DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

JAN 16 1997

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Dear Madam/Sir:

This is in response to the letter dated December 20, 1996 regarding the Notice of Violation enforcement action pursuant to the following:

Docket No. 030-01786 License No. 19-00296-10

We have addressed the stated violation in the enclosed document, REPLY TO A NOTICE OF VIOLATION, National Institutes of Health (NIH), in accordance with the instructions within the Notice of Violation.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research

Enclosure

cc: Mr. Hubert Miller, Regional Administrator
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406

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Docket No. 030-01786
License No. 19-00296-10

REPLY TO A NOTICE OF VIOLATION
National Institutes of Health
NRC Inspection Conducted September 16-20, 1996

Statement of Violation

Condition 29 of License No. 19-00296-10 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in Condition 29. The documents listed in Condition 29 include a letter submitted by the licensee in support of license renewal on September 6, 1988. Attachment 6 of the September 6, 1988 letter describes the licensee's "Procedures for Safely Opening packages Containing Radioactive Material". Item 5 of this procedure requires that the individual opening the package "verify that the stated contents agree with the order placed by the Authorized User".

Contrary to the above, on August 8, 1996, an individual opening a package containing radioactive material did not verify that the stated contents agreed with the order placed by the Authorized User. Specifically, on August 6, 1996, an Authorized User ordered 500 microcuries of phosphorous-33 but, because of a data entry error, Radiation Safety Branch records indicated that only 250 microcuries of phosphorous were ordered. On August 8, 1996, the licensee received the package containing 500 microcuries of phosphorous-33 in two vials (250 microcuries of phosphorous-33 per vial). Licensee personnel reviewed the Radiation Safety Branch record of the order which indicated that only 250 microcuries of phosphorous-33 were ordered. Personnel opened the package but failed to identify that the package contained two vials, each containing 250 microcuries of phosphorous-33.

Response

1) NIH denies that a Severity Level IV violation has occurred. The basis for this denial is contained in the following paragraphs and in the NRC's *General Statement of Policy and Procedures for Enforcement Actions*, NUREG 1600, July 1995.

NUREG 1600 states that "Severity Level IV violations are less serious but are of more than minor concern: i.e. if left uncorrected, they could lead to a more serious concern." 60 Fed. Reg at 34385. NIH believes that this error should be properly characterized as a single "minor error" and not result in escalated enforcement action in the form of the issuance of a Notice of Violation. This error should be properly classified as a "Non-Cited Violation" in accordance with Section IV of NUREG 1600. 60 Fed. Reg at 34385. This was an isolated

instance of human error that did not cause any breach of allowable limits on the amount of the nuclide in the laboratory and is not indicative of any failure of the Radiation Safety Program that could be characterized as of "more than minor concern".

Radiation Safety Branch (RSB) package inspection procedures require confirmation that the contents of the package match the data contained in the RSB computer database. However, as stated above in the Statement of Violation, the package inspection technician did not notice the discrepancy between the contents of the package and the entry in the database. A contributing factor in this was the error made in manually entering the order information into the database when the ordering information was not properly electronically transmitted to RSB's database from NIH's Administrative Database.

The error was identified during the inspection when the inspector noticed that laboratory records indicated that 500 microcuries of P-33 was delivered to the laboratory, instead of 250 microcuries. The researcher that accepted delivery of the package noted the correct amount on the laboratory inventory records, but did not notify RSB of the discrepancy because the amount delivered matched the amount originally ordered by the researcher. The activity ordered was verified by checking the original ordering records contained in NIH's Administrative Database. It was then noticed that the amount ordered did not match the information in RSB's database, due to the data entry error. However, the amount delivered to the laboratory was well within acceptable limits for use in routine experiments and would not have required any additional safety procedures above the standard operating procedure. Furthermore, the user was prepared to handle that amount safely, because it was the amount that had been ordered.

The inspection report dated December 20, 1996 notes that there were approximately 13,000 orders available for review by the inspector (representing orders for approximately a 6 month period). Furthermore, NIH has well established procedures for inspection of radioactive material orders. The procedures have been reviewed and approved by the NRC and during this inspection the procedures were observed to be properly executed by the package opening technicians.

The error noted was a human error for a single order, out of the 13,000 available for inspection, which represents a 0.008% error rate. No other errors were noted and it should have been concluded that this is not a widespread problem with the package receiving program that should be characterized as a "more than minor concern". Finally, the materials involved in this situation would have been delivered to the laboratory even if the database had been correct, as the amount was well within the allowable limit to an NIH lab for this nuclide. Thus, this

isolated error would not have led to "a more serious concern", a requirement for classifying the error as a Severity Level IV violation.

2) To minimize the possibility of another such error in the future, the Chief, Materials Acquisition Unit, RSB immediately met with all government and contractor personnel involved in radioactive material ordering, receipt, inspection and delivery upon discovery of the error in September, 1996 and re-emphasized the importance of following established package inspection and data-entry procedures. In addition, a refresher training session was held with the same personnel to review procedures required for radioactive material package receipt, opening, and inspection. Also, a quality assurance review is conducted on a statistically significant number of the orders to ensure proper data entry.

3) See 2) above.

4) Full compliance was achieved at the conclusion of the NRC inspection.