

Joint U.S. Nuclear Regulatory Commission/Agreement State Working Group

Licensing of a New Tc-99m Production
Device Charter

PURPOSE

To evaluate the need to develop licensing guidance for the RadioGenix™ system (functionally known as TechneGen Generating System), a new technetium-99m (Tc-99m) generator developed by NorthStar Medical Radioisotopes, LLC. (NorthStar).

BACKGROUND

The United States currently lacks a domestic supply of molybdenum-99 (Mo-99) and most of it is produced with either highly enriched uranium (HEU) reactors or HEU targets. Most current production facilities are at least four decades old and have unpredictable outages; the largest supplier is set to permanently shut down in October of 2016, which may trigger another global shortage of Mo-99 and therefore its daughter radionuclide technetium-99m (Tc-99m). In an effort to encourage nonproliferation, bring production facilities to the United States, and support the global demand for Tc-99m, the U.S. Department of Energy (DOE), National Nuclear Security Administration (NNSA) has engaged in four cooperative agreements to promote Mo-99 production.

In September of 2011, the NNSA signed a cooperative agreement with NorthStar. The agreement supports the domestic development and implementation of non-HEU produced Mo-99 by means of conversion of Mo-98 or Mo-100 to Mo-99. The NorthStar proposal involved development of a device (the RadioGenix™ system) for the on-site processing of Mo-99 into a form that permits elution of its daughter radionuclide, Tc-99m. Tc-99m is used extensively in medical imaging and affects the care of over 50,000 patients daily in the United States.

NorthStar's RadioGenix™ system is an automated, computer operated, Tc-99m producing device for on-site use at medical facilities and commercial radiopharmacies. NorthStar plans to produce Mo-99 in conjunction with Missouri University Research Reactor (MURR) (utilizing neutron bombardment of Mo-98) until their new linear accelerator facility is completed in Wisconsin (which uses an input of Mo-100). Both methodologies contain no uranium and produce low specific activity Mo-99. The RadioGenix™ system maximizes the elution of Tc-99m from its low specific activity parent. NorthStar plans to ship the Mo-99 to hospitals and commercial radiopharmacies so they may produce Tc-99m independently with the RadioGenix™ system.

Due to the newness of this production system, the Agreement States and the U.S. Nuclear Regulatory Commission (NRC) need to evaluate whether the RadioGenix™ system is significantly unique, necessitating special consideration outside of the existing generator use and licensing requirements in 10 CFR Parts 30 and 35. If it is deemed significantly unique, NorthStar's RadioGenix™ system would be regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," and it will be necessary to develop 35.1000 licensing guidance for use by licensees and regulators. The Working Group (WG) will further need to evaluate whether the RadioGenix™ system necessitates a sealed source and device registration by drawing from previous emerging technology precedents.

MEMBERSHIP

The WG is sponsored by the Organization of Agreement States (OAS). It will operate as an NRC/Agreement State WG as described under NRC Management Directive 5.3 "Agreement State Participation in Working Groups." The WG will be co-chaired by a representative from the Agreement State (Wisconsin) and from the NRC Office of Nuclear Material Safety and Safeguards (NMSS), Division of Material Safety, State, Tribal, and Rulemaking Programs. The membership and responsibilities are depicted in the following table:

Organization	Working Group Members
OAS	Mark Paulson/WI - Co-chair
NRC	Donna-Beth Howe, Ph.D. - Co-Chair
OAS	Elaine Crescenzi/PA
OAS	Karl Von Ahn/OH
OAS	Jason Kelly/TX
NRC	Lymari Sepulveda
NRC	Cassandra Frazier
NRC	Maryann Abogunde

NMSS may choose to designate an Advisory Committee on Medical Uses of Isotope member to serve as a WG member or advisor. The WG may seek additional technical expertise on an as-needed basis.

OBJECTIVE

The WG's objective is to (1) evaluate NorthStar's RadioGenix™ system and if appropriate, (2) establish a licensing approach. The WG members will determine the direction in which they choose to proceed, and may include (but are not limited to) the following tasks:

- a) Evaluate and document the need, or lack thereof, to license the RadioGenix™ system under 35.1000 because it cannot meet all the regulations stated in a similar modality category in 10 CFR Part 35 Subparts D-H, or it contains unique components that require additional radiation safety precautions. The evaluation will include a review to determine if the delivery system requires registration as a device in the National Sealed Source and Device Registry.
- b) Consider if this potential licensing guidance can be broad enough to include possible future Tc-99m or other radionuclide production devices utilizing similar methodologies as the RadioGenix™ system.
- c) If necessary, identify new regulatory requirements and develop a 35.1000 licensing guidance document in accordance with the outcomes corresponding to the above tasks.

SCHEDULE

The WG will begin meeting after both the OAS and NRC co-chairs accept this charter in November of 2014. The goal is for the WG to complete a final draft licensing guidance document for submission to the OAS and NRC management for review by September of 2015.

LEVEL OF EFFORT

WG members should expect to provide a substantial commitment to this activity until the objectives are completed. The expected level of effort is 4-8 hours per week, with bi-weekly meetings.

The WG is expected to communicate with NorthStar to obtain user manuals (and other user guidance), service manuals (and other service guidance), along with any other information necessary to complete its task.

The WG may, at its discretion, organize travel to NorthStar in Wisconsin to see the product and a demonstration of its function.

All work associated with the development of this supplemental inspection guidance (i.e., meetings, reviews, travel and revisions), should be charged to TAC J00140 for NRC staff, Working Groups and Guidance.

MEETINGS

It is anticipated that most meetings will be via teleconference. Maximum use will be made of available electronic communication options to facilitate interaction within the WG and among its members. Examples of these options include conference calls, e-mail, SharePoint, and the GoToMeeting® service.

/RA/	11/28/2014
Catherine Haney, Director, NRC/NMSS	Date
/RA/	12/3/2014
Michael Welling, Chairman	Date

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Michael Welling, Chairman

Date

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OFC	NMSS/MSEA	NMSS/MSEA	NMSS/MSEA	NMSS/MSTR	NMSS	NMSS
NAME	DHowe	MFuller	DBollock	LDudes	CPoland	CHaney
DATE	11/05/14	11/06/14	11/07/14	11/14/14	11/20/14	12/01/14

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