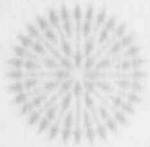

ABBOTT Biotech

July 12, 1991

Abbott Biotech, Inc.
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Needham Heights, MA 02194
Telephone 617-449-6002
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Mr. John D. Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 20-14076-04
Routine Inspection No. 030-19118-001

Dear Mr. Kinneman:

This letter is in response to your letter of May 15, 1991 regarding Mr. Eric Reber's routine safety inspection of our facilities and activities authorized by NRC license No. 20-14076-04. We are responding at this time in accordance with an extension granted by Mr. Eric Reber on June 11, 1991.

Below we have restated the two violations cited in Appendix A (Notice of Violation) of your letter and included our responses.

Violation A:

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

A. Contrary to the above, surveys were not made to determine that individuals were not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103. Specifically, surveys were not made on August 24, 1990 and July 26, 1990, when iodinations were performed during which iodine-125 was withdrawn from a stock vial containing 5 mCi of iodine-125.

This is a Severity Level IV violation. (Supplement IV).

Response:

Although no bioassay was performed following the radio-iodinations which were performed on July 26 and August 24, 1990, external exposure to radiation was monitored by both extremity and whole-body dosimeters. No extraordinary

radiation exposure was detected by these dosimeters, nor did routine smear surveys disclose the presence of any contamination. We will hereafter require bioassay as described in Appendix A of this letter following any future radioiodinations. These procedures will be integrated into our Radiation Safety Manual. All materials required to implement this plan have been acquired. All personnel authorized for work with iodine-125 attended a formal training session regarding these practices on June 14, 1991. We believe these activities satisfy the regulations.

B. Contrary to the above, surveys were not made to assure compliance with 10 CFR 20.106, which limits the yearly average concentration of radioactive material(s) in air discharged to unrestricted areas. Specifically, surveys were not made on August 24, 1990 and July 26, 1990, when iodinations were performed during which iodine-125 was withdrawn from a stock vial containing 5 mCi of iodine-125.

This is a Severity IV violation. (Supplement IV).

Response:

The aforementioned radioiodinations were conducted in a hood in room 2205B whose effluent was not monitored. The radioiodinations performed on July 26 and August 24, 1990 were conducted in an enclosed glove box which was inside a conventional fume hood. This glove box has a recirculating closed loop ventilation system with an activated charcoal filter which is designed to prevent the release of radioiodine into the laboratory. The fume hood in which the glove box is located is ventilated by a centrifugal fan mounted on the roof of the building. There is also an activated charcoal filter in this system, between the fume hood and the fan. Although no survey of the effluent exhaust air was performed during the previously mentioned iodinations, we feel confident that there was very little if any radioiodine released to the environment. Since the inspection of May 2 and 3 the handling of all isotopes in this hood has been suspended until such time that renovations and adaptations to measure effluent of the hood in room 2205B have been completed. An inclusive engineering study of the hood has been initiated. No further radioiodinations will be performed without appropriate surveys of the radioiodine effluents.

The temporary suspension of radioiodinations and the establishment of and training in appropriate surveys will bring the program into compliance with specified guidelines.

We trust that you will deem the corrective actions described above to be adequate to assure the safety of our employees and the environment. We will address the remaining issues regarding Violation B in a timely manner. Thank you for your consideration.

Sincerely,

ABBOTT BIOTECH, INC.

Regina M. Reilly

Regina M. Reilly, Ph.D.
Radiation Safety Officer

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Appendix A

Bioassay Procedure for ^{125}I

I. Introduction

Bioassay is necessary when an individual handles in unsealed form any millicurie amounts of iodine-125. In efforts to comply with these guidelines a program has been instituted at Abbott Biotech, Inc. which is to be implemented on a per-use basis by individuals involved in experiments involving the use of iodine-125. Persons using iodine-125 may comply with the requirements by performing the prescribed bioassay both 24 hours prior to and within 24 hours following their experiments. The bioassay is designed to detect and quantitate levels of iodine-125 which may have been uptaken by the thyroid.

II. Materials

1. A rate or survey meter with gamma radiation (NaI scintillator) detector (e.g., Eberline RM-19 instrument with an LEG-1 probe; Ludlum model 3 or 12 instrument with a 44-7 probe).

2. A known quantity of iodine-125 or iodine-129 (simulated source)standard in an acrylic rod which is NIST traceable. The current such source is New England Nuclear NES-211S.

3. A lucite (water-filled) neck phantom to be used for calibration and determination of efficiency. The current phantom available is provided as #10-0560-898 from Atlantic Nuclear, Inc.

III. Procedure

1. In a low background area, place window of the detector against the phantom so that the window is as close as possible to the source holder in the phantom (Fig. 1). Measure and record background counts per minute(cpm).

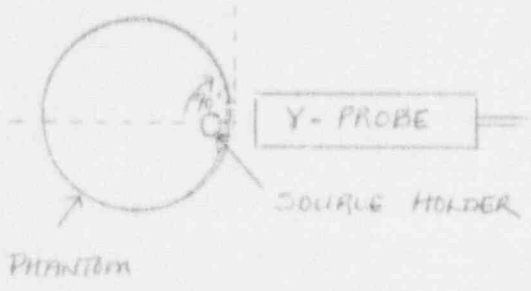

FIGURE 1: TOP VIEW

Appendix A

Bioassay Procedure for ^{125}I

2. Put the sealed source rod in the holder in the phantom. Position the window of the detector probe against the phantom as described in step 1 and shown in Figure 1 above. Measure and record cpm. Calculate and record cpm minus background cpm.

3. Place the detector probe against the throat of the individual being scanned in a position as close as possible to the thyroid gland. Record cpm minus background cpm.

4. Convert these data (step 3) from cpm to microcuries and record:

   o source cpm divided by current activity in source expressed in microcuries = cpm/microcurie

   o thyroid cpm divided by cpm/microcurie = microcuries uptaken into the thyroid

IV. Abbott Biotech, Inc. Limits:

1. Thyroid uptake should not exceed 0.05 microcurie. If the result of a thyroid scan is greater than 0.05 microcurie, that individual may not work with iodine-125 until the thyroid scan measures less than 0.05 microcurie.

2. Steps should be initiated to determine the cause of the high uptake and precautions taken to prevent recurrence of the incident.

3. If levels in the thyroid are in excess of allowable limits, the Radiation Safety Officer should be notified immediately. She/he will arrange a consult with Corporate Employee Health.