



109 Michigan St. NW
Suite 700
Grand Rapids, MI 49503

bamfhealth.com

July 24, 2023

Materials Licensing Branch
Attn: Laura Cender
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: Response to Request for Additional Information for MedTrace Amendment
(License No. 21-35632-02, Docket No. 030-39295)

Ms. Cender,

This letter is in response to your July 12, 2023, request for additional information regarding our amendment request dated May 16, 2023, to authorize the use of MedTrace P3 MT-100 system.

Response to Request 1a and 1b: As described in the user manual for the P3 MT-100 system, the device serves as a radiosynthesis, manufacturing, and dose administration all-in-one machine. Therefore, operation of the system will be performed by both nuclear pharmacy and medical clinic staff within their respective roles.

The nuclear pharmacy staff under the supervision of the authorized nuclear pharmacists and authorized users listed on NRC License No. 21-35632-03MD will perform the radiosynthesis and manufacturing operations. Any nuclear pharmacy staff member that has been trained on the normal and emergency operations procedures may operate the system including radiopharmacy operations specialists, authorized nuclear pharmacists, or authorized users.

The medical clinic staff operating under NRC License No. 21-35632-02 will perform the dose administration to the patient under the supervision of the medical authorized user as permitted by 10 CFR 35.27. Specifically, nuclear medicine technologists or medical authorized users that have been trained on the operation of the system will connect the appropriate tubing to the patients; initiate and monitor the patient infusions as described in Sections 4.1.3 and 4.1.4 of the P3 MT-100 User Manual; and disconnect the tubing from the patient.



109 Michigan St. NW
Suite 700
Grand Rapids, MI 49503

bamfhealth.com

As soon as the oxygen-15 passes into the medical clinic space we consider it to be transferred to our medical License No. 21-35632-02.

The nuclear pharmacy staff that will prepare the dose will be doing so under License No. 21-35632-02. As a result, we request that the following individuals be named as ANPs on License No. 21-35632-02:

1. Matthew DeLong, PharmD, State of Michigan License No. 5302036242
2. Olexandra Kovalenko, PharmD, State of Michigan License No. 5302414243
3. Tony Koehn, PharmD, State of Michigan License No. 5302041464

All three pharmacists are currently listed as ANPs on License No. 21-35632-03MD and have active State of Michigan pharmacist licenses.

Response to Request 2: One of the daily pre-operational checks for operation of either cyclotron includes verifying that the effluent system is operating above the minimum air flow rate. Specifically, our standard operating procedure RS-006, Effluent Monitoring and Evaluation, requires the exhaust flow rate to be checked and recorded prior to use each day.

Response to Request 3: We confirm that the lead doors of the MedTrace system will not be opened until at least 20 minutes after exiting the production phase of use.

Response to Request 4: The requested delegation of authority memorandum is attached.

If you have any questions, please contact me at (949) 939-2641 or mark.sitek@bamfhealth.com.

Respectfully Yours,

Mark A. Sitek

[Mark A. Sitek \(Jul 24, 2023 09:08 PDT\)](#)

Mark A. Sitek, MS, CHP

Corporate Radiation Safety Officer

BAMF Health NRC License #21-35632-02 MedTrace Amendment RAI #2 7-13-23

Final Audit Report

2023-07-24

Created:	2023-07-24
By:	Colten Conrad (colten.conrad@bamfhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAaeQE9mod6TljKKIB9qRGpoXCou2MLINb

"BAMF Health NRC License #21-35632-02 MedTrace Amendme nt RAI #2 7-13-23" History

 Document created by Colten Conrad (colten.conrad@bamfhealth.com)


2023-07-24 - 3:44:54 PM GMT

 Document emailed to mark.sitek@bamfhealth.com for signature

2023-07-24 - 3:45:08 PM GMT

 Email viewed by mark.sitek@bamfhealth.com

2023-07-24 - 4:07:16 PM GMT

 Signer mark.sitek@bamfhealth.com entered name at signing as Mark A. Sitek

2023-07-24 - 4:08:00 PM GMT

 Document e-signed by Mark A. Sitek (mark.sitek@bamfhealth.com)

Signature Date: 2023-07-24 - 4:08:02 PM GMT - Time Source: server

 Agreement completed.

2023-07-24 - 4:08:02 PM GMT

Martha Pavon

From: Laura Cender
Sent: Wednesday, July 26, 2023 8:42 AM
To: Martha Pavon
Cc: Sandy Pavon
Subject: File for ADAMS BAMF Health, Inc.
Attachments: RAI Response Delegation of Authority.pdf; RAI Response 7-24-23.pdf

Hello Martha,

Could you please enter the two attached files into ADAMS?

Licensee: BAMF Health, Inc.
License No. 21-35632-02
Docket No. 030-39295
Control No. 635643

Please let me know if you have any questions.

Thank you!
Laura

Laura Cender
Pronouns: She/Her
U.S. Nuclear Regulatory Commission
Materials Licensing Branch
E-mail: Laura.Cender@nrc.gov
Phone: (630) 829-9712