



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

(FSME-12-014, February, Other, Bracco Diagnostics, Inc.)

February 6, 2012

ALL AGREEMENT STATES

**BRACCO DIAGNOSTICS, INC. TO MEET WITH NRC AND AGREEMENT STATE STAFF TO DISCUSS THE CARDIOGEN-82® RE-INTRODUCTION PLANS (FSME-12-014)**

**Purpose:** To provide an opportunity for Bracco Diagnostics Inc. to brief U.S. Nuclear Regulatory Commission (NRC) and Agreement State staff regarding the CardioGen-82 re-introduction plan, enhanced labeling and training, user certification, and the quality control database.

**Background:** On July 15, 2011, The U.S. Food and Drug Administration (FDA) alerted the public; in particular, the medical imaging community; about the potential for inadvertent, increased radiation exposure in patients who underwent or will be undergoing cardiac positron emission tomography (PET) scans with rubidium (Rb)-82 chloride injection from the CardioGen-82® generator. On July 25, 2011, Bracco Diagnostics, Inc. voluntarily recalled all of the CardioGen-82® rubidium generators from the market.

**Discussion:** The U.S. Nuclear Regulatory Commission (NRC) plans to conduct a public meeting on February 16, 2012, in Rockville, Maryland, to meet with representatives from Bracco Diagnostics, Inc., manufacturers of the CardioGen-82® rubidium generator. Please see the enclosed public meeting announcement for access to the webinar.

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

POINT OF CONTACT: Lisa Dimmick  
TELEPHONE: (301) 415-0694

INTERNET: [Lisa.Dimmick@nrc.gov](mailto:Lisa.Dimmick@nrc.gov)  
FAX: (301) 415-5955

**/RA/**

Brian J. McDermott, Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
Public Meeting Notice

February 01, 2012

MEMORANDUM TO: Christian Einberg, Chief  
Radioactive Materials Safety Branch  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

FROM: Michael Fuller, Team Leader */RA/*  
Medical Radiation Safety Team  
Division of Materials Safety  
and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

SUBJECT: BRACCO DIAGNOSTICS, INC. TO MEET WITH NRC AND  
AGREEMENT STATE STAFF TO DISCUSS THE CARDIOGEN-  
82® RE-INTRODUCTION PLANS

DATE & TIME: Thursday, February 16, 2012, 1:00 pm to 4:00 pm

LOCATION: U.S. Nuclear Regulatory Commission  
Two White Flint North  
11545 Rockville Pike  
Rockville, MD 20852

PURPOSE: Provide an opportunity for Bracco Diagnostics Inc. to brief U.S.  
Nuclear Regulatory Commission (NRC) and Agreement State staff  
regarding the CardioGen-82 re-introduction plan, enhanced  
labeling and training, user certification and the quality control  
database.

CATEGORY: This is a Category 2 meeting. The public is invited to observe the  
meeting and will have an opportunity to communicate with the  
NRC after the business portion, but before the public portion of the  
meeting is adjourned. Members of the public who wish to attend  
are encouraged to telephone or email the contact listed below.

NRC ATTENDEES: May include but not be limited to Brian McDermott, Pamela  
Henderson, Christian Einberg, Michael Fuller, Donna-Beth Howe,  
various subject matter experts from NRC Regions I, III, and IV.

C. Einberg

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OTHER  
ATTENDEES:

Organizations that have been contacted regarding participation in the meeting:  
Agreement States  
Bracco Diagnostics, Inc.

CONTACTS:

Michael Fuller, FSME/DMSSA  
301-415-0520  
Lisa Dimmick, FSME/DMSSA  
301-415-0694

WEBINAR ACCESS:

Reserve your Webinar seat at:  
<https://www1.gotomeeting.com/register/838139880>

DIAL IN ACCESS:

NRC will also establish a telephone bridge line. If you wish to participate by telephone, please call 888-324-6989, and use the passcode: 62378, followed by the # symbol. The telephone bridge line will be in "listen only mode." Questions and comments will have to be submitted via the webinar.

Enclosure: Agenda

C. Einberg

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Enclosure: Agenda

Distribution:

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B. McDermott P. Henderson JJenelle

**ML12032A246**

OFFICE	DMSSA	DMSSA
NAME	MFuller	CEinberg
DATE	02/01/12	02/01/12

**OFFICIAL RECORD COPY**

## AGENDA

<b>Public Meeting</b>	
BRACCO DIAGNOSTICS, INC. TO MEET WITH NRC AND AGREEMENT STATE STAFF TO DISCUSS THE CARADIOGEN-82® RE-INTRODUCTION PLANS	
Date	Time
Thursday, February 16, 2012	1:00 pm – 4:00 pm

Session Time	Topic	Participants
1:00 pm	Introductions, Opening Remarks, and Ground Rules	NRC
1:30 pm	Bracco Diagnostic, Inc. Presentation	Bracco Diagnostics, Inc.
2:30 pm	Qs and As Between NRC and Agreement State Staff, and Bracco Diagnostics, Inc.	All Participants
3:30 pm	Opportunity for Members of the Public to Ask questions of and/or Provide Comments to NRC Staff	NRC/Public
4:00 pm	Adjourn	All