July 28, 2011

ALL AGREEMENT STATES, MICHIGAN

NOTIFICATION OF ISSUANCE OF IMPORTANT VOLUNTARY RECALL INFORMATION CONCERNING THE CARDIOGEN-82 RUBIDIUM-82 GENERATOR **(FSME-11-076)**

Purpose: To provide the Agreement States with a copy of the U.S. Food and Drug Administration (FDA) Drug Safety Communication (DSC) issued July 26, 2011, alerting healthcare professionals to stop performing heart scans with CardioGen-82 due to the potential for increased radiation exposure to patients. The DSC is attached and can also be found at the following link: http://www.fda.gov/Drugs/DrugSafety/ucm265278.htm. The manufacturer, Bracco Diagnostics, Inc., is voluntarily recalling the CardioGen-82, and the DSC was issued to inform users of the voluntary recall.

Background: Rubidium-82 is a positron emission tomography (PET) myocardial perfusion imaging (MPI) agent. A previous letter was sent to all users providing important information related to the importance of the mandatory strontium-82 and strontium-85 breakthrough checks after two individuals who previously underwent Rb-82 PET MPI imaging triggered radiation detectors when travelling to/from the United States. Radiation analyses indicated the presence of Sr-85 and Sr-82. As a result of further investigations by FDA and the manufacturer, the manufacturer has voluntarily recalled the product.

Discussion: Enclosed for your information is a copy of the FDA DSC concerning the product recall. The U.S. Nuclear Regulatory Commission is coordinating with the FDA on this and will keep you informed as more information becomes available. This recall was initiated following manufacturer discussions with the FDA regarding reports of unexpected radiation exposure in two individuals who underwent cardiac PET scans with CardioGen-82. The recall is being undertaken while the unexpected radiation exposure is being further investigated. There are over 100 users of CardioGen-82 and many are located in Agreement States.

If you have any questions regarding this communication, please contact me at 301-415-3340, or the individual named below.

POINT OF CONTACT: Donna-Beth Howe, Ph.D EMAIL: Donna-Beth.Howe@nrc.gov
TELEPHONE: (301) 415-7848 FAX: (301) 415-5955

/RA/

Terrence Reis, Acting Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
FDA Drug Safety Communication

If you have any questions regarding this communication, please contact me at 301-415-3340, or the individual named below.

POINT OF CONTACT: Donna-Beth Howe, Ph.D EMAIL: Donna-Beth.Howe@nrc.gov
TELEPHONE: (301) 415-7848 FAX: (301) 415-5955

/RA/

Terrence Reis, Acting Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
FDA Drug Safety Communication

DISTRIBUTION:
MSSA r/f

ML112082808

OFC	FSME/RMSB	FSME/RMSB	FSME/MSSA	FSME/MSSA
NAME	DHowe (CEinberg for)	CEinberg	JLuehman	TReis
DATE	7/28/11	7/28/11	7/28/11	7/28/11

OFFICIAL RECORD COPY