



FOOD AND DRUG ADMINISTRATION
Winchester Engineering and Analytical Center
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September 5, 1990

Docket No. 030-04675

License NO. 20-08361-01

U.S. Nuclear Regulatory Commission
Region I
Attn: Mr. John Kinneman, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards

Dear Mr. Kinneman:

The results of the inspection conducted on July 31 and August 1, 1990 showed a subsequent violation. It was noted and acted upon.

The violation was as follows:

- 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.

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 in air discharged to unrestricted areas. Specifically, as of August 1, 1990 the airborne effluent monitoring system indicated a dose rate in millirem per hour and calculations could not be produced to demonstrate that values in 10 CFR 20, Appendix B, Table II had not been exceeded.

- b. This has been corrected by purchasing an in-line sampling filter system. It is a SAIC-RADE Co Model AVS-28A Constant Flow Air Sampler with a combination filter/cartridge holder. The holder can accommodate a Model BG-390 Radioiodine Sampler Cartridge or filter paper. It will monitor the possible release of airborne radioactive materials to unrestricted areas. The purchase order was issued on August 22, 1990 and 30 day delivery is expected.

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- c. When the system is received it will first be calibrated. Then we will monitor the airborne effluent for radioactivity during periods of use. This will also allow us to measure the radioactivity in the event it is being released. There after it will be measured periodically to assure that the releases, if any, are below the values in Appendix B, Table II of 10 CFR 20. Future Compliance will be assured by incorporating this task into the Radiation Safety Oversight Program of the "Health Physics Recurring Duties."

The data for full compliance should be sixty-days after receipt of the "in-line filter sampling system." The target data for receipt of this system is September 22, 1990.

Should any further action be necessary, please let us know.

James W. Fitzgerald
James W. Fitzgerald
Director, Winchester
Engineering and
Analytical Center

cc: E. J. Baratta
Radiation Safety Officer, WEAC