

Weaver, Deborah

From: Tarah Bolas <bolast@rbm-services.com>
Sent: Tuesday, January 22, 2019 2:28 PM
To: Struckmeyer, Richard
Subject: [External_Sender] RE: Your response to NRC RAI
Attachments: Response NRC_22Jan2019.pdf

Good Afternoon –

Please see the attached signed letter that documents this response:

No, the mechanical holder does not contain any mechanism that moves or positions the Na-22 source when the holder is inserted into the CardioGen-82 infusion system.

The holder does not contain any parts or mechanisms that are activated by the user or by the system into which it is inserted.

Please let me know if you require a hardcopy of this response to be mailed to you.

Thank You -
Tarah Bolas
Q&RA Manager/RSO
RbM Services LLC
101 Valley Court Suite B
Oak Ridge, TN 37830
865-483-0067 x117
bolast@rbm-services.com

From: Struckmeyer, Richard [mailto:Richard.Struckmeyer@nrc.gov]
Sent: Tuesday, January 22, 2019 1:43 PM
To: bolast@rbm-services.com
Subject: Your response to NRC RAI

Ms. Bolas,

We have received your letter of January 17, 2019, in response to our Request for Additional Information dated December 20, 2018.

We need further clarification of your response to item 2. While we appreciate the additional explanation of the mechanical holder that you provided, the wording of your response does not explicitly answer the questions as stated, which I will repeat here:

“Specifically, does this mechanical holder contain any mechanism that moves or positions the Na-22 source when the holder is inserted into the CardioGen-82 infusion system? Stated another way, does the holder contain any parts or mechanisms that are activated by the user or by the system into which it is inserted?”

Depending upon the answers to these questions, we may be able to conclude the review of your application fairly soon.

Regards,

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
301-415-5477



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January 22, 2019

Richard K. Struckmeyer
Headquarters
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Materials Safety, Security, State, and Tribal Programs
Materials Safety Licensing Branch
Mail Stop: T5B60
Washington, D.C. 20555-0001
Richard.Struckmeyer@nrc.gov

Re: Response to the NRC's Email Dated January 22, 2019 regarding *Your response to NRC RAI*
[CONTROL NUMBER 610517]

Mr. Struckmeyer:

Please see our response to your question:

We need further clarification of your response to item 2. While we appreciate the additional explanation of the mechanical holder that you provided, the wording of your response does not explicitly answer the questions as stated, which I will repeat here:

“Specifically, does this mechanical holder contain any mechanism that moves or positions the Na-22 source when the holder is inserted into the CardioGen-82 infusion system? Stated another way, does the holder contain any parts or mechanisms that are activated by the user or by the system into which it is inserted?”

RbM's Response:

No, the mechanical holder does not contain any mechanism that moves or positions the Na-22 source when the holder is inserted into the CardioGen-82 infusion system.

The holder does not contain any parts or mechanisms that are activated by the user or by the system into which it is inserted.

Please do not hesitate to contact me with any further questions.

Sincerely,

A handwritten signature in blue ink that reads 'Tarah K. Bolas'.

Tarah K. Bolas

Quality and Regulatory Affairs Manager/Radiation Safety Officer/Management with
Executive Responsibility