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Donna-Beth Howe, Ph.D.
US Nuclear Regulatory Commission
Washington, DC 20555-0001

OPPORTUNITY TO COMMENT ON DRAFT REVISION 1 OF THE NORTHSTAR MEDICAL RADIOISOTOPES, LLC, RADIOGENIX™ MOLYBDENUM-99/TECHNETIUM-99M GENERATOR SYSTEM LICENSING GUIDANCE (RCPD-19-010)

Dear Dr. Howe:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed draft Revision 1 of the Northstar Radiogenix Molybdenum-99/Technetium-99M Generator System Licensing Guidance and offers the following comments.

1. The Board believes that the NRC should focus its RadioGenix licensing guidance on bigger picture radiation safety risks and commitments, rather than prescriptive, situational requirements. The RadioGenix guidance should focus on the product line, rather than specific models, taking into account expected future enhancements. We acknowledge that licensing guidance may quickly become obsolete as the manufacturer receives additional approvals from the FDA. For a diagnostic system which is not yet a mature product, licensing guidance should be flexible enough to remain relevant as NorthStar's product line develops. To the degree possible, the guidance should focus on 1) license commitments rather than submission of documentation and 2) performance-based flexibility.

2. We note that our last several comment letters are leaning towards less complex and more risk informed licensing and training criteria. (See Board comments on RCPD-19-006 Y-90 Licensing Guidance and STC-19-023 Training and Experience for Radiopharmaceuticals.) In keeping with that general principle, the Board cannot support the very detailed licensing and training requirements down to the Model number. The materials and activities within the RadioGenix System do not warrant this level of oversight. The Board suggests that where possible, licensing requirements should be linked to what is contained in the Safety Evaluation Report.

3. More specifically, the Board objects to listing the RadioGenix model number on the license. It is not good regulatory practice to list a model number on the license and then allow licensees to acquire a different model via notification. This is counterintuitive. If the radiation safety risks

are not high enough to warrant requiring an amendment prior to taking possession of a device, then the Board believes that requiring a model number on the license is not necessary.

4. NRC should not list individuals on the license as authorized for a specific model of the RadioGenix system. There is no credible radiation safety risk basis for authorized individual status to be limited by model number and specifically approved by regulators for the following reasons.

a. The NorthStar RadioGenix system is used by highly trained radiation workers who are already generically approved via authorized nuclear pharmacist status to handle large amounts of radioactive material on a routine basis.
b. The device has no direct interface with a patient.
c. Similar curie quantities of PET isotopes, in analogous radiochemical operations, are handled in cyclotrons without highly specific training requirements (see Section 8.7.2 of NUREG-1556, Vol. 21), yet the molybdenum-99 and technetium-99m in the RadioGenix system are much easier to shield and have lower risk to radiation workers.

5. A generic commitment (similar to what is in Section 5.3 for supervised individuals) that individuals will receive training prior to using a new device is adequate to cover authorized individual training on future RadioGenix models. There is no added radiation safety benefit for regulatory agencies to review and approve training for RadioGenix users, specific to model number, as all the RadioGenix training must be provided by NorthStar or an individual certified by NorthStar to provide the training, in accordance with the Safety Evaluation Report.

6. The Board notes that Wisconsin has put considerable effort into the Safety Evaluation Report (SER) and can develop adequate limitations of use and training for future RadioGenix models. NRC's transfer of this SER enhances the co-regulator aspect of the National Materials Program (NMP) and demonstrates that an Agreement State can competently assess the radiation safety concerns with this new technology and other new medical technologies in the future. This aligns perfectly with the NMP Centers of Excellence concept.

7. The Board supports the broad commitments in Sections 5.3, 7.2 and 8.3, but believes that "supervision" is not adequately defined in section 5.3. (See suggestions in comments 8 and 9 below.)

8. Throughout the 2018-2019 T&E comment periods and at the recent OAS meeting, there has been significant, ongoing discussion between NRC and Agreement States regarding the role of the 10 CFR 35.27 supervising individual. The Board recognizes that at many medical facilities using technetium-99m, the authorized users do not take ownership of the supervisory responsibilities described in 10 CFR 35.27. In practice, the nuclear medicine technologists handle radioactive material independently while authorized users are rarely, if ever, involved in radiation safety oversight.

The Board notes that the RadioGenix System gives one individual (the System Administrator) the responsibility for managing user roles and limiting user access to specific protocols for which the user is trained. This user hierarchy is an ideal example of how the 10 CFR 35.27 model of supervision was intended to work. The Board strongly encourages NRC to designate the System

Administrator as the supervising individual as described in 10 CFR 35.27. This change would align with existing regulatory structure and would be consistent with the radiation safety hazards of the RadioGenix device.

9. The Board recognizes NRC's desire to place restrictions on licenses authorizing the RadioGenix device for reasons that prompted the device's classification in 10 CFR 35.1000. However, you appear to be using notification as a "compromise position" between requiring an amendment in advance of possession and having no model-specific license restrictions. The Board believes, however, that notification, as described in the draft guidance, is not an appropriate compromise because it merely shifts the timing of the administrative work rather than provide any reduction in regulatory effort. The Board estimates that the Agreement State administrative effort involved in processing a notification from a licensee to be 10 hours per notification, which is equivalent to processing a license amendment.

The Board proposes two options for alternate compromises:

a. A license condition to authorize use of the RadioGenix by, or under the supervision of, the System Administrator (without a limitation on model). This would allow regulators to confirm that the individual primarily responsible for radiation safety of the RadioGenix device has received appropriate initial training. It would also give regulators relief from 1) processing numerous notifications requiring license changes and 2) tracking training for individuals who are working under the supervision of the System Administrator.
b. NRC could, by license condition, require licensees to notify regulators of model upgrades but not track the model number on the license document itself. By doing so, regulators would not have the accompanying licensing burden, but agency inspectors would be aware, in advance, of the RadioGenix model possessed at the facility and could adequately plan for inspections.

We appreciate the opportunity to provide these comments and stand ready to answer any questions you may have.

Sincerely,

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