11636 Administration Drive, St. Louis, Mo 63146 • (314) 567-3905

SmithKline Bio-Science Laboratories

SKBL

DMB COPY

January 21, 1988

Bruce S. Mallett, Ph.D
Chief, Nuclear Materials Safety and
Safeguards Branch
United States Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

30-2380

RE: License No. 24-13299-01

Dr. Mallett:

We are in receipt of your letter of December 23, 1987, itemizing our NRC license violations observed by Ms. T. L. Simmons during her recent visit. We have been very diligent and have begun corrective actions with each. Our progress is noted for each area below. Please also note that we have restructured our management forces to better reflect our committment to our responsibilities in radiation safety.

Violation (1): While quarterly audits of all users were not performed in a timely manner, all audits on records have now been conducted. A Radiation Safety Committee meeting was held on January 7, 1988 and the measures outlined in Attachment A were adopted as a means to assure compliance.

Violation (2): All laboratory personnel using radioactive materials have received training during their employment with SmithKline Bioscience Laboratories, but we have not been in compliance with Section H of our license. Therefore, a comprehensive training course and examination is scheduled to be given to all users of radioactive material by March 31, 1988.

Violation (3): Personnel in the shipping and receiving area have been instructed in the procedures outlined in Section O and are currently performing external package surveys (Steps A1 through 5). RIA staff have been instructed in the procedures outlined in Section O and are concluding these surveys (Steps A6 and 7). Records of these sruveys are now being maintained.

JAN 2 2 1988

IE07

1/1

Violation (4): Leak testing of all sealed sources was performed on January 20, 1988, and satisfactory results received on January 21, 1988.

Violation (5): The raw disposal data Ms. Simmons observed on Dec. 2, and 4th quarter, 1987 data have now been calculated and sewerage disposal records are up-to-date.

Violation (6): Weekly wipe-tests are now performed in all areas where greater than 100 microcuries are used. In addition, weekly surveys are to be performed in storage areas, as of January 25, 1988.

B. Corrective Action to be Taken to Avoid Further Violations:

On January 7, 1988, a Radiation Safety Committee meeting was held to discuss the process of management control of Radiation Safety. Attachment A outlines the assignment of responsibility for comprehensive implementation of our Radiation Safety Program. Furthermore, it delineates review processes, responsibilities and frequencies.

C. All of our records have been reviewed and updated and are available for your inspection. Our personnel training will be completed by March 31, 1988, and will bring us to full compliance at that time.

If you have any questions or additional suggestions please do not hesitate to contact me.

Sincerely,

Roman L. Patrick

Roman L. Patrick, M.D.
Laboratory Director

RLP:sag

ATTACHMENT A

MANAGEMENT CONTROL

This is in response to the fourth paragraph in your letter dated December 23 concerning management control.

General management control will follow the laboratory organizational structure with the Manager of RIA and Radiation Safety Officer (same individual) reporting to the Laboratory Director.

The Laboratory Director has overall responsibility and accountability to ensure that the licensure requirements are met and that other individuals are fulfilling responsibilities with appropriate documentation and followup action in the event of non-performance or lack of documentation.

A separate process of checking, auditing and inspecting to verify that activities affecting safety related functions have been performed and documented has been assigned to the Quality Assurance Specialist, who reports directly to the Laboratory Director.

Documentation is a key part of the management control. All documentation will be kept in one place in the RIA department to allow periodic and on-going assessment of actions performed, date performed and by whom.

The specific duties to be performed are delineated in the licensure and deficiencies stated in your letter dated December 23, 1987. These are assigned as follows:

DUTIES AND RESPONSIBILITIES

LABORATORY DIRECTOR:

- Chair Radiation Safety Committee meeting.
- Appoint members of R-S-C.
- Determine that other members of the organization are fulfilling duties and responsibilities during periodic overall personnel evaluations and specifically in meeting NRC licensure requirements and correcting deficiencies noted in the letter of December 23.
- Evaluate Quality Assurance verification auditing and inspecting that activities affecting safety related functions and training have been correctly performed and documented.
- Fo'lowup action in the event that deficiencies are noted in Quality Assurance reviews with appropriate personnel actions if indicated.

- Ensure that the Radiation Safety Officer and other members of the Radiation Safety Committee have sufficient qualification through training and experience to fulfill responsibilities.

QUALITY ASSURANCE SPECIALIST:

- Serve as a member of the Radiation Safety Committee.
- Periodic audits, verification and inspecting areas using or handling radioactive materials including documentations of safety and training - using the NRC license and the recent list of deficiencies as a guideline. These audits will be performed quarterly.
- Prepare written reports to Laboratory Director of audit findings with copies to RIA Manager.

MANAGER, RADIOIMMUNOASSAY AND RSO:

- Establish and review procedures for area monitoring, personnel exposure monitoring, waste disposal and package monitoring.
- Assure that waste disposal leak tests of sealed sources and survey instrument calibrations are performed appropriately by an outside vendor.
- Review records pertaining to personnel exposures, radioactive material receipts and evaluations, equipment evaluations and leak tests of sealed sources, and report findings to the Radiation Safety Committee on a quarterly basis.
- Review and process files of approved users of radioactive material, relevant State and Federal regulations, licenses and licensing correspondence, as needed.
- Assure that a continuing program of training of personnel regarding the safe use of ionizing radiation is conducted.
- Provide consultation and assistance, covering:

  a. Decontamination of personnel and areas subsequent to accidental spills of radioactive material.

  b. Prenatal radiation exposure.

SUPERVISOR, RIA:

- Assure that appropriate procedure and pertinant records are maintained in a timely fashion.

  a. Personnel exposures (Quarterly)
  b. Radioactive materials receipts (Monthly)
  c. Sewerage disposal records (Quarterly)
  d. Wipe tests and area surveys (Weekly)

- Assure that users in RIA remain in constant compliance with the regulations of 10CFR 20 and with the procedures included in the Radiation Safety Manual.

- Hold Radiation Safety training sessions with users in RIA on a quarterly basis so that retraining on an annual basis is assured. Training records will include dates, topic covered, who attended and who presented the topic.

SUPERVISOR, MAILROOM AND SUPPLY:

- Assure that personnel handling radioactive materials shipments are properly trained in the procedures outlined in Section O.

- Assure that incoming shipments of Radioactive materials are appropriately handled, and that pertinant records are properly maintained.