



NEVADA STATE HEALTH DIVISION
Patient Information Notice
CardioGen-82 update

CardioGen-82, manufactured by Bracco Diagnostics, Inc. (Bracco), is a generator used to produce Positron Emission Tomography (PET) drugs that are injected directly into patients for some cardiac imaging studies. CardioGen-82 was recently approved by the U.S. Food and Drug Administration (FDA) for a phased re-introduction following their investigations and an improved Package Insert detailing many new limits on the use of the generator.

1. There will be limits on volume used on the generator to draw the Rubidium-82 off of the column to be used on patients.
2. The Strontium breakthrough quality control (QC) testing procedure has been changed to reduce the limits of allowed breakthrough prior to requiring more testing of the generator in the same day.
3. The manufacturer has created an online database to monitor and track the QC performed daily by the users.

In addition to these changes, the Nevada Radiation Control Program (RCP) has requested:

1. All issues, complaints, updates and trainings having to do with the generator processes be reported directly by the manufacturer and the licensed facility to the RCP.
2. The use of more sensitive equipment is used by the users of the generator to better detect strontium breakthrough (well counter –vs- dose calibrator).
3. Training of the generators is performed on site with a live generator versus a “Dummy” generator and paperwork training.

The FDA and Bracco have completed their investigations. The RCP investigation is ongoing and the RCP continues to work with the FDA and the U.S. Nuclear Regulatory Commission (NRC) to push for the RCP recommended changes to the CardioGEN-82 generator processes.

The link to updated information by the FDA can be found at:

<http://www.fda.gov/Drugs/DrugSafety/ucm291758.htm>

The link to a preliminary final report by the FDA can be found at:

<http://www.fda.gov/Drugs/DrugSafety/ucm287413.htm>

For more information about the Nevada State Health Division, go to: <http://health.nv.gov>.

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SIGNATURE

DATE

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