**Section 335.4020 Permissible Concentrations of Molybdenum-99, Strontium-82 and Strontium-85**

a) A licensee shall not administer to humans a radiopharmaceutical that contains more than:

1) 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15µCi of molybdenum-99 per mCi of technetium-99m);

2) 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of strontium-82 per mCi of rubidium-82); or

3) 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of strontium-85 per mCi of rubidium-82.

b) To demonstrate compliance with subsection (a), a licensee shall measure:

1) The concentration of molybdenum-99 in each eluate from a molybdenum-99/technetium-99m generator; and

2) The concentration of strontium-82 and strontium-85 before the first patient use of the day on each day that a strontium-82/rubidium-82 generator is used.

c) A licensee shall maintain a record of the concentration tests required by subsection (b) for 5 years. The record shall include for each measurement, the time and date of the measurement, the name of the individual who made the measurement and, for the corresponding measurement in subsection (b):

1) The ratio of the measure expressed as kBq of molybdenum per MBq of technetium-99m (or µCi of molybdenum per mCi of technetium); or

2) The ratios of the measures expressed as kBq of strontium-82 per MBq of rubidium-82 and kBq of strontium-85 per MBq of rubidium-82 (or µCi of strontium per mCi of rubidium).

d) A licensee shall notify the Agency and the distributor of the generator for each occurrence of a concentration exceeding the limits specified in subsection (a) as follows:

1) Notification by telephone within 7 days after the discovery that an eluate exceeded the permissible concentration. The notification shall include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

2) By an appropriate method listed in 32 Ill. Adm. Code 310.110, the licensee shall submit a written report to the Agency within 30 days after discovery that an eluate exceeded the permissible concentration at the time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subsection (d)(1).

(Source: Amended at 46 Ill. Reg. 966, effective December 21, 2021)