NRC FORM 591M PART 1
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
BAMF Health 109 Michigan St. NW Grand Rapids, Michigan 49503 REPORT NO.: 2022-001	Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER	4. LICENSE NUMBER	5. DATE OF INSPECTION
030-39300	21-35632-03MD	July 19, 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 violations 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/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 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.

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	Mark Sitek, RSO		7-19-2022
NRC INSPECTOR	Jason Dykert, Health Physicist		7-19-22
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Geoffrey M. Warren	Digitally signed by Geoffrey M. Warren Date: 2022.08.10 10:40:00 -05'00'

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
BAMF Health, LLC	030-39300	21-35632-03MD

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	July 19, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Dykert	02500	2	IP 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Mark Sitek, RSO	mark.sitek@bamfhealth.com	949-939-2641

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☑ Initial	☑ Main Office ☐ Field Office	07/19/2024
☐ Routine ☑ Announced	☐ Temporary Job Site ☐ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This was an initial inspection of BAMF Health LLC's radiopharmacy license. The two Authorized Nuclear Pharmacists and two Authorized Users worked onsite at the BAMF facility; one AU was the on-site RSO. The radiopharmacy had completed approximately 20 production runs of fluorine-18, oxygen-15, or gallium-68 for use with BAMF's accelerator license and nuclear medicine licenses (docket nos. 030-39267 and 030-39295).

The inspection consisted of interviews with two of the ANPs and an AU, demonstrations and observations of licensed activities, review of selected records, walk-downs and surveys of the work areas used for transfer of accelerator produced isotopes and the hot cells, and independent surveys. The licensee's facility was secured from unauthorized access, and laboratory dress requirements and the controlled radiation areas were clearly delineated. The inspector toured the area, observed a hot cell in use by an ANP, observed a clean hot cell for demonstration of procedural process control of radioisotope, and discussed the facility operations with the on-site RSO.

Hot cell interlocked shielding movements, dose rate indication equipment, remote handling equipment and fume hood air velocity measurements were observed. The licensee utilized synthesis modules to assist with automated production of PET diagnostic tracers. The 12 hot cells and five fume hoods were as described in the license. Records of drug isotope QA testing via FDA requirements, staff training, daily surveys, equipment operation checks, dose calibrator required calibrations (constancy, linearity, etc.), survey instrument calibration and availability, area monitoring and staff dosimetry, spill procedures and production use or decay-in-storage records were reviewed without issue.

At the time of inspection, the licensee had not distributed isotopes to licensees other than the BAMF nuclear medicine license, but procedures for distributing were prepared and the staff was knowledgeable about related requirements. Labeling of isotopes and use of shielded isotope containers was adequate. The ventilation system was observed to be running at pressure/flow and temperatures as described in the license tie-downs. Effluent air releases for 2021 were calculated using EPA COMPLY software as described in Reg Guide 4.20 Rev. 1, and were well below limits. Staff dosimetry results for whole body and extremity monitoring demonstrated low doses to the ANPs and AUs. The inspector performed independent surveys and concluded that the licensee's dose rate survey records and area postings were adequate, and that no dose limits were likely to be exceeded from the facilities operation.

No violations of NRC requirements were identified as a result of this inspection.