



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

January 23, 2017

EA-16-231

Mr. Chad Pew, Senior Vice President
and Chief Operating Officer
Wyoming Medical Center
1233 East Second Street
Casper, WY 82601

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-03495/2016-001

Dear Mr. Pew:

This letter refers to the routine, unannounced inspection conducted on September 20, 2016, at your facility located in Casper, Wyoming. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety, the common defense and security, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel.

In the NRC letter dated December 7, 2016, (Agencywide Documents Access and Management System (ADAMS) ML16298A224) transmitting the subject inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated December 27, 2016, (ML17009A081) Mr. Michael Fernald (your radiation safety officer) provided a response to the apparent violation.

Based on the information developed during the inspection and the information that you provided in response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to ensure that certain written directives included all required information after the administration of therapeutic doses of radiation from byproduct material.

Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40 requires that written directives for therapeutic doses of radiation from byproduct material contain certain information to ensure that the administration is carried out in accordance with the physician's orders. The NRC considers that a programmatic failure to comply with these requirements merits consideration for escalated enforcement action. Although there were no medical events or other actual consequences identified as a result of the failure to comply with the requirements, there was a

significant potential for such consequences. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,000 is considered for a Severity Level III violation.

Because Wyoming Medical Center has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Based on the commitments documented in the letter dated December 27, 2016, the NRC has concluded that *Corrective Action* credit is warranted. These commitments included revision of the written directive forms to remove information that is not required so that it is easier to complete, and retraining of all personnel on the new forms and the regulatory requirements, to include the radiation safety officer.

Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject your facility to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the letter from you dated December 27, 2016. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, should you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

C. Pew

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If you have any questions concerning this matter, please contact Mr. Ray Kellar of my staff at 817-200-1191.

Sincerely,


Kriss M. Kennedy
Regional Administrator

SCOTT A. MORRIS
(ACTING)

Docket No. 030-03495
License No. 49-00152-02

Enclosure: Notice of Violation

cc:
Scott Ramsay
Wyoming Office of Homeland Security
Radiological Services Manager
5500 Bishop Blvd.
Cheyenne, WY 82009

NOTICE OF VIOLATION

Wyoming Medical Center
Casper, Wyoming

Docket No. 030-03495
License No. 49-00152-02
EA-16-231

During an NRC inspection conducted on September 20, 2016, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(b)(6) requires, in part, that written directives must contain, for brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) before implantation: treatment site, the radionuclide, and the 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).

Contrary to the above, between January 15 and December 22, 2015, the licensee failed to prepare written directives that contain, for brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) before implantation: treatment site, the radionuclide, and the 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). Specifically, on 15 occasions the licensee prepared after implantation written directives that were missing the number of sources and the total strength, and in some of the 15 occasions, the post implantation written directives were missing the radionuclide and total dose.

This is a Severity Level III violation (NRC Enforcement Policy Section 6.3.c.2).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in your letter dated December 27, 2016, (ML17009A081).

However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-16-231," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 23rd day of January 2017

Enclosure

Notice of Violation and NRC Inspection Report 030-03495/2016-001 dated January 23, 2017.

DISTRIBUTION:

Kriss.Kennedy@nrc.gov;
Scott.Morris@nrc.gov;
Mark.Shaffer@nrc.gov;
Michael.Hay@nrc.gov;
Leela.Sreenivas@nrc.gov;
Kerstun.Norman@nrc.gov;
Jenny.Weil@nrc.gov;
Jeremy.Bowen@nrc.gov;
Juan.Peralta@nrc.gov;
Anthony.Huffert@nrc.gov;
John.Tappert@nrc.gov;
 RidsOgcMailCenter Resource;
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 R4Enforcement;

Karla.Fuller@nrc.gov;
Bill.Maier@nrc.gov;
Linda.Howell@Nrc.gov;
S.Woods@nrc.gov;
Casey.Aldredge@nrc.gov;
Andrea.Kock@nrc.gov;
Michele.Burgess@nrc.gov;
Glenn.Tracy@nrc.gov;
Scott.Moore@nrc.gov;
Bill.VonTill@nrc.gov;
 RidsOeMailCenter Resource;
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 RidsSecyMailCenter Resource;
 EDO_Managers;

Patricia.Holahan@nrc.gov;
Francis.Peduzzi@nrc.gov;
Nick.Hilton@nrc.gov;
John.Kramer@nrc.gov;
Victor.Dricks@nrc.gov;
Russell.Arrighi@nrc.gov;
Angel.Moreno@nrc.gov;
Marc.Dapas@nrc.gov;
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SUNSI Review By: JEV1		ADAMS X Yes <input type="checkbox"/> No	X Publicly Available <input type="checkbox"/> Non-Publicly Available		X Non-Sensitive <input type="checkbox"/> Sensitive	Keyword: EA-16-231	
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SIGNATURE	/RA/	/RA/	/RA/	JK for	/RA/	/RA/	/RA/ SAM for
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