16. Scope and Observations:

Announced

Unannounced

Routine

Non-Routine

Michigan Mobile PET Imaging (MMPI) a mobile imaging service provider authorized to use byproduct material for diagnostic medical purposes at temporary job sites in NRC jurisdiction. At the time of the inspection, the licensee operated two PET trailers which traveled between various Beaumont Health and St. Joseph Mercy medical facilities in Michigan. The scope of this inspection was limited to observations of licensed activities (PET scans) on Trailer #1 at Beaumont Hospital - Wayne (030-02099). The trailer was routinely stationed there every Tuesday afternoon and all day on Thursdays, and was staffed by two nuclear medicine technologists.

Field Office

Remote

No Change

Normal

Reduced

Extended

No change

Main Office

Temporary Job Site

The inspector learned during a routine inspection of Beaumont Hospital - Wayne that a mobile nuclear medicine service provider would be performing PET scans there later in the day. After completing the routine inspection, the inspector returned to find an imaging trailer parked at the southwest corner of the facility. The inspector joined the MMPI staff and observed several administrations of F-18 and Cu-64. The inspector found the technologists to be knowledgeable of radiation protection principles and noted the use of adequate ALARA practices, personnel dosimetry, and calibrated and operable radiation detection instruments. Sealed reference sources on the trailer were adequately secured and blocked and braced for transport. The inspector performed radiation surveys in and around the trailer with patients and doses present. No evidence of residual contamination was noted, nor were any exposures in unrestricted areas noted in excess of regulatory limits to members of the public. The inspector also confirmed that the licensee had a written and signed agreement with Beaumont Hospital - Wayne per 10 CFR 35.80(a) and reviewed the most recent medical physics consultant audit of the trailer (December 2021) as well as a selection of dose records, survey records, and personnel dosimetry reports.

During a review of dose records from the last week, the inspector identified a SLIV violation of 10 CFR 35.63(d) for administering doses outside of the ranges prescribed by an authorized user. The licensee's technologists administered three doses of F-18 radiopharmaceuticals that were outside of their respective ranges, even after accounting for residual material in the syringe post-injection. The root cause of the violation was a lack of attention to detail. Contributing factors included the staff working for multiple mobile PET imaging licensees, each with slightly different prescribed dose ranges, and the staff incorrectly assuming that there would be more residual material post-injection.

As corrective action, the licensee reviewed the prescribed dose list with an authorized user, who revised it slightly to improve consistency. The licensee also sent all technologists a memo reiterating the requirement in 10 CFR 35.63(d) and requiring them to sign a copy attesting to their understanding.

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