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Katanic, Janine

From: Heather Sutyak <H.Sutyak@ampmedicalphysics.com>
Sent: Wednesday, June 8, 2022 3:34 PM
To: Katanic, Janine
Cc: Michael Fernald
Subject: [External_Sender] Follow-up Additional Info Wyoming Medical Center
Attachments: Final Letter 6-8-2022- Additional Info Needed Brachytherapy Wyoming Medical Cente....pdf; Final Attachments Wyoming Medical Center 6-8-2022.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Hello Janine,

I have attached a letter explaining the questions you may have had from the recent inspection. There is a separate PDF of all the documents used to verify the information provided. Please let me know if there is anything else you may need. I have copied the RSO, Michael Fernald in this email. I appreciate your time and allowing us to further explain our radioactive materials program at Wyoming Medical Center.

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Wyoming Medical Center

June 8, 2022

Janine F. Katanic, PhD, CHP
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Materials Inspection Branch
Division of Radiological Safety and Security
US Nuclear Regulatory Commission
Region IV
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RE: Wyoming Medical Center: Additional Information Needed for Inspection Follow-Up

Dear Dr. Katanic,

Thank you for allowing us to gather information to help with your recent inspection of Wyoming Medical Center. We hope to provide you with a better understanding and a timeline of clear improvement in our Brachytherapy program.

Most of your concerns are with the Brachytherapy program, and we would like to show a progression of improvement based on NRC recommendations, inspections, and self-identification. We also have our outside quarterly consultant reviews to self-identify any issues and make changes to our program based on the findings.

Starting with our Brachytherapy Policy and Procedure, we offer three revisions. After your visit in 2021, we immediately got to work and have developed our current policy, attached as Exhibit A. Also included are Exhibit B, our earlier version last updated in 2020, and Exhibit C, our version from before the 2016 inspection. These updated policies represent a response to the suggestions from the inspectors at that time. The revisions show a positive working relationship with the NRC and the outcomes of the requests from inspections, which Wyoming Medical Center had taken seriously and made immediate changes.

Our Radiation Committee Meeting minutes offer documented discussions on the policies and improvements we immediately put into place. We offer Exhibit D, our RSC meeting minutes from 2021. On two separate occasions (8/25/21 and 5/5/21), we discussed the revised written directive form and the Brachytherapy policy updates. Also noted on the RSC minutes is using a consultant as an outside representative to review the Brachytherapy paperwork. All these changes were based on the suggestions from your most recent visit and immediately enacted. Attached, Exhibit E shows RSC meeting minutes following the 2016 Inspection. On two occasions (9/28/16 and 12/14/16), we discussed updating the Written Directive for Seed Implants and the corrected inspection violations noted from the 2016 Inspection.

Our Written Directive Form seems the most concerning; therefore, we would like to address the changes made from each inspection. Specifically, in 2021 the changes we have made to our Written Directive Form, Exhibit F, cover all required elements as verified in NUREG 1556 Vol. 9 Rev 3: we verify patient identity, confirm that the written directive is signed and dated by the AU prior to the administration, and in accordance with 10 CFR 35.40, and includes the name of the patient. We verify that the administration is in accordance with the treatment plan and record the treatment site, radionuclide, and total source apparent activity for source strength (as suggested by your recent inspection in 2021), as required by 10 CFR 35.40(b)(6)(i). After implantation, but before the patient leaves the post-treatment recovery area, we record the treatment site, the number of sources implanted, the total source apparent activity implanted,

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for source strength, as suggested by your recent inspection in 2021, and the date, as required by 10 CFR 35.40(b)(6)(ii).

The written directive form had also been updated before the 2016 inspection as offered in Exhibit G. Wyoming Medical Center proactively updated the written directives in response to self-identified deficiencies. With self-identifying and the guidance from inspectors, Jason vonEhr and James Thompson, at the 2016 inspection, we felt that the written directive form followed all aspects of the regulations. Our response to the NRC in 2016, including the 2016 updated written directive, were accepted. The subsequent inspection in 2017, as offered in Exhibit H, by inspector Jason Dykert shows a clear verdict on the "previous violation as closed," furthering our belief that the written directive followed NRC regulations.

On July 16, 2018, in the Federal Register Vol. 83, No. 136, the U.S. Nuclear Regulatory Commission issued updated rules governing the Medical Use of Byproduct Material found in 10 CFR Part 35. Permanent implant brachytherapy pre-treatment written directives must now record the total source strength, and the requirement to document dose was rescinded. Before the patient leaves the post-treatment recovery area, the written directive must also record the total number of sources implanted, the total source strength implanted, and the date of the assessment. For other types of brachytherapy treatment, the licensee must still record the dose on the written directives. With regards to these changes, there is no definition of "source strength." Not having a working definition has left us confused about what to record.

Since source strength is clearly not source activity, and the source strength varies by the composition of the containment material of the implant, it logically seems that the author(s) of the rule considers that the air kerma (known as U, S_K) of the implant is the "source strength" of the implant. For sealed source brachytherapy treatments, the energy emitted, not the mCi of isotope, drives the dose calculation. While undoubtedly there is a relationship between the activity and source strength, the latter considers the density of the containment materials and is a more accurate prescription method and means of deriving the dose delivered to the patient.

Knowledge of the activity alone is insufficient to calculate the dose delivered to the patient in every circumstance because of the variances in the containment material of the seeds.

Lastly, we would like to submit an email detailing a discussion of education materials available on HealthStream as a training module for PACU and OPD on prostate seeds and radiation safety. Email discussions around updating the module are offered as Exhibit I.

We hope these documents and additional information satisfy your issues with the Brachytherapy program at Wyoming Medical Center.

Sincerely,

Michael Fernald, RSO

EXHIBIT A Newest Brachytherapy Policy

Brachytherapy

Wyoming Medical Center

Policy Title: LDR Prostate Brachytherapy Policy and QMP

Policy Number: New
Effective Date:
Replaces:
Review Date: 12/1/2024

Purpose: This policy is written to promote high confidence that brachytherapy radiation treatments will be administered as directed by the authorized user, and in doing so, ensure that patients, staff, and public are not exposed to unnecessary radiation. It aims to monitor and evaluate the brachytherapy application of radioactive materials and resolve identified problems in order to ensure accurate radiation dose delivery, minimize risks to patients and personnel, and ensure compliance with applicable laws and regulations.

Policy: LDR Prostate Brachytherapy Policy and QMP

1. Scope
    a. The brachytherapy policy and QMP document is designed to define a policy as well as define the program to monitor and evaluate the use of brachytherapy by Authorized Users.
2. Procedures
    a. The following are the steps followed from the point of seed ordering to the disposal of the seeds
3. Pre-Implant Procedures
    a. Seeds for new cases are ordered using the vendor order form.
    b. Seed packages are delivered by a carrier to Banner Wyoming Medical Center receiving and are handled per receiving procedures.
    c. A representative from Nuclear Medicine or other personnel trained and authorized by the Radiation Safety Officer to handle radioactive materials shall obtain and secure the package in the hot lab. A receipt log in the hot lab shall be filled out noting package integrity and package survey.
    d. The package is opened, and the inner paperwork is removed and reviewed. The isotope is verified. The date, number of seeds, and activity are recorded in the seed log. A copy of the seed log is maintained in the hot lab.
    e. The package is stored in the hot lab.
    f. On the day of the procedure, or before, the physicist, or other personnel trained and authorized by the Radiation Safety Officer, shall compare the patient's name, number of seeds, activity, and loading of preloaded needles (if applicable) with the plan prior to the implant. Review of the seed assay and date of implant from seed paperwork must take place prior to the implant and must match the plan.
    g. Check the calibration on the survey meter and conduct a constancy check. Record values. Ensure tweezers, shielded container plan, survey meter, lead aprons, plan, Written Directive, and seeds are on the cart before going to the OR.
4. OR Procedures
    a. **Confirm the Written Directive is signed and date/time stamped.** Confirm all parameters match between the Written Directive, Plan, and Seeds. Place a sticker

EXHIBIT A 2021

authorized individual, shall enter the number of seeds remaining for decay. The remaining seeds, if any, will be stored in a shielded container in the hot lab. Seed containers should be labeled with patient initials and current date.

b. Review the Written Directive and associated documentation for completeness.

6. Storage and Disposal of Unused Seeds
   a. Seeds will be stored as outlined in 3.e. All seeds will be held for at least 10 half-lives before being disposed of in regular trash. Seeds must be surveyed prior to being disposed of and must not be above background radiation levels. The cumulative radiation exposure rate from the garbage can must not exceed background radiation levels with all disposed seeds.
   b. The disposed seeds must be logged in the seed logbook as disposed of along with the date that seeds are disposed.
7. Written Emergency Procedures for responding to an abnormal situation to include broken or leaking source, would be to immediately notify the RSO in which you would notify the NRC immediately within 5 days. Follow model procedure for spills which lists radioactive hazards according to amount.
   a. Emergency response equipment will be available near each surgery suite during specimen handling. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radiative materials (CRAM) labels.
8. Seed Return
   a. If implantation is cancelled, seeds must be returned to vendor or decayed for 10 half-lives. The following procedure for returning seeds should be followed.
      i. Physicist or RSO contacts vendor and requests a return authorization kit
      ii. Return kit is used and filled out properly by a DOT/HAZMAT approved individual
      iii. Logbook is updated in the hot lab
      iv. (Decayed seeds) Follow procedure outlined in 3.1.4.1.
9. Clinical Medical Physics Procedures:
   a. Planning (includes dosimetrist)
      i. Import the Ultrasound Images.
      ii. Align the grid.
      iii. Contour the appropriate structures (e.g., urethra, rectum).
      iv. Follow the contour created by the urologist to create the prostate volume.
         1. Check as you contour that the area/volume of the contour matches the area/volume from the mapping study.
         2. If a clinically significant discrepancy, arises; stop and discuss with the Authorized User.
         3. The Authorized User may contour a Relevant Target Volume which may be different from the prostate.
      v. Confirm the planning dose with the Authorized User. Discuss any special characteristics of the case from the Authorized User's perspective as well as from the planning perspective (e.g., potential pubic arch obstruction).

EXHIBIT A 2021

1. Common doses used are 85Gy for a Pd-103 boost and 125Gy for a Pd-103 monotherapy

vi. The planner should use at least 2 seeds in each needle.
vii. Once the plan is complete, review the plan with the Authorized User. Confirm if any extra needs and seeds are desired.
viii. After the Authorized User approves the plan, prepare the paperwork to order seeds.

b. Physics Second Check
   i. Import the plan into RadCalc and perform a second check calculation.
   ii. The second check should be within 10%. If the 10% limit is exceeded, choose different points. If the difference continues to persist, the plan must be re-generated.
c. Ordering seeds and documentation
   i. Submit via secure email an order form and copy of the needle loading from the plan.
   ii. Indicate any extra needles and seeds on the order form.
d. Seed calibration
   i. Seeds are assayed by the vendor. The seeds should be within +/- 5% of the specified strength. If seeds are outside this tolerance, they should not be used.
e. Source accounting
   i. The patient should return for a CT scan. The treatment planning system will be used to count the number of seeds.
f. Post-Implant CT scan and QA
   i. Between 2 and 4 weeks after the implant, the patient should have a CT scan. The images from the CT scan are used to create the post plan.
   ii. Import the CT scan into the planning system.
   iii. Contour the normal tissues (e.g., rectum, bladder) and find the seeds.
   iv. The Authorized User will contour the prostate, or relevant target volume
   v. If the D90 of the prostate or relevant target volume is greater or less than 120% or 80%, respectively, notify the Radiation Safety Officer.
g. Brachytherapy Review and QA
   i. The seed cases for the quarter will be reviewed by the RSO. Any Medical Events or other issues will be discussed at the Radiation Safety Committee Meeting.
   ii. The review includes:
      1. Each patient's documentation
      2. Post plan, if available

10. Criteria and Tolerances
    a. Quality Control Procedures
       i. Seeds
          1. The following instances must be reported to the Radiation Safety Officer

EXHIBIT A 2021

a. Any lost or misplaced radioactive source, for any period of time
b. Unlogged sources

ii. Safety
1. The following instances must be reported to the Radiation Safety Officer
a. Failure to perform a radiation survey
b. Failure to wear dosimetry badges
c. Failure to wear lead shielding

iii. Treatment
1. The following instances must be reported to the Radiation Safety Officer
a. Any treatment delivered without a completely filled out Written Directive
b. Any found errors resulting in the relevant target volume receiving outside +/- 20% of the prescribed dose to D90 (e.g., mis-calibrated seeds, implant performed on the incorrect day

11. Applicability of QA Standard
a. The quality assessment standards described in this document may be temporarily suspended under special circumstances or by direct order of an Authorized User when such action is clearly in the patient's best interest. Such suspension must be reported at the next Radiation Safety Committee meeting.

12. Patient Discharge Instructions
a. After your implant, it is normal to experience some difficulty with your urination. You may experience a burning sensation when you pass urine the first few times and a small or trace amounts of blood or clots may be present in the urine. This usually resolves in a day or two. Other common urinary side effects are a need to urinate more frequently and a strong need to urinate (urgency). You may also experience more difficulty in emptying your bladder. NOTE: On rare occasions, a complete blockage of urination may occur. If this happens, you will need to see your physician or go to the hospital Emergency Room to have a catheter placed in the bladder. In most situations, side effects are moderate. The following medications and recommendations can improve or lessen your symptoms.

13. Foods
a. Some foods and liquids (acidic food or certain proteins) can be slightly irritation to the bladder, causing increased urinary frequency, discomfort, and a slower urinary stream. Generally, it is not necessary to completely eliminate these foods from your diet, but you may wish to decrease their amount, particularly if you are experience frequent or excessive symptoms
i. Acidic Foods
1. Alcoholic beverages
2. Grapes/grape juice

EXHIBIT A 2021

3. Carbonated beverages
4. Chilies/spicy foods
5. Citrus fruits and drinks
6. Tomatoes
7. Chocolate
8. Cranberries and juice
9. Coffee including decaf
10. Pineapple, plums, strawberries
11. Tea
12. Vinegar

14. Special Instructions
    a. Special Instructions Related to the Seeds
        i. Children and pets should not sit on the patient's lap for the first two months after the procedure.
        ii. Pregnant (or possibly pregnant) women should avoid prolonged close contact with the patient for the first two months after the procedure. Pregnant women can greet the patient briefly and then move to a distance of three feet or more away. At a six-foot distance, there is no limit to the length of time she can be in the same room with the patient.
        iii. Iodine and palladium are low energy radioactive materials. The emitted radiation is not deeply penetrating and loses energy at short distances. Your prostate will absorb most of the radiation. Objects that are touched or used by the patient do not become radioactive.
        iv. It is unlikely that you will pass a seed in your urine. However, as a precaution, for the next week, urinate through the strainer that you received when you left the hospital. The seeds are silver in color and are about as large as a grain of rice. If you find a seed, pick it up with tweezers, place it in a plastic container, and store in a corner of your home. Please call Rocky Mountain Oncology to coordinate retrieval of the seed.
        v. Body wastes (urine and stool) or body fluids (saliva, tears, semen, or blood) are not radioactive
        vi. You may resume sexual relations two weeks after the procedure. A condom should be used for the first two months. Your semen may be dark brown or black; this is normal and is related bleeding that may have occurred during the implant. After two months, condom use should return to normal public health recommendations.
    b. After two months, no further precautions are necessary.

Definitions: None

Materials & Equipment: See above

EXHIBIT A 2021

Procedure / Guidelines: None

Reference(s) / Related Policies: None

Related Documents: None

Key Reviewer/Owner: Director of Nuclear Medicine, Director of Radiology, Radiation Safety Officer

Stakeholders: Director of Nuclear Medicine, Director of Radiology, Radiation Safety Officer

Review Date: 12/2024

EXHIBIT A 2021

EXHIBIT B

Brachytherapy Policy updated 2020

Brachytherapy

Wyoming Medical Center

LDR Prostate Brachytherapy policy and QMP

Policy Number: 7000
Effective Date:
Replaces:
Review Date:

Purpose:

Policy: LDR Prostate Brachytherapy Policy and QMP

BM 10/1/20

1. Goals

1. This policy is written to promote high confidence that brachytherapy radiation treatments will be administered as directed by the authorized user, and in doing so, insure that patients staff, and public are not exposed to unnecessary radiation. It aims to monitor and evaluate the brachytherapy application of radioactive materials and resolve identified problems in order to ensure accurate radiation dose delivery, minimize risks to patients and personnel, and ensure compliance with applicable laws and regulations.

2. Scope

1. The brachytherapy policy and QMP document is designed to define a policy as well as define the program to monitor and evaluate the use of brachytherapy by Authorized Users.

3. Procedures

1. The following are the steps followed from the point of seed ordering to the disposal of the seeds

    1. Pre-Implant Procedures
        1. Seeds for new cases are ordered using the vendor order form.
        2. Seed packages are delivered by a carrier to Wyoming Medical Center receiving and are handled per receiving procedures.
        3. A representative from Nuclear Medicine or other personnel trained and authorized by the Radiation Safety Officer to handle radioactive materials shall obtain and secure the package in the hot lab. A receipt log in the hot lab shall be filled out noting package integrity and package survey.
        4. The package is opened and the inner paperwork is removed and reviewed. The isotope is verified. The date, number of seeds, and activity are recorded in the seed log. A copy of the seed log is maintained in the hot lab.
        5. The package is stored in the hot lab.
        6. On the day of the procedure, or before, the physicist, or other personnel trained and authorized by the Radiation Safety Officer, shall compare the patient name, number of seeds, activity, and loading of preloaded needles (if applicable) with the plan prior to the implant. Review of the seed assay and date of implant from seed paperwork must take place prior to the implant and must match the plan.
        7. Check the calibration on the survey meter and conduct a constancy check. Record values.
        8. Ensure tweezers, shielded container plan, survey meter, lead aprons, plan, Written Directive, and seeds are on the cart before going to the OR.

    2. OR Procedures

EXHIBIT B 2020

1. **Confirm the Written Directive is signed and date/time stamped.** Confirm all parameters match between the Written Directive, Plan, and Seeds. Place a sticker from the vendor on the Written Directive, if available.
2. Prior to beginning the seed implant, survey the patient for any radioactivity. Record the results.
3. Tape the plan on the ultrasound or another conspicuous location for the Authorized User to see.
4. Confirm the patient two ways. This is commonly done during the Time Out procedure.
5. Hand the needle tray to the OR Nurse.
6. NOTE:
    a. If radiation contamination or loose seeds are found, STOP individuals from continuing their work (as long as it will not interfere with the care of the patient) while you locate and secure the radioactivity.
    b. Survey individuals for possible contamination.
    c. If the OR room continues to be contaminated, its use must be discontinued. It must be decontamination before it can be used again.
    d. Notify the Radiation Safety Officer that radioactivity was found and whether it is secured, or not.
7. Following the implantation, document the number of seeds used. The Authorized User should sign the Written Directive prior to the completion of the procedure. The completion of the procedure is defined in this document as the patient leaving the recovery area.
8. Before the patient is moved, conduct a survey of the areas on the Survey Form. Copies of the survey will be kept with the patient seed implant paperwork.

3. Post-Implant Procedures
    1. Upon returning from the OR, the physicist, or trained and Radiation Safety authorized individual, shall enter the number of seeds remaining for decay. The remaining seeds, if any, will be stored in a shielded container in the hot lab. Seed containers should be labeled with patient initials and current date.
    2. Review the Written Directive and associated documentation for completeness.

4. Storage and Disposal of Unused Seeds
    1. Seeds will be stored as outlined in 3.1.3.1. All seeds will be held for at least 10 half-lives before being disposed of in regular trash. Seeds must be surveyed prior to being disposed of and must not be above background radiation levels. The cumulative radiation exposure rate from the garbage can must not exceed background radiation levels with all disposed seeds.
    2. The disposed seeds must be logged in the seed log book as disposed of along with the date that seeds are disposed.

5. Seed Return
    1. If implantation is cancelled, seeds must be returned to vendor or decayed for 10 half-lives. The following procedure for returning seeds should be followed.
        a. Physicist or RSO contacts vendor and requests a return authorization kit
        b. Return kit is used and filled out properly by a DOT/HAZMAT approved individual
        c. Log book is updated in the hot lab
        d. (Decayed seeds) Follow procedure outlined in 3.1.4.1.

EXHIBIT B 2020

2. Clinical Medical Physics Procedures:

1. Planning (includes dosimetrist)
    1. Import the Ultrasound Images.
    2. Align the grid.
    3. Contour the appropriate structures (e.g., urethra, rectum).
    4. Follow the contour created by the urologist to create the prostate volume.
        a. Check as you contour that the area/volume of the contour matches the area/volume from the mapping study
        b. If a clinically significant discrepancy, arises, stop and discuss with the Authorized User
        c. The Authorized User may contour a Relevant Target Volume which may be different from the prostate.
    5. Confirm the planning dose with the Authorized User. Discuss any special characteristics of the case from the Authorized User's perspective as well as from the planning perspective (e.g., potential pubic arch obstruction)
        a. Common doses used are 85Gy for a Pd-103 boost and 125Gy for a Pd-103 monotherapy
    6. The planner should use at least 2 seeds in each needle.
    7. Once the plan is complete, review the plan with the Authorized User. Confirm if any extra needs and seeds are desired.
    8. After the Authorized User approves the plan, prepare the paperwork to order seeds.

2. Physics Second Check
    1. Import the plan into RadCalc and perform a second check calculation.
    2. The second check should be within 10%. If the 10% limit is exceeded, choose different points. If the difference continues to persist, the plan must be re-generated.

3. Ordering seeds and documentation
    1. Submit via secure email an order form and copy of the needle loading from the plan.
    2. Indicate any extra needles and seeds on the order form.

4. Seed calibration
    1. Seeds are assayed by the vendor. The seeds should be within +/- 5% of the specified strength. If seeds are outside this tolerance, they should not be used.

5. Source accounting
    1. The patient should return for a CT scan. The treatment planning system will be used to count the number of seeds.

6. Post-Implant CT scan and QA
    1. Between 2 and 4 weeks after the implant, the patient should have a CT scan. The images from the CT scan are used to create the post plan.
    2. Import the CT scan into the planning system.
    3. Contour the normal tissues (e.g., rectum, bladder) and find the seeds.

EXHIBIT B 2020

4. The Authorized User will contour the prostate, or relevant target volume
5. If the D90 of the prostate or relevant target volume is greater or less than 120% or 80%, respectively, notify the Radiation Safety Officer.

7. BrachyTherapy Review and QA
    1. The seed cases for the quarter will be reviewed by the RSO. Any Medical Events or other issues will be discussed at the Radiation Safety Committee Meeting.
    2. The review includes:
        a. Each patient's documentation
        b. Post plan, if available

4. Criteria and Tolerances

1. Quality Control Procedures

    1. Seeds
        1. The following instances must be reported to the Radiation Safety Officer
            a. Any lost or misplaced radioactive source, for any period of time
            b. Unlogged sources

    2. Safety
        1. The following instances must be reported to the Radiation Safety Officer
            a. Failure to perform a radiation survey
            b. Failure to wear dosimetry badges
            c. Failure to wear lead shielding

    3. Treatment
        1. The following instances must be reported to the Radiation Safety Officer
            a. Any treatment delivered without a completely filled out Written Directive
            b. Any found errors resulting in the relevant target volume receiving outside +/- 20% of the prescribed dose to D90 (e.g., mis-calibrated seeds, implant performed on the incorrect day

5. Applicability of QA Standard

1. The quality assessment standards described in this document may be temporarily suspended under special circumstances or by direct order of an Authorized User when such action is clearly in the patient's best interest. Such suspension must be reported at the next Radiation Safety Committee meeting.

6. Patient Discharge Instructions

1. After your implant, it is normal to experience some difficulty with your urination. You may experience a burning sensation when you pass urine the first few times and a small or trace amounts of blood or clots may be present in the urine. This usually resolves in a day or two. Other common urinary side effects are a need to urinate more frequently and a strong need to urinate (urgency). You may also experience more difficulty in emptying your bladder. NOTE: On rare occasions, a complete blockage of urination may occur. If this happens, you will need to see your physician or go to the hospital Emergency Room to have a catheter placed in the bladder. In most situations, side effects are moderate. The following medications and recommendations can improve or lessen your symptoms.

EXHIBIT B 2020

1. Foods
    1. Foods
        a. Some foods and liquids (acidic food or certain proteins) can be slightly irritation to the bladder, causing increased urinary frequency, discomfort and a slower urinary stream. Generally it is not necessary to completely eliminate these foods from your diet, but you may wish to decrease their amount, particularly if you ar experience frequent or excessive symptoms
        b. Acidic Foods
            i. Alcoholic beverages
            ii. Grapes/grape juice
            iii. Carbonated beverages
            iv. Chilies/spicy foods
            v. Citrus fruits and drinks
            vi. Tomatoes
            vii. Chocolate
            viii. Cranberries and juice
            ix. Coffee including decaf
            x. Pineapple, plums, strawberries
            xi. Tea
            xii. Vinegar

2. Special Instructions
    1. Special Instructions Related to the Seeds
        a. Children and pets should not sit on the patient's lap for the first two months after the procedure.
        b. Pregnant (or possibly pregnant) women should avoid prolonged close contact with the patient for the first two months after the procedure. Pregnant women can greet the patient briefly and then move to a distance of three feet or more away. At a six foot distance, there is no limit to the length of time she can be in the same room with the patient.
        c. Iodine and palladium are low energy radioactive materials. The emitted radiation is not deeply penetrating and loses energy at short distances. Your prostate will absorb most of the radiation. Objects that are touched or used by the patient do not become radioactive.
        d. It is unlikely that you will pass a seed in your urine. However, as a precaution, for the next week, urinate through the strainer that you received when you left the hospital. The seeds are silver in color and are about as large as a grain of rice. If you find a seed, pick it up with tweezers, place it in a plastic container, and store in a corner of your home. Please call Rocky Mountain Oncology to coordinate retrieval of the seed.
        e. Body wastes (urine and stool) or body fluids (saliva, tears, semen or blood) are not radioactive
        f. You may resume sexual relations two weeks after the procedure. A condom should be used for the first two months. Your semen may be dark brown or black; this is normal and is related bleeding that may have occurred during the implant. After two months, condom use should return to normal public health recommendations.
    2. After two months, no further precautions are necessary.

EXHIBIT B 2020

7. Quality assurance

1. Review of Paperwork
    1. Written Directive, Treatment Plan, Post Plan
        1. The paperwork for prostate seed implants will be reviewed by the RSO periodically.
2. Treatment Planning System QA
    1. Treatment planning system
        1. Whenever a new version of the treatment planning software is installed, a complete commissioning is performed.

Definitions: None

Materials & Equipment: See Above

Procedure / Guidelines: None

Reference(s) / Related Policies: None

Related Documents: None

Key Reviewer/Owner: Director of Nuclear Medicine, Director of Radiology, Radiation Safety Officer.

Stakeholders: Director of Nuclear Medicine, Director of Radiology, Radiation Safety Officer.

Review Date:

EXHIBIT B 2020

OLD Brachytherapy Policy
EXHIBIT C
2007

Wyoming Medical Center

GENERAL PROCEDURES FOR ALL SEALED SOURCE IMPLANTS

1. Verify that an initial written prescription including type of procedure and target dose to anatomical site or volume has been completed and signed.

2. Prepare the implant materials:

   A. For Ir-192 implants:

      i). Prepare the Iridium implant tray for sterilization.

      ii). Perform a pre-implant computer plan if necessary.

      iii). In consultation with the physician and medical physicist, determine the activity per source, number of sources per ribbon, and number of ribbons required to execute the implant as described by the planning calculation above.

      iv). Complete the source ordering section of the ordering receipt disposal log, then order the sources.

      v). When the sources arrive, the Medical Physicist will perform the in-bound survey and wipe tests and record the results in the Receipt Survey section of the inventory form. A container number is recorded. The in-bound shipping documents and manufacturer's assay documents are filed in the appropriate section of the patient folder.

      vi). Using the Ir-192 dose calibrator ribbon measurement jig, measure a representative sample of each activity of ribbon. Record the results of this check in the "Radioactive Source Calibration Verification" section of the ordering receipt disposal form. If the calculated average activity per seed differs from the manufacturer's assay value decayed to the time of the measurement by more than 10%, contact the manufacturer immediately. Possible sources of measurement error are: wrong position of the source in the dose calibrator, wrong dose calibrator setting (wrong isotope), bad manufacturer's assay, and failing dose calibrator.

   B. For Cesium-137 Intracavitary Procedures:

      (i) Perform a pre-implant computer plan if necessary.

EXHIBIT C 2007

patient's room and instructing the nursing staff. These will include the QMP form, a room survey form, a "Caution Radioactive Materials" sign, a visitor's instruction form, a copy of the appropriate nursing instructions, a cute pie type ionization survey meter is the most appropriate instrument for the initial patient room survey and the personal dosimeter.

9. Prepare the patient's room with lead shields, oversized trash cans, linen hamper and place the safe line on the floor. Move any chairs in the room to the opposite side of the safe line.

10. Transport the sources to the patient's room and assist the physician in loading the implant.

11. Perform an environmental radiation survey of the patient's room (Form 10) recording the exposure rates at the head, foot, bedside shielded and the bedside unshielded positions. In addition the hall and all adjacent areas must be surveyed including room above and below. Record the results on the implant room survey form. Complete the implant loading checklist initialing each item certifying that the item has been properly completed.

Permanent implant patients who have had an implant of the prostate gland are generally released the same day and are not monitored past the recovery room.

12. Calculate the maximum visitation time and maximum nursing time at bedside per shift using the following formulas:

Recommended Maximum visitation time per day (100 / Visitor's dose rate / # days of implant) = hours/day **Most likely the visitor's time will be set to 30 min/day**

Recommended Maximum nursing time at bedside per hour = 2mR / unshielded bedside exposure * 60 min **Time per hour usually ranges 4.0 to 10.0 min/Hr**

THESE VALUES MAY VERY DEPENDING ON THE NEEDS OF THE PATIENT

Record these values on the room survey form in the appropriate places.

13. Post the room door with the radiation caution sign, the visitor's instruction sheet and the room survey. Place a copy of the nursing instructions in the patient's hospital chart. On the nursing instructions, complete the header information to include; patient's name, room number, anatomical site, total implanted activity, expected total treatment time and expected time and date of removal. This information must also be entered into the

EXHIBIT C 2007

17. Return the sources to the storage area in the Radiation Therapy Department. Complete the exit checklist on the room survey form initialing each item.

18. Complete the inventory log for the implant sources.

19. For the Cesium-137 sources return each source to its designated position in the storage safe. It is a good idea to verify the serial numbers of each source as it is returned to the safe from its respective position in the after loading apparatus.

20. Return spent sources to the manufacturer. This process will normally be performed by the medical physicist in accordance with the applicable DOT regulations. Record the data required in the disposal section of the Brachytherapy Source Inventory Form. Place the outgoing shipping documents to the appropriate batch incoming shipping documents kept in the Radioactive materials QA Record Book.

21. Complete the Quality Management Summary Log in the Radioactive Materials QA Record Book. Record the prescription dose and the final actual dose and calculate the percentage difference. Comment on any dosimetry differences. Doses with a discrepancy of ± 20 % need to be reported as a medical event. Doses of ± 10% should be documented as a recordable event. If the difference exceeds the threshold for a recordable event, initiate the proper reporting procedures according to 10 CRF 35 and Red Guide 10.8.

Revised May 2005

EXHIBIT C 2007

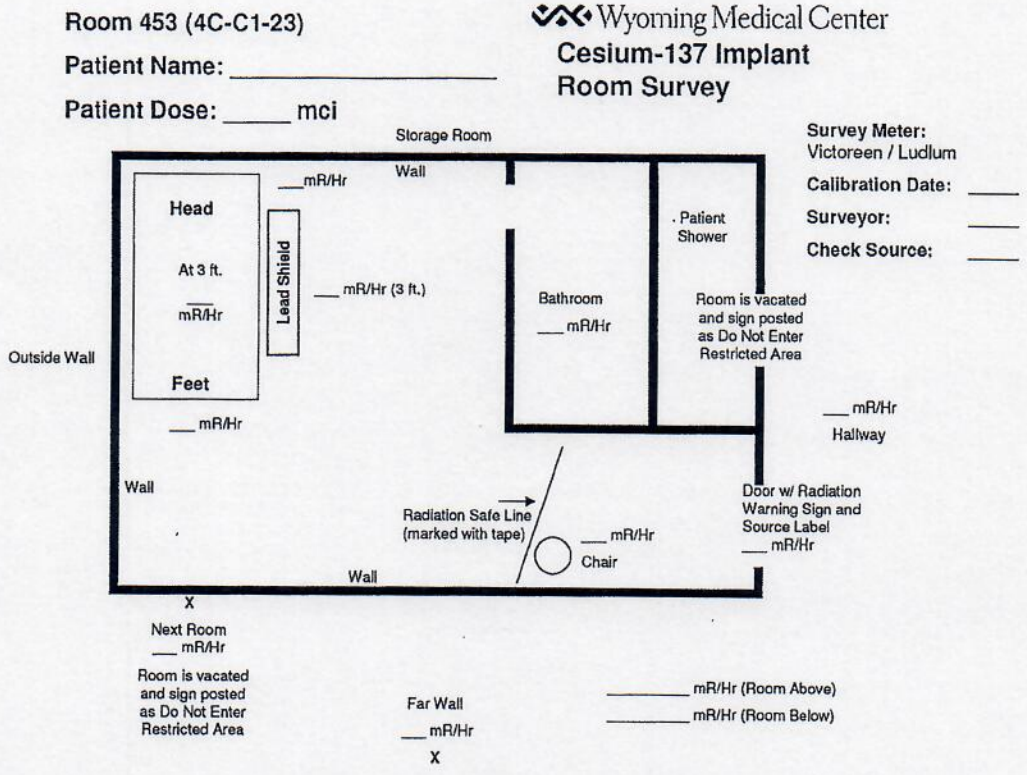
Wyoming Medical Center

Cesium-137 Implant Room Survey Form

Form 10

Patient Name: _____

Room: _____



- **No pregnant visitors allowed**
- **Visitors should sit at least 6 ft. (or 2 meters) from the patient and should remain no longer than _____ hours each day.**

EXHIBIT C 2007

1. Caution signs were posted on the door of patient's room, patient's bed and patient's chart when radioactive sources were in the patient.

2. Nurses assigned to the brachytherapy patient were given film badges to monitor radiation exposure.

3. The bed linens for the brachytherapy patient were checked with a radiation survey meter (Ludlum meter) before being removed from the patient's room to ensure that no dislodged sources were displaced in them.

4. After the radioactive sources were removed from the patient, a radiation safety survey was made in the patient's room with a radiation survey meter (Victoreen or Ludlum meter) immediately. The reading was _____ mR/hr.

5. Radioactive sources were counted by _____ during the removal of the sources from the patient and recounted by _____ during returning to the "radioactive material storage room".

6. A log book was used to check-out and check-in the radioactive sources.

Signature _____

Name: _____

Date: _____

Form 10: Revised May 2005

EXHIBIT C 2007

Wyoming Medical Center

Prostate Permanent Seed Implant Education
Post-Operative Instructions

For Patients Receiving Radioactive Palladium-103 Seed Prostate Implants

Patient Name_____ Medical Record # _____

Physician's Name_____ Date of Implant _____

Small radioactive seeds have been placed in your body. Each seed is about 1/4 of an inch long, similar in size and shape to a piece of a small paperclip. To minimize exposure of radiation to others from the radioactive source inside your body, we recommend that you do the following:

- Follow your discharge instructions.
- We recommend that a condom be used during sexual relations for the first two months following the procedure.
- Minimize close contact with children, pregnant women and others by trying to stay a distance of four (4) feet away for two months. Brief social relations such as touching, shaking hands and kissing are permissible.
- Whenever possible, separate sleeping arrangements are recommended for two months. Unless the distance between yourself and your partner during the sleeping portion of the night is greater than four (4) feet.

If you find a seed or pellet that falls out:

1) Do not handle with your fingers. Use something like a spoon or tweezers to place it in the toilet and flush twice.
2) Under no circumstances are you to save the seed as a memento of your procedure.
3) If you have any questions, contact Wyoming Medical Center Radiation Oncology Department at 307-577-7920 to speak to a radiation oncology physician.

Additional Precautions: _____

Patient _____ Spouse/Other _____ Relationship_____

I have read and understand the above instructions.

Instructor _____ Date _____

Form 11: Revised May 2005

EXHIBIT C 2007

EXHIBIT D

RSC Meeting Minutes

Wyoming Medical Radiation Safety Committee

Date	12/1/2021
8/25/2021	Radiation Safety Committee Meeting Minutes

Members Present	April Perez (Radiology manger) Michael Fernald (RSO) Heather Sutyak (Health Physicist Consultant) Drew Parcell (Cath Lab), Bob Bellomy (Radiology Director) Deb McGee (Nursing) Sheldon Gilbert (OR) Dr. Wells (Oncology) 35.400 Dr. Rhea (Radiologist)
Not present	Dr. John Purviance (oncologist, 35.300, 35.400) Dr. Burke Morin (Radiology Medical Director) 35.100, 35.200)

Called to Order	7:40
Approval of minutes	August 25, 2021 approval of minutes April Perez approved
Topic	Action
Administrative Report	• License amendment request for Cs-131, removing physicians, and adding Dr. Satterfield and Dr. Wells is pending ⊄ Waiting to hear from NRC
Badges	• 3 over ALARA I • Letters sent to those individuals
Cardiology	• Exposure CD's for RSO to review
Cath Lab	• Nothing to report
Interventional Radiology	• Nothing to report
Nuclear Medicine	• East Campus NRC license has been fulling decommissioned • Staffing update – down to 1 member temporarily. Requesting an FTE for staff who will be out on medical leave
Nursing	• Nothing to report

EXHIBIT D 2021

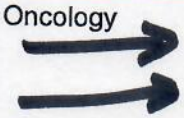
Oncology 	• Waiting for NRC on the Cs 131 regulations • New Written Directive Form • Policy for Seed Implants – April to add language from Heather. April will bring to group for approval. • Heather will continue reviewing Brachytherapy exams.
OR	• Michael did rounding and noticed that lead aprons were not hung properly. Sheldon will address this to staff.
Radiology	• April introduced two policies that have been approved. Banner Radiation Safety and Banner Radiation Protective Equipment Inspection Program. • April reminded the group when receiving new lead – to make sure it goes to the RPE team for documentation
Concluded	7:53

EXHIBIT D 2021

RSC Meeting Minutes

Wyoming Medical Radiation Safety Committee

Date	8/25/2021
5/5/2021	Radiation Safety Committee Meeting Minutes

Members Present	April Perez (radiology mgr), Michael Fernald (RSO), Heather Sutyak (health physicist consultant), Dr. Burke Morin (radiology medical director, 35.100, 35.200), Drew Parcell (cath lab), Bob Bellomy (radiology director), Deb McGee (nursing), Sheldon Gilbert (OR)
Not present	Dr. John Purviance (oncologist, 35.300, 35.400)

Called to Order	7:45
Approval of minutes	Will send out via email for approval August 26, 2021 approval of minutes Dr. Burke Morin approved Deb Magee second the approval
Topic	Action

Administrative Report	• License amendment request for Cs-131, removing physicians, and adding Dr. Satterfield and Dr. Wells is pending
	  ○ We learned that the NRC is not staffing their mail room and as such, the amendment request has not been received
	• JC visit - all good from nuclear medicine
	• NRC visit last week
	  ○ Few forms recommended to be updated
	  ○ Issue where one I-131 ablation was not signed by Dr. Purviance, it was documented that he was at the procedure
	  ○ Issue with written directive on prostate seed plans
	  ■ Heather Sutyak will start reviewing prostate seed implant paperwork
	  ○ We will have a recap call with the NRC sometime in the next few weeks and can provide more detail at the next meeting
	  ○ Radiation Safety Committee robustness
	• Question from Drew: Obtain the TLD Badge request from Casey for new employees
	• Transfer of control document is with Rachel Bryant; Bob has been working with Dr. Hanny and Michael on the transition

EXHIBIT D 2021

Badges	• Gary Idlechik exceeded LDE ALARA I for Q1, 2021 (267 DDE mrem, limit 125 mrem) - ALARA Letter will be sent out. • Missing badge report - Landauer updated their website and we can now see missing badges broken down by department. ○ Report sent to managers, but we are still missing badges (around 38 badges) - all of GI lab and some from surgery • Review EDE2 participants
Cardiology	• Nothing to report
Cath Lab	• Nothing to report
Interventional Radiology	• Nothing to report

Nuclear Medicine	• East Campus - decommissioning the nuclear medicine department
	  ○ Moving calibration sources to Central
	• Central Campus - door lock update, door lock changeout is complete
	  ○ The change makes their workflow smoother and less likely to drop radioactive materials
	• Additional FTE opening (hopefully by the end of the year)

Nursing	• Nothing to report
Oncology	• Proposing a new form to aid in planning & review to provide high confidence. Committee is in agreement to use the new form. ○ Positive feedback from NRC reviewer on the form

OR	• Bi-plan room will have additional cases on every other Thursday, starting in October - might see an additional person in Cath Lab as well
	• Change in o-arm procedure earlier this year.
	  ○ The change involved where scrubbed in staff stand relative to the o-arm, inside the OR suite versus outside.
	  ○ RSO was asked to provide brief education to OR staff, which was completed in Q2.
	• Adding information to time out about lead and badges - coming but we don't yet have a date1

Radiology	• Request to remove lead shielding for x-ray diagnostic procedures
	  ○ Are we ready to formalize the policy or do we need more time? Still in a holding pattern on this new policy.
	  ○ Date of change? Reviewing Banner's policies, we don't yet have a date. Next meeting we will discuss the policy changes (or via email)

Concluded	8:30

EXHIBIT D 2021

EXHIBIT E 2016

Wyoming Medical Center

Radiation Safety Committee

September 28 2016

Members Present: Michael Fernald, Dr. Flaherty, Dr. Tobin, Jan Nixon, Lori Peloquin

Others Present:

Invitees/Members Absent: Drew Parsell, Russ Easterling

Called to Order: **5:00 pm**
Approval of Minutes: Michael Fernald

Administrative Report	Michael Fernald • Discussed Nuclear Regulatory Commission inspection findings • Discussed 2015 ALARA review • Discussed Associates in Medical Physics difficulties in performing audits for Nuclear Medicine
1. Nuclear Medicine	• Keith Ostrom is scheduled to come and provide Nuclear Medicine audit
2. Cardiology Report	• nothing to report
3. Oncology Report	• Michael Fernald – Updated seed implant form
4. Radiology Report	• Dr. Flaherty requested that the Radiation Safety Committee meeting is conducted following tumor board
	Action
1. Film Badge Exposure Reports for Quarter/Year to date	• Lori Peloquin – • Nothing new to report
2. Survey Equipment Calibrations	• Equipment calibrations current

EXHIBIT E 2016

Wyoming Medical Center

Radiation Safety Committee

December 14 2016

Required Members Present	Michael Fernald	~~Dr. Lauro~~
	Dr. Flaherty	Chad Pew
	~~Dr. Tobin~~	Deb Magee
	Dr. Purviance	
Members Present	Lori Peloquin	~~Damian Lucero~~
	Drew Skinner	~~Russ Easterling~~
	~~Kim Vogel~~	

Called to Order: **8:00 am**
Approval of Minutes: Michael Fernald

Administrative Report	Reviewed ALARA Review and let members know where the report is held. NRC letter came in. Response required within 30 days. All issues were fixed at the time of the NRC visit.
1. Nuclear Medicine	Still short on technologist. One traveler filling in currently
2. Cardiology Report	Nothing to report
3. Oncology Report	Robust LDR therapy program in 2016
4. Radiology Report	3 fetal badges currently out
1. Film Badge Exposure Reports for Quarter/Year to date	Nothing to report
2. Survey/Equipment/Calibrations	New stereo biopsy unit replacing the old one

EXHIBIT E 2016

New Form - Updated 2021
EXHIBIT F

WYOMING MEDICAL CENTER
PALLADIUM-103 PERMANENT IMPLANT
WRITTEN DIRECTIVE

Patient Name _____

Medical Record Number _____ D.O.B. _____

Implant Date _____ Room # _____

Route of Administration Transperineal

PRIOR TO IMPLANTATION

Prescription Dose (to a relevant target volume) _____ Gy

Treatment Site Prostate Gland

Radioisotope Pd-103

Number of Seeds Ordered _____

Number of seeds Planned _____ Activity per Seed _____ mCi

(Number of seeds planned) x (activity per seed) _____ mCi

Authorized User _____ Date _____ Time _____

AFTER IMPLANTATION

Total Dose _____ Gy

Treatment Site Prostate Gland

Radioisotope Pd-103

Number of Seeds Implanted _____

Total Activity Implanted _____ mCi

Authorized User _____ Date _____ Time _____

Number of seeds returned to hot lab _____

EXHIBIT F 2021

WYOMING MEDICAL CENTER
PALLADIUM-103 PERMANENT IMPLANT
BRACHYTHERAPY SURVEY FORM

Patient Name_____

Medical Record Number_____D.O.B._____

Implant Date_____Room #_____

INSTRUMENT

Instrument name_____Serial_____

Calibration date_____

Check source reading_____Check source expected_____

Check source serial_____

ROOM SURVEY BEFORE IMPLANTATION

Background_____mR/hr

Patient prior to procedure_____ mR/hr / bkg

ROOM SURVEY AFTER IMPLANTATION

Stepper/stand_____mR/hr / bkg

Urine/blood bag_____ mR/hr / bkg

Cystoscope_____ mR/hr / bkg

Instruments/sterile table_____ mR/hr / bkg

Trash/floor_____ mR/hr / bkg

Patient symphysis_____mR/hr

1 meter from symphysis_____mR/hr

Surveyor_____Date_____Time_____

EXHIBIT F 2021

WYOMING MEDICAL CENTER
RADIATION SAFETY CHECKLIST FOR PROSTATE CANCER
PERMANENT IMPLANT THERAPY

NEEDED ITEMS

( ) WMC ID Badge

( ) Calibrated GM detector

( ) Relevant paperwork: Written directive, Survey form

PREPARATION

( ) Ensure arrival of preloaded needles in hot lab

( ) Verify correct needle loading, activity, calibration, implant date

( ) Perform survey of package

( ) Record seed arrival in inventory log book

IMPLANT

( ) Confirm that the patient has been identified by two methods (birthdate, ID bracelet, or name check).

( ) Make sure written directive signed before and after implant.

( ) Survey the area surrounding the patient to be sure no sources were misplaced during the implant.

( ) Measure dose rates on the surface of the patient and at 1 meter from the patient.

EXHIBIT F 2021

Self Reporting & OLD Written Directive Form Exhibit G

7-13-2016

After a thorough, months long review of the Low Dose Rate Prostate Seed Brachytherapy procedures, there were a few things noticed by the Radiation Safety Officer that needed to be addressed with the paperwork.

First, it was notice that there were a handful of items not filled out on some the forms we use for seed implants. The forms that were used were complicated with legacy blanks from the time when WMC performed Cs implants. To the best of our ability, these outstanding items were corrected. And, because of this, a new form was created that is much simpler in nature, eliminating the potential for items not being filled out.

Second, it was noticed that some post plan CTs were not completed. After interviewing personnel involved in prostate seed implants, it was found that some patients denied follow up appointments and the treatment planning computer had suffered a hard drive failure and data was lost. To the best of our ability, we have rescheduled those patients for CTs to perform post plan studies. To remedy patients not receiving post seed plans, we purchased a new treatment planning computer and we now store CTs in two locations. That way, in the event of another drive failure, any outstanding post plans can be re-created.

Lastly, to ensure in the future that no information is missing, the binders holding patient information have been re-organized. Now, all planning (pre, post) documents, shipping documents, etc. are stored together for each case. This was done as a pre-emptive, quality improvement measure.

Michael Fernald

Michael Fernald, MS, RSO

OLD written Directive form
Exhibit G

Brachytherapy Prescription and Patient Record

Patient Name:_____

Patient Billing #:_____ M#_____ Room #:_____

Diagnosis: Prostate CA Procedure: US Guided Prostate Seed Implant

PHYSICIAN WRITTEN DIRECTIVE/PRESCRIPTION

Radioisotope	No. of Sources	~~mCi~~/Source	mgm/Source	Geometry	Dose Points
Pd-103					

Prescription (to a relevant target volume):

Physician Signature:_____ Date:_____ Time:_____

Revisions (if necessary):

Physician Signature:_____ Date:_____ Time:_____

[illegible]

Pt. Identification Verification (Circle method used): B-date / ID Bracelet / Name Check / Physician/ Other:_____

Route of Administration (Circle method used): Transperineal

Radioisotope: Pd-103 Treatment Site: Prostate

Total mCi:_____ Total Time: Permanent

Patient surveyed at 1 meter after source implant(circle) yes no _____mR/Hr Survey meterS/N:_____Surveyed by:_____

Radiation survery of ambient area. Area released for general use. yes no

Calculated By:_____ Plan Saved As:_____

VerifiedBy:_____ Date:_____ Time:_____

	Day	Date	Time	Initials	Total Hours
Sources In					

Treatment Summary

Total Dose:_____Site: Prostate Rectum:_____Bladder_____Other_____

Calculated By: _____ Double Checked By: _____

Physician Signature: _____ Date:_____

Physicist's Signature: _____ Dosimetrist's Signature: _____

Revised 7/05

Written Directive Revised before 2016 Inspection Exhibit G

WYOMING MEDICAL CENTER
PALLADIUM-103 PERMANENT IMPLANT
WRITTEN DIRECTIVE

Patient Name_____

Medical Record Number_____ D.O.B._____

Implant Date_____ Room #_____

Route of Administration___Transperineal_____

PRIOR TO IMPLANTATION

Prescription Dose (to a relevant target volume)_____ Gy

Treatment Site___Prostate Gland_____

Radioisotope____Pd-103_____

Number of Seeds Planned/Ordered_____ Activity per Seed_____

Authorized User_____ Date_____ Time_____

AFTER IMPLANTATION

Total Dose_____ Gy

Treatment Site___Prostate Gland_____

Radioisotope____Pd-103_____

Number of Seeds Implanted_____

Total Activity_____

Authorized User_____ Date_____ Time_____

EXHIBIT H 2017 Inspection closing Prev Violation

NRC FORM 591M PART 1
(4-2008)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Wyoming Medical Center 1233 East Second Street Casper, Wyoming REPORT NO.: 030-03495/2017-001	U.S. Nuclear Regulatory Commission Region IV, 1600 East Lamar Blvd Arlington, Texas 76011-4511

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE(S) OF INSPECTION
030-03495	49-00152-02	September 25, 2017

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

* ☑ 1. Based on the inspection findings, no violations were identified.
* ☑ 2. Previous violation(s) closed. *
☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy to exercise discretion, were satisfied.

☐ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	Chris Beckley		9-25-17
NRC INSPECTOR	Jason Dykert		9-25-2017
BRANCH CHIEF			

NRC FORM 591M PART 1

☐ Non-Public ☐ Sensitive – Security-Related ☒ Public ☒ Non-Sensitive

Education Email discussing Seeds

Perez, April

Subject: FW: Radiological seed implant training

2021 Exhibit I

From: Michael Fernald <mfernald@wyomingmedicalcenter.org>
Sent: Wednesday, February 10, 2021 10:58 AM
To: Michelle Steinert <msteinert@wyomingmedicalcenter.org>
Cc: Casey Robberson <crobberson@wyomingmedicalcenter.org>; Bob Bellomy <rbellomy@wyomingmedicalcenter.org>; April Perez <aperez@wyomingmedicalcenter.org>; Sheldon Gilbert <sjgilbert@wyomingmedicalcenter.org>; Jolynn Roy <jroy@wyomingmedicalcenter.org>
Subject: Re: Radiological seed implant training

Thanks, Michelle.

A few minutes ago, the sales rep sent me a couple of images of the Cs-131 seeds. I've attached them here. They look a whole lot like the Pd-103 seeds - but I do like the relative scale from the dime. I think you'd be safe to use any of the pictures (these, or the ones from earlier) as representative of both Cs-131 and Pd-103. I'll leave that up to you and what works best for you.

Have a great rest of your week,
-Michael

On Wed, Feb 10, 2021 at 10:42 AM Michelle Steinert <msteinert@wyomingmedicalcenter.org> wrote:

Will do. I will update and send it out to the staff over the next few months.

On Wed, Feb 10, 2021 at 10:09 AM Michael Fernald <mfernald@wyomingmedicalcenter.org> wrote:

Hi Michelle,

Here is the information for the Cs-131 slide:
Cesium-131 has a half-life of 9.7 days and emits only characteristic x-rays of 29.4 kev with no beta radiation. The seeds are able to deliver their dose more quickly than Pd-103 due to their shorter half life.
source: https://pubs.rsna.org/doi/abs/10.1148/85.6.1117

I have requested some images of the Cs-131 from the vendor and will send those when I get them.

As I looked through the presentation one more time, I did see that Pd-103 is listed as beta radiation. I vaguely remember saying that when we spoke last year and I did misspeak. Pd-103 gives off low energy x-rays versus beta radiation. Sorry for the confusion.

Thanks!
-Michael

Exhibit I 2021

On Tue, Feb 9, 2021 at 11:59 AM Michael Fernald <mfernald@wyomingmedicalcenter.org> wrote:

Thanks Everyone,

I do remember working on the education, but for some reason I thought there was some staffing transitions and perhaps the education didn't get implemented- my mistake!

It's very appreciated that is the training module in there. Is it possible to share the module with me? One thing that we could potentially need to add is a picture of the seeds. I think seeing a copy of the training would be the best step forward (and I do apologize if I've seen it- I can't find a copy in my email).

Thanks again!
-Michael

Sent from my iPhone

On Feb 7, 2021, at 2:05 PM, Casey Robberson <crobberson@wyomingmedicalcenter.org> wrote:

I would say that PACU and OPD are good if Michael had collaborated with you. Michael is there anything new that wouldn't have been in the education from last year?

Thanks,

Casey Robberson BSN, RN
Nurse Manager Perioperative Services
Wyoming Medical Center
P: 307-577-2284
C: 307-797-0951
F: 307-577-2239
1233 E Second Street
Casper, WY 82601
crobberson@wyomingmedicalcenter.org

Banner Health. | Wyoming Medical Center

On Thu, Feb 4, 2021 at 3:57 PM Michelle Steinert <msteinert@wyomingmedicalcenter.org> wrote:

I developed a training module for PACU and OPD on prostate seeds and radiation safety March/ April of 2020. I put together a Healthstream Module in collaboration with information from Michael Fernald. It had a quiz as well that measured their knowledge.

Do we need to re educate staff on radiation safety?

If so, I can incorporate it into a revised Healthstream training module for staff and they can do a module? Just a suggestion.

On Thu, Feb 4, 2021 at 12:13 PM Michael Fernald <mfernald@wyomingmedicalcenter.org> wrote:

Hi everyone,

Exhibit I 2021

Casey and Sheldon, thank you for your willingness to add this education in. I promise to make it quick and as painless as possible. I'm working on the instructions right now and hope to have them done by next Wednesday. I will send it out to the entire group in this email. If anyone needs to be added in the meantime, please let me know.

Thank you,
-Michael

On Feb 3, 2021, at 4:26 PM, Casey Robberson <crobberson@wyomingmedicalcenter.org> wrote:

Thanks Bob! Please loop Michelle Steinert and Jolynn Roy into education as they are our Periop Educators.

Thanks,

Casey Robberson BSN, RN
Nurse Manager Perioperative Services
Wyoming Medical Center
P: 307-577-2284
C: 307-797-0951
F: 307-577-2239
1233 E Second Street
Casper, WY 82601
crobberson@wyomingmedicalcenter.org

Banner Health. | Wyoming Medical Center

On Wed, Feb 3, 2021 at 2:12 PM Bob Bellomy <rbellomy@wyomingmedicalcenter.org> wrote:

> Yes, I think it should be inclusive of all who care for the patient.
>
> I will let your team decide who all needs to be included and then Michael can help facilitate the learning component.
>
> Thank you
>
> On Wed, Feb 3, 2021 at 13:02 Casey Robberson <crobberson@wyomingmedicalcenter.org> wrote:
>
> > Should this education be extended to PACU and OPD as well since they care for patients post-op?
> >
> > Thanks,
> >
> > Casey Robberson BSN, RN
> > Nurse Manager Perioperative Services
> > Wyoming Medical Center
> > P: 307-577-2284

Exhibit I 2021

C: 307-797-0951
F: 307-577-2239
1233 E Second Street
Casper, WY 82601
crobberson@wyomingmedicalcenter.org

Banner Health. | Wyoming Medical Center

On Wed, Feb 3, 2021 at 8:48 AM Sheldon Gilbert <sjgilbert@wyomingmedicalcenter.org> wrote:

> No concern at all.
>
> Thank you!
>
> On Wed, Feb 3, 2021 at 8:12 AM Bob Bellomy <rbellomy@wyomingmedicalcenter.org> wrote:
>
> > Good morning Sheldon and Casey,
> >
> > I met with our RSO (Radiation Safety Officer) this morning. He is a physicist at Rocky Mountain Oncology, he works in tandem with Dr. Purviance and others. Part of his work is to ensure that all hospital staff receive adequate training for Radiation producing items. The prostate seeds that are implanted fall into that category. He is going to develop a simple document that provides safety information to staff that work with any patient that has seeds placed.
> >
> > This is likely going to be a one page document and then the staff member would need to sign an attestation of receipt and base understanding.
> >
> > Do you have any concern of this?
> >
> > Thank you
> >
> > --
> > Bob Bellomy R.T. (R) (CT) (MR) (ARRT)
> > Director of Imaging Services
> > Wyoming Medical Center
> > 6550 East 2nd St.
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