NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Ascension Providence Hospital	030-02022	21-02802-03

4. Report Number(s):	5. Date(s) of Inspection:
2023001	11/27/2023-9/11/2025

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason vonEhr, Jon Pfingsten (for RIII Assist)	02240/02120/20220	2	87130/87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Vikram Kinni, M.D., RSO	vkinni1@hfhs.org	248-849-3000

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☐ Hybrid	
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	11/27/2025 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Location(s) Inspected List:
47601 Grand River Ave., Novi, MI
16001 W. Nine Mile Rd., Southfiled, MI

17. Scope and Observations:

Program Overview

This was a routine, announced inspection of Ascension Providence Hospital, a large medical licensee with facilities in Southfield and Novi, Michigan, as well as mobile operations. The licensee was authorized for a wide range of sealed and unsealed radioactive material for medical use under 10 CFR Part 35, including diagnostic and therapeutic nuclear medicine under 10 CFR 35.100-300, manual brachytherapy under 10 CFR 35.400, and yttrium-90 microspheres authorized under 10 CFR 35.1000. The licensee used these authorizations at its pair of fixed facilities in the Detroit metro area, as well as an authorization for the 10 CFR 35.100 and 35.200 nuclear medicine studies in mobile medical coaches at temporary job sites in NRC jurisdiction. A parallel radioactive materials license (NRC License No. 21-26632-01) under a joint venture between Ascension Providence and the University of Michigan was co-located at the licensee's Southfield facilities, though without overlap in the detailed areas of use, and was authorized for a 10 CFR 35.600 high dose-rate remote afterloader. The inspection was announced to maximize efficiency of government resources in the travel and execution of the inspection and permitted the planning of other inspections around risk-significant operations anticipated at the licensee.

Licensing Overview

The license was amended four times between the onsite inspection initiated in November 2023 and the prior routine inspection, which was started on September 29, 2021. These amendments included Amendment Nos.: 98, issued on May 5, 2023, which removed the radium-226 sealed source authorization; 97, issued on December 23, 2022, which removed a satellite location of use in Southfield, Michigan; 96, issued on October 3, 2022, which added an Associate Radiation Safety Officer (ARSO) and several authorized users (AUs), and released a location within the facility for unrestricted use; and 95, issued on May 10, 2022, which added an authorization for radium-226 for storage only, pending disposal. During the in-office review that followed the on-site inspection, an additional amendment was issued: Amendment No. 99, issued on November 29, 2023, which removed an AU. The license was set to expire on January 31, 2024, in response to which the licensee provided a renewal application dated December 6, 2023 (ADAMS Accession No. ML23347A147), to NRC Region III, consistent with 10 CFR 30.36(a). Therefore, the license

was in timely renewal status (ADAMS Accession No. ML23347A218), postponing the expiration of the license.

Observation and Findings – Nuclear Medicine
The inspection was initiated at the Southfield location's nuclear medicine department. A second nuclear medicine area at the Southfield facility was dedicated to cardiac nuclear medicine operations. This area was likewise reviewed for operations, equipment, and personnel. The inspector observed daily equipment quality assurance/quality control (QA/QC) testing, package receipt, and patient administrations. Licensee staff wore appropriate dosimetry, utilized appropriate shielding, and appropriately handled the radioactive materials. Staff were interviewed and found to be knowledgeable regarding licensee practices, policies, and procedures. Bulk technitium-99m was ordered twice daily to cover emergent or emergency needs. Staff used xenon-133 frequently and iodine-123 or -131 approximately weekly. While a fume hood was present, it was not operational. Reviews were performed of local records such as area surveys, wipes, package receipt, administrations, and written directives and patient releases for 35.300 uses. The inspector performed independent and confirmatory radiation surveys – radiation levels were consistent with the type, form, and quantity of radioactive material authorized and possessed under the license and the licensee's postings and controls. No issues of greater-than-minor concern were identified.

The inspector's review continued with the licensee's Novi facility. At the Novi facility were three nuclear medicine areas performing licensed activities: a general nuclear medicine, a dedicated cardiac unit, and a physician's group operating under the Ascension license ("Novi Heart Institute"). In each of the three nuclear medicine areas, the inspector toured the physical facilities, observed patient administrations and, as time allowed, observed daily equipment QA/QC. Similar to the observations and reviews at the Southfield facility, radiation levels were assessed with independent surveys by the inspector and were consistent with the type, form, and quantity of radioactive materials authorized and possessed under the license, as well as the licensee's postings and controls. Staff were interviewed and found knowledgeable regarding the licensee's practices, policies, and procedures. The licensee maintained adequate calibrated radiation instrumentation across the licensee's nuclear medicine facilities.

Observations and Findings – Mobile PET
The inspector reviewed the licensee's mobile medical operations, which consisted of Positron Emission Tomography (PET) in mobile coaches operating at temporary job sites supporting various licensee or licensee-associated facilities. The licensee had one mobile PET coach in commission, with a second, identically constructed truck undergoing commissioning at the time of the inspection and was expected to be operational within weeks or a few months. As the second truck was identical to the first, the inspector determined that no new information was needed to address the shielding evaluation as it was already described within the NRC license (License Condition 13.A as of Amendment No. 98).

The inspector observed the licensee's preparation and administration of PET radiopharmaceuticals from the mobile coach, which during the day of that inspection activity was servicing the licensee's own fixed and licensed facility. The licensee used flourine-18, copper-64, and gallium-68 PET radiopharmaceuticals. The licensee used its own facility during the patient's uptake period, which was questioned as these locations were not previously described anywhere on the license and would traditionally be part of the licensee's shielding evaluations, provided pursuant to NUREG-1556, Volume 9, Revision 3, Section 8.9.1. The licensee performed and provided surveys demonstrating the ability to house patients administered PET radiopharmaceuticals while complying with public dose limits and restricted area requirements. This is in accordance with the licensee's application dated December 6, 2023, and letter dated May 7, 2024.

Observation and Findings – Manual Brachytherapy
The inspector reviewed the licensee's implementation, documentation, and training related to its manual brachytherapy authorized under 10 CFR 35.400. The inspector interviewed the physics staff, an AU, and reviewed the treatment planning process from referral, dosimetry/treatment planning, seed ordering, administration, pre- and post-administration written directives, and medical event reviews. The inspector had the opportunity to observe a

patient administration and the handling of the seeds throughout the process. Required surveys were performed with adequate and calibrated instrumentation. Both in the observed case and the sample of patient records reviewed, no medical events were identified either by the licensee or the inspector. Room and patient surveys, inventories, seed disposition (either by administration to the patient or through decay-in-storage or return to the manufacturer), were completed without issue and adequately documented. No radiation safety concerns were identified.

One item of concern was identified by the inspector which involved the pre-implant written directive prepared pursuant to 10 CFR 35.40(a) and 35.40(b)(6). Specifically, the licensee's practice was to prepare a pre-implant written directive without being dated or signed and, in the operating room immediately prior to administration, have the AU verbally approve the written directive. The licensee described this as a necessary measure to ensure the integrity of the sterile field while ensuring the strict accuracy of the treatment plan, which was, by the licensee's process, itself contingent on imaging performed in the operating room immediately prior to administration of the radioactive material. This was found to be inconsistent with 10 CFR 35.40(a), which requires the AU to sign and date a written directive before the administration of any therapeutic dose of radiation from byproduct material. The licensee's practice further appeared to be inconsistent with the expectations of 10 CFR 35.40(a)(1), which permits an oral written directive if, "because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health". The licensee's process also appeared to be inconsistent with the expectations of 10 CFR 35.40(c)(2), which permits an oral revision to a written directive under similar medical necessity ("…if the delay would jeopardize the patient's health"). The licensee's patients did not appear to have emergent conditions or other medical circumstances that would have prevented signing and dating prior to the time or date of the implant (e.g., at the time of initial patient imaging, seed ordering or scheduling of the procedure) while retaining the option to make an oral revision based on the imaging performed in the operating room immediately prior to administration, if medically necessary. The failure to sign and date the written directive prior to the administration was determined to be a Severity Level IV violation of 10 CFR 35.40(a), consistent with the NRC Enforcement Policy Section 6.3.d.1 as a result of the following: (1) the violation was an isolated failure, as it only involved one of the modalities authorized under the license and only one part of that modality's written directive requirement, (2) the violation did not result in a medical event, (3) the violation was not evidence of a programmatic weakness in implementation, and (4) the violation appears only to be limited to the manner of approval, and no indications existed to suggest that the AU ever failed to provide approval for an administration that otherwise occurred. The licensee committed to correcting this violation by preparing the pre-implant written directive earlier in the treatment planning process, such as at the time of the initial patient imaging (well ahead of the administration) and/or the ordering of the radioactive material. This would allow the AU the opportunity to sign and date the written directive consistent with 10 CFR 35.40(a) well ahead of the administration and without the risk of compromising the sterile field in the operating room.

Observation and Findings – Y-90 Microspheres
The inspector performed a review of the licensee's yttrium-90 microsphere program. This review included interviews with the physics and nuclear medicine staff, as well as the responsible AUs. Staff and physicians described the licensee's process from initial referral, imaging and lung shunt assessment, determination of the dosage, ordering, receipt, administration, and post-administration surveys and imaging. A sample of yttrium-90 administrations were reviewed – written directives were completed with required information consistent with the licensee's commitments related to the microsphere program (License Condition 13.A, dated July 2013 – note the NRC's latest guidance is addressed in the NRC Licensing Guidance, Revision 10.2, dated April 2021, and a copy of which was provided to the licensee for consideration for their pending NRC license renewal). Between 10 and 20 yttrium-90 microsphere cases were performed each year. No medical events were identified either by the licensee or the inspector.

The inspector reviewed dosimetry reports for personnel participating in NRC-licensed activities. For most program areas, such as the nuclear medicine, PET, and manual brachytherapy areas, exposures were reasonable and consistent with the inspector's expectations relative to the type and frequency of the licensed activity.

However, a concern was identified with regards to the yttrium-90 microsphere program occupational exposures. For staff and physicians working in the interventional suite, the licensee issued two dosimeters along with a protective lead apron and other personal shielding. The dosimeters were worn at the collar above the lead shielding and at the waist below the lead shielding, consistent with standard industry practices. The inspector found that two interventional radiologists and AUs had near-zero exposure, which was far less than is anticipated for physicians performing this type and frequency of work. The third AU also had limited exposure, but significantly different scope-of-work outside of the microsphere administrations, and therefore this limited exposure was judged by the inspector to be reasonably consistent with the AU's type and frequency of work, as described by the AU and associated supervisors/managers. The inspector interviewed each of the three AUs to understand the type and scope of work, professional and educational experience, training within and without the licensee, and potential explanations for lower-than-expected occupational exposure values. The first two AUs were involved in yttrium-90 microspheres through the date of the inspection only so far as to observe, rather than directly handle the microsphere administration, however their participation in NRC-licensed activities also included administering technitium-99m for the purpose of mapping/assessment of the anticipated exposure/effect on the lungs from the eventual microsphere administration.

For the first AU, of the 36 dosimeter reports reviewed at the Novi facility, only 4 reports from the collar dosimeter had recorded exposure, with strong variance (3 millirem; 12 millirem, 322 millirem, and 419 millirem), and similarly only three from the waist dosimeter had recorded exposure (2 reports with 1 millirem each, and one report with 104 millirem). Similar limited exposures were recorded for the first AU at the Southfield facility. At the Southfield facility, 23 dosimeter reports were available with 10 of the 23 recording a collar dosimeter exposure of under 10 millirem. Furthermore, across all the above-described reports, 26 reports reported the dosimeter as "unused" by the vendor and 18 as "minimal" or less-than-recordable exposures.

For the second AU, of the 36 dosimeter reports (only the Southfield facility was noted), only one collar badge exceeded 10 millirem, while one dosimeter was reported as "unused" and 19 reported 'minimal' exposure. These dosimeter readings appeared to be inconsistent with readings expected for the type and frequency of work described by the physicians, including their work with machine-produced x-rays such as a fluoroscope. The discussion above is provided for demonstration, as collar dosimeters are intended to be worn above the lead apron and therefore have no interspersed shielding between the dosimeter and the primarily-scatter radiation from a fluoroscope or similar equipment.

This was determined to be a Severity Level IV violation of 10 CFR 20.1502 for the failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee, including the failure to require the use of individual monitoring devices by adults likely to receive, in 1 year from source external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a).

In addition, the licensee was not taking account occupational exposure from outside the immediate license Ascension Providence Hospital (namely the two fixed facilities in Novi and Southfield, Michigan) but still under the overall Ascension health system. These other facilities utilized separate dosimeters that were not taken into account by the licensee to determine a cumulative occupational exposure for a given year. The exposure at the other facilities outside of this license were less significant than the activities at this licensee but nonetheless were required to be accounted for within the occupational exposure records of this licensee to ensure compliance with the occupational dose limits in 10 CFR Part 20. This was determined to be a Severity Level IV violation of 10 CFR 20.1201(f).

In response, the licensee performed dosimetry reconstructions for the AUs. The licensee ensured through audits and administrative-process changes that dosimeters were worn from December 2023 forward and used the results of these dosimeters to back-calculate the AUs occupational exposures for calendar years 2022 and 2023. The results of the licensee's final calculations were captured in a letter to the NRC dated April 1, 2024 (ADAMS Accession No.

ML24094A229), with an associated enclosure detailing the consultant physicists' report (ADAMS Accession No. ML24094A230), with a non-public attachment identifying the two AUs (ADAMS Accession No. ML24094A274). The licensee's report concluded that the two AUs had occupational exposures of 1,023 millirem and 1,279 millirem (AU1, Calendar Year 2022 and 2023 respectively), and 81 millirem and 53 millirem (AUs Calendar Year 2022 and 2023 respectively). In addition, the licensee performed outreach with the external entities the two AUs supported in Calendar Year 2022 and 2023 and concluded that the exposures from these facilities were no-more-than 40 millirem to the AUs, and that the support by the two AUs for these facilities was limited in both frequency, complexity of cases, resulting in limited additional occupational exposure.

One final concern was noted in the dosimetry sub-accounts reviewed by the inspector – in many, but not all, of the monthly reports reviewed, the licensee's control badge readings were noted as unusually elevated. Dosimetry vendors instruct licensees to store control badges in low radiation areas to prevent exposures that are not related to the travel and processing of the licensee's collective dosimeters on distribution or return to the vendor. While background radiation may be noted on control dosimeters, the inspector noted control dosimeters with a monthly recorded exposure exceeding 300 millirem in three instances, and above 100 millirem in 12 instances. In no instance during the on-site inspection did the inspector identify a control badge that was inappropriately stored or handled. The licensee did not have any explanation as to why the control dosimeters were so elevated. This was referred back to the licensee for additional action under the occupational radiation monitoring program, however the inspector did not have sufficient information, nor was a path available to acquire sufficient information, to determine whether the licensee failed to comply with any NRC regulatory requirement or license condition.

Observations and Findings – Additional Remote Review
The inspector performed additional remote reviews following the on-site inspection. These remote reviews included reviews of the onboarding or refresher training for the AUs involved with yttrium-90 microspheres as it related to radiation safety or dosimetry policies/practices, as well as radiation safety committee (RSC) meeting minutes, and occupational exposure monitoring records for select groups of staff and physicians. The documentation also addressed various issues that were identified or documentation not reviewed during the on-site inspection efforts, such as program reviews or audits of the oncology programs, potential contaminated package concerns at one of the nuclear medicine departments, mobile medical agreements pursuant to 10 CFR 35.80, shipping papers for the movement of radioactive materials for the mobile PET program, and dosage measurement equipment QA/QC records. Noncompliances of minor significance were passed on to the licensee for action throughout the inspection, an example of which was the absence of adequate identification of the radiation survey meter used for a variety of surveys required by regulation to demonstrate the adequacy of the instrument used.

Regarding the licensee's RSC, maintained pursuant to 10 CFR 35.24(f), the licensee provided records of its meetings from calendar year 2021 forward. The inspector reviewed these meeting minutes and determined that large gaps existed where the licensee had inadequate representation and oversight for the scope of its authorized activities. 10 CFR 35.24(f) requires, in part, that the committee must include an AU of each type of use permitted by the license, the Radiation Safety Officer (RSO), a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee met quarterly to perform their oversight function, with twelve meetings from January 21, 2021, through October 19, 2023. Between these dates, the licensee's RSO, who was also an AU for 10 CFR 35.100, 35.200, and 35.300 uses, attended six of the twelve meetings, with no other AU for 10 CFR 35.100 through 35.300 present during the six remaining meetings the RSO was absent for. In addition, the ARSO attended ten of the twelve meetings, but the two meetings the ARSO was absent for overlapped with the meetings the RSO was also absent for. The licensee did not have an AU who was authorized for 35.400 and 35.1000 (yttrium-90 microspheres) present for ten of the meetings. In eight of the twelve meetings, the licensee did not have a representative of the nursing service present. Only the management component of the licensee's committee was present for all meetings, usually with multiple representatives representing various parts of the hospital's organization. The licensee did not have evidence of material participation after-the-fact by qualified parties for the periods with noted absences. For example, there was no evidence that an AU, the RSO, or the nursing

Materials Inspection Record (Continued)

service representative reviewed the draft meeting minutes or supplied meaningful feedback to the committee following their absence, which would have addressed the spirit of the regulation. Therefore, a violation of 10 CFR 35.24(f) was identified due to the gaps in attendance and coverage of the RSC. This was determined to be Severity Level IV violation, as the absence of the required representatives for non-isolated instances inhibited effective oversight by the committee of NRC licensed activities.

The prior NRC inspection was performed on September 29 through October 4, 2021, with no violations identified. During the 2023 routine inspection, four Severity Level IV violations were identified concerning the licensee's failures to: (A) reduce the dose an individual may receive by the amount of dose received while employed by any other person; (B) perform adequate occupational exposure monitoring of two AUs involved in the Y-90 microsphere program; (C) have membership on the RSC including the RSO, AUs covering the modalities authorized on the NRC license, and representatives of the nursing staff; and (D) ensure an AU signed and dated a pre-implant written directive for 10 CFR 35.400 manual brachytherapy.

*Note to the next inspector: (1) it is recommended that the next inspector announce the inspection to permit the coordination of the inspection around risk-significant activities to permit the observation of these activities, and (2) it is further recommended that, for the efficient use of NRC resources, the next inspector consider inspecting the Ascension Providence Hospital license in parallel with the closely-related and co-located Providence Hospital, Providence Cancer Center (NRC License No. 21-26632-01).

*Note Regarding a Reported Medical Event: On February 1, 2024, a medical event (EN 56945) was identified at Ascension Providence Hospital concerning an yttrium-90 microsphere administration. This was reported to the NRC as a medical event under 10 CFR 35.3045(a)(1)(i) on February 2, 2024, the timing of which was consistent with 10 CFR 35.3045(c). The NRC determined that a reactive inspection was necessary and further determined that this would be documented separately from this routine inspection. The resultant inspection report was issued on March 1, 2024 (ADAMS Accession No. ML24059A094) and determined that no violations of NRC requirements were identified.

Signature and Date - Branch Chief

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