

Medicine  
Health Physics  
Industrial Hygiene  
Toxicology  
Medical Department/3M

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**3M**

June 20, 1985

U.S. Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Attention: D. G. Wiedeman, Chief  
Nuclear Materials Safety Section I

Gentlemen:

Subject: License Nos. 22-00057-06, 22-00057-07,  
22-00057-61

This is in response to the Notice of Violation which was included  
with your letter dated May 17, 1985.

I. License 22-00057-06

- A. Failure to Wear Shoe Covers in "Red Area". Section IV of the  
3M Health Physics Manual clearly states that shoe covers are  
to be worn in a "Red Area". The employee which the NRC inspectors  
observed entering a "Red Area" without shoe covers clearly  
violated the procedure. She has been reminded of the rule  
and has not been observed violating it again. Corrective action  
was taken immediately following the inspection and we believe  
the reminder is adequate to prevent a recurrence.
- B. Quarterly Safety Squad Meeting. The failure of the Building  
575 emergency squad to meet during the 4th quarter of 1983  
and the failure of the Building 675 emergency squad to meet  
during the 1st quarter of 1984 was discovered by internal  
3M audits prior to the NRC inspection. The failures were noted  
in written and oral reports submitted to the Isotope Committee.  
Reminders had been given to emergency squad captains and the  
emergency squads had resumed their quarterly meetings at the  
time of the inspection. No further action appears necessary.

II. License 22-00057-07

- A. Failure to Monitor Soil at Woodbury Farm. Section III of the  
3M Health Physics Manual clearly states that Health Physics  
Services will monitor soil which has been used for radioisotope  
studies before products are grown on it for human or animal

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consumption. After the 1973 experiments were concluded the project was terminated and the personnel involved were eventually assigned other jobs within 3M. Health Physics Services was not notified at the time and learned of the situation at a later date. Although it was then too late to monitor the soil before crops had been grown on the land, a radiological assessment was performed. This assessment showed that the concentration of radioactivity which might have remained in the soil did not exceed  $8 \times 10^{-4}$  uCi/g of C-14. The exempt concentration limit in 10 CFR 30.70, Schedule A, Column II is  $8 \times 10^{-3}$  uCi/g, therefore, the remaining soil concentration is insignificant in terms of a public health hazard. The complete radiological assessment was reviewed by the NRC inspectors during their visit.

No studies other than those reviewed by the NRC inspectors have been conducted at the Woodbury farm, but studies have been conducted in recent years in the states of Alabama and Washington. In each case monitoring was performed at the conclusion of the experiments and reviewed by the respective state licensing agencies. In Alabama this took place in 1980 and 1983 and in Washington in 1983. Accordingly, Health Physics Manual procedures have been followed since the Woodbury incident.

- B. Testing Incoming Packages For Contamination. Section III of the 3M Health Physics Manual states that all packages of radioactive material are to be tested for contamination within 3 hours after receipt and it also states that the 3 hour time restriction for conducting the contamination test is a regulatory requirement. At the time the Manual was prepared it was our intention to follow exactly the regulatory requirements specified in 10 CFR 20.205, but we did not want to repeat the requirements verbatim in the Manual. In condensing 10 CFR 20.205, we erroneously left the impression all packages would be monitored instead of just those requiring it.

3M's practice has been to perform package monitoring as required by 10 CFR 20.205. It is our intention to continue this practice and to change the wording in the Health Physics Manual to make it clear. An application to renew license 22-00057-07 was submitted to the NRC on April 23, 1984. Since final action on the renewal request has not been taken, we will be sending a revised page for the Manual clarifying the incoming package monitoring requirements. The date when full compliance will be achieved will depend upon when the license is renewed.

III. License 22-00057-61

- A. Physical Presence of Designated Individuals. It is clear from our license application dated Jan. 5, 1979 and our renewal request dated Jan. 27, 1984, that it was not 3M's intention to operate the irradiator in the continuous physical presence of a fully trained supervisor. The irradiator is designed to send alarm signals to an on site security guard during off hours and the security guard is to call a supervisor when needed. Until the issuance of IE Information Notice No. 85-01 dated Jan. 10, 1985 the irradiator was operated as stated in our applications. Since that time the irradiator has been operated in accordance with the Notice. Therefore, corrective action had been taken before the NRC inspection on April 8, 1985.

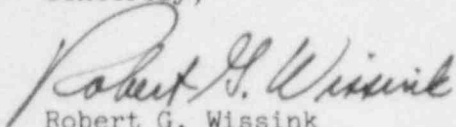
3M disagrees with the requirement that a fully trained supervisor as specified in Notice 85-01 or "responsible individual" as defined in the Draft Regulatory Guide for the Preparation of Applications for Irradiators must be physically present at all times during operation. Our views on this matter were thoroughly discussed in a letter to the Commission dated March 26, 1985 in which we commented on the draft guide. We understand and agree with the Commission's concern about the need for prudent and conservative operation of facilities using megacurie quantities of radioactive material and that no safety system, however redundant, cannot fail. However, we know of no evaluation conducted by the NRC, or others, which shows how an irradiator's safety system could fail in such a manner that public health and safety would be threatened; or that the threat could be eliminated or reduced by having a fully trained supervisor present. If the Commission believes this possibility exists, the Commission should demonstrate how and under what circumstances a fully trained supervisor's physical presence would make a difference. We believe that an adequate degree of safety can be accomplished by other methods such as having trained security personnel on site at all times and for these people to notify a supervisor when needed.

- B. Quarterly Audits. On January 27, 1984 we submitted a renewal request for License 22-00057-61 in which we changed the quarterly audits by Health Physics Services to semi-annually. After performing quarterly audits since 1980 it became clear that this frequency was not needed. Thinking that the license would be renewed within a few months, we subsequently scheduled the semi-annual audits for the 2nd and 4th quarters respectively and the 3rd quarter 1984 audit was not performed. We have

rescheduled quarterly audits until such time as the Commission takes final action on our renewal request. This particular non-compliance citation points out the need for the Commission to be more responsive to license renewal requests. It has been  $1\frac{1}{2}$  years since we submitted the renewal application with the changed audit frequency.

In summary, 3M had taken action prior to the inspection on all items of non-compliance listed in your May 17, 1985 letter except items I.A and II.B above. The first was corrected on the spot and the second will be corrected by changing the wording in the Health Physics Manual to comply with actual practice and 10 CFR 20.205.

Sincerely,

A handwritten signature in cursive script, reading "Robert G. Wissink".

Robert G. Wissink  
Manager, Health Physics Services

RGW:lmo