

July 3, 2019

David L. Pelton, Director
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

License No. 13-35179-03
Docket No. 030-38903

Re: Response to Disputed Notice of Violation; NRC Routine Inspection Report No.
03038903/2018001(DNMS)

Dear Mr. Pelton,

Zevacor received a letter from your office dated, May 16, 2019, in response to the disputed notice of violation that Zevacor contested in a letter to the NRC dated January 10, 2019.

During the NRC inspection, Mr. Jason Draper measured readings from the bio-safety cabinet with the radiation dose rate of approximately 500 millirem in 1 hour at 30 centimeters from the radiation source and 200 millirem in 1 hour at 30 centimeters from the surface that the radiation penetrated was not controlled by any of the methods described in 10 CFR 20.1601(a) or (b).

The main reason for the abnormally high exposure rate was due to a gap in the shielding measuring approximately 8 inches wide. Zevacor has since installed an additional lead door that covers the gap and provides shielding overlap on both sides of the door. Matthew Trusner, Radiation Safety Officer, completed surveys after the installation of the door and found a dramatic drop in the exposure rate. The exposure rate at the time after the installation was 0.7mrem/hour at the surface of the bio-safety cabinet.

The "High-Radiation Area" signs have been removed from the doors of the QC lab and replaced with "Radiation Area" signs. The "High-Radiation Area" signs were placed on the doors of the QC lab as result of the original finding from the NRC inspection. Since that time, a phone call between Mr. Draper and Mr. Trusner has occurred and it was deemed the bio-safety cabinet is not an area that is considered accessible to individuals, therefore, the only required posting on the bio-safety cabinet will be a "Caution: Radioactive Materials" sign. However, Zevacor will voluntarily post a sign on the bio-safety cabinet instructing employees to make sure the bio-safety cabinet doors are closed when not in use.

Additionally, Zevacor personnel will have positive control over the entry of the bio-safety cabinet. The Zevacor employee that has positive control over the entry of the bio-safety cabinet will ensure that all other personnel in the area of the bio-safety cabinet will be notified of the entry into the bio-safety cabinet, therefore, preventing inadvertent exposure to personnel. Zevacor confirms the doors of the bio-safety cabinet will not remain open for more than 8 hours as stated in 10 CFR 20.1903.

Mr. Trusner completed mandatory, company-wide training in regards to the changes in the QC Lab.

Zevacor commits to continue to conduct its program in accordance with current license conditions.

If you have any questions regarding the submitted request, please contact me at the information provided below.

Sincerely,



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