



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

bamfhealth.com

January 17, 2024

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

Re: Amendment 6 to License No. 21-35632-03MD, Docket No. 030-39300

To licensing,

Please amend our radioactive materials license No. 21-35632-03MD to add research and development (R&D) activities related to the pre-production of radiopharmaceuticals. We plan to start improving and developing radiopharmaceuticals which will require various in-vitro benchtop laboratory and radiochemistry activities. The R&D work will include various testing, validation, and qualification activities required for FDA approval of radiopharmaceuticals. We will not perform studies or activities involving live animals.

We reviewed the guidance provided in NUREG-1556, Volume 7, Rev.1, to develop our request as follows:

Radioactive Material and Purpose:

Byproduct, source, and/or special nuclear material	Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days
Chemical/Physical Form	Any
Maximum Possession Limit	2 curies per radionuclide and 10 curies total
Authorized Use	For research and development as defined in 10 CFR 30.4, including the pre-production of radiopharmaceuticals for testing, validation, and qualification of FDA regulated drug products.



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The requested maximum possession limits are needed to account for radioactive decay and losses during the synthesis of radionuclides into radiopharmaceuticals.

Individuals Responsible for the Radiation Safety Program

The radiation safety officer, authorized user, and authorized nuclear pharmacists currently named on our license will use and/or directly supervise the use of radioactive material for R&D activities. The nature of our R&D activities will be similar to our licensed radiopharmaceutical production activities. As a result, the individuals currently named on our license have appropriate training and experience. In addition, Colten Conrad and Mark Sitek are named as R&D authorized users on our medical use license (No. 21-35632-02).

Training for Individuals Working in or Frequenting Restricted Areas

The nature of our R&D work will be similar to our licensed radiopharmaceutical production activities. As a result, our existing training program adequately covers our planned R&D activities.

Facilities and Equipment

All research and development activities will be performed in areas previously described in our initial license application dated December 17, 2021. The facility was initially designed with designated rooms for research and development as noted in the diagrams and description submitted with the initial license application. The shielded hot cells and fume hoods along with all other applicable aspects of the facility have remained the same as that described in our initial license application.

Radiation Safety Program

Our existing radiation safety program covers our planned R&D activities.



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Waste Management

Our existing radioactive waste management program covers our planned R&D activities.

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

Respectfully Yours,

A handwritten signature in black ink that reads "Mark A. Sitek". The signature is written in a cursive style.

Mark A. Sitek, MS, CHP
Corporate Radiation Safety Officer



Martha Pavon

From: Tammy Tomczak
Sent: Wednesday, January 17, 2024 4:37 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: BAMF Health (21-35632-03MD) Amendment Request
Attachments: 21-35632-03MD Amendment No. 6 01-09-2024.pdf

Good afternoon, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Mark Sitek <mark.sitek@bamfhealth.com>
Sent: Wednesday, January 17, 2024 4:23 PM
To: Tammy Tomczak <Tammy.Tomczak@nrc.gov>
Subject: [External_Sender] BAMF Health (21-35632-03MD) Amendment Request

Hi Tammy,

Please see the attached amendment request.

Thank you,

Mark A. Sitek, MS, CHP
Corporate Radiation Safety Officer
BAMF Health
949-939-2641

Martha Pavon

From: Magdalena Gryglak
Sent: Wednesday, May 8, 2024 1:44 PM
To: Martha Pavon
Subject: Declaring a document public
Attachments: 665 638612 ML24018A031 Incoming Amendment Request.pdf

Hello Martha,

Can we please change/declare the attached document public?

Thank you

Also, when I actually complete the licensing actions, do I need to provide the 665 for these documents which were already declared public?

Thanks again