



Nevada State Health Division Technical Bulletin



Topic: Immediate Cessation of the Use of CardioGen-82 PET Scan

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TO: Health Care Providers and Public/Medical Imaging Providers

The U.S. Food and Drug Administration (FDA) recently received reports concerning two patients (one of whom is a Nevada resident) who had undergone positron emission tomography (PET) myocardial perfusion imaging scans using CardioGen-82. The reports disclosed that unexpectedly elevated levels of radiation were detected in both patients several months subsequent to the imaging procedure.

CardioGen-82 consists of a generator used at clinical sites to produce rubidium (Rb)-82 chloride injection. A CardioGen-82 PET scan is one of several nuclear medicine scans that use radioactive drugs to evaluate the heart.

On July 25, 2011 the drug manufacturer Bracco Diagnostics, Inc. initiated a voluntary recall of the CardioGen-82 PET generator. On July 26, 2011 the FDA alerted health care professionals to stop using CardioGen-82 PET generator.

The FDA estimated the amount of excess radiation the two patients received to be similar to what other patients may receive with multiple, cumulative exposure to certain other types of heart scans. The FDA believes that the risk of harm from this exposure is minimal; however exposure to any excess radiation is undesirable.

Currently, the FDA is investigating the CardioGen-82 failure. Effective immediately, the Nevada State Health Division is directing medical imaging providers in Nevada to stop using CardioGen-82. Additionally, the Nevada State Health Division advises healthcare providers to notify their patients who have had CardioGen-82 PET scans about the FDA ongoing investigation.

Should you have any questions, recommendations or suggestions please do not hesitate to contact Dr. Azzam at the Nevada State Health Division at 775-684-5911.

For further information on this event please refer to the following websites:

<http://interactive.snm.org/index.cfm?PageID=10881>

<http://www.fda.gov/Drugs/DrugSafety/ucm265278.htm>

<http://interactive.snm.org/index.cfm?PageID=10892>

Signed:

A handwritten signature in black ink, appearing to be "Ihsan Azzam".

Date: July 28, 2011

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Nevada State Health Division