



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, D.C. 20555-0001

January 2, 2020

ChemPro Technologies, Inc.  
dba Environics USA  
ATTN: Michael Phillips  
1107 Wonder Drive, Suite 103  
Round Rock, TX 78681

**SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING CHEMPRO  
TECHNOLOGIES, INCORPORATED EXEMPT DISTRIBUTION LICENSE  
APPLICATION AND SEALED SOURCE AND DEVICE REGISTRATION  
CERTIFICATE APPLICATION**

Dear Mr. Phillips:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the ChemPro Technologies, Inc. application dated November 13, 2019 for amendment to your Exempt Distribution License and Sealed Source and Device (SSD) Registration Certificate. The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed in the enclosure.

The information related to review of your Exempt-Distribution License application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 32.23, 32.24, and 32.26 and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

The information related to review of your Sealed Source and Device amendment application is required by 10 CFR 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

If you have any questions regarding the SSD Registration Certificate you can contact Lymari Sepulveda at (301) 415-5619 or by e-mail at [Lymari.Sepulveda@nrc.gov](mailto:Lymari.Sepulveda@nrc.gov). For questions related to the Exempt Distribution License, please contact me at (301) 415-5452 or by e-mail at [Donald.Lowman@nrc.gov](mailto:Donald.Lowman@nrc.gov).

Sincerely,

***/RA Tomas Herrera for/***

Don Lowman  
Materials Safety and Tribal Liaison Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Request for Additional Information

Docket No. 030-38904  
Mail Control No. 616997

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TECHNOLOGIES, INCORPORATED EXEMPT DISTRIBUTION LICENSE  
APPLICATION AND SEALED SOURCE AND DEVICE REGISTRATION  
CERTIFICATE APPLICATION

DATED: January 2, 2020

**ADAMS ACCESSION No.: ML19322A0004 (pkg)****ML19352F898 (Letter)**

OFC	NMSS/MSTB	NMSS/MSTB	NMSS/MSTB	NMSS/MSTB	NMSS/MSTB
NAME	RStruckmeyer Via email	DLowman Via email	LSepulveda	THerrera	Tomas Herrera for DLowman
DATE	12/19/2019	12/20/2019	1/2/2020	1/2/2020	1/2/2020

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**CHEMPRO TECHNOLOGIES, INC. LETTER DATED NOVEMBER 19, 2019**  
**REQUEST FOR ADDITIONAL INFORMATION**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the ChemPro Technologies, Inc. (ChemPro) letter dated November 13, 2019 and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

**A. Exempt Distribution License**

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, Sections 30.20, 32.26, 32.27, 32.28, 32.29, and 32.210 and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>).

Please provide the information required by the regulations. These regulations apply to companies that import products as well as those that manufacture products within the United States. Note that it is the applicant's responsibility to confirm the validity of all information.

1. Paragraph 32.26(a) of 10 CFR requires the applicant to satisfy the general requirements specified in 10 CFR 30.33. To do so, please provide us with a copy of your revised Texas possession license to account for the addition of Model X. Please note that an exempt distribution license cannot be issued until you have provided a copy of the revised possession license in your response to us.
2. Please update your radiation exposure evaluation found in your initial application for the Model X as per 10 CFR 32.26, "Requirements to license to manufacture, process, produce, or initially transfer" as follows:
  - 32.26(b)(4) - Solubility in water and body fluids of the forms of the identified byproduct material.
  - 32.26(b)(6) - Maximum external radiation levels at 5 and 25 centimeters from any external surface for the model X, averaged over an area not to exceed 10 square centimeters, and the method of measurement or calculation.

In your letter dated November 13, 2019, under the section titled, Change B, it states that for the new ChemPro X "The max radiation level at 100 mm (3.93 in.) is 27.2  $\mu$ rem/hr." The radiation levels of the previous models were 1.3  $\mu$ rem/hr at 5 cm thus the radiation level is higher at the longer distance. If you experience the same anomaly when you take the radiation measurements at the distances stated in the above bulleted item, please explain the increase in radiation levels between the ChemPro X and the previously registered models in the ChemPro series. Please note that previously submitted radiation profiles do not support the new values.

- 32.26(b)(8) - Total quantity of byproduct material expected to be distributed annually for model X.

Enclosure

## **B. Sealed Source and Device Registration**

1. We note a change in dimensions in the sensor unit between the previously registered devices in the ChemPro Series and the sensor unit requested for the ChemPro X. Please describe the difference between the two.
2. Please discuss if there were any changes made to the source shield assembly. This includes any changes in materials or dimensions. If changes were made please provide the prototype testing results and procedures in order to demonstrate that the device will maintain its integrity during normal use and likely accident conditions. Please see NUREG-1556, Volume 3, Rev. 2, Section 10.5, "Prototype Testing", for the forms acceptable prototype testing.