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**Junod, Rebecca**

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**From:** Arroyo, Jose R <jose\_arroyo\_rivera@baxter.com>  
**Sent:** Friday, October 02, 2015 2:57 PM  
**To:** Miller, John  
**Subject:** [External\_Sender] Baxter Healthcare of Puerto Rico Response to Request for Additional Information - Mail Control no 586267  
**Attachments:** Baxter Healthcare of Puerto Rico License Renewal RAI Response.pdf

Mr. Miller,

Attached please refer to responses to Request for Additional Information received by email dated 09/04/2015, regarding Baxter Healthcare of Puerto Rico License Renewal Application - Mail Control no 586267.

If you have any question, or require additional information, please do not hesitate to contact me. Please let me know if paper submittal of these responses is required.

Please confirm receipt of this communication.

52-21175-01  
03019882

Regards,

Jose

**José R. Arroyo**  
**Senior Principal Engineer**  
**Sterilization Operations – Gamma & Steam**  
**Radiation Safety Officer – RSO**  
**Medical Products**  
**Baxter Healthcare - Aibonito**

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**Aibonito, PR 00705**

October 2, 2015

John J. Miller  
Health Physicist  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

**Subject: Response to Request for Additional Information – Baxter Healthcare of Puerto Rico License Renewal Application**

Baxter Healthcare of Puerto Rico – Aibonito  
License No. 52-21175-01  
Docket No. 030-19882  
Control No. 586267

Mr. Miller,

Attached please refer to responses to Request for Additional Information received by email dated 09/04/2015, regarding Baxter Healthcare of Puerto Rico License Renewal Application

If you have any question, or require additional information, please do not hesitate to contact the undersigning at 787-954-2284 office, 787-365-5247 mobile, or by email at [jose\\_arroyo\\_rivera@baxter.com](mailto:jose_arroyo_rivera@baxter.com)

  

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**Jose Arroyo**  
Radiation Safety Officer

Enclosures:

1. Response to Request for Additional Information.

October 2, 2015

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Signature on Original

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**Jose Arroyo**  
Radiation Safety Officer

Enclosures:

1. Response to Request for Additional Information.

**Response to Request for Additional Information – Baxter Healthcare of Puerto Rico License Renewal Application**

Baxter Healthcare of Puerto Rico – Aibonito  
License No. 52-21175-01  
Docket No. 030-19882  
Control No. 586267

1. In item 2. of your application dated June 29, 2015, you state that your name is “Baxter Healthcare.” Your present license, Amendment No. 18, lists the licensee as “Baxter Healthcare of Puerto Rico.” Have you changed your name or has your company experienced a change of control? You are encouraged to consult NUREG-1556, Vol. 15, “Program Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses,” in formulating your response.

Response – Our name is still Baxter Healthcare of Puerto Rico as our current license states. This was an omission on the license renewal submittal. Item 2 of our Application should read:

Baxter Healthcare of Puerto Rico  
PO Box 1389  
Aibonito, PR 00705

2. Section 8.10.3 of NUREG-1556, Vol. 6, “Program Specific Guidance about 10 CFR Part 36 Irradiator Licenses,” requires that licensees develop, maintain, and implement a procedure to account for licensed material. The NUREG recommends that licensees verify that no sources have been lost, when sources are added to, removed from, or moved within the irradiator or, at a minimum, every three years. Please confirm that you will perform such verification or submit a procedure that is equivalent.

Response – For the Baxter Healthcare of Puerto Rico irradiator, Nordion, which is the manufacturer of our irradiator and the manufacturer and supplier of our sources, is the only authorized party to handle, add, remove, or relocate sources. During source reloads, Nordion establishes the location of the cobalt sources and provide us with a report containing total sources installed and the sources’ serial numbers, activity, and location. This report provided by Nordion certifies total source accountability. Baxter Healthcare of Puerto Rico maintain a record of these reports and update them after source reloads or every three years in order to demonstrate total sources accountability.

In addition, Baxter Healthcare of Puerto Rico performs annual source accountability and transfer transactions as part of the NRC’s National Source Track System (NSTS) requirements.

Also, as part of Baxter Healthcare of Puerto Rico sterilization process, the activity of the source is accounted in a daily basis to obtain sterilization time parameters. The resultant dosage within specification received by the product after the sterilization process, as determined by the time parameters calculated with the source activity, provides additional assurance of total source accountability.

Baxter Healthcare of Puerto Rico understand that these actions describe above are adequate to maintain accountability of our license material.

3. Please confirm that the interlock system for the irradiator will prevent the source from being moved out of its shielded position if the door or product barrier were open.

Response – Baxter Healthcare of Puerto Rico confirms that the irradiator control/interlock and sensors systems prevent the sources from being moved out of its shielded position if irradiator maze door or the product inlet or outlet barrier doors were open.

4. Please confirm that the lock for source control movement is designed such that the key cannot be removed from the console if the sources are in the unshielded position.

Response – Baxter Healthcare of Puerto Rico confirms that the irradiator control console locks the irradiator key and it cannot be removed from the source enable switch if the sources are in the unshielded position.

5. In your application you have described how your radiation monitor is integrated with the personnel access door interlocks to prevent room access when the sources are unshielded. Please confirm that room access will also be prevented if the radiation monitor malfunctions or is turned off.

Response – Baxter Healthcare of Puerto Rico confirms that irradiator room access is not allowed if the radiation monitor malfunctions, its probe is disconnected, or the monitor is turned off. The irradiator control console requires constant feedback from the radiation monitor to allow access to the irradiator room.

6. It was not clear in your application that you intend to perform non-routine operations. Non-routine operations may include the following:
  - Source loading, unloading and repositioning
  - Troubleshooting the control console
  - Clearing stuck source racks
  - Investigating/remediating removable contamination/leaking sources
  - (Re)installing source cables
  - Any other activity during which personnel could receive radiation doses exceeding NRC limits

Please indicate that the irradiator manufacturer or other person authorized by NRC or an Agreement State will perform non-routine operations or submit the information listed in Appendix I of NUREG-1556, Vol. 6 if you wish to perform non-routine operations.

Response – Baxter Healthcare of Puerto Rico does not intend to perform non-routine operations. The irradiator manufacturer or any other party license by the NRC or Agreement State will perform such non-routine operations. Baxter Healthcare of Puerto Rico will contract a licensed party to perform non-routine operations on behalf of Baxter Healthcare of Puerto Rico

7. Thank you for describing the inspection and maintenance checks that you routinely perform. NUREG-1556, Vol. 6 also recommends that you periodically check the electrical wiring on required safety systems for radiation damage and periodically determine the amount of water that has been added to the pool to ascertain whether the pool is leaking. Please confirm that you will incorporate these checks into your inspection and maintenance program and specify the frequency at which they will be performed.

Response – Baxter Healthcare of Puerto Rico performs checks to the electrical wiring on the irradiator safety systems for radiation damage as part of our Quarterly Maintenance Checks (Item 2 of Form 1187846 submitted with Renewal Application). The document used for these tasks will be revised to clarify this inspection. The amount of water that has been added to the pool is verified and documented on a weekly basis as part of our Weekly Maintenance Checks. The documentation is done on Form AI-PD-007-777 “Contabilización del Agua de “Make Up” para la Piscina del Irradiador Gamma” (Accountability of Make-Up Water for the Gamma Irradiator Pool), refer to attached document.

8. In the section of your application that addresses the irradiator pool, there appears to be a typographical error at the bottom of the page below Figure 11. Please confirm that if the water level rises above a preset limit, the switch activates a high water level alarm.

Response – Baxter Healthcare of Puerto Rico confirms that if the water level rises above the preset high limit of the float switch, it activates a visible and audible High Water Level Alarm.

9. 10 CFR 36.33(e) requires that pool water conductivity be maintained at 20 microsiemens per centimeter or less. In your application, specifically the section that describes the pool water purification system, you indicated that you will maintain conductivity of the pool water to less than 10 microsiemens and later you state 20 microsiemens will not be exceeded. Please clarify.

Response – Baxter Healthcare of Puerto Rico maintains an action limit for irradiator pool water conductivity of less than 10 microsiemens per centimeter. The purpose of this limit is to take proactive actions to avoid conductivity exceeding the 20 microsiemens per centimeter as required by regulation. Baxter Healthcare of Puerto Rico confirms that conductivity will be maintained at 20 microsiemens per centimeter or less.

