



Banner Health

Denali Center

Fairbanks Memorial Hospital

1650 Cowles Street
Fairbanks, AK 99701
Phone 907-452-8181
Fax 907-458-5324
www.fmhdc.com

September 7, 2016

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

SUBJECT: REPLY TO A NOTICE OF VIOLATION IN THE NRC INSPECTION REPORT 030-03509/2016-001

Dear Mr. Kellar:

Pursuant to the provisions of 10 CFR 2.201, Fairbanks Memorial Hospital provides this response to the above referenced letter regarding the inspection conducted on June 23, 2016 and associated Notice of Violation.

The U.S. Nuclear Regulatory Commission (NRC) conducted an unannounced inspection on June 23, 2016. As a result of the inspection, The NRC determined that one Severity Level IV Violation (Section 6.3.d) of NRC requirements occurred. The violation involved a failure to follow NRC regulations in regards to written directives dated and signed by an authorized user before administration of any therapeutic dose of radiation from byproduct material and failed to ensure that the before implantation written directive contain the treatment site and radionuclide.

10 CFR 35.40(a) requires, in part, that written directives be dated and signed by and authorized user before the administration of any therapeutic dose of radiation from byproduct material.

10 CFR 35.40(b)(6) requires, in part. that the written directive must contain the patient or human research subject's name and for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) before implantation: treatment site, the radionuclide, and dose, and (ii) after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Pursuant to 10 CFR 35.40(a) and 10 CFR 35.40 (b)(6)

REPLY:

Fairbanks Memorial Hospital has taken corrective action to insure compliance with the NRC. Our written directives have been modified to a "Planned Written Directive" and a "Delivered Written Directive."

The Planned Written Directive follows the NRC guidelines 35.40 of the before implantation, to include but not limited to the treatment site, radionuclide, and dose. The Planned Written Directive will be signed and dated by both the authorized user and the Physicist.

A Delivered Written Directive has been created for the after implantation aspect of the process. The new Delivered Written Directive will include but not limited to, the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose). This form will be signed and dated after implantation but, before completion of the procedure by the authorized user.

JED7
RGN-1V

The new forms for both written directives will be adopted and implemented immediately. Both forms are enclosed for your review. Management has communicated with Staff to implement the new process.

To further adopt better safety measures, the brachytherapy Intra-Operative Grid Form will now include the date and signatures of both the authorized user and the Radiation therapist. This will improve patient safety, incorporating the team approach that all parties are on the same level of understanding during the procedure.

To insure that Fairbanks Memorial Hospital is compliant in all matters with its Brachytherapy Seed Implant program, an Audit Check List has been created to insure that all forms and documentation are completed during the actual process from start to finish.

Fairbanks Memorial Hospital appreciates the time the NRC has taken to help us correct any issues that might prevent us from giving the best patient care. Should you have any questions regarding this letter or the enclosed documents, please contact me at 907-458-5310.

Sincerely,



Karl Sanford
Associate Administrator, Professional Services
Fairbanks Memorial Hospital

Docket: 030-03509
License: 50-13648-01

Enclosures:

Reply to a Notice of Violation in the NRC Inspection Report 030-03509/2016-001
Planned Written Directive
Delivered Written Directive
Intra – Operative Grid Form
Brachytherapy Seed Implant Audit Check List

cc w/Enclosures:

Clyde E. Pearce, Chief
Radiological Health Program
Section of Laboratories
State of Alaska/DH&SS
5455 Dr. Martin Luther King, Jr., Ave.
Anchorage, AK 99507-1207

Dr. Greg Johnson, CEO
Fairbanks Memorial Hospital
1650 Cowles Street
Fairbanks, AK 99701

Regional Administrator
Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011