

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
OFFICE OF WASTE, AIR, RADIATION AND REMEDIATION  
BUREAU OF RADIATION PROTECTION  
HARRISBURG, PA 17101

January 24, 2020

BRP INFORMATION NOTICE 2020-01 STRONTIUM-82/RUBIDIUM-82 GENERATOR  
ELUTION EVENTS AND ISSUES

## ADDRESSEES

All Pennsylvania Department of Environmental Protection (DEP) Specific Licensees that use strontium-82 / rubidium-82 generators.

## PURPOSE

The DEP is issuing this Information Notice (IN) based on recent Nuclear Regulatory Commission (NRC) Information Notice 2019-11. NRC wants to raise awareness to reduce the occurrence of strontium (Sr)-82 / rubidium (Rb)-82 generator elutions events where patients are receiving greater activities of Sr-82 and Sr-85 than those permitted under the concentration criteria in Title 10 of the Code of Federal Regulations (10 CFR) 35.204 "Permissible molybdenum-99, strontium-82 and strontium-85 concentrations."

## DISCUSSION

In 2011, 2018, and 2019 NRC has documented four (4) separate events involving approximately ninety (90) patients being administered Rb-82 chloride for cardiac imaging contained Sr-82 and Sr-85 concentrations exceeding regulatory limits. None of the licensees identified breakthrough of Sr-82 (parent radionuclide) or Sr-85 (production contaminate) in the generator elutions before administrations. Patients in two (2) of these events exceeded the medical event criteria in 10 CFR 35.3045, "Report and notification of a medical event."

The attached NRC Information Notice 2019-11 reviews the four (4) events in detail and emphasizes the importance of the daily breakthrough tests on these Rb-82 generators. Two (2) events resulted from overuse and the daily eluting of these generators becoming so routine, that the details and departures from a normal generator set-up for elution can and were missed. The other two (2) events were precipitated by a Food and Drug Administration recognized shortage of sterile saline and some suppliers substituting Ringer's Lactate, which contains other additives such as calcium that interchanges with the strontium molecules on the generator column. This caused the Sr-82 and Sr-85 to be washed into the eluate along with the Rb-82. The lessons learned from these events will help all licensees that use strontium-82 / rubidium-82 generators to avoid similar events in the future. We encourage licensee staff to review the attached information.

## CONTACT

This Information Notice requires no specific action or response. If you have any questions about the information in this notice, please contact the Radiation Control Division at 717-787-3720.

Issued By:  
David J. Allard, CHP, Director  
Bureau of Radiation Protection

Attachment: NRC INFORMATION NOTICE 2019-11