From:	CJ Karchon
To:	Struckmeyer, Richard
Subject:	Re: Second RAI for amendment to exempt-distribution license 21-26460-02E (Mail Control No. 579632)
Date:	Thursday, June 13, 2013 2:39:44 PM
Attachments:	TRDH 1990 (2).pdf Pages from Tritium Devices Health & Safety Manual.pdf

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Richard,

Please review an excerpt from an older version of the "Tritium Radioluminescent Devices Health and Safety Manual" in the attachment called **TRDH 1990 (2).** Formula 6.18 is what we used for our Basic Equation. This represents the sum of the three components of dose due to inhalation. Please read from the bottom right of page 6.7 (marked) through to the end to understand where it is derived from.

As was stated previously, this conversion factor of 1.26E-4 is doubled to take into account the intake rate for absorption.

We have also attached an excerpt from the 1995 version of "Tritium Radioluminescent Devices Health and Safety Manual" (**attachment: Pages from Tritium Devices Health & Safety Manual)**. This same formula (6.18) is found at the bottom of page 6.8 with slightly different rounding for the conversation factor (128.8E-6 instead of 126.0E-6). This is perhaps where there may have been some confusion.

This equation takes into account doses to the whole body. The variable units are as follows:

H = the committed dose equivalent, rem
Q = the quality factor, dimensionless
C = the activity concentration of tritium in air, uCi/mL
T = the exposure time, minutes

Please let me know if there are any other questions.

Best Regards,

CJ

Christopher J. Karchon
VP of Sales

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On Jun 4, 2013, at 2:40 PM, Struckmeyer, Richard wrote:

Mr. Karchon:

I am still having difficulty understanding the equation you provided for calculating dose in rem due to inhalation.

I have reviewed the relevant portions of the "Tritium Radioluminescent Devices Health and Safety Manual" that you referenced as the source of the equation, but do not see the basic equation H = (Q)(1.26E-4)(C)(T), although I see similar equations from which this may have been derived.

In order to have confidence that you are providing accurate estimates of dose in Attachment 4 to your letter dated April 24, 2013, please explain how you obtained the basic equation.

Also, it seems likely that the doses you calculated are meant to be whole body doses, but as far as I can tell you haven't specifically stated this. Without further explanation it is difficult to determine whether you may have provided the whole body dose, the committed dose equivalent to the lungs, or some measure of dose equivalent.

Furthermore, the numerical value (1.26E-4) obviously must have units associated with it to provide the proper conversion. In the "Tritium Radioluminescent Devices Health and Safety Manual" it appears that the units were expressed as "mL-rad/μCi-min," but these units do not appear to correspond to those used in your Attachment 4, which seems to add a further conversion from rad to rem, and a factor to convert minutes to years. Clarification of this issue may help in my understanding of the basic equation.

Thank you for continuing to provide these explanations.

Richard K. Struckmeyer
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301-415-5477

From: CJ Karchon [mailto:cj@cammenga.com]
Sent: Thursday, May 30, 2013 12:31 PM
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)

Mr. Struckmeyer,

Thank you again for walking through all of the open questions from our last submission.

Regarding tritium solubility in water and body fluids: H-3 has a low retention in the body subsequent to inhalation and the skin absorption intake for H-3 in this form is relatively insignificant (NUREG/CR-0215). However, as was mentioned the previous email response, the H-3 gas may be converted into tritiated water on contact with the atmosphere. Tritiated water is completely soluble in normal water and body fluids. Inhaled tritiated water vapor is assumed to be totally absorbed in body fluids (ICRP 30). The body naturally excretes this relatively quickly. Half of the body's tritium is excreted in 10 days after exposure.

Basic Equation Clarification: The basic equation we stated in our previous submissions was listed as H = (Q)(1.26E-4)(C)(T). The 1.26E-4 is the conversion factor representing inhalation of tritiated water vapor. Cammenga decided to use a quality factor (Q) of 2 because it is more restrictive.

Your question is over the transition to the following simplified equation: H = (5.04E-4)(C)(T).

It was stated in the Safety Criteria enclosure's opening paragraph that the intake rate of absorption through the skin is between 50% and 100% of the intake rate of inhalation. We decided to use equal rates for both inhalation and absorption because it is more restrictive. Therefore, the conversion factor for inhalation (1.26E-4) will ALSO be used for absorption. So we first multiplied this 1.26E-4 factor by 2 to get 2.52E-4. This number represents the combined conversation factors for both inhalation and absorption of tritiated water vapor. We then multiplied 2.52E-4 by the (Q) of 2 to equal 5.04E-4.

This results in a simplified equation of H = (5.04E-4)(C)(T). This result of (H) represents the committed dose equivalent (rem).

B.6. Section 32.22(a)2(vii), 10 CFR 32:

You were correct in adjusting our last submission that our Compass' Military Specification was Attachment 5, instead of Attachment 11. This military specification was referenced because it was the basis for the prototype and production testing procedures we take the knives through. The tests accurately depict the extreme circumstances soldiers may take the knives through based on various climates.

"Answer number 3" in the Conditions section of 4/24/13 submission explains two things: 1.) Why we use MIL-PRF-10436N as the basis of our durability tests. 2.) How Cammenga "tamper proofs" the knives to prevent end-users from gaining access to Tritium inside the Grilamid handles.

Regarding the degree of access to human beings: The design of our Model TK3 knives assures that the borosilicate tritium vials are not accessible during normal use, storage, handling, or maintenance. Since the tritium gas is in the borosilicate glass vials, no inhalation or ingestion is expected from normal use. Full protection is guaranteed by using our patented Tritium Guards, Grilamid handles, custom screws and Dow Corning Sealants. In the interest of being thorough, Cammenga probably provided too much information in responding to this item in previous submissions. Please omit from our response any excessive information, such as "Attachment 10" or "Answer number 3" as this may have been confusing.

B.12. Section 32.22(a)(2)(xv), 10 CFR 32:

Regarding the outstanding quality concerns: please omit any previous submission references to Attachment 9 and Attachment 11 (corrected to Attachment 5) for Cammenga's quality control measures. The only relevant information is that we are ISO 9001:2008. In NUREG 1556, Vol. 8. Section 9.1.3 it states, "Current practice allows acceptance of the submission of a QA program in lieu of a QC program because the QA program puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through distribution."

Richard, thank you for informing me you spoke with John Jankovich, who informed you of ISO 9001:2008's various procedures and high level of standards required for accreditation. Previously, we referenced Attachment 6 and Attachment 10 of

the 4/24/13 submission to address both our prototype testing AND our production testing procedures. We would like to omit this information as well.
Thank you for your help in clarifying all of these items.

Best Regards,

CJ

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VP of Sales

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<image001.png>

On May 21, 2013, at 4:11 PM, Struckmeyer, Richard wrote:

Mr. Karchon:

Thank you for your response to our second RAI for amendment to your exempt-distribution license. It appears that you have not yet provided complete responses to some of our questions.

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.

You provided an equation in Attachment 4 of your original 12/20/12 submission to calculate dose in rem due to inhalation which you attribute to "Tritium Radioluminescent Devices Health and Safety Manual," Pacific Northwest Laboratory, Richland, WA.

Please indicate how this equation takes into account the solubility of tritium

in water and body fluids. Note that when tritium enters the body, it could possibly be in gaseous form or liquid form. The solubility of these forms is not the same.

Possible alternative ways to answer this could include:

- State whether one or both of these forms are dominant with regard to dose to humans, and how the equation you are using takes it (or them) into account, or

- Explain what relative value(s) of solubility (insoluble, slightly soluble, very soluble, etc.) is (are) assumed to apply in the equation, and why this (or these) value(s) are appropriate, or

- Provide any other explanation that describes how the intent of the regulation is met.

The issue of solubility may have been addressed in Cammenga's original application for an exempt-distribution license or in a subsequent amendment application. If so, you may want to restate that information in response to this question. Another source may be the document you referred to in Attachment 4.

In addition to the above, two more questions arose from further review of Attachment 4.

- In Section 1 "General Discussion" you noted that intake occurs by means of absorption through the skin as well as inhalation, and stated that you will use equal rates for inhalation and absorption. However, in Section 2 "Basic Equation," you provide the basic equation to calculate dose in rem due to inhalation. No further mention is made of dose due to absorption. Please explain this apparent discrepancy.

- In Section 2 "Basic Equation" you provided the following equation:

  H = (Q) (1.26E-4) (C) (T)

  and stated that you would use a value of Q = 2. You then restated the equation as:

  H = (5.04E-4) (C) (T)

  which implies that you multiplied 1.26E-4 by 2 and obtained 5.04E-4. It would appear that the correct value should be 2.52E-4. Please explain how you obtained the value of 5.04E-4.

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.

You indicated that we should refer to Attachment 11 of the original 12/20/12 submission, your compass's Military Specification. However, your original 12/20/12 submission does not contain an Attachment 11. You may have intended that we refer to Attachment 5 of that submission, but this needs to be clarified. You also referred to Attachment 10 and to the Conditions and Use "answer number 3" of the 4/24/13 submission.

This "referral" approach is not adequate for the following reasons:

- Unless you are able to demonstrate otherwise, the Military Specification is assumed to contain only the requirements that the customer expects your product to meet, rather than documentation that the product has actually met these specifications.

- To the extent that Attachment 10 is applicable, you must explain exactly what content in that document is pertinent to the "degree of access of human beings to the product during normal handling and use."

- "Answer number 3" in the Conditions and section of the 4/24/13 submission appears to be a reference to Attachment 4, which contains examples of dose calculations. This does not address the issue of access.

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.

You stated that attachment 9 of your 4/24/12 submission explains a number of measures Cammenga & Associates takes to ensure the utmost quality is met with regards to Tritium vial assembly. However, Attachment 9 contains your "Radiation Safety Program," which applies to radiation worker training and safety. It does not appear to specifically address the requirements of Section 32.22(a)(2)(xv). If you believe that this attachment addresses this requirement, please explain explicitly how it does so.

You indicated that we should refer to Attachment 11 of the original 12/20/12 submission, your compass' Military Specification. However, your original 12/20/12 submission does not contain an Attachment 11. You may have intended that we refer to Attachment 5 of that submission, but this needs to be clarified.

You mentioned your ISO 9001:2008 certification, and cited the ISO Certificate in Attachment 8 of your 4/24/12 submission. Please explain the relevance of this certification to the specific 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, in order to demonstrate that you meet the requirement of Section 32.22(a)(2)(xv). In other words, please describe (or

provide a copy of) the procedure that implements ISO 9001:2008 within your company.

Your response implied that Attachment 6 and Attachment 10 of the 4/24/13 submission are relevant to the requirements of Section 32.22(a)(2)(xv). However, both of these attachments appear to address prototype testing rather than 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. If you believe that these attachments address this requirement, please explain explicitly how they do so.

Thank you,

Richard K. Struckmeyer
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From: CJ Karchon [mailto:cj@cammenga.com]
Sent: Thursday, May 16, 2013 3:30 PM
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)

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 theproduct.

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 product. 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
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