



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

March 30, 2015

Symetrika, Inc.  
ATTN: Dr. Matthew Dallimore  
Radiation Safety Officer  
63 Great Road, Suite 106  
Maynard, MA 01754

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION; SYMETRICA,  
INCORPORATED; NEW LICENSE APPLICATION DATED MARCH 11, 2015

Dear Dr. Dallimore:

This letter is in response to your application for a license dated March 11, 2015. In reviewing your application, we find that additional information is required to complete our review. In order to continue with our review, please address the issues listed below.

1. Your Massachusetts License No. 55-0582 does not currently authorize the possession of the byproduct material in the products described in your license application.

In accordance with 10 CFR 30.33, an NRC license authorizing exempt distribution of these products will not be issued until the corresponding possession license has been issued by the Commonwealth of Massachusetts.

Please provide a copy of an amendment of your Massachusetts license authorizing the possession of the byproduct material in the products that are described in your license application.

2. In Item 5 of Parts 1 and 2 of your application, you requested a maximum amount of activity incorporated into each product of "1  $\mu$ Ci No stabilization module to exceed 10 exempt quantities." Please clarify this request; specifically, state whether you intend to be authorized to distribute stabilization modules containing up to 10 sources, each source containing 1  $\mu$ Ci of Na-22. Your application included drawings of stabilization modules that appear to contain only 1 source. In your response, please address whether and how the stabilization devices would contain up to 10 sources if you intend to be authorized for devices that contain more than 1 source.
3. Part 2 of your application requested authorization to distribute the Model 410-0348 stabilization device. However, a model number was not given for the device in the drawings in section 6.2 of Part 1 of your application.

Please clarify the model numbers of the stabilization modules for which you are requesting authorization. For your information, model numbers of devices are listed on licenses authorizing distribution under 10 CFR 32.14.

4. In accordance with 10 CFR 32.14 (b)(3), applicants are required to provide the method of containment or binding of the byproduct material in the product.

Your application has not specified the method of containment or binding of the byproduct material in the stabilization modules described in your application.

In your response, please provide information concerning the method of containment or binding of the byproduct material for the two types of stabilization modules described in your application.

5. In accordance with 10 CFR 32.14 (b)(4), applicants are required to submit procedures for, and results of, prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product.

Your application did not include the procedures nor the results of prototype testing as required by 10 CFR 32.14 (b)(4).

In your response, please submit the procedures for, and results of, prototype testing as required by 10 CFR 32.14 (b)(4).

6. In accordance with 10 CFR 32.14 (b)(5), applicants are required to submit quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

Your application included information about your quality assurance program including the titles and reference numbers of several procedures; however, copies of the relevant procedures were not provided.

Please submit copies of procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

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.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

M. Dallimore

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In accordance with 10 CFR 2.390(a), a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

If you have any questions, please contact me at (301) 415-5608 or by email at [Eric.Reber@nrc.gov](mailto:Eric.Reber@nrc.gov).

Sincerely,

**Shirley Xu for:**  
**/RA/**

Eric Reber, General Engineer  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Mail Control No. 586268  
Docket No. 03036248

M. Dallimore

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In accordance with 10 CFR 2.390(a), a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

If you have any questions, please contact me at (301) 415-5608 or by email at [Eric.Reber@nrc.gov](mailto:Eric.Reber@nrc.gov).

Sincerely,

**/RA/**

Eric Reber, General Engineer  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Mail Control No. 586268  
Docket No. 03036248

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OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Eric Reber	Shirley Xu	Hipolito Gonzalez	Eric Reber
DATE	03/24/2015	03/26/2015	03/27/2015	03/30/2015

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