

4731.4435 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82, AND STRONTIUM-85 CONCENTRATION.

A. A licensee may not administer to humans a radiopharmaceutical that contains:

(1) more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

(2) more than 0.02 microcuries of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride); or

(3) more than 0.2 microcuries of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kBq of strontium-85 per MBq of rubidium-82).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical must measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with item A.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical must, before the first patient use of the day, measure the concentration of strontium-82 and strontium-85 radionuclides to demonstrate compliance with item A.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee must retain a record of each measurement according to part 4731.4509.

E. The licensee must report any measurement that exceeds the limits in item A at the time of generator elution, in accordance with part 4731.4528.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440; 46 SR 791*

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