



Materials Inspection Report

1. Licensee/Location Inspected: Advanced Accelerator Applications 8520 Challenger Drive Indianapolis, Indiana 46241 Report Number(s) 2023001	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) 030-39292	4. License Number(s) 13-35658-01MD	5. Date(s) of Inspection July 21, 2023
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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)

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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2023.08.11 13:51:49 -05'00'</small>
BRANCH CHIEF	Rhex Edwards, Chief, MIB	 <small>Digitally signed by Rhex A. Edwards Date: 2023.08.17 07:28:54 -05'00'</small>



Materials Inspection Record

1. Licensee Name: Advanced Accelerator Applications		2. Docket Number(s): 030-39292		3. License Number(s) 13-35658-01MD	
4. Report Number(s): 2023001			5. Date(s) of Inspection: July 21, 2023		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02511	8. Priority: 5	9. Inspection Guidance Used: 87125	
10. Licensee Contact Name(s): Beth Brock, RSO Carter Jaynes, AU		11. Licensee E-mail Address: beth.brock@novartis.com carter.jaynes@novartis.com		12. Licensee Telephone Number(s): Work: 317-499-3320	
13. Inspection Type: <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 07/21/2025 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input checked="" type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: Main office: 8520 Challenger Drive, Indianapolis, Indiana 46241					
17. Scope and Observations: This was an announced initial inspection of a radiopharmaceutical manufacturing and distribution license located in Indianapolis, Indiana. The licensee was authorized to manufacture, prepare, package, and distribute radioactive drugs to authorized clients. The licensed facility was operated for the production of Lutetium-177 (Lu-177), a radiopharmaceutical used in treating certain cancers. The licensee was staffed with three authorized users and planned to add seven more. Approximately 74 personnel worked at this facility, most of whom worked with radioactive materials. The licensee received lutetium-177 from two sources; 1. MURR, and 2. ITM -Isotope Technology Munich, Germany. The licensee received material as lutetium chloride. The material is moved into hot cells to make different batches, then to the synthesis cell to be radio-labeled with peptide to make drug substances. It next goes to a dispensing cell where it is reformulated and diluted to make bulk products, then dispensed into a vial for individual patient dose. Each vial is packaged and prepared for distribution from the site as unit dose. At the time of inspection, the licensee received three doses of Lu-177 for sample production and laboratory QC. The licensee was awaiting final authorization from FDA to begin commercial distribution of the product. The State of Indiana inspector accompanied this inspection. The inspector recommended that the next inspection be set at two years because the licensee had not yet begun full operation and distribution from this facility. <p style="text-align: center;">PERFORMANCE OBSERVATIONS</p> This inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. The inspector toured all areas of the facility involved in production of materials. Licensee personnel demonstrated and described receipt and surveys of the materials, security of the materials, master inventory tracing system, chemistry procedures, cleaning and monitoring of hot cells, automated preparation and packaging of dose vials, dosimetry and bioassay procedures, quality assurance testing, waste tracking and disposal, equipment calibration and testing, and other procedures. The inspector noted no concerns with these activities. The inspector observed that staff wore their assigned dosimetry ring and body badge, wore					

Materials Inspection Record (Continued)

gloves and protective clothing while handling radiochemical, and monitored their hands and feet for contamination before exiting the restricted area. Review of dosimetry records indicated no exposures of concern. Interviews with licensee staff and demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations of NRC requirements were identified during this inspection.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2023.08.17 07:28:26 -05'00'