Aventis Pasteur

Aventis

April 7, 2003

US Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

P-8

Attn: Ms. Judith Joustra

re: Inspection response, Byproduct Material License Number 37-17938-01,
Docket Number 030-13723

Dear Ms. Joustra:

This is in response to your additional questions regarding the termination of activities in formerly used rooms and buildings.

With respect to disposal via the sanitary sewers, the Swiftwater Aventis site and its predecessor, Connaught Laboratories had a policy of not disposing any form of waste (radioactive, biological, or chemical) via the sanitary sewers. This was a policy based on the fact that the facility had its own treatment plant that discharged into the creek running through the property and did not want to introduce any hazardous materials into the stream, even in permitted quantities.

Building 2: Three rooms were listed in NRC files: 103, 104 and 108. Room 103 is a general lab in which a small corner was sectioned off and labeled as Room 104. A small bench-top laminar flow hood, rated for biological preparations, was used in 103/104 for incubating and drying antigen preparations. The hood was later moved to room 108, adjacent to 103 and the walls enclosing 104 were removed creating a single rectangular 103. This hood never had a water supply or a drain. All radiological samples were prepared in Building 4 and sealed vials were carried to the adjacent Building 2. The sealed vials were placed in the incubator in the hood. Following drying, the sealed vials were returned to Building 4 for analysis. The only radioactive materials used in this building were tritium and chlorine 36. The hood was last used on February 9, 2002 according to lab notebook entries. It was on our routine monthly wipe SOP and was last wiped on March 27, 2002. No contamination was found (62 dpm/100 cm^2 compared to a blank of 65 dpm/100 cm^2). Wipe analyses were made in one of the liquid scintillation counters which have a 50 percent efficiency. A copy of the last wipe results was submitted in our October 10, 2002 response. On February 25, 2003 wipes were taken of the hood and its exhaust. The hood interior again showed non-detectable removable radiological contamination (123 dpm compared to a blank of 108 dpm). The exhaust vents also showed non-detectable removable radiological contamination (114 dpm compared to a blank of 108 dpm). Based on the historical lack of contamination, this hood and room was removed from our wipe testing SOPs and is considered acceptable for release for unrestricted (radiological) uses.

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Building 6: Rooms 110A was a small room that contained a single counter. Sealed samples were carried from the preparation labs and placed in the counter for analysis. The counter and bench top were routinely wiped and had a history of not showing detectable radioactive contamination. Room 110B was a small room in which a freezer and refrigerator were located. These were not the primary freezer and refrigerator for radiological storage in this building and were used only in the case of excess samples or radioactive supplies. They were on the routine wipe schedule and had a history of not showing detectable radioactive contamination. No preparations were performed in these two areas.

Building 38:(former waste storage room): There were actually two Building 38 designations and the waste storage rooms in both were designated Room 126. Neither room had floor drains. We have no information of a Room 116 being associated with radioactive materials. The old Building 38 was attached to Building 37, a manufacturing building. This Building 38 housed a spare parts warehouse, some offices, and a storage room (126) used by the environmental people for storage of hazardous waste prior to shipment. Radioactive waste held for decay (iodine 125) and waste packaged for disposal were also stored in this room. There is a Room 116 in this building but it is a women's rest room in the center of the building, well removed from Room 126. Sometime in late 1998 or early 1999 time frame, a new Building 38 was constructed to house the warehouse and all waste handling (hazardous and non-hazardous) and a new Room 126 was constructed to house both radioactive and other hazardous waste prior to shipment. The storage rooms in both buildings, had bare concrete floors and epoxy coated concrete block walls. The radioactive waste was stored in plastic lined steel drums placed in "bathtub pallets" (the same pallets were used in both buildings). Both buildings were included in the routine wipe tests and had a history of not showing significant removable contamination. We cannot locate data from the old Building 38; however, there is no recollection that radiological contamination was ever found. A copy of the termination survey wipe results for the new Building 38 was submitted in our October 10, 2002 response. The analyses of wipes were made on the same liquid scintillation counter described for Building 2 and has a 50% efficiency. The area comprising the former Building 38 now houses a vaccine packaging line and all surfaces are new. Wipes were made on February 25, 2003 of the floor and the empty pallets which are still present in the new Building 38 waste storage room. A low area on the floor was wiped and showed a net activity of 288 dpm and the pallets had net activities of 69, 76 and 64 dpm compared to the blank (108 dpm). The wipes were below the action level of 500 dpm and this room was released for unrestricted use.

Should there be any questions regarding the application, please contact me at (570) 839-5651 or Mr. LaMastra at (610) 756-4153.

Sincerely,

John J. Podczasy, Ph.D.
Platform Leader, Clinical Immunology