FOUNDATION FOR BLOOD RESEARCH
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August 29, 1985

Docket No. 030-15048
License No. 18-18420-01
EA 85-90

Mr. Thomas T. Martin
Director, Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
631 Park Avenue
King of Prussia, Pennsylvania 19406

RE: Inspection No.: 030-01769/85-01

Dear Sir:

I am writing in reply to your letter of August 22, 1985 to Robert F. Ritchie, M.D. in my capacity as RSO concerning violations discovered during inspection No 030-01769/85-01 on June 24, 1985. Corrective action was taken on each item immediately upon notification by Mr. T.K. Thompson. Detailed response to each specific violation is given below.

A. Release of I-125 into the Sanitary Sewer System

My interpretation of 10CFR Paragraph 20.301 was that allowable average concentration limits of I-125 could be calculated based on either a daily or monthly basis, at the user's option. This interpretation was reinforced by conversations with RSO's at other facilities where calculations are based on other than daily averages. In reviewing the practice with Mr. Thompson, it is now clear that daily, monthly, and yearly concentration limits must all be adhered to.

The excess daily disposal of I-125 occured only on occasions when outdated label was pooled and discarded on the same day. Daily disposal of I-125 by decanting of assay supernatants directly into a designated sink, even for our largest assays, never exceeds 5-6 uCi, well below our allowable 120 uCi daily limit. Daily disposal records have been and will continue to be maintained for this type of disposal.

With regard to disposal of pooled outdated material, the following steps were implemented effective on the date of Mr. Thompson's inspection:

1. Outdated label will be pooled and an aliquot counted. The concentration of radioactivity in uCi/mL and the total uCi of I-125 will be calculated using CPM and counter efficiency data. This data will be entered into FBR's inventory book.

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2. The volume in mL of label corresponding to 100 uCi or less will be calculated (below our 120 uCi limit). After checking the daily discharge records to ensure that daily discharge limits of 120 uCi will not be exceeded, this volume will be discarded into a designated sink. This daily discharge will continue until the pool is discarded. Records will be maintained for each discharge.

3. On occasion, the pool may be temporarily stored in a lead pig in a secured refrigerator to allow further decay before disposal according to 1 and 2.

B. Monthly Smear Surveys

Smear surveys were not performed for the months of March and April, 1985. This period was a particularly stressful time for the clinical laboratory because of personnel shortages and smear surveys were overlooked. Monthly smears recommenced on May 2, 1985 and have continued, as required, to the present. To avoid a repetition of this problem, monthly surveys will be reviewed and signed by the RSO (or designated substitute) to ensure that the smears are taken.

C. Lab Coats

With occasional exceptions, laboratory personnel have been conscientious in wearing lab coats when setting up and performing assays involving the use of radioactivity. In some cases, however, personnel have been lax in wearing coats when adding non-radioactive substances to radioactive assays because it has not been considered critical. Personnel have now been informed of the necessity of wearing coats at all times and the RSO will monitor compliance with this requirement.

D. Transport Notice

Transport of limited quantities of I-125 from Ventrex Laboratories has been in accordance with the requirements of 49CFR 170-189 with regard to packaging and shielding. A bill of lading describing the contents, category of material, names and addresses of shipper and consignee have been carried at all times. In reviewing this procedure with Mr. Thompson, I was made aware that the statement contained in 49CFR 173.421 must appear on the shipping papers and box as well. Effective immediately, the shipping papers and the outside of the shipping box, will be stamped with the required notice along with other required information.

One of the dilemmas for a small facility such as the Foundation for Blood Research, where the RSO has many additional responsibilities, is correctly interpreting regulations or keeping current with changing requirements. Several of the violations identified during the recent inspection resulted from misinterpretation or unfamiliarity with NRC or DOT regulations. To help ensure that the potential for such problems is minimized, the FBR is engaging Murray M. Bolton, Jr., from the Massachusetts Institute of Technology as a Health Physics and Radio Chemistry Consultant. We plan to have him visit the FBR periodically to review our program and to assist us in ensuring that we comply with regulations.

With the steps outlined above we hope to avoid repetition of the violations described.

Sincerely,

George J Knight

George J, Knight, Ph.D.
Director, Radioimmunoassay Laboratory

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cc: Bulletin Board