

From: [Roldan-Otero, Lizette](#)
To: [Traci Hollingshead](#)
Subject: Confirmatory Order and NRC Investigation Report 4-2019-007 - IA-21-061
Date: Wednesday, August 24, 2022 10:17:00 AM
Importance: High

ADAMS Accession no. ML22241A067

Dear Traci Hollingshead –

We have completed the review for the presentation submitted to ensure it meets the criteria set forth in the Confirmatory Order. Here is the assessment:

The order states that the training provided will include at least the following 5 criteria:

- Criteria 1 – a summary of the events that led to the discovery of physically modified dose calibrators at Avera McKennan
- Criteria 2 – the importance of compliance with NRC regulations
- Criteria 3 – the consequences of engaging in willful violations
- Criteria 4 – what to do if there is a perceived or actual medical issue that conflicts with NRC regulations
- Criteria 5 – any personal lessons-learned associated with this issue

Summary of Review:

- Criteria 1 is satisfied in slides 24-26 of presentation.
- Criteria 2 is satisfied in slide 28 of presentation.
- Criteria 3 is satisfied in slide 29 of presentation.
 - Comment – Slide 29 is missing that the NRC can take an action of referring cases to DOJ during or upon completion of an OI investigation involving will violations for potential criminal prosecution.
- Criteria 4 is satisfied in slide 31 of presentation.
 - Comment – “The NRC will direct you to a person who will advise on how to proceed.” This comment on Slide 31 gives the impression that the NRC will consult with the licensee and the whole order of the slide seems to put the onus on the NRC.
 - Comment – Consider reorganizing the content of slide 31 to not only list but actually provide instruction on what should be done (in chronological order) once a perceived or actual medical issue that conflicts with NRC regulations is discovered. For example, stopping work and ensuring the safety of the patients and staff should be done prior to contacting the supervisor and RSO.
- Criteria 5 is quasi-satisfied in the sense that there is a slide titled lessons learned (slide 32) but does not discuss any personal lessons learned associated with this issue.
 - Comment – Add any personal lessons learned associated with this issue.

Let me know if you wish to discuss further.

Thanks,

Lizette Roldán-Otero
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