



RESEARCH & DEVELOPMENT

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September 28, 1994

U. S. Nuclear Regulatory Commission
Regional Administrator
Region 1
475 Aliendale Road
King of Prussia, Pennsylvania 19406

Docket Nos. 030-32793
030-32921

License Nos. 37-28764-01
37-28764-02

Dear USNRC Regional Administrator:

Subject: Reply to a Notice of Violation

During an NRC inspection on June 22 and 29, 1994 of our Glenolden Laboratory Site violations of NRC requirements were identified. This is a response to the Notice of Violation letter for Inspection Nos. 030-32793 and 030-32921/94-001 dated September 7, 1994.

The first listed violation involved the lack of monthly surveys and wipe tests of the extended interim radioactive waste storage areas during the period April 1, 1994 to June 29, 1994. The person responsible for performing this task was the facility Radiation Safety Officer. This person left the company on March 30, 1994. In his absence no one was identified to assume the responsibility of surveying the radioactive waste storage area. A full time, on-site Environment, Health and Safety (EHS) staff member has been assigned this task as of June 29, 1994. The radioactive waste storage area is now being surveyed and wipe tested monthly. The Site Radiation Safety Officer will review the monthly survey results. The RSO will contact personnel responsible for conducting surveys if monthly reports are not submitted in a timely fashion. This item was fully addressed on June 29, 1994.

The second violation involved the Radiation Safety Officer for the facility. Condition 11B of License No. 37-28764-01 stated Michael C. Frederick was the RSO. Mr. Frederick left the company March 30, 1994, at that time Frieda Fisher-Tyler was appointed RSO for the facility. The NRC was not notified of this change for the irradiator license 37-28764-01. Subsequently a new Staff Health Physicist has been hired. An Amendment for both the irradiator and materials NRC licenses was submitted on August 15, 1994 naming John Nicholson the RSO.

The third violation involved the lack of written documentation approving two individuals as users of our Gammacell 40 irradiator. These two individuals had received the necessary training but used the unit from January 1, 1994 to June 24, 1994 without written RSO approval on file. On June 27, Frieda Fisher-Tyler reviewed the training records of the two individuals and placed written documentation in the irradiator user file.

During the exit meeting on June 29, 1994, Ms. Mary Cahill of the USNRC summarized the findings of her inspection, which indicated an apparent lack of oversight of the Radiation Safety program for our irradiators. We have taken several steps to improve irradiator safety.

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Two research scientists have been named as proprietors of the Gammacell 40 unit. They will be responsible for training new users. All trainees and potential new users must obtain prior approval from the Radiation Safety Committee. The committee will review the individuals previous training, and experience; planned irradiator use and precautions to be taken. The Committee must approve this user authorization request prior to any use/new user training, see Attachment 1 authorization form.

One of the Gammacell irradiator proprietors has been appointed to the Radiation Safety Committee. A review of irradiator work will be presented at each meeting.

To control access to the irradiator the lock to the room door has been changed. Room and irradiator keys have been issued to four staff members: the two proprietors of the unit, the on-site EHS staff member, and the Facility Director. Personnel using the Gammacell unit must obtain keys from one of these individuals and return them when irradiator work is completed.

A standard operating procedure has been drafted and is currently being reviewed by the Committee, and will be approved at the October 11, 1994 meeting. The Gammacell SOP describes the training, authorization and approval process, and the procedure for use of the irradiator.

A log sheet has been created to document irradiator use. Personnel using the unit must complete a log entry for each use. Information recorded includes users name, date, dose and total time of irradiation, and the type of dosimeter worn. This log will be collected monthly and reviewed by the Radiation Safety Officer and filed with the irradiator records, see Attachment 2.

The Gammacell proprietors are responsible for training new users. This will consist of on the job training supervised by one of the proprietors and reading the operators manual. A check list of hands-on practical knowledge of Gammacell irradiator use will be completed for each new user by one of the proprietors. This check list will be filed to document irradiator training has been successfully completed.

A staff health physicist has been hired. Part of the job responsibilities of this position include Radiation Safety Officer function for the Glenolden Laboratory facility. This person will be based at the Experimental Station but will be on-site at the Glenolden site at least 20% of the work week to oversee the radiation safety program. As stated, license amendments have been submitted naming this person as the new RSO for both the irradiator and broad scope licenses.

I trust this response is adequate to address the letter and Notice of Violations we received from your Region I Office. Please contact John Nicholson, Staff Health Physicist, (302) 695-7211 or (215) 237-7837, if you have any questions or need additional information. I may be contacted at (302) 695-7171.

Sincerely,



Raymond D. Andrews
Senior Director
R&D Planning and Operations

Attachments (2)

cc: USNRC Document Control Desk

DuPont Merck Pharmaceutical Co.
Glenolden Laboratory

USER AUTHORIZATION FORM FOR IRRADIATOR

Date: _____

TO: RSO

FROM: _____

LOCATION: _____ EXTENSION: _____

REQUEST FOR AUTHORIZATION TO USE CESIUM IRRADIATOR

I have determined that there is not a viable alternate protocol that reduces or eliminates the need for use of the irradiator and, therefore, request approval.

Please indicate application, methods, facilities, and precautions on the reverse side of this form.

New Request: _____
Transfer: _____ (Requested by)

Signature of Immediate Supervisor

USE PERMIT
(to be completed by radiation safety committee)

Radiation Safety Committee Signatures:

(RSO)

