



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 16, 2019

EA-19-007

Mr. Matthew Trusner
Radiation Safety Officer
Zevacor Molecular
14395 Bergen Boulevard
Noblesville, IN 46060

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION; NRC INSPECTION
REPORT 03038903/2018001(DNMS) – ZEVACOR MOLECULAR

Dear Mr. Trusner:

On January 10, 2019, you provided Zevacor Molecular's response to U.S. Nuclear Regulatory Commission (NRC) Inspection Report 03038903/2018001(DNMS) and its enclosed Notice of Violation, dated December 14, 2018. A copy of your response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>, using ADAMS Accession Number ML19011A335. A copy of the NRC's inspection report can be found in ADAMS using ADAMS Accession Number ML18351A162. In your response, you accepted Violations A and B, and contested Violation C. The contested violation is for the failure to ensure that each entrance or access point to a high radiation area has one or more of the control features described in Title 10 of the *Code of Federal Regulations* (CFR) 20.1601(a) or continuous direct or electronic surveillance that is capable of preventing unauthorized entry, as described in 10 CFR 20.1601(b). By letter dated February 8, 2019 (ADAMS Accession Number ML19039A187), the NRC acknowledged your letter and advised you that NRC staff was evaluating your response and would inform you of the results of NRC's evaluation.

The NRC has completed its evaluation of your response to the Notice of Violation. The evaluation was conducted by individuals from the Division of Reactor Safety (DRS), independent from the NRC staff in the Division of Nuclear Material Safety (DNMS) who originally identified the violation and issued the inspection report. Based on this independent evaluation, the NRC has determined that Violation C occurred as stated in the Notice of Violation. Details of the evaluation are provided in the enclosure to this letter.

In summary, with respect to the contested violation, you contended that you had in place continuous electronic surveillance that was capable of preventing unauthorized entry in accordance with 10 CFR 20.1601(b). Through its independent review, the NRC determined that while your system of limiting personnel access, electronic key cards, electronic key card readers on doors, and administrative actions appeared to be effective at preventing non-licensee individuals from accessing your licensed material, it did not provide electronic surveillance as required by 10 CFR 20.1601(b) because it did not include the continuous observation of attempted entries and the ability to prevent entry of licensee employees or escorted visitors who were not authorized to enter the high radiation area.

Additionally, the NRC independently evaluated whether the controls you described in your response would have satisfied the requirements of 10 CFR 20.1601(a). The NRC determined that your controls did not meet the requirements of 10 CFR 20.1601(a)(1) or 10 CFR 20.1601(a)(2) because you did not utilize a control device to either reduce the level of radiation to an individual or energize a conspicuous visible or audible alarm signal upon entry. The inspectors also determined that your controls did not meet the requirements of 10 CFR 20.1601(a)(3) because you did not maintain positive control over each individual entry into the high radiation area since all Zevacor Molecular radiation workers at the facility had access to the area and were not aware of the radiation hazards.

Because the NRC has concluded that Violation C is a valid violation and you did not provide specific corrective actions for this violation in your January 10, 2019, response, you are required to implement and provide corrective actions as directed in the Notice of Violation issued on December 14, 2018. Additionally, because the NRC concluded that the controls you had in place did not meet the requirements for control of a high radiation area, your corrective actions for Violation B appear to be inadequate as it is inappropriate to post an area as a high radiation area without the required controls in place. Please provide a clarification to your corrective actions for Violation B with your corrective actions for Violation C.

When preparing your response, please follow the instructions specified in the original Notice of Violation. This response is required within 30 days of the date of this letter. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your reply will be available electronically for public inspection in the NRC's Public Document Room or ADAMS. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Sincerely,

/RA/

David L. Pelton, Director
Division of Nuclear Materials Safety

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

Enclosure:
Review of Disputed Violation

Letter to Matthew Trusner from David Pelton, dated May 16, 2019.

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION; NRC INSPECTION REPORT 03038903/2018001(DNMS) – ZEVACOR MOLECULAR

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OFFICE	RIII-DNMS	C	RIII-DRS	C	RIII-DNMS	C	RIII-EICS	C
NAME	JDraper		SBell		AMcCraw		JCameron KLambert for	
DATE	04/22/2019		04/22/2019		04/22/2019		05/9/2019	
OFFICE	OE	C	RIII-DNMS	C				
NAME	JPeralta (via email)		DPelton					
DATE	05/15/2019		05/16/2019					

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**RESPONSE TO DISPUTED NOTICE OF VIOLATION
NRC INSPECTION REPORT 03038903/2018001(DNMS) – ZEVACOR MOLECULAR**

RESTATEMENT OF THE VIOLATION

Title 10 of the *Code of Federal Regulations* (CFR) 20.1601(a) states, with exceptions not applicable here, that the licensee shall 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 mSv) in 1 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 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).

SUMMARY OF LICENSEE RESPONSE

The licensee disagrees with the violation. The licensee believes it complied with 10 CFR 20.1601(b) by having continuous electronic surveillance that is capable of preventing unauthorized entry. The licensee further states that a radiation worker must go through three separate locked doors (D1, D4 and D5, respectively) to enter the high radiation area. These doors were D1 facility entrance main door; D4 entrance to the Restricted Area; and D5 entrance to the Quality Control Laboratory which contained the high radiation area. The Quality Control Laboratory is part of the Restricted Area. The licensee added that these doors remain locked as part of their electronic security system. Additionally, the licensee stated this system can in real-time, remove someone from the authorized entry list. The licensee closed by stating that control of the high radiation area was maintained.

NRC ACTIONS

The inspectors contacted the licensee to independently assess compliance with U.S. Nuclear Regulatory Commission (NRC) requirements. The discussion focused on the electronic security system referenced in the licensee's response and the basis for the licensee's assertion of compliance with NRC requirements.

The licensee described the process for controlling access within the Zevacor Molecular facility. These controlling functions included limiting personnel access, providing electronic key cards, electronic key card reader on doors, electronic database that controls the doors, and administrative functions.

Limiting Personnel and Electronic Key Cards

The building can only be accessed (Door D1) by Zevacor Molecular employees after the employee is issued an electronic key card and receives safety training, radiation safety training and radiation dosimetry. The door to the building has a camera and a door bell system that allows scheduled visitors to notify Zevacor Molecular employees upon arrival.

Electronic Key Card Readers

Doors (D4 and D5) within the building also have electronic key card readers. The doors to the building and rooms within the building remained locked until the employee presents the electronic key card to the key card readers on the outside of the door. The employee does not need to present the electronic key card to an electronic key card reader to leave the room(s).

Electronic Database

When the employee presents the electronic key card to the electronic key card reader, the electronic security system queries the electronic database. If the key card (representing the employee) is authorized for the area, then the door unlocks. If the key card is not authorized to enter the area, the key card reader buzzes to inform the person they are not authorized and creates a log of the unsuccessful attempt in the electronic database. All employees have the same level of access to all doors and can enter all areas within the facility at any time.

The licensee stated that the ability to remove a key card from the database in real-time is maintained. Additionally, the licensee stated that this electronic database feature is the distinction that defines the system as an electronic surveillance system instead of an electronic lock system.

Administrative Actions

The licensee indicated that the log of unsuccessful attempts is periodically reviewed. Although there is not a defined frequency for this review, the licensee indicated this occurs roughly on a monthly basis. Additionally, the licensee indicated that visitors, or non-employees, that need to access rooms within the building are continuously escorted by an employee with technical knowledge of the area being visited.

NRC EVALAUTION

10 CFR 20.1601(b)

The system described by the licensee seemed to be more in line with an electronic lock system, as opposed to continuous direct or electronic surveillance that is capable of preventing unauthorized entry as required by 10 CFR 20.1601(b). The inspectors reviewed several NRC documents to determine whether the NRC previously defined what constitutes electronic surveillance that is capable of preventing unauthorized entry as it pertains to compliance with Section 20.1601.

Section 56 FR 23377-23378, May 21, 1991, Statement of Consideration

Subpart G—Control of Exposure from External Sources in Restricted Areas: Proposed Sections 20.601, 20.602, and 20.603, Control of Access to High and Very High Radiation Areas [Sections 20.1601, 20.1602, and 20.1603 in This Final Rule].

Comment: Meaning of “direct surveillance.” Several Commenters thought that the term “direct surveillance” used in the proposed Section 20.601 could be interpreted to require stationing an observer at the entrance to the “high” or “very high” radiation areas.

Response: The final rule permits “... continuous direct or electronic surveillance over a high radiation area that is capable of preventing unauthorized entry ...” This removes the burden of having to station a person in or near a “radiation area,” but requires interlocks or electronic locks so that the remotely located observer may prevent entry into the area when necessary.

NUREG-1736, Consolidated Guidance: 10 CFR 20—Standards for Protection Against Radiation

20.1601, Control of Access to High Radiation Areas

Statement of Requirement:

- (b) In place of the controls required by Paragraph (a) of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance capable of preventing unauthorized entry.

Discussion:

Any licensee may use direct (visual) or electronic (e.g., closed-circuit TV) surveillance to prevent unauthorized entry into high radiation areas, instead of the controls in 20.1601(a).

Statement of Applicability:

All licensees whose possession of radioactive materials could result in accessible areas where doses in excess of 100 mrem could be received within 1 hour.

Guidance Statement:

When using electronic surveillance, the licensee must have the ability to remotely prevent entry into the area. The licensee should have the capability to warn individuals that their attempted entry is unauthorized, and then to alert the proper authorities of the improper entry attempt.

10 CFR 20.1601(a)

The licensee seemed to agree that the controls implemented at time of the inspection did not satisfy the requirements of Section 20.1601(a). However, the inspectors independently evaluated whether the electronic security system implemented would have satisfied the requirements. The inspectors reviewed NRC documents to determine whether the NRC

previously defined whether an electronic key card system was sufficient to demonstrate compliance with Section 20.1601(a).

NUREG-1736, Consolidated Guidance: 10 CFR 20—Standards for Protection Against Radiation

20.1601, Control of Access to High Radiation Areas

Statement of Requirement:

- (a) The licensee shall 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 mSv) in 1 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.

Discussion:

The regulation provides three options for controlling workers' access to high radiation areas. One or more of these options must be used. A licensee can: (1) use a control device to reduce radiation levels when a worker enters the area; (2) use an alarm to alert the worker and the supervisor of the activity when an entry is made; or (3) keep the areas locked and maintain positive control over each individual entry.

Statement of Applicability:

All licensees whose possession of radioactive materials could result in accessible areas where doses in excess of 100 mrem could be received within 1 hour.

Guidance Statement:

Access to and work within high radiation areas need to be properly controlled to protect individuals from unplanned, uncontrolled exposures that could lead to overexposures. Maintaining positive control over access to high radiation areas means limiting entries to the area only to authorized individuals who have been trained and are aware of the radiation hazards. In addition to these access controls for authorized entries, licensees use physical controls (barriers) to prevent unauthorized entries.

NRC CONCLUSION

The inspectors determined that the system of limiting personnel access, electronic key cards, electronic key card readers on doors, and administrative actions utilized by the licensee did not

meet the requirements of 10 CFR 20.1601(b) as it was not continuous direct or electronic surveillance that is capable of preventing unauthorized entry as required by 10 CFR 20.1601(b). This conclusion was based on: 1) the clarifying information provided in the Statements of Consideration for this regulation that indicate that continuous electronic surveillance requires interlocks or electronic locks so that a remotely located observer may prevent entry into the area when necessary, and 2) the guidance in NUREG-1736, which states that when using electronic surveillance, the licensee must have the ability to remotely prevent entry into the area. The electronic system utilized by the licensee appeared to be an effective system to prevent non-licensee individuals from accessing the licensed material, but the system did not provide electronic surveillance as required by 10 CFR 20.1601(b) because it did not include the continuous observation of attempted entries and the ability to prevent entry of licensee employees or escorted visitors who were not authorized to enter the high radiation area.

Additionally, the inspectors determined that the controls utilized by the licensee did not meet the requirements of 10 CFR 20.1601(a)(1) or 10 CFR 20.1601(a)(2) because the licensee did not utilize a control device to either reduce the level of radiation to an individual or energize a conspicuous visible or audible alarm signal upon entry.

Finally, the inspectors determined that the controls utilized by the licensee did not meet the requirements of 10 CFR 20.1601(a)(3) as the licensee did not maintain positive control over each individual entry. This conclusion was based on the guidance in NUREG-1736, which states that maintaining positive control over access to high radiation areas means limiting entries to the area only to authorized individuals who have been trained and are aware of the radiation hazards. At the time of the inspection, the licensee had not performed surveys to identify the high radiation area, thus the individuals who were given access to the area were not aware of the radiation hazards.

REFERENCES

1. NRC Routine Inspection Report No. 03038903/2018001(DNMS) and Notice of Violation, Zevacor Molecular, dated 12/14/2018.
2. Zevacor Molecular Response to NRC Routine Inspection Report No. 0308903/2018001(DNMS) and Notice of Violation, dated 01/10/2019.
3. Teleconference with Zevacor Radiation Safety Officer (RSO) on 02/19/2019.
4. Teleconference with Zevacor RSO on 03/07/2019.