



Mountain View  
Hospital

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Dr. Janine Katanic  
NRC Site Inspector  
NRC Region IV

Regarding the Site Inspection of Mountain View Hospital (Lic# 11-35120-01)

Dr. Katanic,

We are writing to you to update you regarding the inspection that you just completed and the preliminary findings that you discussed with us during the exit interview you provided.

We are genuinely concerned regarding the multitude of findings surrounding our Lutathera program. While we recognize that your findings were only preliminary, that the preliminary findings required no immediate actions on our part, and that any actions we take today may require additionally actions in the near future once your final report has been provided to us; we wanted to take immediate actions that will prevent any further infractions as we continue to work toward a final resolution regarding the preliminary findings and final report.

We quickly called a meeting that included executive administration, departmental directors, and clinical staff that included David Theel, the RSO for Mountain View Hospital, Ned Hillyard, Chief Clinical Op/Compliance Officer, Marian Walker, Chief Nursing Officer, Amy Larsen, Director of Ancillary Services, and Lisa Anderson, Manager of Medical and Radiation Oncology. David Theel described the findings regarding the Lutathera program and reaffirmed his decision to indefinitely suspend all Lutathera activities at both Teton Cancer Institute and Mountain View Hospital effective as of November 17, 2020 in the email from Debra Fuelling, Supervisor of Radiation Oncology.

A discussion along with a formal notice letter was sent to Idaho Falls Community Hospital, to inform them that the Lutathera program was indefinitely suspended, and that no further patients would be sent to them for Observation and Lasix protocols.

As Dr. Katanic has demonstrated, this program was ill-conceived in its development from the beginning. The staff training and education was inappropriate or completely missing. The patient treatment process was not thoroughly thought through, and appropriate management of patient care was never fully discussed, documented, and implemented. Contingencies for poor patient clearance or emergent medical needs were developed outside of the appropriate hospital mechanisms and did not include the Radiation Safety Committee, the hospitals comprehensive expertise of professionals in various departments, nor the appropriate documentation of the decision points that were implemented.

The shortcomings of this program are many and exist to at least some extent in all phases of the program, and so the decision has been made to recreate the program from the ground up. We will



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begin immediately on recreating the policy and procedures surrounding this program, the education materials for the various staff members that will be working with this program, the training of those individuals through vendor specific training and facility specific training, and all of this will go through the hospital's existing mechanisms to ensure that the concerns regarding the Lutathera program are addressed and resolved.

We understand that the findings presented by Dr. Katanic at the exit interview were preliminary, but we feel that the glaring deficiencies offer us an opportunity to immediately begin to make programmatic corrections. We fully realize that when the final report is complete that there may be additional findings to address, however, as this program is important to our physicians and community, we find no reason to delay in creating a robust and comprehensive response to the findings that were preliminarily presented to us.

Additionally, we will be discussing the role of the Radiation Safety Committee at our next meeting and rededicating ourselves to creating a comprehensive forum where the meeting of experts within various fields will encourage productive discussions in the future that will hopefully intervene to prevent future programmatic short comings from being developed. We will reaffirm that the Radiation Safety Committee is the forum for decision points and programmatic changes are to be meaningfully discussed and documented. We will also look at how the Committee can be expanded to include expertise from other departments so that a more robust review of the issues might avoid a recurrence of these issues in the future.

The Mountain View Hospital staff will continue to meet as we develop these new processes, policies and procedures, as we disassemble the ineffective silos that became such a daunting barrier, and as we learn from the mistakes that we have made in this programs implementation to create a new and better Lutathera program that will serve our community.

We will keep you and the NRC appraised of the changes that we are making here at Mountain View Hospital as we await the final report and findings.

Thank you very much for your time and attention as we work toward making our facility safer for staff, patients, and the public.

David Theel, DABR  
Idaho Falls Community Hospital  
Radiation Safety Officer

Ned Hillyard Ph.D., Chief Clinical Op/ Compliance Officer  
Mountain View Hospital

## Katanic, Janine

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**From:** David Theel <dtheel@tetoncancer.com>  
**Sent:** Monday, November 23, 2020 1:36 PM  
**To:** Katanic, Janine; David Theel  
**Cc:** Ned Hillyard  
**Subject:** [External\_Sender] MVH Response Letter to Inspection 11/16  
**Attachments:** MVH Response to NRC Inspection 11-16.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Hello Dr. Katanic,

As I mentioned Thursday afternoon, the executive administrators for Mountain View Hospital directed me to send an immediate response to the preliminary findings of your site inspection from 11/16/2020.

If you have any questions, or would like any additional information, please do not hesitate to contact me.

I look forward to working toward a successful resolution of all outstanding issues once the final report is released.

Thank you,  
David Theel, DABR  
Radiation Safety Officer