

PDR

OCT 17 1989

30-03547

License No. 53-07998-03

Accupath Laboratory
Smith Kline Bio-Science Laboratories
440G Kalanianaʻōle Highway
Honolulu, Hawaii 96821

Attention: Mr. Barry F. Hopkins
General Manager

Gentlemen:

Thank you for your letter dated September 6, 1989 informing us of the steps you have taken to correct items which we brought to your attention in our letter dated August 10, 1989. Your corrective actions will be verified during our next inspection.

Your cooperation with us is appreciated.

Sincerely,

Original signed

Robert J. Pate, Chief
Nuclear Materials Safety and
Safeguards Branch

bcc w/copy of ltr. dated 9/6/89:
Docket File
G. Cook
B. Faulkenberry
J. Martin
State of Hawaii

bcc w/o copy of ltr. dated 9/6/89:
M. Smith

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Dave

SmithKline Bio-Science Laboratories Accupath

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September 6, 1989

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

Subject: REPLY TO A NOTICE OF VIOLATION

License No. 53-07998-03
Docket No. 030-03537

Gentlemen:

In response to the recent NRC Inspection (7/13/89) and subsequent "Notice of Violation" dated August 10, 1989, we have taken the following steps to ensure improvement in the effectiveness of our overall management control system.

1. All radiation activities records have been consolidated into one set of binders. In particular, weekly wipe-test records; monthly by-product materials shipment receipt records; decay storage records; whole body badge records; and employee training records are now located together.
2. All records in (1) above are reviewed monthly by both the Radiation Safety Coordinator and the site RSO (Clyde Kaneshiro, Ph.D.). In addition, the site General Manager is reviewing all records on a quarterly basis.
3. A Radiation Safety Committee has been established to suggest improvements and changes to the program and to keep personnel focused on program requirements and activities. The committee is made up of the site RSO, the Radiation Safety Coordinator, and two Medical Technologists. The committee meets bio-monthly.

We feel confident that these changes will result in more consistent active involvement by all personnel handling RIA materials. This heightened awareness should in turn eliminate the repetitive nature of the "wipe test" violation and ensure that all requirements of our license are met.

The following are responses to the specific violations noted in the "Notice of Violation".

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- A.1 Item 17, of the application dated September 18, 1980, requires monthly wipe test surveys.

The missed wipe test surveys during September and October of 1986 and again during March, June, and July of 1987 occurred during a time when personnel on the third shift who were responsible for performing the surveys were newly hired. There were unexpected turnover in third shift personnel twice within that period of time. There was no active periodic review of wipe test records at the time, so the omissions went undetected. However, records do show that since that time, wipe tests have been performed regularly as required.

Since the July 13, 1989, inspection by your office, all employees involved in the wipe-testing program have received a review of the survey requirements and procedures. To insure that the surveys are performed as scheduled, all records will be routed to our Radiation Safety Coordinator each month. Both he and the site RSO have responsibility for reviewing and signing the survey records.

- A.2 Item 12, of the application dated September 18, 1980, requires the training of all employees using licensed material.

Four of the five employees who had no documentation of training were hired under the Accupath general license (see A.3 below for an explanation of this "general license"). When the laboratory was relocated back to the 4400 Kalaniana'ole Highway address in September 1986 (site of the current license), no one realized that the training records of the four individuals were not adequate. The fifth employee in question received training, but his records could not be found at the time of the inspection. They have been redone and are now on file.

All five employees who had not received training will complete the required training by September 15, 1989. The training includes radiation safety and safety equipment, basic radiation physics and instrumentation, the use and measurement of radioactivity, and our handling and disposal procedures for radioactive material. Because we only use I¹²⁵ material, most of the training discussions are focused on this isotope.

With copies of all training records in the same location as the other radiation program records, active review will insure that new and transfer employees will be properly trained in accordance with our materials license.

- A.3 While it is true that we incorrectly terminated our whole body monitoring program in 1985, there were mitigating circumstances that caused us to take such action. In April 1985, the holder of the license, Bio-Science Laboratories, was merged with another laboratory, Accupath Laboratories, which held a general license for by-product material. All the RIA testing was transferred to the Accupath site at that time. A number of significant differences existed between the Accupath general license and the Bio-Science Laboratories license. Of particular relevance was that the wearing of monitoring badges was not required under the Accupath Laboratory license. It was at this point that the whole body badge program was terminated. RIA testing continued at the Accupath site for about 17 months until September 1986, when the laboratory was moved back to the now renovated Bio-Science site (4400 Kalaniana'ole Hwy.). At that time we were particularly careful to reinstitute our decay storage program for both solid and liquid RIA wastes. However, we unfortunately neglected to note that our license required the use of whole body badges.

We are contacting a number of health physics companies to reinstate our whole body badge program. This should be started by the end of September. We will notify you when this program begins.

- B. 10 CFR 20.203(e) provides that each room in which licensed material is used or stored shall be posted with sign(s) bearing the radiation symbol and the words "Caution, Radioactive Materials".

At the time of the inspection, only small labels bearing the radiation symbol and the words "Caution, Radioactive Materials" were being used. These were posted on all walls, storage barrels, and liquid waste containers. The room itself is locked and can be accessed by only three individuals, the site RSO, the Radiation Safety Coordinator, and a maintenance man who by instruction never touches the storage containers. However, it was agreed at the time of the inspection that the signs were inadequate.

"Caution, Radioactive Material" signs have been posted in the "Bunker" storage building. These 7 x 10 inch signs are located on the doors, walls, and shelf of the Bunker. In addition, we have posted additional signs in the two laboratory areas and old worn signs on two refrigerators have been replaced.

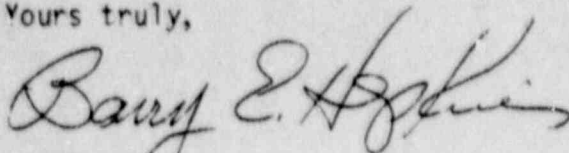
- C. 10 CFR 20.203(f)(1) provides that each container of licensed material shall bear a label with radiation symbol and the words "Caution, Radioactive Materials".

As mentioned in (B) above, at the time of the inspection, all barrels for solid wastes and plastic containers for liquid wastes were labelled with small labels bearing the radioactive symbol and the words "Caution, Radioactive Materials". These barrels and containers are all located inside a locked "Bunker" with access allowed for only three staff members. Again however, it was agreed at the time of the inspection that the labels were inadequate.

All 34 barrels have been labelled with 2 x 4 inch labels bearing the radiation symbol and the words "Caution, Radioactive Material". Also extra labels are in stock should we need to use additional barrels. Two waste containers in the laboratory testing areas were also relabelled with larger 7 x 10 inch signs.

In summary, we believe we have adequately covered all issues raised from the inspection. We agree with your concern about the effectiveness of our past management control system. We truly feel that with the active periodic review system now in place, a repeat of past violations will not occur. Should you have any other questions or concerns, please contact me.

Yours truly,



Barry E. Hopkins
General Manager

BEH:whk
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cc: Regional Administrator, Region V
U.S. Nuclear Regulatory Commission
1450 Maria Lane, Suite 210
Walnut Creek, CA 94596