UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

September 28, 2022

EA-22-061

Rachel Bryant, Chief Operations Officer
Banner Health Wyoming Medical Center
1233 East 2nd Street
Casper, WY 82601

SUBJECT: BANNER HEALTH WYOMING MEDICAL CENTER, NRC INSPECTION REPORT 030-03495/2021-001

Dear Rachel Bryant:

This letter refers to the routine announced inspection that was conducted on August 17, 2021, at your facility in Casper, Wyoming. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of activities, independent radiation measurements, and interviews with personnel. The enclosed inspection report presents the results of this inspection. The inspector discussed the preliminary inspection findings with Bob Bellomy, Director of Imaging Services; April Perez, Radiology Director; Michael Fernald, Radiation Safety Officer; and you at the conclusion of the onsite portion of the inspection. On September 15, 2022, a final exit briefing was conducted via videoconference with you and Deborah Weise, Interim Leader; April Perez, Radiology Director; Paul Hanny, Corporate Radiation Safety Officer; Michael Fernald, Radiation Safety Officer; and Heather Sutyak, Consultant.

Based on the results of this inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failures to: (1) ensure that written directives were dated and signed by an authorized user, and (2) ensure that written directives contained the required information.

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and other members of your staff during the videoconference exit meeting on September 15, 2022.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the

conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-03495/2021-001; EA-22-061" and should include for each 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 (or has been) achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your written response, should you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Mary Muessle, Director, Division of Radiological Safety and Security, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or 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 in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

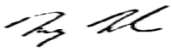
In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

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

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, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC's website 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 Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Signed by Muessle, Mary
on 09/28/22

Mary C. Muessle, Director
Division of Radiological Safety & Security

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

Enclosure:
NRC Inspection Report 030-03495/2021-001

cc w/Enclosure:
Dillon Conner,
Radiological Program Manager
Wyoming Office of Homeland Security
5500 Bishop Blvd.
Cheyenne, WY 82002
dillon.conner@wyo.gov

BANNER HEALTH WYOMING MEDICAL CENTER - NRC INSPECTION
REPORT 030-03495/2021-001 - DATED SEPTEMBER 28, 2022

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ADAMS ACCESSION NUMBER – ML22269A423

X SUNSI Review by: JFK	ADAMS **X** Yes □ No	**X** Publicly Available □ Non-Publicly Available	**X** Non-Sensitive □ Sensitive	Keyword: EA-22-061

OFFICE	RIV:MIB	BC:MIB	ACES:TL	RIV: RC	OE	NMSS	OGC	D: DRSS
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-03495
License No.:	49-00152-02
Inspection Report No.:	030-03495/2021-001
EA No.:	EA-22-061
Licensee:	Banner Health Wyoming Medical Center
Locations Inspected:	1233 East 2nd Street Casper, Wyoming 82601
Inspection Date:	August 17, 2021
Exit Meeting Date:	September 15, 2022
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Approved by:	Lizette Roldán-Otero, PhD Chief, Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Banner Health Wyoming Medical Center (WMC)
NRC Inspection Report 030-03495/2021-001

On August 17, 2021, the NRC performed an announced, routine inspection of WMC. The inspector continued in-office review through August 31, 2022. The scope of the inspection was to examine the activities conducted under the NRC license issued to WMC and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

Program Overview

The NRC license issued to WMC authorizes uptake, dilution, and excretion studies under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.100; imaging and localization studies under 10 CFR 35.200; unsealed radioactive material for which a written directive is required under 10 CFR 35.300; and manual brachytherapy under 10 CFR 35.400. (Section 1)

Inspection Findings

Under 10 CFR 35.300, the inspector reviewed written directives for 27 administrations of sodium iodide I-131 requiring a written directive. The inspector determined that one written directive was prepared for an administration of 150 millicuries of I-131 sodium iodide and was not dated and signed by an authorized user prior to the administration of the licensed material.

Under 10 CFR 35.400, the inspector reviewed written directives for 14 permanent implant prostate brachytherapy procedures. The inspector found that 14 of the "before implantation" sections of the written directives did not contain the total source strength, and that 10 of the "after implantation" sections of the written directives did not contain the total source strength implanted.

Two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives were dated and signed by an authorized user as required by 10 CFR 35.40(a), and (2) ensure that written directives contained information as required by 10 CFR 35.40(b)(6). (Section 3)

Corrective Actions

As corrective actions, on August 17, 2021, prior to the conclusion of the onsite inspection, the licensee revised its written directive form for permanent implant prostate brachytherapy to include the information required by regulation. The licensee also revised its permanent implant brachytherapy policy, is using the services of a consultant to review permanent implant prostate brachytherapy procedures, and is routinely discussing its permanent implant prostate brachytherapy program at its quarterly Radiation Safety Committee meetings. (Section 4)

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87131, IP 87132)

1.1 Program Scope

Banner Health Wyoming Medical Center (WMC or licensee) is authorized under NRC Materials License No. 49-00152-02 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facility in Casper, Wyoming.

1.2 Observations and Findings

On August 17, 2021, the NRC performed an announced, routine inspection of WMC. The inspector continued in-office review through August 31, 2022. The scope of the inspection was to examine the activities conducted under the NRC license issued to WMC and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

Banner Health Wyoming Medical Center is the largest hospital in the state of Wyoming and is a full-service, acute care hospital that provides comprehensive medical services to Casper, Wyoming, and the surrounding geographic community. The NRC license issued to WMC authorizes uptake, dilution, and excretion studies under 10 CFR 35.100; imaging and localization studies under 10 CFR 35.200; unsealed radioactive material for which a written directive is required under 10 CFR 35.300; and manual brachytherapy under 10 CFR 35.400.

2 Background (IP 87131, IP 87132)

2.1 Regulatory History

On April 24, 2002, the NRC amended its regulations regarding the medical use of byproduct material (67 *Federal Register* 20250). With respect to licensed activities requiring a written directive, it was noted that the requirements for written directives only include what is essential to provide high confidence that the licensed material will be administered as directed by the Authorized User (AU). The regulations regarding written directives were written such that in addition to the required contents of the written directive, licensees had the flexibility to include additional information that they felt was necessary to perform a procedure according to the directions of the AU.

The amended regulations became effective on October 24, 2002. The specific elements required to be included in written directives were provided in 10 CFR 35.40(b). The specific elements required to be included varied by modality, such as for administrations of sodium iodide I-131 and high dose rate remote brachytherapy. Permanent implant brachytherapy procedures fell under the requirements for "all other brachytherapy" under 10 CFR 35.40(b)(6).

The 2002 amended regulations in 10 CFR 35.40(b)(6) required, in part, that written directives contain, for all other brachytherapy, (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).

Based on the recommendations from the Advisory Committee on the Medical Use of Isotopes, which advises the NRC on policy and technical issues in the regulation of the medical use of radioactive material, the NRC staff submitted a paper to the Commission, SECY–05–0234, ‘‘Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public,’’ dated December 27, 2005. In this paper, the NRC staff recommended that the Commission approve, for permanent implant brachytherapy, the NRC staff’s plan to revise the medical event definitions in 10 CFR 35.3045 and the associated requirements for written directives in 10 CFR 35.40 to be activity-based, instead of dose-based. On February 15, 2006, the Commission directed the NRC staff to proceed directly with the development of a proposed rule to modify both the written directive requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy, to convert the requirements from dose-based to activity-based criteria.

On July 16, 2018, the NRC amended its regulations related to the medical use of byproduct material (83 *Federal Register* 33046). The amended regulations, which became effective on January 14, 2019, modified the written directive requirements in 10 CFR 35.40. The amended regulations established specific written directive requirements for permanent implant brachytherapy, rather than it being captured under “all other brachytherapy.”

The 2018 amended regulations in 10 CFR 35.40(b)(6) for permanent implant brachytherapy, which were the regulations in effect at the time of the current inspection, require that written directives for permanent implant brachytherapy consist of two portions. The first portion of the written directive must be prepared before the implantation, and the second portion of the written directive must be completed after the procedure but before the patient leaves the post-treatment recovery area. The amended regulations in 10 CFR 35.40(b)(6) require, for permanent implant brachytherapy, that the written directive portion prepared before the implantation must contain the treatment site, the radionuclide, and the total source strength, and that the post-implantation portion of the written directive must contain the treatment site, the number of sources implanted, the total source strength implanted, and the date.

2.2 Inspection History

As the result of an NRC inspection conducted on September 20, 2016, the licensee was issued a Severity Level III violation of 10 CFR 35.40(b)(6), NRC Inspection Report 030-03495/2016-001 (ML17025A029). Based on the regulation language that was in effect at that time, the inspectors identified 15 occasions when the after implantation (but before completion of the procedure) written directives did not contain information regarding the number of sources, and total source strength; some did not contain the total dose.

In a letter dated December 27, 2016, the licensee provided its corrective actions to address the identified finding (ML17009A081). The licensee stated that a new written directive form was created to be consistent with the NRC requirements and that training was performed for the relevant staff. The licensee noted that a system was in place for

keeping abreast of new or modified NRC requirements, which included reviewing all mailings from the NRC as well as periodically reviewing the NRC website.

On September 25, 2017, the NRC performed a routine inspection that included review of the licensee's corrective actions to address the previous escalated enforcement action. The inspector verified that written directives for permanent implant brachytherapy contained the required information, and the previous violation was closed (ML17325A818).

3 Licensed Activities Requiring a Written Directive

3.1 Inspection Scope

On August 17, 2021, the NRC performed an announced, routine inspection of WMC. The inspection consisted of an examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

3.2 Unsealed Byproduct Material- Written Directive Required

3.2.1 Observations and Findings

Under 10 CFR 35.300, the licensee performed administrations of sodium iodide I-131. At the time of the inspection, there were 12 AUs listed on the WMC license, Amendment No. 93, dated June 27, 2019. Ten of the AUs were authorized for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131.

Based on the records provided to the inspector for administrations of sodium iodide I-131, the inspector reviewed written directives for 12 administrations that occurred in 2021, 7 administrations that occurred in 2020, and 8 administrations that occurred in 2019. Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an AU before the administration of I-131 sodium iodide greater than 30 microcuries.

For administrations that occurred in 2019 and 2020, all of the written directives were signed by an individual that was listed as an AU on the license for 10 CFR 35.300. For administrations that occurred in 2021, six of the written directives were signed by an individual that was listed as an AU on the license for 10 CFR 35.300. For the other six written directives from 2021, all were signed by an individual that was not an AU on the license. However, in five of six cases, the written directive was countersigned by an AU that was listed on the license and authorized for 10 CFR 35.300 activities. Therefore, there was one written directive for an administration of 150 millicuries of sodium iodide I-131 that was signed by an individual that was not an AU listed on the license and was not countersigned by an AU listed on the license. In this one case, the AU listed on the license was aware of the administration, as it was this AU that obtained the patient's consent for the administration and was present during the administration. However, the AU listed on the license neglected to countersign the written directive as had been done for other five written directives. As a result, the written directive was not dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries.

Apparent violation of 10 CFR 35.40(a)

Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries.

Contrary to the above, on February 4, 2021, the licensee failed to prepare written directives that that were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. Specifically, a written directive was prepared for 150 millicuries of I-131 sodium iodide and was not dated and signed by an authorized user prior to the administration of the material on February 4, 2021.

The licensee's failure to ensure that written directives were dated and signed by an authorized user before the administration of sodium iodide I-131 greater than 30 microcuries was identified as an apparent violation of 10 CFR 35.40(a). (030-03495/2021-001-01)

3.3 Manual Brachytherapy- Written Directive Required

3.3.1 Observations and Findings

Under 10 CFR 35.400, the licensee performed permanent implant manual brachytherapy. Specifically, since the last NRC inspection the licensee had performed permanent implant prostate brachytherapy using palladium-103. At the time of the inspection, there were 2 AUs for 10 CFR 35.400 activities listed on the WMC license, Amendment No. 93, dated June 27, 2019.

Based on the records provided to the inspector for permanent implant brachytherapy procedures, the inspector was able to review written directives for 14 procedures that occurred in 2021. When preparing for a permanent implant prostate brachytherapy procedure, the licensee's medical physicist plans the administration using specialized software. The contouring of the relevant target volume is verified by the AU. The AU discusses with the medical physicist the planned dose to be delivered, in units of gray (Gy). For palladium-103 seeds (sources), the licensee commonly prescribed a dose of 80 Gy to be delivered to the target volume for a radiation "boost" as a supplement to external beam radiation therapy, and a dose of 125 Gy to be delivered to the target volume for brachytherapy monotherapy. The completed plan provides the number and activity of palladium-103 seeds needed to deliver the desired prescribed dose. This number of seeds is the "planned" number of seeds. In addition to the planned number of seeds that are necessary to deliver the desired dose to the target volume, the AU will often order extra seeds. At the time of implantation, the AU could choose to implant the extra seeds if needed, based on the AU's medical judgement.

As described in Section 2.1, on July 16, 2018, the NRC amended its regulations related to the medical use of byproduct material (83 *Federal Register* 33046). The amended regulations, which became effective on January 14, 2019, modified the written directive requirements in 10 CFR 35.40. The amended regulations established specific written directive requirements for permanent implant brachytherapy. In particular, the revised 10 CFR 35.40(b)(6) requires that, for permanent implant brachytherapy, the written directive must contain the following information: (i) before implantation: The treatment

site, the radionuclide, and the total source strength; and (ii) after implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date. As described in the Background section of the final rule published in the *Federal Register*, "total source strength" is an activity-based value rather than a dose-based value.

The licensee had a written directive form with two sections: "Prior to Implantation" and "After Implantation."

The licensee's "Prior to Implantation" portion of its written directive contained inputs for the following items: prescription dose (in units of gray); treatment site (prefilled out as prostate gland), radioisotope (prefilled out as palladium-103), number of seeds planned/ordered, activity per seed, and a place for the AU's signature, date, and time.

Of the 14 permanent implant brachytherapy procedures reviewed, for the licensee's "Prior to Implantation" written directives:

- In the area for "number of seeds planned/ordered," all 14 written directives provided the number of palladium-103 seeds "ordered" instead of the number of seeds "planned." Therefore, the value provided by the licensee in the written directive included the planned seeds to deliver the prescribed dose plus the extra seeds ordered. In all 14 cases reviewed, the number of seeds ordered was always higher than the number of seeds planned.

- In the area for "activity per seed":

    - Nine written directives provided a value that was an "air kerma strength," which is a dose-based unit and not a unit of activity. Air kerma strength is the product of the air kerma rate in a vacuum at a distance and the square of this distance and is typically expressed in units of microgray-meter 2 per hour and represented by the symbol "U". For example, a WMC "Prior to Implantation" written directive stated that the "number of seeds planned/ordered" was 72, and the "activity per seed" was "1.5 U."

    - Five written directives provided a numerical value but did not provide a unit of measurement, although in all cases the licensee stated that the value was air kerma strength but was missing the symbol "U." For example, a WMC "Prior to Implantation" written directive stated that the "number of seeds planned/ordered" was 100, and the "activity per seed" was "2.1".

In summary, for the 14 "Prior to Implantation" sections of written directives reviewed, since the "activity per source" was not provided in actual units of activity, and the actual number of seeds planned to be implanted was not provided, the total source strength in terms of cannot be determined from any of the 14 reviewed "Prior to Implantation" written directives.

The licensee's "After Implantation" portion of its written directive contained inputs for the following items: total dose (in units of gray); treatment site (prefilled out as prostate gland), radioisotope (prefilled out as palladium-103), number of seeds implanted, total activity, and a place for the AU's signature, date, and time.

Of the 14 permanent implant brachytherapy procedures reviewed, for the licensee's "After Implantation" written directives, in the area for "total activity":

- Eight written directives provided a value that was an "air kerma strength," represented by the symbol "U," which is dose-based and not a unit of activity. For example, a WMC "After Implantation" written directive stated that the "total activity" was "105 U."

- One written directive provided a numerical value but did not provide a unit. For example, a WMC "After Implantation" written directive stated that the "total activity" was "87.1".

- One written directive was blank with no numerical value and no unit provided.

In summary, for the 14 "After Implantation" sections of written directives reviewed, in 10 cases, since the "total activity" was not provided in actual units of activity or was not provided (blank), the total source strength implanted cannot be determined based on the information in the "After Implantation" written directives.

Based on the information reviewed by the inspector, although there were deficiencies in the preparation of the prior to implantation and after implantation sections of written directives, it did not appear that the deficiencies resulted in any medical events.

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

Title 10 CFR 35.40(b)(6) requires, in part, that the written directive for permanent implant brachytherapy must contain the following information: (i) before implantation: the treatment site, the radionuclide, and the total source strength; and (ii) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Contrary to the above, between January 1 and August 17, 2021, the licensee failed to ensure that written directives for permanent implant brachytherapy contained the following information: (1) before implantation: the treatment site, the radionuclide, and the total source strength; and (2) after implantation: the treatment site, the number of sources implanted, the total source strength implanted, and the date. Specifically, 14 "before implantation" sections of written directives did not contain the total source strength; and 10 "after implantation" sections of written directives did not contain the total source strength implanted.

The licensee's failure to ensure that written directives contained required information was identified as an apparent violation of 10 CFR 35.40(b)(6). (030-03495/2021-001-02)

3.4 Causal Evaluation

A formal root cause analysis was not performed as it was beyond the scope of the inspection. General inspection observations indicated that the licensee lacked familiarity with NRC's revised requirements regarding written directives for permanent implant brachytherapy. As a result of a 2016 inspection, the licensee was cited for a violation of 10 CFR 35.40(b)(6) and believed that it had corrected the issues with its written

directives. This belief was further bolstered by the NRC's inspection in 2017 which found that the violation had been corrected and that there was no recurrence of the violation. However, the NRC's regulations in this area were revised in 2018 and became effective on January 14, 2019. In reviewing the revised regulation, the licensee expressed that it was left confused as to what to record in the written directive. As a result, the licensee did not make the necessary revisions to its permanent implant brachytherapy written directive form or seek further guidance regarding the regulatory requirements.

The Radiation Safety Officer (RSO), who is also a medical physicist at the facility, was directly involved in the planning and performance of permanent implant prostate brachytherapy procedures. The RSO relied on their own knowledge and expertise as well as that of the AU in performing permanent implant prostate brachytherapy procedures properly. The RSO expressed that the deficiencies in the written directive forms did not have any bearing on the actual treatment planning or execution.

The RSO felt strongly that air kerma strength is a valuable dosimetric quantity and could be used to represent source strength. While this may be a valuable dosimetric quantity from a medical physics standpoint, it is not an activity-based value as required by regulation to be documented in the written directive. The licensee can record air kerma strength on the written directive form as supplemental information; however, the licensee is still required to record activity-based values for the total source strength on the before implantation written directive, and for the total source strength implanted on the after implantation written directive.

3.5 Conclusions

Two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives were dated and signed by an authorized user as required by 10 CFR 35.40(a), and (2) ensure that written directives contained information as required by 10 CFR 35.40(b)(6).

4 Corrective Actions

On August 17, 2021, during the inspection, the inspector discussed the concerns regarding the written directives with licensee representatives. Prior to the conclusion of the onsite inspection, the licensee revised its written directive form for permanent implant prostate brachytherapy.

The licensee's revised "Prior to Implantation" portion of its written directive contained inputs for the following items: prescription dose (in units of gray); treatment site (prefilled out as prostate gland), radioisotope (prefilled out as palladium-103), number of seeds ordered, number of seeds planned, activity per seed (in units of millicuries), a multiplication of the number of seeds planned and the activity per seed (in units of millicuries), and a place for the AU's signature, date, and time. The multiplication of the number of seeds planned and the activity per seed will provide the total source strength in millicuries, which is an activity-based unit.

The licensee's revised "After Implantation" portion of its written directive contained inputs for the following items: total dose (in units of gray); treatment site (prefilled out as prostate gland), radioisotope (prefilled out as palladium-103), number of seeds implanted, total activity implanted (in units of millicuries), and a place for the AU's

signature, date, and time. The total activity implanted represents the total source strength implanted in millicuries, which is an activity-based unit.
The licensee also submitted a letter on June 8, 2022, to provide additional information to describe its permanent implant prostate brachytherapy program, including its updated policy (ML22188A114). The licensee also noted that a consultant would be periodically reviewing permanent implant prostate brachytherapy procedures, including the content of written directives. The licensee's Radiation Safety Committee has also been routinely reviewing items related to the permanent implant prostate brachytherapy program at its quarterly meetings.

5 Exit Meeting Summary

On September 15, 2022, a final videoconference was conducted with Rachel Bryant, Chief Operations Officer; Deborah Weise, Interim Leader; April Perez, Radiology Director; Paul Hanny, Corporate RSO; Michael Fernald, RSO; and Heather Sutyak, Consultant to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report; (2) request a predecisional enforcement conference, or (3) request alternative dispute resolution. The licensee did not identify any proprietary information.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Rachel Bryant, Chief Operations Officer
Bob Bellomy, Director of Imaging Services
April Perez, Radiology Manager
Deborah Weise, Interim Leader
Damian Lucero, Nuclear Medicine Technologist
Kimberly Vogel, Nuclear Medicine Technologist
Michael Fernald, Radiation Safety Officer
Heather Sutyak, Consultant, Associates in Medical Physics

INSPECTION PROCEDURES USED

IP 87131	Nuclear Medicine Programs, Written Directive Required
IP 87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-03495/2021-001-01	AV	Failure to ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries. (10 CFR 35.40(a))
030-03495/2021-001-02	AV	Failure to ensure that written directives contained the required information. (10 CFR 35.40(b)(6))

Closed: None

Discussed

030-03495/2016-001-01	VIO	Failure to ensure that written directives contained the required information. (10 CFR 35.40(b)(6))

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AU	Authorized User
AV	Apparent Violation
I-131	iodine-131
IP	Inspection Procedure
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer
WMC	Banner Health Wyoming Medical Center