



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD – SUITE 102  
KING OF PRUSSIA, PA 19406-1415

January 21, 2025

Jose' Carrera, General Manager  
Baxter Healthcare of Puerto Rico, LLC  
P. O. Box 1389  
Aibonito, PR 00705

**SUBJECT: BAXTER HEALTHCARE OF PUERTO RICO, LLC, REQUEST FOR  
ADDITIONAL INFORMATION, MAIL CONTROL NO. 644844**

Dear Jose' Carrera:

This is in reference to your letter dated January 17, 2025, requesting to amend NRC License No. 52-21175-01. In order to continue our review, we need the following additional information:

1. Section 8.7.1, "Radiation Safety Officer Training and Experience," of NUREG-1556, Volume 6, Revision 1 (Vol.6, Rev.1), "Consolidated Guidance About Materials Licensees – Program-Specific Guidance About 10 CFR Part 36 Irradiator Licensees," states that the named individual should agree, in writing, to assume the duties of the Radiation Safety Officer (RSO). Appendix F of the above NUREG contains a Delegation of Authority for this purpose. Please complete and submit the Delegation of Authority for your proposed RSO.
2. Your letter states that the proposed RSO has completed the Gamma Irradiator Operator Training requirements. Please submit the documentation of this training for our review, include the number of hours and the topics covered.
3. Your letter states that the proposed RSO has completed On-the-Job Training under a certified RSO. License Condition 11 of NRC License No. 52-21175-01 requires, in part, that the licensee maintain records of individuals designated as users for three years following the last use of licensed material by the individual. Please submit a copy of the designation by an RSO that your proposed RSO meets the training requirements of License Condition 11.
4. Please note that the Commission does not list Alternate (Auxiliary) Radiation Safety Officers on the license. If an RSO should be unable to perform their duties for a short period of time, a qualified individual may act on their behalf for that period. The circumstances permitting the use of Auxiliary RSO are in NUREG-1556, Vol.6, Rev. 1, Section 8.7.1. The qualifications of the individual would be examined during the inspection process.
5. Our records indicate that Marco Torres-Delgado was the 10 CFR Part 37 Reviewing Official. Since they are no longer with the company, please indicate their replacement and their qualifications for being the Reviewing Official.

6. Please provide contact information for your proposed RSO (email and phone number).

We will continue our review upon receipt of this information. Please reply to my attention at:

[R1DRSSMail.Resource@nrc.gov](mailto:R1DRSSMail.Resource@nrc.gov)  
Reference – Steven Courtemanche  
Mail Control No. 644844

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: [www.nrc.gov](http://www.nrc.gov). Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5075 or via electronic mail at [Steven.Courtemanchw@nrc.gov](mailto:Steven.Courtemanchw@nrc.gov).

Thank you for your cooperation.

Sincerely,

Steven Courtemanche, Health Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Radiological Safety and Security  
Region I

License No. 52-21175-01  
Docket No. 03019882  
Mail Control No. 644844

cc: Waleska Torres Ortiz, Acting Radiation Safety Officer

SUBJECT: BAXTER HEALTHCARE OF PUERTO RICO, LLC, REQUEST FOR  
ADDITIONAL INFORMATION, MAIL CONTROL NO. 644844 DATED JANUARY  
21, 2025

SUNSI Review Complete: Steven Courtemanche

After declaring this document "An Official Agency Record" it **will** be released to the Public.

OFFICE	RI:DRSS			
NAME	SCourtemanche/src			
DATE	01/21/2025			

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