ADAMS Accession# ML22122A135

NRC FORM 591M PART 1
(4-2008)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Advanced Isotopes of Idaho P.O. Box 2105 Pocatello, Idaho 83206 Location Inspected: 4968 Rainbow Lane, Chubbuck, Idaho 83202 REPORT NO: 2022-001	U.S. Nuclear Regulatory Commission Region IV 1600 East Lamar Boulevard Arlington, Texas 76011-4511

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATEs OF INSPECTION
030-37048	11-29216-01MD	January 24, 2022

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. The violations, specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy to exercise discretion were satisfied.

☐ Non-Cited Violation was discussed involving the following requirements and Corrective Actions:

☒ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

A. 10 CFR 32.72(c)(1) requires, in part, that the licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. In addition, the licensee shall perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary.

Contrary to the above, from July 23, 2019, to January 24, 2022, for instrumentation used to measure the radioactivity of radioactive drugs, the licensee failed to perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary. Specifically, for dose calibrators used to measure the radioactivity of drugs, the licensee failed to perform a test for geometric dependence for 10 milliliter vials, which were used by the licensee in its dose calibrators to measure the radioactivity of technetium-99m radioactive drugs.

This is a Severity Level IV Violation (Section 6.3.d.).

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Licensee's Statement of Corrective Actions for Item 4, above.

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	Date
LICENSEE'S REPRESENTATIVE	Catherine Heyneman		3/22/2022
NRC INSPECTOR	Janine F. Katanic, PhD, CHP	Janine F. Katanic Digitally signed by Janine F. Katanic Date: 2022.03.22 14:45:07 -05'00'	March 22, 2022
BRANCH CHIEF	Lizette Roldan-Otero, PhD	Lizette Roldan-Otero Digitally signed by Lizette Roldan-Otero Date: 2022.04.30 07:12:32 -05'00'	

☐ Non-Public ☐ Sensitive – Security-Related ☒ Public ☒ Non-Sensitive

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As corrective actions, on January 24, 2022, immediately after the inspection, the licensee performed geometry dependence tests for its three dose calibrators using technetium-99m in 10 milliliter vials. All three dose calibrators passed the test with no correction factors or adjustments needed. The licensee committed to updating its policies and procedures to specify that the geometric dependence test would be performed annually and upon any repair, relocation, or replacement of its dose calibrators, for all of the types and sizes of vials and syringes measured by the licensee, including for 10 milliliter vials.

B. License Condition 21 of NRC License 11-29216-01MD, Amendment No. 12, dated October 27, 2020, requires, in part, that the licensee conduct its program in accordance with Application dated November 11, 2015.

Application dated November 11, 2015, states that "We have developed and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103."

Contrary to the above, from July 23, 2019, to January 24, 2022, the licensee failed to develop, implement, and maintain adequate written procedures for leak testing that met the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103. Specifically, on multiple occasions, the licensee performed leak test analysis determinations for its own licensed sources as well as for licensed sources possessed by its clients and the licensee's written procedures for leak testing, contained in its Policy and Procedure Manual, Section 6.5, "Sealed Source Leak Testing," did not contain adequate steps to assure that: (1) the current counting efficiency was used in its leak test analysis determinations, and (2) the counting efficiency of the instruments was be determined with a standard source of the same radionuclide or one of similar energy characteristics as the source being tested.

This is a Severity Level IV Violation (Section 6.3.d.).

As corrective actions, the licensee ordered additional sources so that it could check the counting efficiency of its instruments with standard sources of the same radionuclides, or sources with similar energy characteristics, as the sources being tested. The licensee also committed to revise its written procedures for leak testing to be consistent with the guidance in Appendix H, "Model Leak Test Program" of NUREG-1556, Vol. 13, Rev. 2., Program-Specific Guidance About Commercial Radiopharmacy Licenses.