ADAMS Accession# ML23172A297

Saint Alphonsus
A Member of Trinity Health

DATE: June 2nd, 2023

TO: United States Nuclear Regulatory Commission,
FROM: David McFadyen, President Saint Alphonsus Regional Medical Center, Boise, Idaho
RE: Response to Apparent Violations in NRC Inspection Report 030-32263/2022-001; EA-23-012
Apparent Violation of failure to ensure that written directives for permanent implant brachytherapy contained information required by regulation:

1) Reason for violations specific to missed and incorrect element of written directives for pre and post implantation total source strength in a unit of activity was due to an oversight for not converting planned dose to mCi and noting it in the specific line item on the written directive. The incorrect specific activity on a second written directive occurred due to not accounting for the mathematical difference in the planned dose versus the final dose administered relative to the change in the number of planned tiles and implanted tiles.
2) Corrective steps that have been taken/or will be taken and the results achieved. The written directive with the missing strength in a unit of activity was revised to include the converted amount in mCi. That missing element is now demonstrated on the written directive. The second written directive was also corrected to account for the difference in the planned dose versus final dose. That correction is now demonstrated on the written directive. Beyond revising the written directives to correct the missing dose in a unit of specific activity error and mathematical/carry over error to meet the requirements of the written directive, a pre and post implantation checklist that was created for this procedure was revised. Prior to and after implantation a line item for the physicist to validate that the written directive has all the required and correct elements of the written directive was added. With respect to the written directive template a revision was made to add a time stamp next to the date field. As of June 2nd another revision was made to the Gamma Tile Written Directive that differs from the revised written directive that was sent out in our initial response on May 22nd. It was felt that there was a further need to put in place corrective actions with respect to the written directive to ensure a clear path plan for the pre-operative written directive as well as the post-operative written directive post implantation. The removal of the verbiage "expected" as part of the pre-operative written directive with subsequent replacement with the verbiage "planned" was made. Also a Quality Management Review element was added that will allow review by both authorized user and medical physicist to validate post procedure the reconciliation of the written directive. This revised written directive has been reviewed by both Authorized User of Gamma Tile and senior physicist. This revised directive will be submitted to the Radiation Safety Committee quarterly meeting in August for approval.

Sincerely

David McFadyen,

Saint Alphonsus
CANCER INSTITUTE

GAMMATILE THERAPY
WRITTEN DIRECTIVE
Department of Radiation Oncology

Patient name:
Patient identification number:
Implanting neurosurgeon:
Authorized user (radiation oncologist):
Is the patient pregnant? ☐ Yes / ☐ No Has the patient signed the Consent Form? ☐ Yes / ☐ No
Special instructions:

PREOPERATIVE DIRECTIVE

Implant site:
LDR applicator: Gamma Tile containing 4 sealed source seeds per tile Radionuclide: Cs-131
Nominal source strength per seed: 3.5 U to deliver a nominal dose of 60 Gy at a depth of 5 mm
Planned number of Gamma Tiles: Planned number of sealed sources:
Planned total activity: mCi
Authorized user signature: Date/Time:

POSTOPERATIVE DIRECTIVE

Implant site:	**Date of implant:**
Mean source strength of preloaded seeds, as per source assay report: U	**mCi**
Implanted source strength within 5% of nominal value? ☐ Yes / ☐ No	
Number of Gamma Tiles implanted:	**Number of sealed sources implanted:**
Total Activity implanted: mCi	
Authorized user signature:	**Date/Time:**

QUALITY MANAGEMENT REVIEW

Written Directive Reviewed by Authorized User:	
Planned Number of Tiles:	**Number of Gamma Tiles implanted:**
Planned number of sealed sources:	**Number of sealed sources implanted:**
Planned Total Activity: mCi	**Total Activity Implanted: mCi**
Authorized user signature:	**Date/Time:**

Written Directive Reviewed by Medical Physicist:	
Planned Number of Tiles:	**Number of Gamma Tiles implanted:**
Planned number of sealed sources:	**Number of sealed sources implanted:**
Planned Total Activity: mCi	**Total Activity Implanted:** mCi
Authorized Medial Physicist Signature	**Date/Time:**

Postoperative radiation survey (maximum exposure at 1 meter): mR/hr
Patient meets criteria to be released based on survey (<=6 mR/hr, recommended by manufacturer isoray): ¨ **Yes** / ¨ **No**
Patient provided written radiation safety instructions/implant card: ¨ **Yes** / ¨ **No**
Post plan based on CT or/and MR images will be needed, see the prescription of the post plan in Aria
Authorized user signature: **Date/Time:**

Written Directive Template sent out May 22nd, 2023 response

Saint Alphonsus
CANCER INSTITUTE

GAMMATILE THERAPY
WRITTEN DIRECTIVE
Department of Radiation Oncology

Patient name:
Patient identification number:
Implanting neurosurgeon:
Authorized user (radiation oncologist):
Is the patient pregnant? ☐ Yes / ☐ No Has the patient signed the Consent Form? ☐ Yes / ☐ No
Special instructions:

PREOPERATIVE DIRECTIVE

Expected Implant site:
LDR applicator: Gamma Tile containing 4 sealed source seeds per tile Radionuclide: Cs-131
Nominal source strength per seed: 3.5 U to deliver a nominal dose of 60 Gy at a depth of 5 mm
Expected number of Gamma Tiles: Expected number of sealed sources:
Total expected nominal source strength: U/ mCi
Authorized user signature: Date/Time:

POSTOPERATIVE DIRECTIVE

Implant site: Date of implant:
Mean source strength of preloaded seeds, as per source assay report: U mCi
Implanted source strength within 5% of nominal value? ☐ Yes / ☐ No
Number of Gamma Tiles implanted: Number of sealed sources implanted:
Total implanted source strength: U/ mCi
Postoperative radiation survey (maximum exposure at 1 meter): mR/hr
Patient meets criteria to be released based on survey (<=6 mR/hr, recommended by manufacturer isoray): ☐ Yes / ☐ No
Patient provided written radiation safety instructions/implant card: ☐ Yes / ☐ No
Post plan based on CT or/and MR images will be needed, see the prescription of the post plan in Aria
Authorized user signature: Date/Time: