From: Roldan-Otero, Lizette
To: Katanic, Janine
Subject: FW: Response to a Notice of Violation, NRC Inspection Report 030-37415/2021-001
Date: Thursday, January 6, 2022 3:20:22 PM
Attachments: NOV Response.pdf
image001.png

Lizette Roldán-Otero, Ph.D., Chief
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From: Amber Mellema <amellema@rockymountainoncology.com>
Sent: Thursday, January 06, 2022 1:29 PM
To: Roldan-Otero, Lizette <Lizette.Roldan-Otero@nrc.gov>
Cc: Michael Fernald <mfernald@rockymountainoncology.com>
Subject: [External_Sender] Response to a Notice of Violation, NRC Inspection Report 030-37415/2021-001

Dear Dr. Roldan-Otero,

Please find our response to the NOV letter sent by Dr. Katanic attached. The signed original of this response has been sent via separate cover as per regulation.

Regards,

ROCKY MOUNTAIN ONCOLOGY
ONE TEAM. ONE FOCUS. LIFE.

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December 30, 2021

Dr. Lizette Roldan-Otero, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76911-4511

RE: NRC Inspection Report 030-37415/2021-001; and Notice of Violation; Response to a Notice of Violation

Dear Dr. Roldan-Otero:

At Rocky Mountain Oncology, we take radioactive material safety and NRC Regulations seriously. We always strive to operate safely and by regulations.

Our response to the Notice of Violation (NOV) letter, sent by Dr. Katanic, will follow NRC Information Notice 96-28.

The NOV letter identifies:

> 10 CFR 35.643(d) requires, in part that to satisfy the requirements of 10 CFR 35.643(a), periodic spot-checks for remote afterloader units must, at a minimum, assure operation of the electrical interlocks at each remote afterloader unit room entrance.
>
> 10 CFR 35.615(b) requires, in part, that a licensee shall equip each entrance to the treatment room with an electrical interlock system that will: (1) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; (2) cause the source to be shielded when an entrance door is opened; and (3) prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed, and the source on-off control is reset at the console.
>
> Contrary to the above, from September 17, 2018, to August 18, 2021, during spot-checks, the licensee failed to assure operation of the electrical interlocks at each remote afterloader unit room entrance. Specifically, on multiple occasions between September 17, 2018, to August 18, 2021, during spot-checks of the licensee's remote afterloader unit, the licensee failed to assure operation of all three required electrical interlock system functions. On multiple occasions, the licensee only assured operation of two of the three required electrical interlock system functions, regularly failing to assure that the electrical interlock will cause the source to be shielded when the entrance door to the afterloader unit room is opened.

Our understanding of the violation is the following: Rocky Mountain Oncology failed to check all three functions listed in 10 CFR 35.615(b) while conducting checks as outlined in 10 CFR 35.643(d). Specifically, that the source becomes shielded when the door interlock circuit is triggered.

Please see our response under the template of the NRC Information Notice 96-28.

1. Conduct a complete and thorough review of the circumstances that led to the violation.

We performed a thorough review of the circumstances that led to the violation. The appropriate course of action was an interview with the Lead Physicist, Michael Fernald. For the following reasons, Mr. Fernald believed that the HDR program was following both the letter and intent of the regulation.

Understanding of 10 CFR 35.643(d):

10 CFR 35.615(b) states that "a licensee shall equip each entrance to the treatment room with an electrical interlock system that will: (1) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; (2) cause the source to be shielded when an entrance door is opened; and (3) prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed, and the source on-off control is reset at the console."

The HDR unit and vault at Rocky Mountain Oncology operate with an electrical interlock system per 10 CFR 35.615(b).

The NRC does not define Interlock, Electrical Interlock, or Electrical Interlock System in 10 CFR 20.1003 Definitions (§ 20.1003 Definitions. | NRC.gov, Accessed 12/13/2021). Mr. Fernald used the general understanding as well stated by Collins Discovery Encyclopedia. "A device, esp one operated electromechanically, used in a logic circuit or electrically safety system to prevent an activity being initiated unless preceded by certain events (Interlock (engineering). (n.d.) *Collins Discovery Encyclopedia, 1st edition.* (2005)).

A reasonable understanding of the electrical interlock is (1) a device operated electromechanically and (2) a component of, but not the entire system. 10 CFR 35.615(b) uses the phrase "electrical interlock system."

The wording of 10 CFR 35.643(d) differs from 10 CFR 35.615(b) by not using the word "system."

Regulation Code	Regulation Text
10 CFR 35.643(d)	periodic spot-checks for remote afterloader units must, at a minimum, <u>assure operation of the electrical interlocks at each remote afterloader unit room entrance</u>.
10 CFR 35.615(b)	a licensee shall equip each entrance to the treatment room with an <u>electrical interlock system</u>

10 CFR 35.643(d) does not refer to the electrical interlock system, but specifically to the electrical interlocks at each remote afterloader unit room entrance.

There is only one entrance to the HDR room at Rocky Mountain Oncology. By Rocky Mountain Oncology's HDR Procedure, we perform a check each treatment day of the "electrical interlock" at the afterloader unit room entrance, per 10 CFR 35.643(a)(1). As a natural consequence, the check also verifies at least a portion of 10 CFR 35.615(b). This type of check is understood as the "spot-check."

Unfortunately, the NRC does not define 'spot-check' in 10 CFR 20.1003 Definitions (§ 20.1003 Definitions. | NRC.gov, Accessed 12/13/2021).

A reasonable understanding of "spot-check" is an abbreviated procedure.

For example, Washington State's Administrative Code chapter on Radiation Protection – X-rays in the Healing Arts defines spot-check as the following: (92) Spot check means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid (WA.gov https://apps.leg.wa.gov/wac/default.aspx?cite=246-225&full=true&pdf=true) (Accessed 12/13/2021).

As Dr. Katanic noted during her inspection, but not in the NOV letter, in all cases, staff checked two of the three items of the "electrical interlock system" by checking the "electrical interlock at each remote afterloader unit room entrance" during every periodic check. All three interlock system modes are validated at a minimum at each source exchange by the vendor, Varian Medical Systems.

It is understood that 10 CFR 35.643(d)(1) can be used to confirm requirements of 10 CFR 35.615(b). In other words, if you check the electrical interlock at the door, you are checking part of the electrical interlock system. The NOV letter states, "10 CFR 35.643(d) requires, in part, that to satisfy the requirements of 10 CFR 35.643(a), periodic spot-checks for remote afterloader units must, at a minimum, assure operation of the electrical interlocks at each remote afterloader unit room entrance."

The regulation 10 CFR 35.643 Periodic spot-checks for remote afterloader units (accessed 12/13/2021) is written as:

> (a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--
>
> (1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;
>
> (2) Before each patient treatment with a low dose-rate remote afterloader unit; and
>
> (3) After each source installation.
>
> (b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
>
> (c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
>
> (d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--
>
> (1) Electrical interlocks at each remote afterloader unit room entrance;
>
> (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
>
> (3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
>
> (4) Emergency response equipment;
>
> (5) Radiation monitors used to indicate the source position;
>
> (6) Timer accuracy;
>
> (7) Clock (date and time) in the unit's computer; and
>
> (8) Decayed source(s) activity in the unit's computer.
>
> (e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
>
> (f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

10 CFR 35.643 does not state that it requires a licensee to check each of 10 CFR 35.615(b) as evidence of fulfilling 10 CFR 35.615(b) or fulfillment of 10 CFR 35.643. This is conflicting with the violation and is more evidence that Mr. Fernald believed that the program was appropriately setup and administered in accordance with the regulations.

Conclusion from the interview:

It is clear to me that because Rocky Mountain Oncology's equipment is equipped with an electrical interlock system, we felt we met 10 CFR 35.615(b). We also felt we met 10 CFR 35.643(b) because we tested the "electrical interlock at the afterloader unit room entrance" each day before the first treatment.

2. Identify the root cause of the violation

From the interview with Mr. Fernald, I determined that the root cause of the violation was a disagreement in interpretation. Mr. Fernald believed that regulations were being followed both in letter and intent.

Considerations in evaluating the root causes of the violation:

1. Has management been informed of the violation(s)?
   Yes, management has been informed.

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
   Yes, the RSO has been tasked with reviewing the regulations in 10 CFR 35.600.

3. Have precursor events been considered and factored into the corrective actions?
   Yes, there are no precursor events at Rocky Mountain Oncology to factor into the corrective actions.

4. In the event of a loss of radioactive material, should security of radioactive material be enhanced?
   This violation is not in regard to a loss of material.

5. Has your staff been adequately trained on the applicable requirements?
   Yes, the staff was trained adequately and was adhering to the procedure at the time in question. The procedure was faulty.

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
   Personnel has been re-trained on the new procedure. Yes, testing has been determined to be adequate.

7. Has your staff been notified of the violation and of the applicable corrective action?
   Yes, the staff has been notified and re-trained on the applicable corrective action.

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
   Yes, audits are detailed and frequently performed. The HDR treatments are reviewed by an Authorized User annually and a Radiation Safety Audit reviews HDR paperwork annually. Because Rocky Mountain Oncology felt it was meeting the requirement, additional audits would not have addressed this issue.

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
   We feel this would be of merit and are investigating retention of an independent consultant.

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed.
    Yes, a new procedure is required. It was developed and staff was trained on the new procedure.

11. Is a system in place for keeping abreast of new or modified NRC requirements?
    This violation is not the result of a new or modified NRC requirement.

12. Does your staff appreciate the need to consider safety in approaching daily assignment?
    Yes, the staff is very cognizant of safety.

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety office been provided sufficient time and resources to perform his or her oversight duties?
    Yes, resources are adequate in all ways, and the radiation safety officer has been provided sufficient time and resources.

14. Have work hours affected the employees' ability to safely perform the job?
    All employees are allotted appropriate work hours.

15. Should organization changes be made (e.g. changing the reporting relationship of the radiation safety officer to provide increased independence)?
    No organizational changes were identified.

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities?
    Do supervisors adequately observe new employees and difficult, unique, or new operations?
    Yes, management and the radiation safety officer are very involved in oversight and implementation of the licensed activities. Supervisors observe new employees and activities that are out of the normal.

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
    Yes, the work environment at Rocky Mountain Oncology is very conducive to reporting concerns.

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
    This is not a concern. Management is very committed to compliance and safety.

19. Has management communicated its expectations for safety and compliance?
    Yes. This was re-communicated during the training of the new procedure.

20. Is there a published discipline policy for safety violations and are employees aware of it? Is it being followed?
    Yes, there is a published discipline policy for safety issues and employees are aware of it. Yes, it is being followed.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

As of December 13, 2021, the HDR daily treatment warm-up procedure has been updated to include the following checks all of the time, instead of a subset:

- Prevent the operator from initiating the treatment cycle unless the treatment room entrance door is closed
- Cause the source to be shielded when an entrance door is opened
- Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console

Additionally, an in service training was performed December 15, 2021 and December 21, 2021 outlining the changes in procedure to meet compliance.

The reason for this violation was the belief that the regulations were being followed in letter and intent. The corrective steps taken were a change in policy and a re-training of the new policy. The date of the new policy (December 13, 2021) and training on the new policy (December 15 and 21, 2021). No HDR treatments were performed between December 13 and the date of this letter. Full compliance to the new policy is expected for all future HDR treatments. Full compliance based on the updated policy and training was achieved December 15, 2021.

Respectfully submitted,

Amber Mellema
Regional Director of Operations/Business Development