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Cc: ylopez@bssmpr.com; evelez@bssmpr.com; [Reichard, Michael](mailto:Reichard,Michael)
Subject: BANCO DE SANGRE DE SERVICIOS MUTUOS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 588970
Date: Monday, November 16, 2015 2:03:00 PM

Docket No. 03033911
License No. 52-25344-01
Control No. 588970

Jose O. Alsina
President
Banco de Sangre de Servicios Mutuos, Inc.
Stop 37 Ponce De León #662
Hato Rey, PR 00918

SUBJECT: BANCO DE SANGRE DE SERVICIOS MUTUOS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 588970

Dear Mr. Alsina:

Please confirm receipt of this communication.

This is in reference to your application dated September 29, 2015 requesting to renew Nuclear Regulatory Commission License No. 52-25344-01. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than your Radiation Safety Officer. Please re-submit your application with your signature. In addition, in order to allow for the appropriate review of management responsibility as described in Section 3 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998, please submit an organizational chart showing the relation of the Radiation Safety Officer to the President.
2. It appears you have request the decayed activity of the sources for the possession limit` of the sources on your license. Please confirm that you request your possession limit to be increased to the maximum activity allowed for future re-charging of the irradiator.
3. Please confirm that the area where the self-shielded irradiator is located is equipped with an automatically operated fire detection and control (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low level radiation risk attributable to fire as required by Section 8.9 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998.
4. Please submit a detailed facility diagram showing the storage location of the irradiator. Identify areas across the walls from the irradiator room and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-1301.html> Guidance for demonstrating that individual members of the public will not receive doses exceeding the allowable limits can be found in Appendix M of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998.

5. Please confirm that you will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG 1556 Vol. 5 "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.
6. Please confirm that physical inventories will be conducted at intervals not to exceed six months to account for all sealed sources and devices received and possessed under this license as indicated by Section 8.10.3 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998.
7. Please choose one of the following responses:
 - a. Confirm that your dosimetry provider is a NVLAP approved processor and clarify who receives dosimeters as indicated in Section 8.10.4 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998, or
 - b. Provide the following confirmation: "Either we will perform a prospective evaluation demonstrating unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the Criteria in the section entitled 'Radiation Safety Program- Occupational Dose' in NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998.
8. Confirm the following two statements as required by section 8.10.6 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998.
 - a. "If we change our operating and emergency procedures without amending our license, we will assure that: the changes are reviewed and approved by licensee management and the RSO; affected licensee staff are trained in the procedures before they are implemented; the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and the changes do not degrade the safety of the program."
 - b. "Operating and Emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled 'Radiation Safety Program-Operating and Emergency Procedures' in NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998."

9. As indicated in Section 8.10.7 of in NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998, confirm the following: "Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization according to the self-shielded irradiator manufacturer's (or distributor's) and kit supplier's instructions. As an alternative we will implement the model leak test program published in Appendix P to NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses ," dated June 1998."
10. As indicated in section 8.10.8 of NUREG 1556 Vol 5. "Consolidated Guidance about Materials Licenses: Program Specific Guidance About Self-Shielded Irradiator Licenses," dated June 1998 please confirm the following:
 - a. "We will implement and maintain procedures for routine maintenance of our self-shielded irradiator according to the manufacturer's (or distributor's) written recommendations and instructions."
 - b. "We will have the self-shielded irradiator manufacturer (or distributor) or other person authorized by the NRC or an Agreement State perform non-routine maintenance."

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 by letter or fax (610) 337-5269, at the Region I Office and refer to Mail Control No. 588970. If you have any technical questions regarding this deficiency letter, please call Robin Elliott at (610) 337-5076.

In order to continue our prompt review of your application, please respond within 30 calendar days from the date of this letter.

Sincerely,

Michael Reichard
Health Physicist
Commercial, Industrial, R&D and Academic
Branch
Division of Nuclear Materials Safety

Robin L. Elliott

Health Physicist

U. S. Nuclear Regulatory Commission

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