



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

May 30, 2025

Luis A. Rivera
Radiation Safety Officer
Centro Radioterapia Auxilio Mutuo
Avenida Ponce de Leon #725
Parada 37 1/2
Hato Rey, Puerto Rico 00918

SUBJECT: CENTRO DE RADIOTERAPIA AT HOSPITAL AUXILIO MUTUO, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 645473

Dear Luis A. Rivera:

This is in reference to your application dated February 26, 2025, requesting to renew NRC License No. 52-30937-01. In order to continue our review, we need the following additional information:

1. If you are an RSO who is an outside contractor or consultant, address the following. If not, please reply that this is not applicable.
 - a. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the program).
 - b. Identify an in-house representative who will serve as the point of contact during the RSO's absence.
 - c. Describe the overall availability of the consultant-RSO to respond to questions operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
 - d. Specify the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his/her presence.
2. Your application listed "Anthony Ortiz Rodriguez" as an authorized medical physicist, but your license currently lists "Anthony Ortiz." Is that the same person? Which name is correct?
3. Confirm the following statement: "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

4. Confirm one of the following statements:
 - a. A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."
AND/OR
 - b. A statement that: "We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."
5. Provide a description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.
6. Confirm one of the following statements:
 - a. "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."
OR
 - b. A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG—1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"
OR
 - c. A description of an alternative method for demonstrating compliance with the referenced regulations.
7. If requesting that your own employee(s), who are trained by the manufacturer, be authorized to perform the activities noted in section 8.10.7 of this NUREG, provide the following: Name of the proposed employee(s) and types of activities requested, Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested, a copy of the manufacturer's training certification and an outline of the training in procedures to be followed, and written commitment from the licensee that the trained employee will follow manufacturer procedures. Otherwise indicate that this is not applicable.
8. Confirm the following statement: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
 - a. license possession limits are not exceeded
 - b. licensed material in storage is secured from unauthorized access or removal
 - c. licensed material not in storage is maintained under constant surveillance and control
 - d. records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."
9. If applicable, confirm the following statement "We will comply with the National Source Tracking System (NSTS) reporting requirement, as described in 10 CFR 20.2207."

10. Confirm one of the applicable statements regarding leak tests:

- a. For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35: “We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.”
OR
- b. For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources): A statement that: “We will conduct leak tests in-house.” AND “The attached leak test procedures will be followed for leak tests conducted in-house.”
AND Attach leak test procedures.
OR
- c. A statement that the applicant will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use. For instance, if an applicant possesses a self-shielded irradiator, the applicant may state, “We will implement the model leak test program published in Appendix N of NUREG–1556, Volume 5, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.”
OR
- d. If a contractor is used to perform leak testing, a statement that: “Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit.”

11. Confirm the following statement: “We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.”

12. Confirm the following statement: “We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92.”

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

R1DRSSMail.Resource@nrc.gov

Reference – Casey Alldredge

Mail Control No. 645473

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. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and

guidance, as well as 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 and its enclosure 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>.

Thank you for your cooperation.

Sincerely,

Casey Alldredge, Health Physicist
Division of Radiological Safety and Security
Region 4

License No. 52-30937-01
Docket No. 030-36635
Mail Control No. 645473

SUBJECT: CENTRO DE RADIOTERAPIA AT HOSPITAL AUXILIO MUTUO, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 645473 DATED MAY 30, 2025

SUNSI Review Complete: Casey Alldredge

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

OFFICE	RI:DRSS			
NAME	Casey Alldredge			
DATE	5/30/25			

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