

January 10, 2019

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532

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

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

To Whom It May Concern,

Please find the response to the letter from the NRC dated December 14, 2018.

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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Attachment:

1. Noblesville Facility Layout QC Lab

- A. Pursuant to Title 10 of the Code of Federal Regulations (CFR) 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Title 10 CFR 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Contrary to the above, as of October 22, 2018, the license did not make surveys necessary for the licensee to comply with 10 CFR 20.1902(b) and 10 CFR 20.1601(a), which require the posting and control of accessible areas in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates. Specifically, the licensee did not make surveys in the area around the bio-safety cabinet in the licensee's quality control laboratory to identify that a high radiation area existed requiring posting and control of the area.

Zevacor agrees with the above (A) violation. During the routine NRC inspection, the inspector's real-time radiation badge starting alarming causing him to investigate the cause of the alarm. Upon inspection, the bio-safety cabinet was reading approximately 500 millirem in one hour at 30 centimeters from the radiation source and 200 millirem in one hour at 30 centimeters from the surface that the radiation penetrated.

Zevacor uses the bio-safety cabinet as a waste holding bunker for various activities in the QC Lab. During the time of the inspection, there was an abnormally large amount of waste in the bio-safety cabinet.

Since the inspection, Zevacor conducted a radiation safety/waste handling meeting with all QC Lab personnel in the QC Lab. Zevacor discussed better RAM handling techniques regarding waste, appropriate survey techniques and, more importantly, Zevacor devised a plan to remove QC Lab waste in the bio-safety cabinet at least every 28 days. The removal of waste every 28 days will tend to reduce the activity stored in the cabinet to levels below those that existed at the time of inspection, such that the radiation levels might be below the high radiation area criteria during significant portions of the time. Regardless of activity, though, the access controls will remain in place as described in section C. The plan to remove QC Lab waste was first executed on November 15, 2018.

Additionally, Zevacor is revising its Standard Operating Procedure (SOP) to give better guidance to the radiation workers performing radiation surveys. The SOP was approved on January 10, 2019.

- B. Title 10 CFR 20.1902(b) states that the licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA.”**

Contrary to the above, on October 22, 2018, the bio-safety cabinet, a high radiation area with a radiation dose rate of approximately 500 millirem in one hour at 30 centimeters from the radiation source and 200 millirem in one hour at 30 centimeters from the surface that the radiation penetrated, was not posted with a sign bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA.”

Zevacor agrees with the above (B) violation. Zevacor posted “CAUTION, HIGH RADIATION AREA” signs upon every entry door to the QC Lab on October 24, 2018. Zevacor did not have any “CAUTION, HIGH RADIATION AREA” signs available for use, therefore, the signs were ordered, shipped, received, and posted within 48 hours.

- C. Title 10 CFR 20.1601(a) states, with exceptions not applicable here, that the licensee ensure that each entrance or access point to a high radiation area has one or more of the following features: (1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 milliSievert) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates; (2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or (3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.**

Title 10 CFR 20.1601(b) provides that, in place of the controls required by 10 CFR 20.1601(a) for a high radiation area, a licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

Contrary to the above, on October 22, 2018, the bio-safety cabinet, a high-radiation area with a radiation dose rate of approximately 500 millirem in one hour at 30 centimeters from the radiation source and 200 millirem in one 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).

Zevacor disagrees with the above (C) violation. Zevacor follows 10 CFR 20.1601(b) by having continuous electronic surveillance that is capable of preventing unauthorized entry.

As seen on attachment *Noblesville Facility Layout QC Lab*, a radiation worker must go through three separate locked doors (D1, D4, and D5 respectively) to enter the High Radiation Area. The locked doors are a part of Zevacor’s electronic security system. This system records, in real-time, the individuals that have entered that particular area. Additionally, this system can, in real-time, remove someone from the authorized entry list. This system has been in place since the inception of Zevacor’s NRC RAM license. Zevacor maintains control of the High Radiation Area.

Noblesville Facility Layout QC Lab

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— = Restricted Area

D1 = Door Locked At All Times

D2 = Door Locked At All Times, Emergency Exit Only, High Radiation Area Sign, Radiation Monitor

D3 = Door Locked At All Times, Emergency Exit Only, High Radiation Area Sign, Radiation Monitor

D4 = Door Locked At All Times, Radiation Worker Access Only, Radiation Monitor

D5 = Door Locked At All Times, Radiation Worker Access Only, High Radiation Area Sign, Radiation Monitor

▨ = Bio Safety Cabinet

NRC Licensed Area 13-35179-02

