

January 12, 2017

Symetrica Inc.
ATTN: Matthew Dallimore
CEO and Radiation Safety Officer
63 Great Road, Suite 106
Maynard, MA 01754

SUBJECT: SYMETRICA INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR A NEW EXEMPT DISTRIBUTION LICENSE

Dear Mr. Dallimore:

This letter refers to your application dated October 12, 2016, and received on December 12, 2016, for an Exempt Distribution License. In reviewing your application, we found that additional information is required.

Title 10 of the *Code of Federal Regulations* (10 CFR) 32.14 requires the applicant to submit sufficient information regarding the product pertinent to evaluation of the potential radiation exposure. Your application did not contain all the required information. Please submit the following information:

1. Provide the method of containment or binding of the byproduct material in the product.
2. In Attachment G, "Quality Control Procedure Overview" of your application, you stated that "Symetrica documents, implements, and maintains its quality management system and strives to continually improve its effectiveness in accordance with the requirements of the ISO 9001:2008 standard." Please clarify whether you obtained an ISO 9001:2008 certificate, if so, provide a copy of the certificate and a copy of the Quality Assurance Program.
3. In addition, as stated in 10 CFR 32.15(a), please confirm that Symetrica's quality control procedures shall:
 - a. Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions;
 - b. Subject inspection lots to acceptance sampling procedures to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded;
 - c. Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit.

We will continue our review upon receipt of this information. 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.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

Shirley S. Xu
Materials Safety License Branch
Division of Material Safety, States, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39014
Mail Control No. 592491

M. Dallimore

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If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

Shirley S. Xu
Materials Safety License Branch
Division of Material Safety, States, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39014
Mail Control No. 592491

Certified Mail No. 7015 0640 0003 2910 1528

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OFC	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
NAME	SXu	DMiller	HGonzalez	SXu
DATE	1/12/17	1/12/17	1/12/17	1/12/17

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