

October 25, 2022

Mary C. Muessle, Director NRC  
Division of Radiologic Safety and Security  
Region IV  
1600 East Lamar Boulevard  
Arlington, Texas 76011

Re: Response to Apparent Violations in NRC Inspection Report, Docket No:030-03495/2021-001;EA-22-061

License number: 49-00152-02

Dear Mary Muessle:

The following is in response to your correspondence dated September 28, 2022 for the inspection conducted on August 17, 2021. Each item of non-compliance will be listed first, followed by its response.

**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, the licensee failed to prepare written directives that were dated and signed by an authorized user before the administered of I-131 sodium iodide greater than 30microcuries.

**Response:**

1. The reason for the apparent violation:

The Authorized physician on the license failed to sign the written directive on February 4<sup>th</sup>, 2021. The supervised physician had prior approval verbally from the AU on the license but did not obtain the AU signature prior to administration as required. It was believed that verbal approval from the AU was acceptable.

2. The corrective steps that have been taken and the results achieved:

An attempt to have the supervised physician obtain AU status was made and denied by NRC due to lack of appropriate training and experience. The AU on the license will sign all

written directives prior to administering I-131 sodium iodide greater than 30 microcuries. The supervised physician will not be allowed to sign the written directive.

3. The corrective steps that will be taken to avoid further issues of non-compliance:

The written directive procedure has been updated to allow only Authorized Users on the license to sign written directives prior to administrations greater than 30 microcuries of I-131. No verbal approval will be allowed.

4. The date when full compliance will be achieved:

Full compliance was achieved by 8/17/21 about educating staff on the written directive procedure to obtain an appropriately Authorized User signature on the license prior to administering written directive materials.

#### **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, the licensee did not include in the “before implantation” sections of written directives the total source strength. The “after implantation” sections of the written directives did not contain the total source strength implanted.

#### **Response:**

1. The reason for the apparent violation:

The physicist used air kerma strength to represent source strength. This value was consistent in both the pre implantation and the post implantation of the written directive. The physicist did not use activity based values for total source strength on the before implantation written directive and for the total source strength implanted on the after implantation written directive. This regulation was revised in 2018 with an effective date of Jan 14, 2019 which the licensee failed to integrate into the brachytherapy program.

2. The corrective steps that have been taken and the results achieved:

The written directive was immediately revised to include (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. The activity based value is now recorded rather than the air kerma units. This revised written directive was offered to the inspector in an email as additional information for follow up from the inspection.

3. The corrective steps that will be taken to avoid further issues of non-compliance:

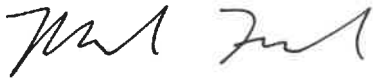
Brachytherapy written directives are now being reviewed by an outside consultant for completeness and to make sure the requirements in 10 CFR 35.40(b)(6) are being met. Also the radiation safety committee routinely reviews radiation safety aspects of the brachytherapy program. Any new or modified NRC requirements including any mailings are discussed in the RSC meetings.

4. The date when full compliance will be achieved:

Full compliance was achieved by 8/17/21 when the brachytherapy written directive was updated to include all requirements 10 CFR 35.40(b)(6). The physicist understands and has counseled others to use activity based values to record total source strength.

We hope the above information is satisfactory. We would also like to make note of a letter we submitted prior to this notice that provided additional information to our brachytherapy program including updated policies (ML22188A114). If further information is needed please feel free to contact us.

Sincerely,



Michael Fernald  
Radiation Safety Officer