

**Wyoming**  
Medical Center

December 27, 2016

Michael Fernald, RSO  
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1233 East 2<sup>nd</sup> St.  
Casper, WY 82601

U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington DC, 20555-0001

RE: Response to an Apparent Violation in NRC Inspection Report 030-03295/2016-001;  
EA-16-231

Dear Sir or Madam:

This letter is in response to an apparent violation during the inspection on September 20, 2016 conducted by Mr. Jason VonEhr and Mr. James Thompson. The apparent violation, which we do not deny, is centered around incompletely filled out written directives.

As noted in the report, the written directives did not contain all information that is required by 10 CFR 35.40(b)(6). Noted in the report, the discrepancy was noticed in early 2016 and a new written directive form was created. Also, noted in the report, is that there have been no deficiencies with the new written directive form. Lastly, noted in the report, the deficiencies did not result in patient care being compromised.

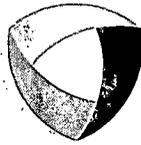
Regarding points 1-4 in paragraph two of the second page of the letter dated December 6, 2016:

(1) The reason for the apparent violation:

Written directives were not fully filled out. The reason for this is rooted in the form that was being used. The form was a hold-over from a time when Wyoming Medical Center performed Cesium implants. It contained the relevant information for both permanent LDR brachytherapy as well as temporary implants. The confusion between which pieces of information to fill out for which procedure was the root cause of the form containing deficiencies at the time of inspection.

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(2) The corrective steps that have been taken and the results achieved:

The written directive not being fully filled out was noticed by the radiation safety officer. Noticing this discrepancy, a new form was created in the spring of 2016. This written directive was put into use immediately and has had 100% compliance and accuracy in its use since the inception.

(3) The corrective steps that will be taken:--

The corrective actions have been in place since the spring of 2016.

(4) The date when full compliance will be achieved:

Compliance was achieved March of 2016.

Under the guidance of NRC Information Notice 96-28 found at <http://www.nrc.gov/docs/ML0612/ML061240509.pdf>, the following comprehensive corrective action is developed.

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

Around the spring of 2016, the radiation safety officer identified that the brachytherapy program was not achieving 100% compliance on information needed in the written directive. The first impression of the RSO was that the written directive form was confusing; and that was a primary contributor to the problem. Additionally, at the time the radiation safety officer identified lack of compliance, training was provided to the individuals involved in the brachytherapy program as to what is required on a written directive, when that information is required, and who is responsible for that information.

Noticing the lack of 100% compliance led to a complete and thorough review of the circumstances that led to the violation was performed over the course of a few months, starting in March, 2016 (prior to the inspection by Mr. vonEhr in September, 2016).

At the time of the review it was noticed by the radiation safety officer that the written directives were not achieving 100% compliance with the required information. A review of every written directive dating beyond the written directives in question was conducted.

The review conducted noticed that a given piece of information that may be missing from a written directive was not dependent on any variable. This led the radiation

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safety officer to believe that the lack of compliance was not the result of an intentionally non-compliant individual.

Conversations with individuals consistently showed that the form used for the written direction caused confusion.

Because of the randomness of missing information and conversations with individuals, it was concluded that the written directive form was the cause of the lack of compliance. This conclusion was further bolstered by the fact that written directive compliance has been 100% since the creation and implementation of the new written directive form in March, 2016.

2. Identify the root cause of the violation:

The root cause of the violation was identified to be the confusing nature of the outdated written directive form.

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

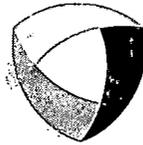
Immediate actions were taken in March of 2016 when the problem was identified. That immediate action included updating the written directive form as well as additional corrective training.

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

Management was notified of the apparent violations during the exit interview with Mr. vonEhr and Mr. Thompson. Additionally, the Radiation Safety Committee was notified during a quarterly Radiation Safety Committee Meeting which took place at the end of September, 2016.

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?

The programmatic implications of the cited violation and the presence of similar weaknesses in other program areas has been considered in formulating the corrective actions. This was done during the review phase of the investigation starting in March, 2016 when all aspects of the LDR Brachytherapy program were reviewed. Additionally, conversations surrounding the violation and other aspects of the radiation safety program were discussed with an independent medical physics consultant.



3. Have precursor events been considered and factored into the corrective actions?

Precursor events were considered and factored into the corrective actions. This was done by addressing the written directive form itself.

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

Not applicable; radioactive material was not lost.

5. Has your staff been adequately trained on the applicable requirements?

The staff and physicians have been trained on the applicable requirements. After using the new form and training, the compliance has been 100%.

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 were re-trained in March 2016 regarding all aspects of the LDR brachytherapy program including information required on the written directive. Additionally, testing is adequate to ensure the understanding of requirements and procedures.

7. Has your staff been notified of the violation and of the applicable corrective action?

Staff was notified of the apparent violation on September 20, 2016, the date of the inspection. Additionally, the applicable corrective action was implemented prior to the citation.

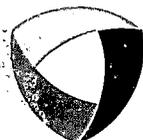
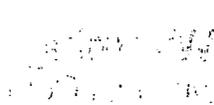
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

Audits are sufficiently detailed and frequently performed. After discussing this LDR brachytherapy programs with two consulting medical physicists, continuing quarterly audits are the recommended frequency.

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9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

We feel that audits by the RSO are sufficient and that an independent technical consultant to audit the area is not required at this time. Our procedures were revised in March of 2016 when use of the new written directive form was implemented. Additionally, the radiation safety officer will be attending remedial training within the next 12 months.

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed.

The new procedures are consistent with current NRC requirements. A new procedure (written directive form) was created and implemented in March of 2016. At this time, no additional clarification is required.

11. Is a system in place for keeping abreast of new or modified NRC requirements?

A system is in place for keeping abreast of new or modified NRC requirements. It includes reviewing all mailings from the NRC as well as periodically reviewing the NRC website.

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

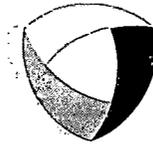
The staff does appreciate the need to consider safety in approaching daily assignments. This is represented by their willingness to use the new written directive form, achieving 100% compliance.

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

The radiation safety officer has been provided sufficient time and resources to perform his duties. As well, the resources are adequate to perform and maintain control over the licensed activities.

14. Have work hours affected the employees' ability to safely perform the job?

Work hours have not affected employees' ability to safely perform the job.



15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

Organizational changes are not required at this time.

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?

Management and the radiation safety officer are adequately involved in oversight. This is evidenced by the radiation safety officer finding the problem in March of 2016. Supervisors have had the importance of this issue stressed and, in turn, stressed its importance to employees.

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

Compliance and safety concerns are encouraged to be reported by all employees.

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

Management has not placed a premium on production over compliance. Management does demonstrate and encourage compliance and safety.

19. Has management communicated its expectations for safety and compliance?

Management has clearly communicated its expectations for safety and compliance.

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

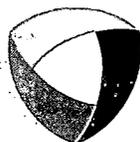
There is a published discipline policy that employees are aware of and is being followed.

When this issue was noticed in the spring of 2016, it was dealt with and corrected swiftly. This correction not only included a new written directive form, but also training for individuals involved in the LDR brachytherapy program. Since the correction was made, the compliance of our written directives has been 100%, which we feel is proof that the problem was addressed in a correct and comprehensive manner.

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The swiftness and manner in which this problem was addressed, we hope, provides evidence to you that it was recognized to be a serious and important issue to resolve by us. Additionally, the radiation safety officer will be attending remedial training within the next 12 months.

We apologize this was an issue and we will take this as a learning experience for our institution.

Respectfully submitted,

Michael Fernald, RSO

Cc: Director Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region IV

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