

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

BAMF Health, LLC
109 Michigan St. NW
Grand Rapids, Michigan 49503

REPORT NO.: 2022-001

2. NRC/REGIONAL OFFICE

Region III
U.S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

3. DOCKET NUMBER

030-39295

4. LICENSE NUMBER

21-35632-02

5. DATE OF INSPECTION

July 19, 2022

LICENSEE:

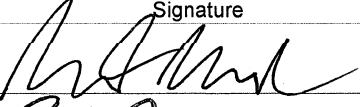

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures 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	James M. Botti, RSO		19-JUL-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 10:44:42 -05'00'



Materials Inspection Record

1. Licensee Name: BAMF Health, LLC		2. Docket Number(s): 030-39295		3. License Number(s) 21-35632-02	
4. Report Number(s): 2022-001			5. Date(s) of Inspection: July 19, 2022		
6. Inspector(s): Jason Dykert		7. Program Code(s): 02200		8. Priority: 3	9. Inspection Guidance Used: IP 87130
10. Licensee Contact Name(s): James M. Botti, RSO Todd Faasse, CNMT		11. Licensee E-mail Address: jbotti@mpcphysics.com Todd.Faasse@bamfhealth.com		12. Licensee Telephone Number(s): 734-662-3197 616-915-6921	
13. Inspection Type: <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <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): 07/19/2024 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input checked="" type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was the initial announced inspection of BAMF Health authorized for nuclear medicine imaging and therapy. There were 3 CNMT's who worked with a contracted RSO to begin operations at the medical center. BAMF utilized a GE Healthcare StarGuide whole body PET scanner and a SPECT/CT camera for imaging. Therapeutic doses of lutetium-177 or radium-223 dichloride had not been administered at the time of inspection, but procedures providing high confidence for administration had been developed. Unit doses for imaging were available from BAMF's production and radiopharmacy licenses (Docket nos. 030-39267 and 030-39300).

The inspection consisted of interviews with select licensee personnel, demonstrations and observations of licensed activities, review of selected records, walk-downs and surveys of two hot labs in the nuclear medicine department. The licensee had two hot labs that were secured from unauthorized access. The inspector observed a linearity test being performed on one of the two dose calibrators. Survey instruments were calibrated, a demonstration of survey instrument use for package receipts or daily surveys was adequate. The inspector observed a CNMT appropriately wearing dosimetry, and dosimetry records indicated no unusual doses. Interviews with staff indicated a good safety culture and knowledge of license requirements.

Physical inventories of sealed sources and corresponding leak tests were reviewed without issue. Procedures for safe use of materials, storage or disposal, administration of therapy doses requiring a written directive, and patient release criteria were reviewed without issue. The RSO performed quarterly audits, provided annual radiation safety and DOT HAZMAT training for the staff, and radiation safety oversight of the program. The inspector performed independent surveys and concluded that licensee area postings were adequate.

No violations of NRC requirements were identified as a result of this inspection. The inspection interval for this license was reduced to synchronize with the inspection schedule for BAMF's production and radiopharmacy licenses, thereby minimizing the number of visits needed to complete routine inspections of all three licenses, not because of any deficiency in the licensee's activities.