



Hoffmann-La Roche

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Direct Dial

October 18, 1990

201-235-3418

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Ave.
King of Prussia, PA 19406

Attention: Messrs. C. Eckert and C. T. Oberg

Ref: Inspection 90-01, September 12-14, 1990

Gentlemen:

This letter is submitted in response to questions raised and concerns expressed during the above-referenced inspection. Set forth below is information regarding actions that were in the process of being completed during the inspection, as well as additional actions subsequently taken to improve the Radiation Safety Program.

Regarding the use of safety glasses and laboratory coats, the Roche Safety Department has prepared a memo that will be distributed to all laboratory personnel. This memo reemphasizes Roche's policy requiring the proper use of safety glasses and laboratory coats while working in a laboratory, and indicates that stronger corrective measures will be taken to enforce this policy. Also, Safety staff have begun to meet with department level safety committees to personally reenforce the importance of complying with this policy.

With respect to the use and storage of film badge dosimeters at our Fairlawn, N.J. site, the site maintenance workers are installing wall-mounted coat hangers near the doors of radionuclide laboratories. The Radiation Users (RUs) have been instructed by the Radiation Safety Officer (RSO) to keep individual dosimeters clipped to laboratory coats, and to hang laboratory coats on the coat hangers just prior to exiting the laboratory.

Regarding the security of radioactive materials, the following steps have been taken:

- On September 30, 1990, a notice was sent to all Principle Radiation Users (PRUs) reemphasizing Roche's policy requiring that radioactive material be secured during any period of time when such material is not under constant surveillance.

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- On September 26, 1990, a formal training session was provided by the RSO to the supervisory and worker staff responsible for the operation of the radioactive waste management area located in Building 43. The training session included both the regulatory requirements and the actions that must be taken to achieve the required security within the building.

- The Radiation Safety Committee has directed the RSO to implement an after-hour security verification program. This program requires that an inspection be conducted at least once per year in all areas where radioactive material is stored and/or used in order to verify that the radioactive material is properly secured. In the event that inadequately secured radioactive material is found during these inspections, the Radiation Safety Office staff will take immediate action to correct the situation. Further, the responsible PRU will be notified by the RSO to take corrective steps aimed at preventing the recurrence of such an event.

- At the Fairlawn, N.J. site, on September 19, 1990, a metal chain-link fence was installed above the radioactive waste storage area, and a key-operated lock was installed on the door to this storage area. Also, the staff was given instructions to keep the door locked when radioactive waste was not being transferred into the storage area.

With respect to the Radiation Safety Office records that document decontamination and resurvey results, the RSO revised a Radiation Safety Office procedure providing that the results of the contamination resurveys will be recorded on the original contamination survey record form.

Regarding the overall Radiation Safety Program at our Fairlawn, N.J. site, the undersigned does not agree with your comments that the distance of the Fairlawn site from the main research site in Nutley, N.J. may potentially attribute to a lower level of compliance by employees at this facility with proper radiation safety practices and procedures. To verify my understanding that the entire Fairlawn staff is firmly committed to exercising proper radiation safety practices and procedures, the undersigned has initiated random site visits to audit operations there. Also, the Chairman of the Radiation Safety Committee

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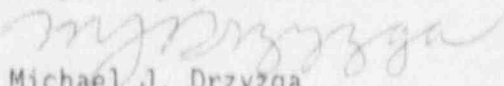
will appoint one of the current PRUs from the Fairlawn site to the RSC before the next regularly scheduled meeting in December 1990, in order to more fully involve site personnel into the administration of Roche's Radiation Safety Program.

Regarding the audit of the Radiation Safety Program by an outside health physics consultant, the funds have been approved and the Radiation Safety Officer currently anticipates that the audit will be completed during the second quarter of 1991.

With respect to radioactive waste disposal procedures, two improvements have been initiated. First, a procedure has been implemented on September 20, 1990 providing that the 5-gallon polypropylene carboys (polyjugs) used in radionuclide laboratories for the collection of liquid radioactive waste are decontaminated, cleaned and relabeled with the appropriate "Caution - Radioactive Materials" labels on an as needed basis. Second, the form used to record the radionuclide and quantity of radioactive waste placed into 5-gallon metal collection cans is revised to include more than one set of data fields in order to more accurately account for the radionuclide waste placed into these collection cans.

We believe that the actions set forth above address the significant comments you made during the inspection. Please feel free to contact the undersigned at the direct dial number above should you desire to discuss any of these matters.

Very truly yours,


Michael J. Drzyzga
Manager, Radiation Safety and
Radiation Safety Officer