low pool water level indicators
- vi. electrical wiring degradation due to radiation damage, and
- ii. pool water conductivity measurements and analysis.

No problems were identified for those specific inspection and maintenance activities. The inspectors reviewed also the operability of the in-line pool water radiation monitor. Item D of the licensee's April 8, 1992 letter, referenced in Condition 20 of NRC Byproduct Material License No. 22-00057-61, included procedures for routine constancy evaluation and calibration of the in-line radiation monitor. Each shift, the operators reviewed the in-line pool water radiation monitor indicator near the console for the irradiator and noted the indication on the operators' log. In addition, once each month, the licensee uses a 6 microcurie (234 kBq) cesium-137 check source to confirm operability and constancy of the radiation monitor.

In Item D of the referenced letter, the licensee committed to perform an annual calibration of the in-line pool water radiation monitor using a solution of potassium chloride. The naturally occurring radioactive potassium-40 contained in the salt served as the radiation source for the calibration. The licensee last performed the calibration of the in-line pool water radiation monitor on February 17, 1994. Interview of the facility RSO indicated that he was not aware of the requirement to perform the annual calibration. **The licensee's failure to perform a calibration of the in-line pool water radiation monitor at least annually appears to constitute a violation of Condition 26 of License No. 22-00059-61.**



The inspectors requested the licensee to perform a constancy check of the monitor during the inspection. Based on the results of that check and review of the results from previous, monthly constancy checks, it appears that the instrument was functioning properly. The inspectors requested the licensee to perform the required calibration as soon as possible. The licensee committed to completing the calibration of the in-line pool water radiation monitor by October 26, 1996 and incorporating the calibration into its routine preventative maintenance program. The licensee completed both of those tasks and the calibration confirmed that the in-line radiation monitor could have detected radioactive contamination in the pool water.

#### 4.3 Conclusions

The inspection identified an apparent violation for the licensee's failure to perform annual calibrations of the in-line pool water radiation monitor since 1994. Notwithstanding that failure, the monitor would likely have been able to detect radioactive contamination in the irradiator pool water above the designated minimum detectable activity.

### 5. Licensee Followup Actions

#### 5.1 Inspection Scope

Following the completion of the onsite inspection on October 7, 1996, NRC requested that the licensee perform an audit of the operators' log and other available information in order to determine if there had been other instances in which the irradiator had been operated without an operator in attendance. In addition, the NRC requested that the licensee include in its audit an evaluation of staffing levels, in comparison to operator workload, and an evaluation of its operator training program in order to determine if other deficiencies existed. The NRC also requested that the licensee determine the root cause of the apparent violations. The licensee agreed to do so, and submitted the results of its audit in a letter to the NRC dated October 25, 1996.

#### 5.2 Observations and Findings

The licensee's audit identified two additional instances in which an operator was not in attendance during operation of the irradiator. One instance occurred on December 23, 1995, between 11:55 a.m. and 2:53 p.m. The other instance identified by the licensee occurred on July 27, 1996, between 11:47 a.m. and 2:53 p.m. The same operator was involved in both of these instances, but was not involved in the two examples identified by the inspectors.

The licensee's audit report failed to adequately address the root cause of the apparent violations. The licensee, in its audit report, stated that the failure to have an authorized user (operator) onsite was due to 3M's failure to " . . . have an effective operational or documentation system in place to ensure compliance."

Based on NRC's preliminary and followup inspection results, the licensee's audit lacked depth and a self-critical approach. The root cause analysis conducted by the licensee failed to provide a basis to explain why the four examples of the apparent violation regarding operator attendance had occurred.

Following receipt of the licensee's audit report, the NRC held a telephone conference with licensee senior management. During the conference, the NRC expressed its concerns regarding the lack of depth and specificity of the licensee's audit and report details. As such, the NRC confirmed five additional actions on the part of the licensee regarding: (1) formalization of the control room key turnover between operator shifts; (2) conduct of a licensee internal audit of its training program; (3) conduct of weekly reviews in order to confirm that an authorized user (operator) had been onsite at all times that the irradiator had been in operation; (4) review of staffing levels, based on 100 percent availability of the irradiator; and (5) addition of two additional trained and certified authorized users by December 1, 1996. These actions were confirmed in a Confirmatory Action Letter, CAL No. 3-96-015, to the licensee dated October 30, 1996.

Because the licensee failed to address the adequacy of its operator training program in its October 25, 1996, audit report, the inspectors requested copies of the licensee's training manuals and returned to the licensee's facility on October 30 and 31, 1996, in order to further evaluate operator training and knowledge of the attendance requirements. The interviews determined, as discussed in Section 2 of this report, that the operators who had left the facility with the irradiator in operation did not understand the operator attendance requirements of 10 CFR 36.65. In addition, the operators' supervisor had the same misunderstanding. Furthermore, the inspectors' review of the licensee's training program determined that it provided only a general discussion of the requirements of 10 CFR Part 36. At the completion of the inspection, the licensee's corrective actions were too general in nature regarding the identified deficiencies in the operator training program. The licensee committed to review the training program "... to improve assurance that regulatory requirements are effectively communicated."

The licensee committed to training two additional operators by December 1, 1996, but did not provide any details of its review of operator staffing levels. Interviews conducted by the inspectors on October 30 and 31, 1996, determined that the operators, including the "float" operator, each worked an average of 50 hours per week. On the surface, it appeared that two additional operators would likely provide sufficient coverage for the irradiator workload; however, that finding is contingent on the licensee conducting a review of its actual workload and staffing needs.

### 5.3 Conclusions

Following the October 7, 1996, onsite inspection, the licensee conducted an audit of operator attendance during irradiator operation and identified two additional examples of when the irradiator had been in operation without an operator onsite.

In each case, it appeared that the operators and their supervisor did not have an adequate understanding of the requirements regarding attendance during operation. The licensee's audit failed to address the deficiencies in the licensee's operator training program, prompting further NRC onsite inspection effort on October 30 and 31, 1996. The results of the NRC's review of the licensee's training program are described in Section 2.

### Exit Meeting Summary

The inspectors discussed the preliminary conclusions described in this report with licensee management during an exit meeting conducted at the licensee's Brookings, South Dakota facility on October 7, 1996. The NRC identified additional concerns following receipt of the licensee's October 25, 1996 audit report, which resulted in a telephone conference with senior licensee management, the issuance of a Confirmatory Action Letter on October 30, 1996, and further NRC onsite inspection effort on October 30 and 31, 1996. The inspectors discussed the findings identified on October 30 and 31, 1996 with facility licensee management. The licensee did not identify any information reviewed during this inspection and selected for inclusion in this inspection report as proprietary in nature.

### Partial List of Persons Contacted

Duane C. Hall, Manager, Health Physics Services (by telephone)  
F. J. Palensky, M.D., Division Vice President, Medical Products Technology  
Division (by telephone)  
Lawrence R. Zobel, M.D., Director, Medical Department (by telephone)  
John Ditlefsen, Plant Manager, 3M Medical Products Technology Division,  
Brookings, South Dakota facility  
Ronald J. Stangeland, Radiation Safety Officer, Brookings, SD  
Robert A. Christianson, Sterilizer Facilitator (Supervisor), Brookings, SD  
Jeff Tostenrud, Resident Engineering Supervisor and Manager, Brookings, SD

### List of Acronyms Used in This Report

3M	Minnesota Mining and Manufacturing
CAL	Confirmatory Action Letter
CFR	Code of Federal Regulations
kBq	kilobecquerels
MCi	megacuries
PBq	petabecquerels
RSO	Radiation Safety Officer