From:	CJ Karchon
To:	Struckmeyer, Richard
Cc:	Wagner, Katie; Sepulveda, Lymari; Jankovich, John; Debbi Spykerman (debbi@cammenga.com)
Subject:	Re: Second RAI for amendment to exempt-distribution license 21-26460-02E (Mail Control No. 579632)
Date:	Thursday, May 16, 2013 3:33:00 PM
Attachments:	Response to RAI Email 5-8-13_CN 579632.pdf

Mr. Struckmeyer,

Thank you for taking my call the other day to discuss the RAI open items. Per our conversation, the attached file is Cammenga & Associates' response to the below email. Please let me know if anything further is needed.

Best Regards,

CJ

Christopher J. Karchon
VP of Sales

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On May 8, 2013, at 8:28 AM, Struckmeyer, Richard wrote:

> Mr. Karchon:
>
> Your April 24, 2013, response to our Request for Additional Information (RAI) does not appear to provide all of the information requested in the attachment, Part B, “Questions pertaining to your Exempt-Distribution Materials License.” Portions of the relevant questions are repeated below using the same numbers as in the RAI.
>
> B.2. Section 32.22(a)(2)(iii), 10 CFR 32, requires the applicant to submit information concerning the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.
>
> Your response did not appear to address any changes in chemical and physical form that may occur during the useful life of the product. Please submit information concerning changes in chemical and physical form that may occur during the useful life of the product, or indicate where this

information may be found. If no changes are anticipated (other than radioactive decay), please so indicate, and the reasons or evidence in support of your position.

B.3. Section 32.22(a)(2)(iv), 10 CFR 32, requires the applicant to submit information concerning the solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

Your response did not appear to address the solubility in water and body fluids of the forms of the byproduct material. Your response referred to Attachment 4, "10 CFR 32.23 Safety Criteria," (conditions of use/dose limit examples) which addresses potential doses for various scenarios, and Attachment 7 "Periodic Report of Transfer," which provides the quantities of products transferred in accordance with your license.

Please submit information concerning the solubility in water and body fluids of the forms of the byproduct material, or indicate where this information may be found.

B.4. Section 32.22(a)(2)(v), 10 CFR 32, requires the applicant to submit information concerning details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

Section 32.22(a)(2)(v) applies to the product as it is to be used after distribution, not to radiation workers. Your response did not appear to address details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the<u>product</u>.

Your response referred to Attachment 4 "10 CFR 32.23 Safety Criteria," (conditions of use/dose limit examples); Attachment 9 for "Radiation Safety Program;" and Attachment 11 for "Tritium Source Removal for Used Knife/Luminous Device Recycling." Attachments 9 and 11 are relevant to your possession and use license, rather than your exempt-distribution license.

Attachment 4 addresses potential doses for various scenarios; it does not address details of construction and design of the product as related to containment and shielding. Attachment 9 addresses worker safety; it does not address safety features of the <u>product</u>. Attachment 11 addresses tritium source removal, but does not appear to address safety of disposal by end users.

Please provide details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of

the product, as required by Section 32.22(a)(2)(v), 10 CFR 32. You may be able to cite portions of the documents you have already provided as long as you can demonstrate how these are relevant to the product and its use by the end user.

B.5. Section 32.22(a)(2)(vi), 10 CFR 32, requires the applicant to submit information concerning maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

You responded that a senior manager of MB Microtec from Bern, Switzerland, informed you that there is no relevant dose of external radiation generated by the H-3 Trigalights (MB Microtec brand name) produced by MB Microtec, and that it is physically impossible for the H-3 Tritium micro vials to generate an external dose rate.

While we accept that this statement is correct, you should have documentation in your possession that confirms this statement, including the reasons why it is correct (having to do with the weak beta energy emitted by tritium and the encapsulation of the source). Please confirm that you have obtained such documentation.

B.6. Section 32.22(a)(2)(vii), 10 CFR 32, requires the applicant to submit information concerning the degree of access of human beings to the product during normal handling and use.

Your response referred to Attachment 5 of your original submission of December 20, 2012, as well as Attachments 4 and 9 to the April 24, 2013, response to our RAI. These attachments do not appear to address the requirements of 32.22(a)(2)(vii) concerning the degree of access of human beings to the product during normal handling and use. Please explain how these attachments may be considered relevant to this requirement, or provide additional information that addresses the requirement.

B.12. Section 32.22(a)(2)(xv), 10 CFR 32, requires the applicant to submit information concerning 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 response referred to, among others, Attachment 9, “Radiation Safety Program.” This attachment does not appear to be relevant to quality control procedures and the standards the product will be required to meet. Please explain how Attachment 9 may be considered relevant to this requirement, or provide additional information that addresses the requirement.

Please submit the requested information within thirty days of the date of this email. If we have not received complete information within thirty days of the

date of this email, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete response.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this email 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).

Any correspondence regarding your amendment application should reference the control number 579632.

Thank you,

Richard K. Struckmeyer
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
301-415-5477