



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

May 15, 2020

José O. Alsina Martínez, MT, President
Banco de Sangre de Servicios Mutuos, Inc.
Stop 37, Ponce de Leon #662
Hato Rey, Puerto Rico 00918

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS* (10 CFR) 30.34(c) AND LICENSE CONDITIONS 13.A. AND 18.A. OF NRC LICENSE 52-25344-01, BANCO DE SANGRE DE SERVICIOS MUTUOS, INC., MAIL CONTROL NO. 618804

Dear Mr. Alsina Martinez:

By emails dated May 4, 2020, and May 6, 2020, (Agencywide Documents Access and Management System [ADAMS] Accession Nos. ML20126G353 and ML20128J488, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.11(a), Banco de Sangre de Servicios Mutuos, Inc. (Banco de Sangre), the licensee, requested exemptions from requirements listed in License Conditions 13.A. and 18.A. of NRC License No. 52-25344-01 and relief from performing annual preventive maintenance.

In Banco de Sangre's request, the licensee stated that the contractors it hired to perform device preventive maintenance, sealed source leak testing, and survey instrument calibrations are not able to perform these services as a result of restrictions related to the COVID-19 public health emergency (PHE).

The exemption provision in 10 CFR 30.11(a) states:

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The license conditions from which the licensee requested exemption were imposed upon the licensee by the U.S. Nuclear Regulatory Commission (NRC) per 10 CFR 30.34(e). The regulation in 10 CFR 30.34(c) requires that the licensee confine its use of the byproduct material to the locations and purposes authorized in the license. Therefore, exemptions to the requirement in 10 CFR 30.34(c) to comply with the terms of a license may be granted pursuant to 10 CFR 30.11.

The NRC staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The licensee is requesting exemptions from:

- A requirement to measure radiation dose and calculate exposure times to achieve specified radiation dose levels, as part of annual preventive maintenance performed on a self-shielded irradiator that is required under Banco de Sangre's written procedures.
- License Condition 13.A., which states that "[s]ealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State." The sealed source and device registry leak test frequency for Banco de Sangre's licensed device is six months.
- License Condition 18.A., which requires the licensee to "use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG 1556, Vol. 5, dated October 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."¹

The NRC determined that the requirement to measure radiation dose and calculate exposure times to achieve specified radiation dose levels as part of annual irradiator preventive maintenance, from which Banco de Sangre requested relief, is a recommendation by the U.S. Food and Drug Administration and a requirement for AABB accreditation, and is not an NRC requirement. Thus, an exemption from the NRC is not necessary.

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 30. The NRC staff has determined that the granting of the requested exemption from license condition 13.A. and 18.A. will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The NRC staff has also determined that:

- The extension of the sealed source leak test time period does not constitute a significant increase in risk to public health and safety, because licensee records show no indication of source leakage and the requested time extension is relatively short (i.e., 3 months) compared to the license-required leak test frequency (6 months).
- The extension of the instrument calibration time period does not constitute a significant increase in risk to public health and safety, because the instrument remains operable, the licensee has a dosimeter placed in the irradiator room to record ambient radiation levels, and the requested time extension to perform instrument calibrations of the survey meter is relatively short (i.e., 3 months) compared to the required instrument calibration frequency (12 months).

¹ This requirement is stated in the licensee's application dated December 16, 2015, which is incorporated into the license by License Condition 18.A.

The NRC staff finds that the requested exemption will not endanger life or property or the common defense and security and is otherwise in the public interest. The NRC staff also notes that by granting these exemptions, it will allow the licensee to follow social distancing guidelines to prevent the spread of the virus that causes COVID-19.

Based on the above findings, the NRC grants the following exemption for the specified period of time:

- From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in License Condition 13.A. of NRC License No. 52-25344-01 to perform leak tests every 6 months or at the frequency specified in the sealed source and device registry. The licensee shall perform the required leak tests within 30 days following the expiration of this exemption.
- From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in License Condition 18.A. of NRC License No. 52-25344-01 to perform survey meter calibrations for no more than 12 months before the date the meter is used. The licensee shall perform the required survey meter calibrations within 30 days following the expiration of this exemption.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(C). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Randolph Ragland by electronic mail at Randolph.Ragland@nrc.gov or by telephone at 610-337-5083.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 52-25344-01
Docket No. 030-33911
Mail Control No. 618804

TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 CODE OF FEDERAL REGULATIONS 30.34(c) AND LICENSE CONDITIONS 13 AND 18 OF NRC LICENSE 52-25344-01, BANCO DE SANGRE DE SERVICIOS MUTUOS, INC., MAIL CONTROL NO. 618804 May 15, 2020

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