

NRC Notification for Sr-82/Rb-82 Generator Users

The following notification was distributed by the U.S. Nuclear Regulatory Commission via its medical list server...

This is to notify medical use licensees that use Strontium-82/Rubidium-82 (Sr-82/Rb-82) generators to produce Rb-82 for cardiac imaging that there have been two incidents in different states since December 2018 with patients injected with Rb-82 contaminated with Sr-82 and Sr-85 from generators eluted with Ringer's lactate solution instead of sterile saline. Ringer's lactate solution is a mixture of sodium chloride, sodium lactate, potassium chloride, and calcium chloride in water. The calcium in the Ringer's lactate solution replaces the strontium on the generator column. This results in the strontium being washed off the column when it is eluted. Ringers lactate should never be used to elute an Rb-82/Sr-82 generator for this reason.

In the December case, 8 patients received Sr-82 and Sr-85 in excess of the breakthrough limits. At least some of these patients are believed to have exceeded the medical event reporting criteria. The second case, occurred on March 21, 2019 and involved 4 patients. The amount of Sr-82 measured the next day by the second licensee was reported to be 18.6 microcuries. (Note: The NRC breakthrough criteria would have been 1 microcurie of Sr-82 for a 50 millicurie Rb-82 dosage.).

Licenses are reminded that they are required in 10 CFR 35.204 to measure the breakthrough for each Sr-82/Rb-82 generator at the beginning of use and the Rb-82 cannot be used on patients if the breakthrough exceeds 0.02 microcuries of Sr-82 per millicurie of Rb-82. They should follow the manufacturer's instructions when performing the breakthrough test and pay particular attention to the measurement and interpretation of the data obtained from the test. Failure to perform or properly interpret the results of the breakthrough test in the first case resulted in the licensee continuing to use the generator even though breakthrough limits were exceeded. This licensee was only aware of the breakthrough when a patient was determined to be radioactive long after the Rb-82 should have decayed to background.