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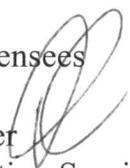
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INFORMATION BULLETIN 2009-04

To: Medical Use Licensees

From: Todd S. Carpenter 
Radiation Protection Services Section



Subject: Exemption from 10 CFR Part 32 and 10 CFR Part 35 Requirements on Procurement and Transfer of Technetium-99m

The U.S. Nuclear Regulatory Commission (NRC) is proposing to exempt all NRC medical use licensees from certain requirements in 10 CFR 35.60(b), 10 CFR 35.100(a)(1) and 35.200(a)(1), and 10 CFR 32.72. These requirements govern calibration tests that use technetium-99m, and distribution of molybdenum-99/technetium-99m generators and technetium-99m radioactive drugs to and from medical use licensees. NRC is issuing these exemptions to ensure that available technetium-99 is being used for patient administrations during periods of shortages of molybdenum-99.

These exemptions will be effective only when there are United States shortages of technetium-99m caused by production shortages of molybdenum-99, as documented in writing by the supplier of molybdenum-99/technetium-99m generators or technetium-99m.

These exemptions are needed in times of molybdenum-99 shortages in the United States to ensure that available technetium-99m is used for patient treatment. On May 14, 2009, the Chalk River National Research Universal reactor in Canada experienced an unexpected shutdown that has resulted in an extended shutdown for safety repairs. The Chalk River reactor produces approximately 50 percent of the United States supply of molybdenum-99 used to produce molybdenum-99/technetium-99m generators.

This resulted in a United States and worldwide shortage of molybdenum-99 for generator production and technetium-99m for medical uses. The High Flux Reactor in Petten, the Netherlands, also produces a substantial amount of molybdenum-99 used to produce generators in the United States and the world. The reactor in Petten is currently operating on a temporary operating permit and expected to be shut down in early 2010 for a number of months for repairs. This will cause molybdenum-99 and technetium-99m shortages in the United States and the world. The supply chain for fission-produced isotopes is fragile and may shrink dramatically at any time when these two, or the other three aging international reactors currently producing these isotopes, are shut down for safety or routine maintenance.

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