



Materials Inspection Report

1. Licensee/Location Inspected: United States Department of Agriculture Office of Homeland Security 5601 Sunnyside Avenue, Beltsville, MD 20705 Location Inspected: Ames, IA Report Number(s) 2024-002	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 030-06923	4. License Number(s) 19-00915-06	5. Date(s) of Inspection 05/16/24; exit 06/03/24
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LICENSEE:
 The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))

B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
 (Violations and Corrective Actions)

Contrary to 10 CFR 20.1902(a), between 03/10/24 and 05/16/24, a room at the United States Department of Agriculture's National Veterinary Services Laboratory in Ames, Iowa, with a radiation dose rate of approximately 7 millirem in one hour at 30 centimeters from the surface of a self-shielded irradiator was not posted with a sign bearing the radiation symbol and the words "CAUTION, RADIATION AREA." As corrective action, the licensee posted the room with the required signage and added markings on the floor to indicate elevated radiation dose rates around the irradiator.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Ryan Craffey	 <small>Digitally signed by RYAN CRAFFEY Date: 2024.06.14 08:30:34 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by RHEX EDWARDS Date: 2024.06.26 13:54:55 -05'00'</small>



Materials Inspection Record

1. Licensee Name: United States Department of Agriculture		2. Docket Number(s): 030-06923		3. License Number(s) 19-00915-06	
4. Report Number(s): 2024-002			5. Date(s) of Inspection: May 16, 2024; exit June 3, 2024		
6. Inspector(s): Ryan Craffey, Carol Dye		7. Program Code(s): 03520	8. Priority: 5	9. Inspection Guidance Used: IP 87143	
10. Licensee Contact Name(s): John Jensen - RSO		11. Licensee E-mail Address: john.jensen@usda.gov		12. Licensee Telephone Number(s): 301-504-2441	
13. Inspection Type: <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Non-Routine <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 07/01/2025 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	
16. Location(s) Inspected List: National Veterinary Services Laboratory - 1920 Dayton Avenue, Ames, IA					
17. Scope and Observations: <p>The USDA was authorized by NRC License No. 19-00915-06 to use various self-shielded irradiators for the irradiation of biological specimens at facilities across the United States. The scope of this inspection was limited to the commissioning of a Foss Therapy Services Gammacell 220F irradiator installed in March 2024 at the National Veterinary Services Laboratory in Ames, Iowa. The licensee plans to use this irradiator to inactivate certain viral reagents so that they can be shipped to state testing laboratories for proficiency panels, which are used to evaluate the recipient's ability to successfully test for certain viruses.</p> <p>The inspectors toured the irradiator facility at the NVSL in Ames. The irradiator had been installed and loaded and was now fully operational. The inspectors observed demonstrations of its use and function of various interlocks, and discussed with an AU how samples, which will contain Select Agents, would be safely handled prior to irradiation. The AU noted that during a pilot sample irradiation two weeks prior, a limit switch failed and the sample drawer could not be electrically raised out of the radiation field. The licensee worked with the manufacturer to manually raise the drawer two days later, and the manufacturer returned to the NVSL the following week to replace the switch. The manufacturer recommended that the licensee cycle the drawer at least weekly to prevent a similar issue in the future (the licensee was already planning to operate the irradiator at least monthly).</p> <p>The inspectors conducted independent surveys of the irradiator and the facility. No exposures in excess of limits to the public were noted in any unrestricted areas; however, readings of 23 mR/hr at the surface of the irradiator, 7-10 mR/hr at 30 cm from the irradiator) were found within the restricted area, which was posted with several "CAUTION, RADIOACTIVE MATERIALS" signs but no "CAUTION, RADIATION AREA" sign. This was noted as a SLIV violation of 10 CFR 20.1902(a) as the restricted area met the definition in 10 CFR 20.1003 of a radiation area. The inspectors determined that the root cause of the violation was an oversight by the licensee after initial surveys were performed by the manufacturer which found similar readings (25.3 mR/hr at the surface, 7.1 mR/hr at 30 cm, and 2.1 mR/hr at 100 cm). A lack of questioning attitude (a trait of positive safety culture) was noted as a contributing factor, as the licensee was accustomed to lower readings from its other irradiators.</p>					


Materials Inspection Record (Continued)

As corrective action, the licensee posted the room with the required signage and added markings on the floor to indicate elevated radiation dose rates around the irradiator. The licensee also performed a public dose assessment at the inspectors' request, as escorted visitors had been and were still present in the irradiator facility to support the unit's commissioning. The licensee concluded from this assessment that no visitors exceeded either public exposure limits nor required instructions per 10 CFR 19.12. The inspectors discussed this assessment with the licensee and found it to be reasonable.

The inspectors also noted that NVSL staff had been provided dosimeters and portable radiation survey instruments. Area monitors had also been provided, but not yet installed. While on-site, the inspectors reviewed the licensee's protocols for irradiator use, as well as emergency procedures and proposed utilization records with licensee staff, who were knowledgeable of radiation protection principles, irradiator operation, and licensee procedures.

Signature and Date - Branch Chief



 Digitally signed by RHEX EDWARDS
Date: 2024.06.26 13:54:34 -05'00'