JUN - 8 1994

Docket No. 030-06922 License No. 19-00296-12

Department of Health & Human Services
National Institutes of Health
ATTN: William J. Walker, Ph.D.
Radiation Safety Officer
Bethesda, Maryland 20892

Dear Dr. Walker:

SUBJECT: ROUTINE INSPECTION NO. 030-06922/93-002

This letter refers to your May 19, 1994 correspondence, in response to our November 22, 1993 and April 26, 1994 letters.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Walter J. Pasciak

Walter J. Pasciak, Chief
Industrial Applications Section
Division of Radiation Safety
and Safeguards

cc:
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Nuclear Safety Information Center (NSIC)
State of Maryland

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 21
Room : 112
(301) 496- 2254

MAY 19 1994

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

Ref: NIH Reply to Notice of Violation
NRC Inspection Report # 030-06922/93-002
License No. 19-00296-12
Docket No. 030-06922

Dear Sir or Madam:

This is in response to the Notice of Violation dated November 22, 1993 and April 26, 1994 regarding the failure of the National Institutes of Health (NIH) to properly notify the NRC of an irradiator failure in accordance with 10 CFR 21.21(c)(3)(i). The Co-60 irradiator with the associated interlocks is operated under License #19-00296-12.

Violation:

10 CFR 21.21(c)(3)(i) requires in part, that a director or responsible corporate officer must notify the Commission when he or she obtains information indicating a defect affecting a basic component that is within his or her organizations responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements of 10 CFR 30. Notification must be made within two days following receipt of information by the director or responsible officer, on the identification of a defect.

Contrary to the above, you did not notify the Commission within two days of information that was obtained indicating a defect affecting a basic component that is within your organizations responsibility and was supplied for an activity that is subject to the licensing requirements under 10 CFR 30. Specifically, on September 24, 1993, both interlocks (basic components) on a custom irradiator containing 91 curies of cobalt-60 and located in your Bethesda, Maryland facilities, Building 10, Room B2B56, failed to perform as designed (defect). These failures resulted in the upper cover/source shield moving away from the lower specimen chamber and source shield while the source in the upper shield was not in the fully up or shielded travel position. This created a substantial safety hazard since the failures had allowed a partial in-air exposure of the source. NRC was not notified of this event until October 5, 1993.

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Response:

(1) On September 24, 1993, both irradiator interlocks failed and the Co-60 irradiator was immediately secured. The NIH failed to notify the NRC of this defect of the safety devices within two days as stipulated in 10 CFR 21.21(c)(3)(i) due to a difference in our interpretation of the regulations. Instead, the NIH discussed the incident during a phone conversation with the NRC on October 5, 1993. A full written report of the incident and the actions NIH took to prevent a significant safety hazard was submitted, dated October 27, 1993. We also disputed the violation in our letter of December 21, 1993. We accept the decision in the NRC letter of April 26, 1994 that this irradiator interlock failure is considered reportable under 10 CFR 21.

(2) and (3) In the future, the NIH will notify the NRC within two days following receipt of information by the Radiation Safety Officer regarding the identification of a defect which could create a substantial safety hazard.

(4) Full compliance was achieved regarding the reporting requirements upon receipt of the NRC April 26, 1994 letter and decision that the irradiator failure is required to be reported in accordance with 10 CFR 21.21(c)(3)(i).

If you have any questions or concerns, please contact me at (301) 496-2254.

William J. Walker, Ph.D.
Radiation Safety Officer

cc: U.S. NRC Regional Administrator, Region I
Dr. Jacob Robbins, Chairman, Radiation Safety Committee, NIH
License File