16. Scope and Observations:

Unannounced

Non-Routine

Purdue University, a public institution with enrollment of approximately 40,000 students, maintained a Type A nonmedical broad scope program authorizing use of material at 18 locations across Indiana and at temporary job sites in NRC jurisdiction. The program was overseen by the Radiological and Environmental Management (REM), staffed by the RSO, two HPs, three HP technicians, and clerical staff. At the time of the inspection, the program had around 120 active and 30 occasional users authorized for research and development, teaching, sample irradiation, animal studies and veterinary use, though only 10 of these users ordered licensed material more than once in the last six months. Notably ongoing activities included: diagnostic and therapeutic administrations of radiolabeled compounds at the veterinary teaching hospital, diagnostic administrations of the same at an equine hospital in Shelbyville, the use of radiopharmaceuticals produced by a RadioGenix unit for pharmacy instruction, the use of sealed neutron sources to create short-lived activation products for physics instruction at the Fort Wayne campus, the use of radiolabeled compounds in drug discovery research, the use of transuranics for coordination chemistry research, and the use of transuranics and sealed neutron sources for the development of novel radiation detectors. The University also possessed self-shielded irradiators, an instrument calibrator, a collection of disused sources and devices, and had recently acquired a new Cd-109 source for future use in research and human use studies. Active locations at the time of the inspection included the main campus, the Animal Sciences Research & Education Center and the Agronomy Center for Research and Education in West Lafayette; a facility on Sagamore Parkway in Lafayette; the Fort Wayne Campus; and the Centaur Equine Specialty Hospital in Shelbyville.

Remote

Reduced

No change

Temporary Job Site

The inspector toured several locations on the main campus, the location on Sagamore Parkway in Lafayette, several locations at the Fort Wayne campus, and the equine hospital in Shelbyville. All areas were adequately posted, all licensed material was adequately secured, and adequate ALARA controls were present throughout. Independent and confirmatory surveys of these areas found no exposures in unrestricted areas above limits to members or the public, nor any evidence of residual contamination. The inspector interviewed principal investigators, laboratory staff, veterinary and animal husbandry technicians, REM staff and management, and other environmental health and safety staff involved in administration of the program to observe demonstrations of licensed activities, discuss safe handling practices for licensed material, confirm their understanding of REM protocols and regulatory requirements, and to evaluate their preparedness for responding to abnormal occurrences such as spills of unsealed material. The inspector reviewed documentation of several such occurrences (all minor), as well as a selection of RSC meeting minutes, personnel dosimetry reports, RSC approvals and periodic surveys by REM of all activities inspected, and routine records (utilization logs, area surveys, etc.) related to the use of material maintained by each user.

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Materials Inspection Record (Continued)

During a review of these records at the Centaur Equine Specialty Hospital in Shelbyville, the inspector identified a SLIV violation of 10 CFR 20.1906(d) for failure to monitor the external surface of labeled packages for contamination.

The staff at this location performed equine bone scintigraphies once or twice a month using 110-170 mCi of Tc-99m HDP, received in labeled Type A packages delivered by couriers from a local radiopharmacy. The staff were required by REM procedure to complete forms documenting their receipt of these packages, which included spaces for radiation and contamination survey results. However, for three packages received since June 2021, a radiation level was not noted, and for all six received since then, a contamination level was not noted. When asked, the staff stated that they did routinely monitor incoming packages for radiation levels, but not for contamination. The inspector reviewed radiation level survey results for these packages, as well as area surveys for the days those packages were received, and found no indication that contamination had been present on any of them.

The root cause of this violation was a lack of understanding of REM procedures and regulatory requirements. As a contributing factor, the well counter intended to be used for this monitoring had been relocated from the imaging area to a break room for unknown reasons (possibly to reduce background readings). It was still plugged in and appeared to be functional, however it had not recorded any use since October 2020, and staff present were unsure of its purpose.

As corrective action, REM staff reviewed relevant procedures with the staff in Shelbyville and retrained them on performing surveys, instituted monthly reminders for Shelbyville staff to send REM package receipt survey results for review, committed to communicate any deficiencies thus identified to the Shelbyville staff, and committed to perform an annual on-site audit of records related to surveys of package receipt, area monitoring, waste disposal and animal release at Shelbyville, and to provide additional training if necessary to address any deficiencies thus identified.

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