

Katanic, Janine

From: Fairbanks, Jeff PhD <fairbanj@slhs.org>
Sent: Friday, January 12, 2018 5:22 PM
To: Katanic, Janine
Cc: Parkinson, Mark; Vanderpool, Jodi; Hay, Michael
Subject: [External_Sender] Reply to Notice of Violation
Attachments: Reply to Notice of Violation EA-17-181.pdf

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Dr. Katanic, attached is the reply to the notice of violation for the two Level IV violations. Please feel free to contact myself, Mark or Jodi regarding any clarifications or follow up you would like on this response. I have also included Mike Hay on this email because he is the one who sent me the letter on Decemer 15, 2017.

Thank you,

Jeff

Jefferson Fairbanks, PhD
Radiation Safety Officer
St. Luke's Health System

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Director, Division of Nuclear Materials Safety
Region IV
1600 East Lamar Blvd
Arlington, Texas 76011-4511

DNMS

January 12, 2018

Reply to a Notice of Violation; EA-17-181

Please find enclosed the response of St. Luke's Regional Medical Center to the Notice of Violation issued by the Nuclear Regulatory Commission and identified as EA-17-181. We take the survey findings very seriously and appreciate the opportunity to describe the actions we have and will take to ensure that we strictly comply with Nuclear Regulatory Commission Rules ("NRC") going forward. We would welcome any feedback the NRC may have with respect to our response that could help us further develop our programs and processes to ensure compliance.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Parkinson", written in a cursive style.

Mark Parkinson
Administrator – Mountain States Tumor Institute
St. Luke's Regional Medical Center

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington D.C. 20555-0001

Director, Division of Nuclear Materials Safety
Region IV
1600 East Lamar Blvd
Arlington, Texas 76011-4511

January 12, 2018

Reply to a Notice of Violation; EA-17-181

This letter is a response to the Severity Level IV violations identified in the letter received by the NRC dated December 14, 2017.

- 1) **Violation:** “The failure to assure operation of the electrical interlocks at a remote afterloader unit room entrance”

Reason for the violation:

Failure of the physicist to perform HDR QA according to St. Luke’s written checklist and NRC requirements. The physicist indicated that she had changed her practice to activating the door interlock while the “dummy source” was extended rather than while the radioactive source was extended due to concerns about radiation exposure during the time while she was pregnant. Following her pregnancy, she had forgotten to return to the previous method of QA.

Corrective steps that have been taken and results achieved:

- September 2017 – Immediately, at the time of finding, intervention to include testing with active source was implemented.
- September 2017 – The Radiation Safety Officer educated the physicist whose failure to follow the checklist and NRC requirements was identified during the survey that performing HDR QA in the required manner posed no risk to a developing fetus or to the physicist herself.
- September 2017 – The Radiation Safety Officer engaged with each of the physicists regarding the St. Luke’s checklist and the NRC Rules. This included the requirement to activate the door interlock while the active source is extended. Each physicist confirmed they would follow – and, in the case of physicists other than the one observed during the survey,

had been following – regulatory requirements to include the active source during testing procedure.

- January 2018 – Clarified checklist to indicate door interlock test is to be performed with the active source rather than dummy source.
- January 2018 – Radiation Safety Officer provided additional training to physicists including formal competency assessments. (Training and competency will be completed annually.)
- January 2018 – Supervisor(s) of Physics Department will meet annually (and when changes with rules and regulations occur) with Radiation Safety Officer. The meeting will include review of and compliance with current standards.

Corrective steps that will be taken to avoid further violations:

- Annual competency documentation will include the full QA procedure form with signoff by the assessor.
- Periodic observation audits of “periodic spot-checks for remote afterloader units” by the Radiation Safety Officer will take place and a report will be submitted annually to the Radiation Safety Committee for review.
- Minutes from Supervisor(s) meeting with Radiation Safety Officer meeting will be reported to the Radiation Safety Committee annually.

Date when full compliance was achieved:

- Full compliance: September 1, 2017
- Additional education and enhancements completed – January 2018

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- 2) **Violation:** “The possession and use of byproduct material in permanent implant brachytherapy sealed sources with model numbers that were not authorized to be possessed and used under your NRC license”

Reason for the violation:

Failure of communication between the Radiation Safety Officer and the medical physicist to get the new radioactive seed model added to the license. Physicist did not read the license to verify new seed had been added before submitting to the seed vendor.

Corrective steps that have been taken and results achieved:

- September 2017 – Radiation Safety Officer submitted amendment request to NRC to add the model number of the brachytherapy seed to St. Luke's NRC license.
- December 2017 – Date of amendment letter received from NRC (December 26, 2017). – NRC Amendment #74 – 12-26-2017.

Corrective steps that will be taken to avoid further violations:

- January 2018 – Ordering physicist will review license at time of order and verify model number is on license. Order will not take place if model number is not on license. Instated checklist for ordering seeds to prompt and document this review at the time of order. This will enhance communication between physicist and Radiation Safety Officer.
- Radiation Safety Officer will audit review process and send report to Radiation Safety Committee annually.

Date when full compliance was achieved:

- December 26, 2017 (date of the amendment letter from NRC).

Please contact me with any further clarifications needed regarding these violations.

Sincerely,



Jefferson Fairbanks, PhD
Radiation Safety Officer, St. Luke's Health System
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