UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

December 7, 2016

EA-16-231

Ms. Jane Nixon
Senior Vice President of Patient Care Services
And Chief Nursing Officer
Wyoming Medical Center
1233 East Second Street
Casper, WY 82601

SUBJECT: NRC INSPECTION REPORT 030-03495/2016-001

Dear Ms. Nixon:

This letter refers to the routine, unannounced inspection conducted on September 20, 2016, at your facility located in Casper, Wyoming, with reviews of additional data provided by your staff through November 9, 2016. 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 examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

The inspectors discussed the preliminary inspection findings with you and members of your staff on September 20, 2016, at the conclusion of the on-site portion of the inspection. A final exit briefing was conducted telephonically with you and Michael Fernald, the Radiation Safety Officer, on November 9, 2016. The enclosed report presents the results of this inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent 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. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action was discussed with you and Mr. Fernald during the inspection exit briefing on November 9, 2016.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on you confirming on the license docket (i.e., in writing) that the corrective actions previously described to the NRC staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond, in writing, to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC, please contact Mr. Ray Kellar, P.E., Chief, Nuclear Materials Safety Branch A, at 817-200-1191, within 10 days of the date of this letter to notify us of your intentions. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in NRC Inspection Report 030-03495/2016-001; EA-16-231," and should include for the apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, TX 76011-4511 within 30 days of the date of this letter. If an adequate response is not received within the time specified and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find an updated excerpt from NRC Information Notice 96-28 on the NRC Web site at http://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and the enclosed inspection report 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.

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

Sincerely,

/RA by VHCampbell Acting For

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

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

Enclosure: NRC Inspection Report 030-03495/2016-001

cc w/enclosure:
Wyoming Radiation Control Program Director

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Sincerely,

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cc w/enclosure:
Wyoming Radiation Control Program Director

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ADAMS ACCESSION NUMBER: ML16298A224

X SUNSI Review By: **JEV1**		ADAMS X Yes ☐ No	X Publicly Available ☐ Non-Publicly Available		X Non-Sensitive ☐ Sensitive		Keyword: EA-16-231
OFFICE	NMSB-A	NMSB-A	C:NMSB-A	RIV:ACES	TL:ACES	RC	D:DNMS
NAME	JEvonEhr	JLThompson	RLKellar	CCAlldredge	MCHay	KSFuller	MRShaffer
SIGNATURE	**/RA/**	**/RA/**	**/RA/**	**/RA/**	**/RA by JGKramer Acting for/**	**/RA by D Cylkowski Acting For/**	**/RA by VHCampbell Acting For/**
DATE	10/25/16	10/25/16	11/07/16	11/10/16	11/18/16	11/23/16	12/7/16

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U.S. Nuclear Regulatory Commission
Region IV

Docket No.	030-03495
License No.	49-00152-02
Report No.	030-03495/2016-001
EA No.	EA-16-231
Licensee:	Wyoming Medical Center
Location Inspected:	1233 East Second Street Casper, Wyoming
Inspection Date:	September 20, 2016
Exit Meeting Date:	November 9, 2016
Inspectors:	James L. Thompson, Senior Health Physicist Nuclear Materials Safety Branch A
	Jason E. vonEhr, Health Physicist Nuclear Materials Safety Branch A
Approved By:	Ray L. Kellar, P.E. Chief, Nuclear Materials Safety Branch A Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Wyoming Medical Center
NRC Inspection Report 030-03495/2016-001

On September 20, 2016, the U.S. Nuclear Regulatory Commission (NRC) performed an unannounced, routine inspection of Wyoming Medical Center at its facility in Casper, Wyoming, with reviews of additional data provided by the licensee through November 9, 2016. The scope of the inspection included the direct observation of licensed activities, discussions with licensee personnel concerning radiation safety, compliance with the Commission's rules and regulations, and the conditions of the license. The inspection also included a review of representative records, as well as interviews with the Wyoming Medical Center Radiation Safety Officer and other personnel. This report describes the findings of the inspection.

Program Overview

Wyoming Medical Center is authorized under NRC License 49-00152-02 to possess and use byproduct material permitted by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100 through 35.400. (Section 1)

Inspection Findings

During a routine, unannounced inspection conducted on September 20, 2016, with continued reviews of licensee data through November 9, 2016, one apparent violation of NRC requirements was identified involving the licensee's failure to ensure that written directives contained all information required by regulation after the administration of therapeutic doses of radiation from byproduct material. (Section 2.2)

Corrective Actions

Prior to the NRC's unannounced inspection, the licensee had self-identified and corrected the inadequate brachytherapy written directives. The licensee designed and implemented use of a new brachytherapy written directive form in the spring of 2016, and all brachytherapy treatments since then have written directives that are fully in compliance with the NRC's regulations. Relevant staff and authorized users were trained on the new forms and procedures. (Section 3)

REPORT DETAILS

1. Program Overview (87131, 87132)

1.1. Program Scope

Wyoming Medical Center (WMC) is authorized under U.S. Nuclear Regulatory Commission (NRC) License 49-00152-02 to possess and use byproduct material permitted by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100 through 35.400. Licensed activities are authorized to be performed only at the licensee's facility located in Casper, Wyoming. The licensee's Radiation Safety Officer (RSO) splits his time between WMC and Rocky Mountain Oncology (also in Casper). WMC has fourteen authorized users (AUs), three of which are authorized for brachytherapy activities under 10 CFR 35.400. Although all licensed activities occur at WMC, a significant portion of the records associated with WMC's brachytherapy program are maintained at Rocky Mountain Oncology.

1.2. Observations and Findings

The inspectors observed licensed activities related to the storage and use of byproduct material for the purposes of nuclear medicine and brachytherapy. The inspectors reviewed records, procedures, and documents maintained by the licensee, interviewed licensee personnel and conducted independent radiation measurements. Collectively, the activities observed, interviews conducted, and documents reviewed represent the licensee's implementation of its radiation safety program.

2. Inspection Findings (87131, 87132)

2.1. Inspection Scope

A routine, unannounced inspection was conducted on September 20, 2016, at the licensee's facility in Casper, Wyoming. At the facility, the inspectors reviewed the licensee's storage and control of licensed material, performance of the radiation safety program, dosimetry program, and radiation surveys and instrumentation. The inspectors reviewed records which include, but are not limited to: contamination surveys conducted, patient release criteria, Radiation Safety Committee meeting minutes, and written directives for administration of therapeutic doses of radiation from byproduct material. The inspectors interviewed licensee personnel including nuclear medicine technologists and supervisors in the radiology department.

2.2. Observations and Findings

Nuclear medicine activities authorized under 10 CFR 35.100 - 35.300 are performed almost completely independently from the licensee's brachytherapy program. The three certified nuclear medicine technologists were interviewed and had minimal job duties related to the performance of brachytherapy administrations; the technologists' activities relating to the brachytherapy program were primarily limited to the receipt and logging of incoming packages containing brachytherapy seeds.

Of the 14 individuals listed on the license as AUs, three are approved for the use of byproduct material for medical uses under 10 CFR 35.400 (brachytherapy). One of the AUs was approved in an amendment dated April 27, 2016 (Amendment No. 90), and did not sign any of the written directives that were reviewed by the inspectors. The other two AUs were not available for interviews at the time of the inspection.

Apparent Violation of 10 CFR 35.40(b)(6)

10 CFR 35.40(b)(6) requires that written directives, for brachytherapy, including low, medium, and pulsed dose rate remote afterloaders must contain: (1) before implantation: the treatment site, the radionuclide, and the dose; and (2) 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).

At the beginning of the brachytherapy program inspection, the RSO informed the inspectors that he had conducted a program review at the beginning of 2016. The RSO's review identified missing fields in the written directives in use at the time of the review. Following this review, the RSO developed a new written directive form for brachytherapy which was first used in March 2016.

In the inspectors' review of the three cases that used the new written directive form, all information required under 10 CFR 35.40 was appropriately included, and no deficiencies were noted. However, the written directives completed before this form change did not contain all required information. The inspectors reviewed written directives and patient files from calendar year 2015 through the date of the inspection. In total, 15 written directives were prepared for brachytherapy administrations for procedures conducted between January 15, 2015, and December 22, 2015, using the "old" written directive forms.

In all 15 written directives prepared between the above dates, at least two pieces of information (the number of sources implanted and total source strength) required under 10 CFR 35.40(b)(6) were not present. Some, but not all of the 15 written directives, were missing other required information, such as total dose or radionuclide used.

The licensee's failure to ensure that written directives for administrations prior to March 2016 contained the information required by regulation for brachytherapy administrations were attributed to several factors. These factors included the complexity of the previous form, which was left over from a time when the licensee's brachytherapy program used cesium implants, and inadequate understanding by the AUs and RSO at the time regarding what sections were necessary and unnecessary to fill out.

The licensee's failure to complete brachytherapy written directives with all required information was identified as an apparent violation of 10 CFR 35.40(b)(6). (030-03495/16001-01)

In addition, the inspectors reviewed data provided by the licensee after the inspection regarding the brachytherapy treatments. On September 30 and October 20, 2016, the RSO provided supporting information and calculations, which combined with the on-site inspection, provided sufficient evidence to conclude that

the brachytherapy treatments were administered as intended, and that the failure to include all required information on the brachytherapy written directives had not affected patient treatment.

2.3. Conclusions

One apparent violation of NRC requirements was identified involving the licensee's failure to ensure that written directives for brachytherapy administrations prior to March 2016 contained all information required by regulation.

3. Corrective Actions

Prior to the NRC's unannounced inspection, the licensee had self-identified and corrected the former practice of completing written directives. The licensee designed and implemented a new brachytherapy written directive form in the spring of 2016, and all brachytherapy treatments since then had written directives that are fully in compliance with regulatory requirements. Relevant staff and AUs were trained on the new forms and procedures.

4. Exit Meeting Summary

A preliminary exit briefing was conducted on September 20, 2016, at the conclusion of the onsite inspection with the Senior Vice President of Patient Care Services and Chief Nursing Officer of Wyoming Medical Center, the RSO, and various radiology staff members. On November 9, 2016, a final exit briefing was conducted with the licensee. The licensee acknowledged the inspection findings. No proprietary information was identified.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Russ Easterling, Certified Nuclear Medicine Technologist
Kim Vogle, Certified Nuclear Medicine Technologist
Damian Lucero, Certified Nuclear Medicine Technologist
Michael Fernald, M.S., RSO
Lauri Pelican, interim Radiology Director
Jane Nixon, Senior Vice President of Patient Care Services and Chief Nursing Officer

INSPECTION PROCEDURES USED

87131	Nuclear Medicine Programs, Written Directive Required
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03495/16001-01	APV	The licensee failed to ensure that written directives for brachytherapy treatments contained all information required by 10 CFR 35.40(b)(6).

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
APV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
D90	The minimum dose delivered to 90 percent of the planned target tissue volume
DNMS	Division of Nuclear Materials Safety
EA	Enforcement Action
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer
WMC	Wyoming Medical Center