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October 16, 1996

US Nuclear Regulatory Commission  
Region III  
801 Warrenville Road  
Lisle, IL 60532-4351

Attention: Mr. James L. Cameron

Dear Mr. Cameron:

Subject: October 7, 1996 NRC Inspection - 3M Brookings, SD Facility  
NRC License 22-00057-61

This letter is a followup to your October 7, 1996 inspection of 3M's Brookings, SD gamma sterilizer and the telephone exit interview conducted on Thursday, October 10, 1996 between you, Ms. Koch and Messrs. Phillips and Caniano of NRC's Region III office and Dr. Larry Zobel and Duane Hall of 3M. We are addressing all issues you have raised and present the following status update.

**Sterilizer Operation**

A number of action steps have been taken at the facility to ensure the presence of an "Authorized User" whenever the sterilizer is in operation. On October 9, 1996, Health Physics Services personnel held an onsite meeting with the sterilizer Radiation Safety Officer, key plant management personnel and "Authorized Users" to underscore the requirement for "Authorized User" onsite presence during sterilizer operation. Additionally, new procedures have been implemented to document passing of the control room key from the outgoing to the incoming operator.

**Records Audit**

Two auditors, one from 3M Health Physics Services and one from the quality assurance group responsible for 3M's health care facilities are currently auditing plant records to determine whether the gamma sterilizer was operated without an "Authorized User" present on the 3M site. We expect this audit to be completed this week. We will present our findings to you during the week of October 21, 1996.

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### **Cobalt-60 In Line Radiation Monitor**

Information on the Cobalt-60 water monitor potassium chloride calibration was located on October 10, 1996. 3M performed the 1994 calibration on February 17, 1994 with the assistance of the instrument vendor. During the calibration, we also established a protocol for testing the instrument alarm and identifying the proper scale response with a Cs-137 check source. The protocol was formalized as a monthly Preventative Maintenance Procedure (PM), which has been part of our routine maintenance program since the February 17, 1994 calibration. Based upon a review of the monthly test results from PM initiation to the present, we are confident that the instrument's response has remained the same and it has functioned properly since the February 1994 calibration.

The water monitor potassium chloride calibration and the PM formalizing it will be completed and incorporated into the gamma sterilizer PM program by October 25, 1996.

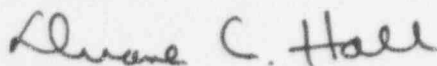
### **Cobalt-60 Source Loading**

We will notify you of the next confirmed Co-60 source loading date when it is established so that you may observe the loading as requested.

Please know that 3M takes this situation very seriously. We shall continue to work closely with your office to expeditiously follow up on these matters.

Please direct any questions to me at 612/733-7316.

Sincerely,



Duane C. Hall, Manager  
Health Physics Services

- c: J.M. Ditlefsen, Plant Mgr., Brookings, 01/036  
R.A. Christianson, Sterilizer Facilitator, Brookings, 01/036  
D.A. Loeser, Health Physics, 220-3W-06  
J. A. Nichol, Mfg. Dir., Medical Products Technology Div., 275-5E-01  
Dr. F.J. Palensky, Div. VP, Medical Products Technology Div., 275-4W-02  
R.J. Stangeland, Radiation Safety Officer, Brookings, 01/036  
K.E. Welke, Group VP, Medical Markets Group, 220-14E-16  
L.R. Zobel, M.D., Director, Medical Dep't., 220-2E-02