

Walt, GERALYN

From: Miller, John
Sent: Friday, September 04, 2015 11:44 AM
To: jose_arroyo_rivera@baxter.com
Subject: Request for Additional Information - Mail Control no 586267

Baxter Healthcare of Puerto Rico
License No. 52-21175-01
Docket No. 03019882
Control No. 586267

Mr. Arroyo

In order to continue the review of your renewal application for your NRC license to use radioactive materials, we need additional information. If you have any questions, please contact me (610-337-5089

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.
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.
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.
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.
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.
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.

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.
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.
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.

Please respond in writing with a **signed and dated letter**. You may submit the signed response document by hard copy, or as a pdf copy attached to an email, or by facsimile to 610-337-5269. Please be sure to include the Control No. 586267 on your response. We would appreciate a response within 30 days in order to expedite review of the license renewal application.

Thank you for your cooperation.

John J. Miller
Health Physicist
Division of Nuclear Materials Safety

Phone: 610-337-5089
Fax: 610-337-5269
E-mail: john.miller@nrc.gov

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Division of Nuclear Materials Safety

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Fax: 610-337-5269
E-mail: john.miller@nrc.gov