



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

May 19, 2014

Docket No. 03035388
Control No. 583606

License No. 52-25519-01

José O. Pabón Quiñones
Chairman of the Board of Directors
Hospital Wilma N. Vázquez
Call Box 7001
Vega Baja, PR 00694-7001

**SUBJECT: HOSPITAL WILMA N. VÁZQUEZ, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO
LICENSE, CONTROL NO. 583606**

Dear Sr. Pabón Quiñones:

This is in reference to your letter dated March 11, 2014 requesting to amend Nuclear Regulatory Commission License No. 52-25519-01. In order to continue with your request, we need the following additional information:

1. I have no further questions regarding the request to delete Drs. Diaz and Sostre as authorized users. Also, Carlos Montalván Miró, M.D. may be listed as an authorized user based on his current status as an authorized user on NRC License No. 52-25589-01.
2. Regarding your request to delete Dr. Diáz as the Radiation Safety Officer and name Carlos Montalván Miró, M.D. as the Radiation Safety Officer, the following regulation applies:

10 CFR 35.50(c)(2) states in part that, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer **to be an authorized user identified on the licensee's license** and have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (c)(2), and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer or authorized user who is authorized for the type(s) of use for which the licensee is seeking approval.

In order to authorize Carlos Montalván Miró, M.D. as the Radiation Safety Officer, we

would first need to amend your license to list him as an authorized user. Therefore, José Díaz, M.D. would need to remain as the Radiation Safety Officer. In the interim, Dr. Díaz would need to document Dr. Montalván Miró training on an NRC Form 313A(RSO) [http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(rso\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(rso).pdf). Specifically, Dr. Díaz, acting as a preceptor for Dr. Montalván Miró, would need to complete Part I, Items 3.c. and 4. and Part II, First Section, Item 3. and Sections Two, Three, and Four of the NRC Form 313A(RSO). Once the training and documentation is completed, you would provide that information to the NRC in an amendment request asking that Dr. Montalván Miró be named as the Radiation Safety Officer.

If you do not wish to pursue the above pathway, another option exists. You mentioned in your letter that Heriberto Torres, Ph.D. will be providing consultant services. Dr. Torres is currently listed as the Radiation Safety Officer on other NRC licenses. Based on his status as a Radiation Safety Officer on NRC licenses of similar types and use, Dr. Torres could be named as your Radiation Safety Officer, if he were to accept the position. In order to pursue this pathway, we would need the following:

- a. Documentation from Dr. Torres stating that he is willing to accept the Radiation Safety Officer position.
 - b. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.
 - c. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
 - d. 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 on-site time (hours per week).
 - e. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
 - f. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.
3. It appears from a review of your previous inspections that you have not used 10 CFR 35.300 materials for some time. Please indicate the last use of these materials, documentation of surveys following the last use, and confirm that you do not possess any of these materials at this time.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov;

select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits**, see our **toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 583606. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5272.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
José Díaz, M.D., Radiation Safety Officer

DOCUMENT NAME: G:\WordDocs\Current\Lic Def Letter\L52-25519-01.583606.doc

SUNSI Review Complete: TWeidner

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

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
NAME	TWeidner /TW/						
DATE	5.19.14						

OFFICIAL RECORD COPY