

December 13, 2023

VIA CERTIFIED MAIL
WITH RETURN RECEIPT REQUESTED

No.: 7018 1130 0002 2055 3495

United States Nuclear Regulatory Commission, Region I
Materials Licensing Branch
Division of Nuclear Material Safety
475 Allendale Rd., Suite 102
King of Prussia, PA 19406-1415

Re: Baxter Healthcare SA – Aibonito Operations
License No. 52-21175-01
Docket No. 030-19882
Notification - Change of Ownership

To whom it may concern:

We hereby provide notice to the Nuclear Regulatory Commission (“NRC”) that Baxter Healthcare SA (“BHSA”) and Baxter Healthcare of Puerto Rico LLC (“BHPR”) entered into a certain agreement under which BHPR, on December 25, 2023, will acquire all assets of BHSA (the “Agreement”), including the facility located at State Road No. 721, Km 0.3, Pueblo Sur Industrial Park, Aibonito, Puerto Rico (the “Facility”). Accordingly, thereafter, BHPR will assume all responsibility in connection to the Materials License No. 52-21175-01 (the “NRC License”)¹, which was issued by the Nuclear Regulatory Commission (“NRC”).

Please note that this transaction represents a change in ownership and operator of the Facility. No change is expected in the day-to-day operations of the Facility nor in the personnel or Radiation Safety Officer, location, facilities, equipment, or procedures related to the current NRC License; therefore, no decommissioning of the Facility will take place.

In addition, BHPR’s surveillance program is in compliance with NRC regulations and requirements. All programs will remain the same at the time control is transferred. BHPR will continue to abide by all constraints, conditions, requirements, and commitments of the licensed program.

Based on the foregoing, we hereby respectfully request the NRC to proceed with the issuance of the NRC License No. 52-21175-01 under the name **Baxter Healthcare of Puerto Rico LLC**.

To that effect, we enclose:

¹ See, Attachment 1.

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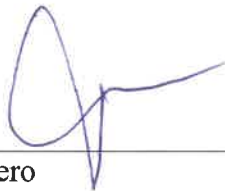
- i) Additional information on the plans for transfer of control of the NRC License. This additional information is in the form of answering the questions from the template “Information Needed for Transfer of Control Application” found in NUREG 1556, Volume 15, Revision 1, Appendix E)²; and
- ii) a copy of a license transfer agreement signed by BHPR and BHSA authorized representatives.³

Last, we respectfully request the NRC to take note of this change and update its records. Note that if, for any reason, the acquisition is delayed or canceled, BHSA and/or BHPR will promptly notify the NRC of such event and of any new effective date – so the NRC License transfer takes effect then on such date.

Thanks in advance for your prompt attention to this matter. Should you have any questions regarding the foregoing, please contact any of the undersigned.


Cordially,

BHSA:
BAXTER HEALTHCARE SA



José Carrero
Plant Manager

BHPR:
BAXTER HEALTHCARE OF PUERTO RICO
LLC



Luz Rivera Madera
Comptroller

Enclosures

CC: Marco Torres-Delgado, Radiation Safety Officer (RSO)

² See, Attachment 2.

³ See, Attachment 3.

ATTACHMENT 1

ATTACHMENT 2

Attachment 2

Information Needed for Transfer of Control Application (From template in NUREG 1556, Volume 15, Rev 1, Appendix E)

Include a contact name and either U.S. Nuclear Regulatory Commission (NRC) regional office or Headquarters telephone numbers for follow-up information, as required.

NRC Region: Region I **Contact:** Marco M. Torres, Radiation Safety Officer
Telephone: 787-954-2455 **e-mail:** marco.torres.delgado@baxter.com

Definitions:

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and, thus, the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Information Needed for Transfer of Control

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.

Licensee Response:

The Transferee, Baxter Healthcare of Puerto Rico LLC, is a separate legal entity from the Transferor, Baxter Healthcare SA. The Transferee will assume full control of the irradiator operations on December 25, 2023.

The organization at the plant level related to irradiator operations and safety is not expected to change. The same plant reporting structure will oversee irradiator operations and the same Radiation Safety Officer will oversee irradiator safety. No change is expected to occur on who oversees operations, safety, and security of the irradiator or their reporting structure.

The Transferee information is the following:

Baxter Healthcare of Puerto Rico LLC – Aibonito

Mailing Address: PO Box 1389, Aibonito PR 00705

Physical Address: State Road No. 721, Km 0.3, Pueblo Sur Industrial Park, Aibonito, Puerto Rico

For the purpose of this license the contact information will be:

Marco M. Torres, Radiation Safety Officer

PO Box 1389, Aibonito PR 00705

marco_torres_delgado@baxter.com

Phone: 787-954-2455

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.

Licensee Response:

No change is expected on personnel or assigned duties at the plant level at Aibonito, PR, which relate to the licensed program. There will be no change in the personnel or Radiation Safety Officer that have responsibility for operation, safety, or security of the irradiator as part of this transfer.

There will be no changes in training and experience required for new personnel. The training material will have minor editorial changes to change references from the Transferor to the Transferee. These editorial changes to the training program will not affect the purpose or intent of the training or reduce safety or security.

3. Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.

Licensee Response:

There will be no changes on the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures related to the licensed program. No changes are expected on the specific contractors used to supply support services.

The only changes to the license will be to the name of the licensee. Minor editorial changes will be made to procedures to change references from, Baxter Healthcare SA, to the new facility owner, Baxter Healthcare of Puerto Rico LLC. Changes to procedures will not affect the purpose or intent of the procedure or reduce safety or security.

4. Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.

Licensee Response:

Operations will continue during the transfer process. All preventative maintenance and surveys will be kept up to date and current through the transfer of control. All records will be transferred

to the new company no later than the date of transfer of control. In addition, all calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records are up to date.

5. If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm that all financial assurance instruments associated with the license will be held in the transferee's name before the license is transferred, and as required by 10 CFR 30.35(f), the licensee must, within 30 days, submit financial instruments reflecting such changes.

Licensee Response:

There will be no changes to the decommissioning funding plans (DFP) as a result of the transfer of ownership and control. No change is expected in the day-to-day operations of the Facility or in the personnel or Radiation Safety Officer, location, facilities, equipment, or procedures related to the current NRC License; therefore, no decommissioning of the facility will be performed.

6. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

Licensee Response:

Pursuant to 10 CFR 30.35(g), the Transferor will maintain drawings and records important to decommissioning and will transfer these records to the Transferee before licensed activities are transferred.

7. Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.

Licensee Response:

See the signed Transfer Agreement included herewith as **Attachment 3**.

8. Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Licensee Response:

See the signed Transfer Agreement included herewith as **Attachment 3**.

9. The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts.

Licensee Response:

Not applicable; the licensed activities are not associated with a fuel cycle.

ATTACHMENT 3

MATERIALS LICENSE TRANSFER AGREEMENT

This Materials License Transfer Agreement (the “Transfer Agreement”), dated as of December 13, 2023, is made and entered into by and between **BAXTER HEALTHCARE SA (“BHSA”)**, a corporation duly organized and existing under the laws of Switzerland, represented herein by its Plant Manager, José Carrero and **BAXTER HEALTHCARE OF PUERTO RICO LLC (BHPR)**, a corporation duly organized under the laws of the Commonwealth of Puerto Rico (the “**BHPR**”) represented herein by its Comptroller, Luz Rivera Madera. For purposes of this Transfer Agreement, BHPR and BHSA are referred to herein collectively as the “**Parties**”.

WITNESSETH:

WHEREAS, in connection with the operation of the facility located at State Road No. 721, Km 0.3, Pueblo Sur Industrial Park, Aibonito, Puerto Rico (the “**Facility**”), BHSA holds certain Permits related to environmental matters, including the following Nuclear Regulatory Commission Materials License (“**NRC License**”) issued by the U.S. Nuclear Regulatory Commission (“**NRC**”):

<u>Facility</u>	<u>License No.</u>	<u>Docket No.</u>	<u>Location</u>
BAXTER HEALTHCARE SA	52-21175-01	030-19882	Aibonito, PR

WHEREAS, the targeted date for the transfer of the NRC License is **DECEMBER 25, 2023**;

WHEREAS, the Parties hereto have agreed to the transfer of control of the NRC License as it relates to the irradiator and irradiator operations at the property and related requirements at the Facility, upon execution of this Transfer Agreement;

WHEREAS, BHPR does not expect to make any changes or modifications to the irradiator, its operation or its related equipment;

NOW THEREFORE, in consideration of the mutual representations, covenants and conditions contained in this Transfer Agreement, BHSA and BHPR agree as follows:

1. BHPR agrees to assume the coverage, responsibility, and liability under the NRC License.
2. The effective date of the NRC License transfer, as it refers to the operation of the irradiator and facility and compliance with the NRC License conditions and requirements thereof, shall be **DECEMBER 25, 2023** (the “**Effective Date**”), unless the proposed transfer is delayed or canceled, of which NRC will be promptly informed by BHSA and/or the BHPR, if it occurs.

3. BHSA and the BHPR agree that, as between them in reference to the NRC License, BHSA shall have license responsibility, coverage, and liability for acts and omissions under the NRC License, prior to the Effective Date.

4. BHSA and the BHPR agree that, as between them in reference to the NRC License, the BHPR shall have license responsibility, coverage, and liability for acts and omissions under the NRC License, on and after the Effective Date.

5. All records related to radiation monitoring, and all drawings and records related to decommissioning will be transferred to BHPR.

6. BHPR agrees to assume control of the licensed material and related activities, and the conditions of transfer.

7. BHSA has made BHPR aware of any open inspection items or any possible resulting enforcement actions.

8. BHPR agrees to abiding by all constraints, conditions, requirements, representations, and commitments of BHSA relative to the NRC License.

9. BHPR agrees to assume responsibility for maintenance of all records concerning the safe and effective decommissioning of the irradiator if and when necessary. These records can include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity as appropriate.

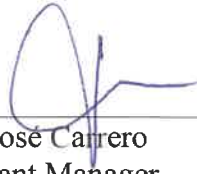
10. Nothing herein is intended to affect any other agreements between BHSA and BHPR and/or other parties.

11. This Transfer Agreement may be executed and delivered by facsimile, PDF or other electronic transmission and shall be deemed to have the same legal effects as delivery of an original signed copy hereof.

IN WITNESS WHEREOF, BHSA and BHPR have caused this Transfer Agreement to be duly executed and delivered as of the day and year first written above.

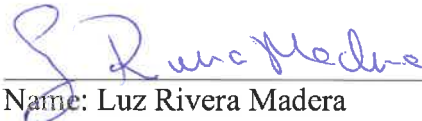
[signature page follows]

BHSA:
BAXTER HEALTHCARE SA

A handwritten signature in blue ink, appearing to read 'José Carrero', written over a horizontal line.

Name: José Carrero
Title: Plant Manager

BHPR:
BAXTER HEALTHCARE OF PUERTO RICO
LLC

A handwritten signature in blue ink, appearing to read 'Luz Rivera Madera', written over a horizontal line.

Name: Luz Rivera Madera
Title: Comptroller