



January 17, 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**

**Re: Response to the NRC's Letter Dated December 20, 2018 regarding RbM
Services, LLC, Request for Additional Information
[CONTROL NUMBER 610517]**

Mr. Struckmeyer:

Please see our responses for your comments:

- 1. You provided a copy of your Tennessee Department of Environment and Conservation Radioactive Material License, Amendment 8, in accordance with the regulations in 10 CFR 30.33; however, this license does not authorize the possession and use of the sodium-22 (Na-22) sources that you intend to distribute. Please provide a copy of the license authorizing such possession and use. An exempt distribution license cannot be issued until the applicant obtains a possession and use license authorizing the specific radionuclide(s) described in the exempt-distribution license application.**

RbM's Response:

RbM's TN Department of Environment and Conservation Division of Radiological Health Radioactive Material License, License number R-01104-E27, Amendment 11 is attached (received on January 17, 2019); please see specifically Items 6.K. and 10.J.

2. In order for the NRC staff to determine whether the Na-22 sources can be authorized under 10 CFR 32.18, we need to know the details of the mechanical holder that you described as "designed to provide the correct geometry."

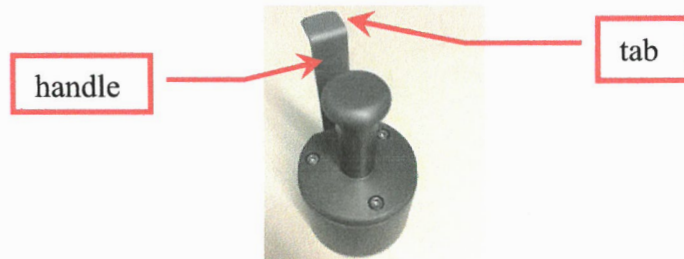
Specifically, does this mechanical holder contain any mechanism that moves or positions the Na-22 source when the holder is inserted into the CardioGen-82 infusion system?

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?

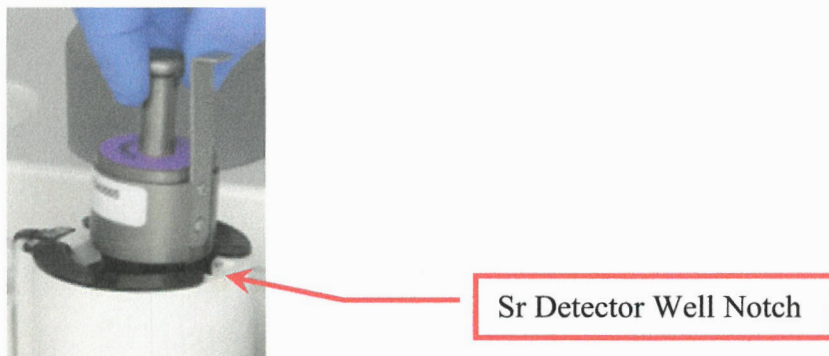
RbM's Response:

The same mechanical holder is used for all of the Na-22 sources (10 μ Ci, 0.6 μ Ci, and 0.04 μ Ci). The source is placed/assembled, following a controlled manufacturing process instruction procedure, inside of the mechanical holder, which includes ensuring that that the source disk seats completely flush inside the mechanical holder's base.

The mechanical holder has a handle with a tab.



The end user places the mechanical holder into the Strontium Detector Well of the CardioGen-82 infusion system and aligns the handle's tab with the positioning notch on the well.



The purpose of this alignment/positioning is so that the handle is at the top of the well and pointing upward (i.e. the Na-22 source is at the bottom of the well and not at the top) and that the mechanical holder is parallel and flush with the bottom of the well (i.e., the Na-22 source is not at an angle with the bottom of the well).

This is necessary to maintain the same geometry of the Na-22 source to the Sr/Gamma detector when this detector takes its readings.



- 3. Please be aware that an exempt distribution license may authorize distribution to the end- use customer, but it does not authorize possession or use, including servicing. Therefore, any service activity should be covered under your possession license.**

RbM's Response:

Thank you; RbM's TN Department of Environment and Conservation Division of Radiological Health Radioactive Material License, License number R-01104-E27, Amendment 10 was issued to include servicing. Please see the attached Amendment 11 (which includes Amendment 10's information), specifically Item 10.A.

Please do not hesitate to contact me with any further questions. I look forward to completing the application process with the NRC so that we can support the Bracco CardioGen-82 Infusion System, Model 1700.

Sincerely,

A handwritten signature in blue ink that reads "Tarah K. Bolas". The signature is fluid and cursive.

Tarah K. Bolas

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