Ascension

October 28, 2025

To: US Nuclear Regulatory Commission, Region III
ATTN: Document Control Desk
Washington DC 20555-0001

Re: Reply to a Notice of Violation, IR 03002022/2023001(DRSS)

During an unannounced routine inspection conducted by the NRC on November 27, 2023, through December 1, 2023, at Ascension Providence Hospital, Southfield MI, which continued in the NRC's offices through September 11, 2025, the NRC identified four apparent violations of NRC requirements. Ascension Providence does not contest the four apparent violations and recognizes their seriousness. Provided below is Ascension Providence Hospital's discussion of those violations, including (1) the reason for the apparent violations, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when Ascension Providence Hospital will achieve full compliance regarding each of the violations.

1. **10 CFR 20.1201(f)** requires that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

   Reason for Violation
   Ascension Providence Hospital did not have an established process for current employees to provide information about occupational dose from outside our two campus locations.

   Corrective Action Steps thus far and results
   Employees have been identified that require declaration of occupational dose received outside of Ascension Providence Hospital. The dosimetry reports from individuals that were identified have been collected and reviewed.

Ascension Providence, Southfield Campus
16001 West Nine Mile Road
Southfield, MI 48075

Corrective Action Steps yet to be completed
Language will be added to the 2026 annual instruction to clearly inform employees of the need to notify Ascension Providence Hospital of occupational exposure outside of our NRC license.

Date of full compliance
October 16, 2025

2. **10 CFR 20.1502(a)(1)** requires, in part, that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. As a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Reason for Violation

Dosimeters were provided to monitor exposure to radiation and radioactive material. However, the dosimeters were not worn consistently for two Authorized Users.

Corrective Action Steps thus far and results

Dose calculations were performed for both individuals, and the information was supplied to the NRC on April 1, 2024. Additional education was given to both individuals about the proper use of dosimeters. Finally, to ensure that the dosimeters were worn consistently, a procedural timeout was added to Interventional Radiology cases.

Corrective Action Steps yet to be completed

No additional corrective action has been necessary.

Date of full compliance

March 24, 2024

3. **10 CFR 35.24(f)** requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35, or two or more types of units under Subpart H of 10 CFR Part 35, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license

   Reason for Violation

   Ascension Providence Hospital has an established Radiation Safety Committee that meets quarterly. Membership includes an authorized user for each use, the Radiation Safety Officer, a nursing representative, and a management representative who is not an authorized user or RSO. However, there were meetings where some of the required members were not present.

   Corrective Action Steps thus far and results

   Alternate members have been identified and added to the committee if the primary member is not able to attend.

   Corrective Action Steps yet to be completed

   Radiation Safety Committee meetings have been moved to a yearly meeting. If the Radiation Safety Officer, authorized users for 35.100, 200, 300, 400 and 1000, nursing representative, or the management representative are not in attendance, the meeting will be canceled and rescheduled to a date that all required members can attend.

   Date of full compliance

   October 16, 2025

4. **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 any therapeutic dose of radiation from byproduct material.

   Reason for Violation

   For prostate seed implant cases, our historical workflow involved developing the treatment plan intraoperatively while the patient was under anesthesia in the operating room (OR). The Authorized User (AU) delineated the target, and the

dosimetrist generated the plan in real time with continuous AU input. To minimize anesthesia duration and maintain a sterile environment, implantation proceeded immediately after the plan was finalized, under the understanding that this constituted a verbal order from the AU.

This real-time approval was treated internally as equivalent to verbal authorization. A free-text statement in the record documented the physician's pre-implant approval; however, the inspection determined that this did not meet the requirements for a valid oral directive and concluded that a dated and signed written directive, as specified in 10 CFR 35.40(a), was not present. The AU subsequently signed the written directive reflecting the verbal order at the conclusion of the procedure, before leaving the OR. The NRC determined that this workflow did not meet the regulatory requirement for a dated and signed written directive prior to administration.

Corrective Action Steps thus far and results:

Although prescription elements such as dose and radionuclide were documented, dated, and approved prior to implantation in a separate record (*Prescribe Treat*), the anticipated total source strength was not included. Immediately following the inspection, the following corrective actions were implemented.

For prostate seed implant cases, the written directive prior to implantation is now documented as a prescription in ARIA and approved by the Authorized User (AU). This directive explicitly includes the nominal total source strength anticipated to be implanted for the procedure—typically 75 U. As in past practice, the planned source strength is documented in the written directive, and the actual source strength implanted is recorded at the end of the procedure, before the patient leaves the post-treatment recovery area. No change has been made to that portion of the written directive.

To reinforce compliance, all staff involved in prostate seed implant procedures have been re-educated on the requirements of 10 CFR 35.40(a), including the distinction between written and oral directives. A hard-stop verification step has been added to the OR checklist to confirm that the AU-signed written directive is present and complete—including treatment site, radionuclide, dose, and total nominal source strength—prior to implantation.

Corrective Action Steps yet to be completed-

None

Date of full compliance

2/20/2024

Respectfully Submitted,

Vicki Nedeljkovic
Director of Radiology
Ascension Providence Hospital, Southfield campus