UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 2020

ALL AGREEMENT STATES

RESPONSES TO THE ORGANIZATION OF AGREEMENT STATES (OAS) REQUESTS REGARDING CLARIFICATION OF COMPATIBILITY CATEGORIES FOR MEDICAL LICENSING GUIDANCE DOCUMENTS; AND USE OF SAFETY EVALUATION REPORTS (SERs) AS A LEGALLY BINDING REQUIREMENT (STC-20-049)

Purpose: The purpose of this letter is to provide the Agreement States (a) clarification of the designated compatibility categories of medical licensing guidance documents regarding Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 uses, (b) confirm that a Safety Evaluation Report (SER) may be used as a legally binding requirement (license condition), and (c) include sample license conditions for the NorthStar Medical Radioisotopes, LLC, Radiogenix™ Molybdenum-99/Technetium-99m Generator System.

Background: The NRC staff received the following requests for information from the Organization of Agreement States (OAS) Board regarding the medical guidance documents issued in the following State and Tribal Communications (STC) letters:

1. STC-19-073: Notification of Issuance of Yttrium-90 Microsphere Brachytherapy Licensing Guidance, Revision 10

   The OAS Board sent a letter to the NRC dated January 15, 2020 (ADAMS Accession No. ML20178A588) regarding the above guidance that was issued on November 8, 2019. The OAS Board did not agree with the working group's resolution of its comments for the training and experience casework requirements for physicians seeking authorization under the alternate pathway. In its letter, the OAS Board noted that Agreement States have been told that Part 35.1000 licensing guidance is designated as Compatibility Category D; thus, the Agreement States would have flexibility in using the guidance. Subsequently, the OAS Board learned that the Part 35.1000 licensing guidance, is a program element designated as Compatibility Category C.

2. STC-20-006: Availability of Revision 1 of the NorthStar Medical Radioisotopes, LLC, Radiogenix™ Molybdenum-99/Technetium-99m Generator System, Licensing Guidance For Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies

   The OAS contacted the NRC staff with the following comments/questions regarding the above guidance that was issued on January 16, 2020:

   The licensing guidance describes a notification process that licensees may use for a change in model of the Radiogenix™ generator system. If an Agreement State has to tie down the letter submitted by a licensee informing its regulator of a model change and committing to the training described in the SER, this is a licensing action for several

Agreement States. The NorthStar device does not have a sealed source and device registry sheet (SSDR), but a SER issued by the State of Wisconsin. Some Agreement States questioned if they could issue a license condition (which is legally binding) for the SER like what is already done with an SSDR.

Discussion: On February 24, 2020, the Standing Committee on Compatibility (Committee) discussed these issues. The Committee made the following determinations:

Regarding item 1:

The 35.1000 yttrium-90 microsphere licensing guidance is a program element designated as compatibility Category C. A compatibility category C designation means that the Agreement States should adopt the essential objectives of the provisions in the guidance. Agreement States do not have to adopt them "essentially as written." However, this licensing guidance contains training and experience (T&E) requirements. The Committee noted that T&E is designated as compatibility category B in other portions of 10 CFR Part 35. Because the 35.1000 guidance is a compatibility category C, the T&E requirements could be adopted differently among the States, and therefore would pose cross jurisdictional issues in the licensing of medical authorized users, i.e., each State's licensing program would not be able to use another State's license authorization for medical users since their regulations would not be identical. The Committee further discussed if the T&E portion of the guidance could be interpreted as a compatibility B designation.

The Committee determined that this cannot be done with regulations identified as compatibility category A or B because determining that something in the guidance is compatibility category A or B would effectively create a mandatory requirement. Because compatibility category B states that "[t]he Agreement State program element should be essentially identical to that of NRC," the licensing guidance should not designate elements as compatibility category B because doing so would make the licensing guidance a legally binding requirement. On the other hand, items in the guidance may be designated as compatibility category C or D because neither compatibility category requires the Agreement State program element to match the NRC requirement. Consequently, the T&E requirements in the of Yttrium-90 Microsphere Brachytherapy Licensing Guidance, Revision 10 are designated as compatibility category C.

Regarding item 2:

The OAS requested clarification as to whether it was legally acceptable to use the SER for the NorthStar Medical Radioisotopes, LLC, Radiogenix™ Molybdenum-99/Technetium-99m Generator System as a legally binding requirement, i.e., license condition, to allow licensees to use the latest model, so long as licensees meet conditions, such as the model specific training requirements that are documented in the safety evaluation report. This could then avoid the need for a license amendment for each iterative change.

The Committee determined that this would be legally acceptable. While safety evaluation reports alone do not constitute legally binding requirements, elements of safety evaluations can be "tied down" in the license as requirements for licensees. The regulation at 10 CFR 35.1000 provides for any conditions the Commission "considers necessary for the medical use of the material," providing a wide latitude in what is considered acceptable. Conversely, there is no specific requirement that would require that the license specifically reference each model number for a generator in its licensing documents.

However, the Committee recommended that the condition be carefully written to avoid adding automatic, new requirements, when updated safety evaluations are published (so-called "dynamic referencing"). In other words, the license needs to be clear as to what the requirements are for a licensee at a given time. Additionally, because safety evaluation reports are not typically written to provide requirements, the Agreement States should be clear about what portions of the safety evaluation reports are tied down. This could also be accomplished by the consistent inclusion of a section documenting what requirements or assumptions the safety evaluation was based on, then referencing this in the license.

While the licensing guidance required NRC licensees to provide notification in the event of a model upgrade; as stated above, the Agreement States have the option to use the SER as a legally binding requirement. In a letter dated June 17, 2020 (ADAMS Accession Number ML20170B104), the OAS Board submitted license conditions to the NRC for a compatibility review. They proposed to use these conditions as a legally binding requirement in the event of a model upgrade to the NorthStar Medical Radioisotopes, LLC, Radiogenix™ Molybdenum-99/Technetium-99m Generator System in lieu of the notification process that was included in the licensing guidance as stated above.

The NRC review determined that the following license conditions as written, were compatible, therefore, the Agreement States may use these conditions without further NRC review:

> [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.
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> [2]. The licensee shall inform the [State Authority] of any NorthStar Medical Radioisotopes LLC RadioGenix® System Model upgrades within 30 days of installation, indicating the Model number and that Condition 1 is adhered to.

If you have any questions on this correspondence, please contact me at (301) 415-3340 or the individual named below:

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ADAMS Accession No.: ML20178A610 ***via e-mail**

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