

MERCK SHARP & DOHME RESEARCH LABORATORIES

DIVISION OF MERCK & CO., INC.

WEST POINT, PENNSYLVANIA 19486

RONALD A. ROSENBERGER  
DIRECTOR OF ADMINISTRATIVE SERVICES

APR 3, 1989

(215) 861-6614

U.S. Nuclear Regulatory Commission  
Region I  
ATTN: John R. White, Chief  
Nuclear Materials Safety Section C  
Division of Radiation Safety and Safeguards  
475 Allendale Road  
King of Prussia, Pennsylvania 19406

SUBJECT: Inspection No. 89-001 of NRC License No.  
37-01531-08

Gentlemen:

This is in response to your letter dated March 8, 1989 and the enclosed Notice of Violation regarding the results of the January 31, 1989 inspection of our NRC irradiator license. We will respond to each of the items individually.

1. Failure to provide 4 hours didactic and 4 hours of hands-on training of authorized users including a written examination.

All authorized users of the two irradiators under this license have attended the 8 hour training program (4 hours didactic and 4 hours hands-on training) outlined in our letter dated July 19, 1988 and have passed a written examination. The training was completed on March 7, 1989. In order to insure that only authorized individuals, i.e. individuals who have received the complete training, use the irradiators we have sent the list of authorized users to the two individuals who have the sign out logs and keys to the irradiator rooms. They have been instructed to allow only authorized individuals the use of the irradiators. This situation will be periodically monitored by the health physics staff.

2. Failure to calibrate the gamma survey meters on at least three points of each scale.

Although we were calibrating our gamma survey meters on two points of each scale, a well recognized health physics standard, we have changed our procedure to now calibrate the meters on three points. All meters used to measure radiation levels in the vicinity of the irradiators have been calibrated on three points.

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3. Failure to supply film badges to all personnel using the irradiators.

We have issued film badges to all individuals presently authorized to use the irradiators. It is now our policy that film badges be issued to all new users of the irradiator.

4. Failure to record pocket dosimeter readings.

Pocket dosimeter readings are and were recorded at the time of the inspection. Unfortunately, we were unable to locate those records at the time of the inspection. However, a copy of those records was sent to your office with a letter dated February 10, 1989. In order to assure that the dosimeter readings are being properly recorded, we are now requiring that all dosimeter readings be kept in a log book which is periodically checked by the health physics staff.

5. Failure to issue keys to the irradiators on a sign-out sign-in basis and require that each operator of the irradiator be accompanied by an assistant.

In order to insure adequate control of use of the irradiators we have designated one individual per irradiator as key holders in addition to the Health Physics Department. These individuals have been given log books to record the sign-out and sign-in of irradiator keys. In addition, these designated individuals have been instructed to issue keys only to individuals who have been authorized by the Health Physics Department and who are accompanied by an assistant. Both the authorized individual and his/her assistant are required to sign the log book. When new users are authorized the Health Physics Department will issue an updated user authorization list to the key holders.

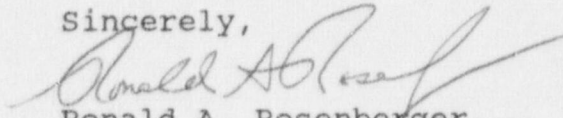
6. Failure to require that all users of the irradiator receive the basic irradiator training program and be approved by the Health Physicist and the Radiation Safety Officer.

As mentioned in paragraph 1. above, all present users of the irradiator have received the basic training program as of March 7, 1989. In addition, we now require that internal permits be issued to all authorized users of the irradiators. Those permits are signed by the Health Physicist and the Radiation Safety Officer after a review to make certain that all training has been successfully completed.

The above response to the six violations are the corrective steps which Merck Sharp & Dohme Research Laboratories have taken to assure compliance and to avoid further violations. Many of these steps were taken immediately following the inspection. However, all steps have been completed as of the date of this letter and we are now in full compliance.

It is the policy and intent of Merck Sharp & Dohme Research Laboratories that our NRC licensed program be managed in full compliance with the spirit and letter of all NRC rules and regulations.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ronald A. Rosenberger", with a long, sweeping horizontal stroke extending to the right.

Ronald A. Rosenberger,  
Director  
Administrative Services