

## Roldan, Lizette

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**From:** Roldan, Lizette  
**Sent:** Tuesday, May 28, 2013 1:43 PM  
**To:** 'jonorullian@msn.com'  
**Subject:** VOID NEW LICENSE APPLICATION CONTROL 580170  
**Attachments:** sr1556v5[1].pdf; sr1556v1r1.pdf; sr1556v4.pdf

License No.: 11-35048-01  
Docket No.: 030-38624  
Control No.: 580170

Dear Mr. O'Rullian:

This is in reference to your application dated March 7, 2013 requesting Nuclear Regulatory Commission License No. 11-35048-01. This action will be voided without prejudice to the resubmission of a new license. The new license application fee will be valid for one year from when the application was received on March 11, 2013. During the license review we noticed you submitted procedures for processes you did not request. Please review your procedures and resubmit them to the NRC excluding processes that you have not requested. For example, procedures for maintenance of radiographic camera repairs, and leak test analysis were included in the application but not requested on your license application. A preliminary assessment of the license application was performed and several deficiencies were identified. In your resubmission, please include the following additional information:

1. The portable and fixed gauge training certificates provided are for radiation safety, gauge use, radiation safety officer training, and DOT requirements. There is no mention of non-routing maintenance. Provide documentation showing that you have received non-routine maintenance training for portable and fixed gauges. Review the section on "Maintenance" in NUREG-1556 Volumes 1 and 4 (attached), and refer to the appropriate appendix (G and N, respectively for each NUREG) for additional guidance on the type of information that must be submitted to be authorized to provide non-routine maintenance for portable and fixed gauges.
2. It is my understanding that you have already performed non-routine maintenance on portable and fixed gauges. Provide the manufacturer and model number for each fixed and portable gauge you have performed non-routine maintenance.
3. NUREG 1556 Volume 5 (attached) provides guidance for non-routine maintenance requirements for self shielded irradiators. Review the section on "Maintenance" in NUREG-1556 Volume 5, and appendix I for additional guidance on the type of information that must be submitted to be authorized to perform source exchanges on self shielded irradiators.
4. Provide the certification of the training you have received from Foss Therapy regarding your irradiator training.
5. Provide a detailed description of the training you received (e.g., a syllabus, course description, topics covered, length, hands on experience etc.) by Foss Therapy.
6. During the pre-licensing visit you mentioned you have performed 4 self shielded irradiator source exchanges. Provide the manufacturer and model number for each self shielded irradiator you have participated in source exchanges.
7. Provide a detailed description of your role during the irradiator source exchanges. How did you perform the source exchange? What was the role of Foss Therapy?

8. Please state whether you have performed any type of service on a gamma knife and provide documentation showing training and experience.
9. There are several sections in your procedure that must be updated to include procedures specific to your license application, for example, on Page 18, of SP-PRO-001, you state that the audits of the Radiation Safety Program shall be conducted in accordance with guidance contained in Appendix M of NUREG-1556, Vol. 11. Please note the NUREG-1556, Vol. 11 is the guidance for broad scope licenses. Please confirm you will also use Appendix I of NUREG-1556 Volume 18 as applicable to audit your service provider license.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please reply to my attention and refer to Mail Control No. 580170. If you have any technical questions regarding this deficiency letter, please call me at (817) 200-1596.

Sincerely,

**Lizette Roldán-Otero, Ph.D.**

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**PUBLIC**

- ☐ Immediate Release
- ☒ Normal Release

**NON-PUBLIC**

- ☐ A.3 Sensitive-Security Related
- ☐ A.7 Sensitive Internal
- ☐ Other: \_\_\_\_\_

Reviewer: Jno Date: 05/30/13