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May 29, 2020

Michelle Beardsley  
State Regulation Review Coordinator  
State Agreement and Liaison Programs Branch  
Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Materials Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington DC, 20555-0001

Re: NorthStar Medical Radioisotopes LLC RadioGenix® System Model License Conditions

Dear Ms. Beardsley:

As you know, the Organization of Agreement States did not concur with some of the content of the Licensing Guidance document for the NorthStar RadioGenix System. Specifically, the guidance includes a requirement to list the Model number on the license. Complicating this are the detailed licensing and training requirements based on this Model number. This necessitates amending a license each time a new Model is obtained, or Authorized User is trained on the new model. Our Director of Rulemaking was informed via the Standing Committee on Compatibility that the NRC's Office of General Counsel deemed license conditions as legally binding requirements and could be used in this case to avoid amending a radioactive material license each time a licensee changes RadioGenix® System Model numbers. The Safety Evaluation Report (SER), developed by the State of Wisconsin includes specific training requirements based on the Model number of the device. The Organization of Agreement States Board requests that the NRC review the following license conditions for compatibility with the above requirements in the licensing guidance as a substitute to amending the license.

[1]. The licensee shall ensure that the System Administrator and Authorized Individuals have successfully completed all training requirements specified in the Safety Evaluation Report (SER) for the specific model number of NorthStar Medical Radioisotopes LLC RadioGenix® System possessed, prior to each individual's first use of upgraded models.

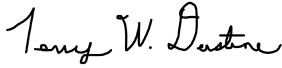
[2]. The licensee shall inform the [State Authority] of any NorthStar Medical Radioisotopes LLC RadioGenix® System Model upgrades within \_\_ days of installation, indicating the Model number and that Condition 1 is adhered to.

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*Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, Wyoming*

We appreciate your willingness to provide this review so that we may share them with other Agreement States. Please contact Jenny Goodman, Director of Rulemaking with any questions.

Sincerely,

A handwritten signature in black ink, reading "Terry W. Derstine". The signature is written in a cursive style with a large, stylized 'T' and 'D'.

Terry Derstine  
OAS Chair  
Radiation Protection Program Manager  
Pennsylvania Department of Environmental Protection  
Southeast Regional Office  
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