



**NATIONWIDE EVALUATION
OF X-RAY TRENDS (NEXT)**

**PROTOCOL FOR
2008-2009 SURVEY OF
CARDIAC CATHETERIZATION**

May 2009

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Nationwide Evaluation of X-ray Trends (NEXT) Protocol for 2008-2009 Survey of Cardiac Catheterization

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Center for Devices and Radiological Health (CDRH)

in association with

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Committee on Nationwide Evaluation of X-ray Trends (H-4)

and

American College of Radiology (ACR)

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May 2009

Published by
Office of Executive Director
Conference of Radiation Control Program Directors, Inc.
1030 Burlington Lane, Suite 4B
Frankfort, Kentucky 40601
www.crcpd.org

This publication was supported in part by grant number FD-U-000005 through a cooperative agreement with the U.S. Food and Drug Administration. Use of the information contained in this document is at the discretion and sole responsibility of the user. This document was prepared by FDA staff in association with a working group of the Conference of Radiation Control Program Directors, Inc. (CRCPD) and accepted by the CRCPD Board of Directors for publication. The contents do not necessarily represent the views of the membership of the CRCPD, of FDA, or of any other federal agency supporting this work. The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the CRCPD or any federal agency.

ACKNOWLEDGMENT

We gratefully acknowledge the contributions from the following individuals, organizations, and facilities for their assistance with the development of this survey protocol and support for the training of state participants.

We are very grateful to Dr. Stephen Balter (Columbia University Medical Center) for his substantial contributions to the development of these survey procedures, and for his valuable instructional support at the surveyor training courses. We also thank Richard Cless (Siemens Medical Solutions, Inc.) for providing informative presentations regarding clinical topics in fluoroscopic imaging at the surveyor training courses. We also appreciate the presentations during surveyor training provided by Dr. Charles Finder and Dr. Stanley Stern, FDA Center for Devices and Radiological Health.

We greatly appreciate the many helpful consultations provided by Dr. Charles Chambers, Wayne Powell, and fellow colleagues with the Society of Cardiovascular Angiography and Interventions, particularly with regard to the drafting of the facility questionnaire. They brought to this survey effort a much needed perspective from the clinical practicing community. We appreciate the helpful input from Stephen Vastagh and fellow members of the Medical Imaging and Technology Alliance, National Electrical Manufacturers Association, who assisted us regarding the technical features of modern fluoroscopic equipment.

We greatly appreciate the generous financial support provided by the American College of Radiology for surveyor travel to training. We thank the following persons from the National Naval Medical Center for providing frequent use of their fluoroscopic equipment during pre-survey equipment testing and the surveyor training courses: HMI R. James Greenblatt Jr., Medical Service Corps, United States Navy, Donald L. Miller, M.D., FACR, Professor of Radiology, USUHS, and CAPT Michael A. Ferguson, MD, FACC, FSCAI, Department Head, Cardiology. Training was also provided at Shady Grove Adventist Hospital in Gaithersburg Maryland, and we thank Patricia Wolcott and Doug Stevenson from the Hospital's Department of Cardiovascular Radiology for their kind assistance in arranging use of their fluoroscopy equipment during busy afternoon hours, and for helpful discussions with our students. We also thank Debra L. Dewald and Mary Duval from Suburban Hospital, Bethesda, Maryland, who also provided access to their fluoroscopic equipment for surveyor training.

Finally we appreciate the industrial skills of Bruce Fleharty and Randolph Bidinger of the CDRH machine shop during the construction of the fluoroscopy phantoms.

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FOREWORD

The Conference of Radiation Control Program Directors, Inc. (CRCPD) is an organization made up of the radiation control programs in each of the 50 States, the District of Columbia, and Puerto Rico, and of individuals, regardless of employer affiliation, with an interest in radiation protection. The primary purpose and goal of CRCPD is to assist its members in their efforts to protect the public, radiation workers, and patients from unnecessary radiation exposure. CRCPD also provides a forum for centralized communication on radiation protection matters between the States and the Federal government, and between the individual States.

One method of providing assistance to the States, as well as to other interested parties, is through technical and administrative publications. Most technical publications of CRCPD are written by various committees, task forces or special working groups. Most administrative publications are written by staff of the Office of Executive Director (OED).

CRCPD's mission is "to promote consistency in addressing and resolving radiation protection issues, to encourage high standards of quality in radiation protection programs, and to provide leadership in radiation safety and education."

This particular publication, *Nationwide Evaluation of X-ray Trends (NEXT) Protocol for 2008-2009 Survey of Cardiac Catheterization*, describes procedures that will be used to collect information for a reference database documenting cardiac invasive fluoroscopic practice, clinical radiation dose management, and indicators of patient dose and image quality with particular emphasis on the impact of new technologies and clinical applications such as radiation dose display features. Based on a random sampling of clinical sites, the results can be used to analyze and understand population exposure trends in the practice of cardiac invasive fluoroscopy in the United States.



John P. Winston, Chairperson
Conference of Radiation Control
Program Directors, Inc.

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PREFACE

This document contains the survey procedures developed to collect information for a population-representative reference database documenting fluoroscopic imaging practice at facilities that provide cardiac catheterization services. Indicators are captured regarding patient dose, clinical image quality, and the impact of new technologies and clinical applications. The 2008-09 NEXT Cardiac Catheterization survey consisted of a site visit by trained state radiation personnel, and a questionnaire to be completed by clinical staff. Most fluoroscopic equipment currently in use in cardiac catheterization programs are equipped with one or more dose display features. These display indicators typically include cumulative values for **air kerma** and **dose-area product**. This NEXT survey protocol includes for the first time a data form for the collection of these dose display values following clinical exams.

Surveyors were requested to elicit responses to the *Facility Questionnaire* from facility staff that are familiar with the site's practice of cardiac invasive fluoroscopy. Surveyors recorded data gathered during their site visit on the *Surveyor Data Form*. Prior to departing the facility, the surveyor assisted clinical staff with recording entries onto the *Clinical Dose Log Survey Form*. Facility staff were asked to collect data for a period of one week following the surveyor's visit. Both the *Facility Questionnaire* and *Clinical Dose Log Survey Form* provide instructions to those persons contributing responses.

The FDA Center for Devices and Radiological Health and the Conference of Radiation Control Program Directors H-4 Committee on NEXT, with instructional support from Dr. Stephen Balter (Columbia University Medical Center, NY), Mr. Richard Cless (Siemens Medical Solutions, Inc.), and financial support from the American College of Radiology, provided training in October and November 2008, to representatives of the following 36 States:

Alabama	Maryland	Ohio
Arizona	Michigan	Oklahoma
Arkansas	Minnesota	Oregon
California	Mississippi	Pennsylvania
Connecticut	Missouri	Rhode Island
Florida	Nevada	South Carolina
Hawaii	New Hampshire	South Dakota
Idaho	New Jersey	Tennessee
Illinois	New Mexico	Texas
Iowa	New York	Virginia
Kansas	North Carolina	West Virginia
Louisiana	North Dakota	Wisconsin

We recognize the voluntary nature of participation in this survey by the various state radiation control programs, and we appreciate these efforts.

The NEXT fluoroscopy phantom and associated image quality test objects must be used with this survey protocol in order to compare acquired radiation data with existing NEXT survey results. Information regarding the fluoroscopy phantom is available from the Food and Drug Administration.



David C. Spelic, Ph.D.
Food and Drug Administration
Division of Mammography Quality and Radiation Programs



Warren Freier, R.T., Chairperson
Committee on Nationwide Evaluation
of X-ray Trends

ABSTRACT

Spelic, David C., CRCPD Committee on Nationwide Evaluation of X-ray Trends, *Nationwide Evaluation of X-ray Trends (NEXT) Protocol for 2008-2009 Survey of Cardiac Catheterization*, CRCPD Publication #E-09-2, May 2009, 53 pp.

This document contains the survey procedures developed to collect information for a population-representative reference database documenting the practice of cardiac invasive fluoroscopy including indicators of patient dose and clinical radiation dose management, and characterizing the impact of new clinical applications and technologies. The NEXT fluoroscopy phantom and associated image quality test objects must be used with this survey protocol in order to compare acquired data with existing NEXT survey results.

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The surveyors were provided with Excel spreadsheets, which are available for downloading:

 *Facility Questionnaire*

 *Facility Dose Record*

 *Surveyor Data Form*

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INTRODUCTION

This survey seeks information regarding cardiac invasive fluoroscopic procedures conducted at clinical facilities. The survey protocol describes procedures that will be used to collect information for a reference database documenting general fluoroscopic practice, measurements of radiation-emission indicators of patient dose, and characterizing the impact of new technologies and clinical applications with particular emphasis regarding dose display features. Based on a random sampling of clinical sites, the results can be used to analyze and understand population exposure trends in the practice of cardiac invasive fluoroscopy in the United States.

Traditionally, NEXT surveys have focused on one selected diagnostic x-ray examination. Cardiac catheterization, however, is actually a broad scope of specific clinical invasive procedures, often performed in combination during a clinical case. This survey will collect dosimetric and exam caseload data for the routine coronary angiography procedure, data regarding other cardiac invasive procedures, and capture fluoroscopic system radiation output using a standard phantom.

Fluoroscopic equipment that are used to conduct cardiac invasive procedures have recently undergone significant technological changes including the widespread use of flat panel image receptors as a replacement for image intensifiers, and dose display features that provide the operator with near-live feedback regarding air kerma and air kerma rate indicators. Dose-area product (DAP) equipment are now a common feature on cardiac fluoroscopy systems. Finally, digital-based cineradiographic recording has replaced cine film camera-based recording as the prevalent technology.

The NEXT fluoroscopy phantom will be used to drive the fluoroscopic system for various x-ray emission measurements. Although the phantom represents a standard size adult patient anterior-posterior (A-P) projection, it will be supplemented with additional filtration to simulate the large tissue paths that result from complex angulations of the x-ray beam employed during cardiac invasive procedures.

The 2008-09 NEXT Cardiac Catheterization survey is comprised of four distinct components:

1. Collection of facility-based information about the routine program of cardiac catheterization obtained through interviews of facility personnel, and measurements of radiation output on the fluoroscopic unit most frequently used for these routine cardiac procedures.
2. A questionnaire to be completed by one or more facility staff which captures cardiac invasive fluoroscopic procedure information, procedure caseload frequencies, quality-assurance and quality-control procedures, and aspects of the facility's dose management program.
3. The capture of clinical patient dose indicators that may be recorded by the facility for cardiac invasive procedures, including cumulative fluoroscopy time, cumulative air kerma, and cumulative values for dose-area product (DAP) or kerma-area product (KAP).

4. Collection and examination of the most recent physics survey report available on the fluoroscopy unit being assessed in the survey.

The following sections discuss preparation for the survey, communicating with the facility, and ensuring the integrity of collected data.

We recognize the voluntary nature of participation in this survey by the various state radiation control programs, and we appreciate these efforts.

GENERAL INSTRUCTIONS

This section provides an overview of the survey procedures and provides contact information for obtaining assistance with various survey components.

The quality of collected data is critical to the success of this survey. Quality *may* be compromised *if*, for example, the data are:

- Incomplete or contain values well outside expected ranges
- Not representative of the facility's routine cardiac fluoroscopy practice. The wrong fluoroscopy unit may mistakenly be surveyed (one that is infrequently used for cardiac invasive procedures), or the responses on the Facility Questionnaire do not correlate reasonably well with comparable data reported on the Surveyor Data Form.
- Gathered using procedures other than those prescribed in this protocol
- Come from a facility that is not on the list of randomly selected sites.

In order to avoid the possibility of compromising collected data, **READ THIS SECTION CAREFULLY**. For assistance with various aspects of the survey, please contact the following persons:

For questions regarding	Please contact
Survey procedures, equipment-related questions, facility sample listing issues, or questions regarding Excel data entry	David Spelic ph: 240-276-3312 e-mail: david.spelic@fda.hhs.gov or Warren Freier ph: 701-328-5189 Email: wfreier@nd.gov
MDH meter and probe calibration	David Spelic or Mary Walker ph: 301-796-2558 e-mail: mary.walker@fda.hhs.gov

You should be provided everything you need to perform these surveys with the exception of aluminum filters for half-value layer measurements. If you are missing any items contact the appropriate person prior to beginning surveys. Please note that extra copies of either the Surveyor Data Form or the Facility Questionnaire can be made by printing out from the template Excel form you received via email. Extra copies can also be obtained from FDA.

You are provided a list of facilities to survey. The sites are randomly selected from a listing of sites known to have at least one fluoroscopic unit appropriate for conducting cardiac invasive fluoroscopic procedures. The list is composed of two groups of sites: primary sites and alternate sites. For each primary site there is listed one or more alternate sites in the event a primary site does not wish to participate. Please contact any facility on the alternate-site list only if a primary-site facility does not wish to or cannot participate in the survey. ***DO NOT substitute for a primary facility any site not on the alternate list.*** Doing so may compromise the random nature of the survey sample. **If you have questions or concerns regarding your facility list please contact FDA staff for assistance.**

The surveyor is asked to enter the collected data into a computer spreadsheet in Microsoft Excel format. Electronic entry will greatly speed the processes of data verification and analysis done by FDA staff.

It is recommended that you submit a completed survey package to FDA staff for review after performing one survey. Quick submittal of the first survey results will preclude the potentially erroneous subsequent completion of data forms. Your first submitted survey package will be evaluated, and you will be provided feedback from FDA. **Submittal of first-completed forms is an important step in ensuring the integrity and quality of collected data.**

Please make a copy of all documents (paper and electronic backup of completed Excel data files) for your records prior to mailing a survey package to FDA. This will avoid a potential disaster in the event your package is never received.

Initiating a survey request with a facility listed on your sample

It is recommended that you initiate a survey request several weeks in advance to permit the facility adequate time to clear with appropriate management and to reserve the fluoroscopy suite. Scheduling early morning visits may often be the best time to conduct the visit. The following items should be addressed during the initial conversation:

1. Inform the facility that this is a ***voluntary*** survey and they have been randomly selected for participation as part of a national program administered by the Conference of Radiation Control Program Directors in a cooperative agreement with the Food and Drug Administration and in collaboration with the *Society of Cardiovascular Angiography and Interventions (SCAI)*.
2. Request access to the fluoroscopy unit used **most frequently** for routine cardiac catheterization procedures, in particular *diagnostic coronary angiography procedures*.
3. Inform the facility that you will need a copy of the most recent medical physics report for the unit to be surveyed, and
4. That they will be requested to complete a questionnaire regarding their general practice of cardiac fluoroscopy, and,

5. That they are requested to provide *de-identified* entries for fluoroscopic dose indicators displayed by the surveyed fluoroscopic unit following invasive procedures. It is important to stress that absolutely no patient identifiers are to be collected. Facilities may be hesitant to provide these data. You should forward a copy of the Clinical Dose Log Survey Form to allow appropriate facility staff to review the types of data that would be collected prior to releasing these data.
6. Attempt to identify a contact person for future reference, preferably someone who is familiar with their cardiac catheterization program, such as the cath lab manager.
7. Fax or mail a cover letter (a sample will be provided) requesting the facility's participation in the survey along with the letter of invitation from the Society of Cardiovascular Angiography and Interventions, the facility questionnaire, and the Clinical Dose data form.

What types of fluoroscopy systems should NOT be surveyed?

You should **NOT** perform a survey on any fluoroscopic unit that is not frequently used for performing *diagnostic coronary angiography* procedures at the facility. If you are unsure whether a fluoroscopy system should be surveyed contact the FDA or a member of the NEXT Committee prior to collecting data.

IMPORTANT

It is important that your fluoroscopy radiation measurements, those facility questionnaire items that pertain to fluoroscopy equipment, the physics survey report, and the collected clinical dose data refer to the same fluoroscopic unit.

Instructions for the Facility Questionnaire

The Facility Questionnaire should be mailed or faxed to the facility prior to the on-site visit. This should allow sufficient time for its completion upon your arrival. The first page of the questionnaire provides instructions to the facility on how to complete the form.

For the most part the Facility Questionnaire is a self-explanatory, self-contained package. At the facility, a paper copy of the questionnaire should be completed by (1) one or more staff members familiar with the facility's program of cardiac fluoroscopy and aspects of patient dose

management, and assisting with the on-site survey *and/or* (2) a staff cardiologist who can provide responses to items pertaining to clinical practice.

Facility staff may need clarification of some points in the questionnaire, and surveyors are encouraged to help the staff should there be difficulties in filling out the form. Surveyors should feel free to contact David Spelic at FDA (240-276-3312) or Warren Freier, NEXT Committee Chairperson (701- 328-5189), when there are questions or concerns that the surveyors may need assistance with. If the facility can complete the questionnaire by the day of the on-site visit the surveyor can collect it at that time.

The Medical Physics Survey Report

You are asked to collect a copy of the most recent medical physics survey report performed on the fluoroscopy unit you will survey. The facility may or may not have this available on-site, depending on whether the person who performed the physics survey is available. Appendix A gives a discussion of the procedures you should follow regarding the medical physics survey. If the facility does not have a medical physics survey completed on the fluoroscopy unit you survey, or if the medical physics survey has been done and the report is not available, make a note of either case and proceed with the NEXT survey of that facility.

The Clinical Dose Log Survey Form

The facility is requested to record on this form the cumulative values of all available dose display indicators following clinical cases conducted over a one week period on the particular fluoroscopic unit that is surveyed. It should be emphasized that *no patient or case identifiers are captured on the form.* The form includes instructions for facility staff regarding the data values requested. The surveyor should complete all applicable entries at the top of the form. The surveyor should also assist the facility with initiating data collection during the site visit, and indicate on the form *a one week period for data collection starting on the day following the site visit.* The facility is asked to fax the completed form to the NEXT surveyor.

The On-Site Survey

Before departing for your visit, it is recommended that you contact the facility and verify your appointment. Cardiac invasive procedures are typically performed throughout the day, and often facilities may unexpectedly need to use the fluoroscopic unit you intend to survey.

Bring with you the following items for a survey:

- Calibrated MDH model 1015 (or 1515) with standard probe, model no. 10X5-6
- **CHECK ITS OPERATION PRIOR TO DEPARTING FOR THE FACILITY!**
- Survey protocol

- NEXT fluoroscopy phantom with two 0.8 mm and one 1.5 mm copper filters, one 3.0 mm lead filter, image quality test tool
- 8 mm of aluminum filters in 1 or 2 mm increments for HVL data collection
- Surveyor Data Form
- Extra copies of Facility Questionnaire, Clinical Dose Log Survey Form (several pages), and tri-fold brochures
- A copy of the *SCAI* letter of Invitation
- Two CD mailers (one addressed to FDA, other addressed to surveyor)
- Tape (suggested)

IMPORTANT

TAKE THE PROTOCOL WITH YOU.

Do NOT rely on just the data form to guide you through the survey. Doing so may result in collection of inaccurate data and possibly a wasted effort by both you and the facility staff assisting you.

When you conduct the on-site visit at the facility:

1. Retrieve the completed Facility Questionnaire and the medical physics survey report. Confirm that these documents provide responses / data pertaining to the same fluoroscopy unit you will survey: the fluoroscopy unit used most frequently for cardiac invasive fluoroscopic procedures.
2. Perform the on-site survey. Review your data to ensure that reasonable values are obtained. This check will avoid a potential revisit or worse, the misrepresentation of how the facility conducts their program of cardiac fluoroscopy.
3. Assist the facility with initiating data entry on the Clinical Dose Log Survey Form. Facility staff may not be familiar with the particular dose display features on the unit you survey. Provide several copies of the form (stapled together). Be certain your contact information is on the form.
4. Prior to leaving try to retrieve any items you still need, namely the medical physics survey report for the unit you surveyed, and the Facility Questionnaire.

Always thank the facility for their participation, and provide them with any available NEXT tri-fold brochures as a means of informing the facility about the NEXT survey program and where they can obtain further information.

Post-survey data entry: Excel computer files for the Surveyor Data Form, Facility Questionnaire, and Clinical Dose Log Survey Form

You are provided with three template Excel spreadsheets with which to record your survey responses for the Surveyor Data Form, the Facility Questionnaire, and the Clinical Dose Log Survey Form. Each time you begin data entry for a survey, start with a completely blank data form. Whenever any piece of information pertinent to an entry is not known or cannot be confirmed, enter **UNKN** in the worksheet cell. This will avoid the problem of trying to determine whether the cell was left blank because the data value did not apply to the facility or because the surveyor unintentionally missed this data value.

It is suggested you maintain one BLANK Excel form for the Surveyor Data Form, Facility Questionnaire, and Clinical Dose Survey Form on your computer. Each time you begin data entry for a completed survey, open the blank template file, and immediately save it using the following format:

STATE CODE + FACILITY NAME + SURVEYOR or FACILITY or CLINICAL.xls

For example, files for a survey conducted in Florida at Southwest General Hospital would be saved as follows.

For the Surveyor Data Form: **FL Southwest General SURVEYOR.xls**

For the Facility Questionnaire: **FL Southwest General FACILITY.xls**

For the Clinical Dose Survey Form: **FL Southwest General CLINICAL.xls**

These formats will allow us to easily identify your particular surveys among the many Excel forms we receive and archive. If you have difficulty with the Excel files contact FDA staff for assistance. Finally, if it is not feasible or convenient for you to work with computer files, then you can submit to FDA just the original, handwritten paper versions of the data forms and facility questionnaires as they are completed.

IMPORTANT

Please do NOT use an Excel spreadsheet you completed earlier as a template for subsequent surveys by merely changing the responses-this may cause entries from the prior survey to remain intact for the subsequent surveys if you don't change all of the data values. Always start with an empty spreadsheet file.

Please make photocopies of the original filled-in paper forms for backup in the event these items are never received by FDA.

Putting your survey package together for submission

The following items are part of a completed survey package:

1. One filled-in Surveyor Data Form. This form should be the original paper, hand-written version you completed at the facility.
2. One electronic version (Excel spreadsheet file) of the completed Surveyor Data Form. This electronic file can be submitted either on a computed disk or as an email attachment.
3. One paper version of the completed Facility Questionnaire.
4. One electronic version (Excel spreadsheet) of the completed Facility Questionnaire.
5. One paper copy of the medical physics survey report you obtained from the facility.

NOTE: There is no Excel spreadsheet for electronic data entry of the physics survey report.

6. One paper copy of the Clinical Dose Log Survey Form.
7. One electronic version (Excel) of the completed Clinical Dose Survey Form.
8. DICOM CD obtained after completion of the onsite visit.

Send your complete survey package to:

David Spelic
FDA/DMQRP
1350 Piccard Drive HFZ-240
Rockville, MD 20850

NOTE: Please confirm via email the above address prior to mailing your survey packet because this particular FDA office will be relocating to a new facility in mid-2009.

We appreciate your efforts!

A. SURVEYOR, SURVEY DATE, FACILITY IDENTIFICATION (ITEMS 1-11)

1) Surveyor name, 2) telephone number, 3) email address

Enter your name, telephone number, and email address in the space provided on the surveyor data form.

4) Survey date: Enter the date on which the on-site visit was conducted, e.g., 2/17/09.

5) Facility name: Enter the name of the hospital, medical facility, or corporation at which the x-ray fluoroscopic system is located.

6) Facility ID no.: If your state program has assigned a unique alphanumeric identifier to the facility, provide this identifier in the space provided. Any combination of characters and numbers may be used.

Facility ID no.

EXAMPLE

23456B7C32

7) State/Agency code: Enter the appropriate two-character code for your state.

State/Agency code

EXAMPLE

VA

8) Facility-type code: Determine the type of facility from the list below and enter the corresponding code.

Item **8a**): If you code data item **8**) as 99 ("other"), briefly describe the facility type in the space provided on the surveyor worksheet directly to the right of facility-type code 99.

Facility-type code

EXAMPLE

01

The following codes and definitions apply to Facility-type (item 8)

Codes for Facility-type

01 = *Private Practice*: An individual practitioner or a group of practitioners engaged in the same specialty, for example, radiology. This category includes groups of general practitioners, and it also includes free-standing imaging centers.

04 = *Hospital Satellite Facility*: A facility affiliated with a hospital or medical center which is physically removed from the hospital/ medical facility (ie: different mailing address)

02 = *Hospital*: A facility that has beds for overnight care of patients. This category includes mobile units that are permanently stationed at a hospital.

99 = *Other*: A facility whose type does not aptly correspond to any of the preceding categories. Please explicitly describe the facility type yourself in the space provided on the surveyor worksheet.

03 = *Multiple Specialty Practice*: A group of practitioners having different specialties. This category includes school infirmaries and outpatient clinics which may be associated with hospitals.

9) Practice-specialty code:

If entry **8) Facility-type code** is "01" (Private Practice), determine the area of specialization of the private practice from the **Practice-specialty code** list provided below, and enter the appropriate code.

If entry **8) Facility-type code** is "02" (Hospital), enter the **Practice-specialty code** of the hospital *department* housing the fluoroscopic unit being surveyed (e.g., **15** for CARDIOLOGY)

If entry **8) Facility-type code** is "03" or "04," enter **XX** for **9) Practice-specialty code**.

9a) If entry **9)** is "99" (Other), please explicitly describe the practice specialty in the space provided on the surveyor worksheet directly to the right of practice-type code 99.

Practice-specialty code

EXAMPLE

15

Codes for Practice-specialty item

XX = Multiple Specialty Practice	16 = Electrophysiology
01 = Dental (except orthodontics)	17 = Endocrinology
02 = Orthodontics	18 = Geriatrics
03 = Medical General Practice	19 = Hematology
04 = Radiology	20 = Immunology
05 = Internal Medicine	21 = Infectious Diseases
06 = Surgery	22 = Nephrology
07 = Urology	23 = Neurology
08 = Pediatrics	24 = Nuclear Medicine
09 = Orthopedics	25 = Oncology (including Radiation Therapy)
10 = Gastroenterology	26 = Ophthalmology
11 = Chiropractic	27 = Otolaryngology
12 = Podiatry	28 = Physical Medicine
13 = Osteopathy	29 = Pulmonary Medicine
14 = Obstetrics/Gynecology	30 = Emergency/Shock/Trauma Medicine
15 = Cardiology	99 = Other

10) Interviewee name & Title/Position:

Enter the name and title/position of all the facility staff persons providing information or other assistance to you during the on-site interview and measurements.

B. FLUOROSCOPIC UNIT IDENTIFICATION AND FEATURES (ITEMS 11-23)

With the assistance of the Cath Lab Manager or other staff, identify the fluoroscopic unit that is used most frequently for performing *Diagnostic Coronary Angiography* procedures. If the facility has several units that are frequently used for these procedures, select a unit that is available for survey. NOTE: It is advised that you consult with department staff regarding the appropriate fluoroscopy unit to survey *prior to your arrival* in order that arrangements can be made to reserve the unit.

11) Room number and location:

Enter the room number and a brief description of the location for the fluoroscopy unit you will survey. If the room has no number, inquire with facility staff if the room/area has an alternate means of identifying the unit.

	<u>Room number</u>	<u>Location</u>
<u>EXAMPLE</u>	<u>C-1</u>	<u>Cardiology</u>

12) Manufacturer:

Enter the name and corresponding 4-character code for the manufacturer of the fluoroscopy unit. A list of known fluoroscopic equipment manufacturers is provided in *Appendix B*.

	<u>Fluoroscopic unit Manufacturer</u>	<u>Code</u>
<u>EXAMPLE</u>	<u>Siemens</u>	<u>SIEC</u>

13) Model name:

Determine the model of the fluoroscopy unit, and enter the model's trade name in the space provided. The trade name of the model may be comprised of a "generic" part, such as *Multistar* (manufactured by Siemens) followed by an alphanumeric qualifier, e.g., *TOP*. Please enter the *entire* trade name (generic part plus qualifier) by which the model is commonly known.

	<u>Fluoroscopic unit Model Name</u>
<u>EXAMPLE</u>	<u>Multistar TOP</u>

14) Facility Service / Site Identification Number

Ask the facility to provide the Service / Site Identification number they use to identify their facility when contacting a service provider regarding the fluoroscopic unit.

	<u>Facility Service/Site Number</u>
<u>EXAMPLE</u>	<u>2100495</u>

15) Provider of service for fluoroscopic system

Enter the one-letter code for the category that best describes the provider of service for the fluoroscopic system. Enter the proper code on the surveyor data form.

- O** = Original equipment manufacturer
- I** = In-house service provider
- T** = Third-party service provider

Provider of Service

EXAMPLE

O

16) Date of fluoroscopic system assembly

Inquire with staff regarding the month and year the fluoroscopic system was installed at the facility. If they can not provide an exact month and year, request a best-estimate.

Date of fluoroscopic system assembly

Month

Year

EXAMPLE

February

2005

17) Type of equipment

Indicate using the appropriate one-letter code the type of fluoroscopic system you will survey.

- C** = Standard C-arm configuration consisting of a single fluoroscopic gantry and x-ray tube
- B** = Bi-plane system consisting of two independent C-arm gantries

Type of equipment

EXAMPLE

C

18) Fluoroscopic image receptor type

Determine the type of image receptor for the fluoroscopic system. Generally the surveyor will encounter two types: *image-intensifier-based systems*, and *flat-panel (digital-based) systems*. Enter the appropriate one-letter code for the type of image receptor.

I = Image intensifier-based receptor

D = Flat-panel (digital-based) receptor

Fluoroscopic image receptor type

EXAMPLE

D

19) Grid used for fluoroscopy

Determine if a grid is routinely used for cardiac invasive fluoroscopic procedures. The facility may use a grid for adult procedures, and remove the grid when performing procedures on pediatric patients. Enter “Y” (Yes), “N” (No), or “U” (unknown). If the facility does not do pediatric procedures, enter “U”.

Grid used for routine cardiac
fluoroscopic invasive procedures?

Adult

Pediatric

EXAMPLE

Y

N

20) Cineradiographic image acquisition equipment type

Determine the type of cineradiographic (e.g. “cine”) image acquisition equipment used during cardiac invasive procedures and enter the appropriate code. Some fluoroscopic systems may have multiple acquisition equipment (e.g. cine film as well as digital cine). Enter the appropriate code representing the equipment that is most frequently used. You should collect survey data regarding the modality you indicate below.

F = Conventional film-based equipment

D = Digital-based equipment

Cineradiographic image acquisition
equipment type

EXAMPLE

D

21) Air Kerma, Dose-Area Product (DAP) and fluoroscopy time display features:

Indicate the dose quantities that are displayed at the fluoroscopist's working position or at the control console (a separate room/area). A fluoroscopic system may have more than one type of dose display (e.g. DAP and air kerma rate/cumulative air kerma). A dose parameter may be displayed at both the fluoroscopist's working location and at the control console. The basic unit of measurement for most dose display features is the *Gray* (abbreviated *Gy*).

Air Kerma Rate and Cumulative Air Kerma

Newer fluoroscopic equipment (manufactured on or after June 10, 2006) must provide at the fluoroscopist's working position displays of air kerma *rate* and cumulative air kerma. These quantities may also be referred to as "*reference point air kerma*" or "*reference-point dose*" because the displayed values for air kerma rate and cumulative air kerma are referenced to a specific point along the x-ray beam axis. Equipment manufactured prior to June 2006 may also have this feature incorporated. Values for air kerma may be expressed in units of mGy, cGy, or Gy. Values for air kerma may be expressed in other units of measurement as well.

Dose-Area Product (DAP)/ Kerma-Area Product (KAP): Rate and Cumulative Values

Dose-Area Product (DAP) and Kerma-Area Product (KAP) display devices can display an irradiation *rate* during fluoroscopy or cine. Values for DAP or KAP *rate* may be expressed in units of cGy-cm²/s (*centigray-centimeter-squared per second*), for example. These devices may also display the DAP or KAP associated with a specific 'event' (e.g. cine sequence). Most will display the cumulative DAP or KAP for a complete study. Values for DAP or KAP may be expressed in the following units: mGy-cm², μGy-cm², or cGy-cm². They may also be expressed in other units of measurement as well.

Display of fluoroscopic irradiation time

Most fluoroscopic equipment will provide some display of fluoroscopic irradiation time, typically in the unit of *minutes*. Newer fluoroscopic equipment (manufactured on or after June 10, 2006) *must* provide *at the fluoroscopist’s working position* a display of the fluoroscopic irradiation time. This particular survey data item distinguishes between systems that actually display fluoroscopic irradiation time *at the fluoroscopist’s working position* and a similar display of fluoroscopic irradiation time at the control console (typically not visible by the equipment operator).

For each type of display indicate (“Y” or “N”) whether the fluoroscopic system provides for such display at the fluoroscopist’s working location or at the control console of the fluoroscopy system.

EXAMPLE

	DAP / KAP display: Rate and Cumulative values	Air Kerma Rate and Cumulative Air Kerma	Fluoroscopic Irradiation Time
Displayed at fluoroscopist’s working location	<u>Y</u>	<u>N</u>	<u>Y</u>
Displayed on the fluoroscopic system control console	<u>Y</u>	<u>N</u>	<u>Y</u>

22) Most recent calibration date of dose display equipment

Skip this item if the fluoroscopic system does not provide any display of DAP (or KAP) or Air Kerma. Otherwise determine the date on which dose display features for the fluoroscopy system were most recently calibrated. If the fluoroscopic system has more than one dose display feature, determine the date of most recent calibration for each. Enter the month and year of calibration. If the facility can not provide a date, enter “UNKN” for the year.

Most recent calibration date
of dose display equipment

		<u>Month</u>	<u>Year</u>
<u>EXAMPLE:</u>	DAP or KAP:	<u>9</u>	<u>2008</u>
	Air Kerma:	<u>9</u>	<u>2008</u>

23) Recording of patient dose display indicators

The facility may record into a permanent record display values for cumulative dose indicators such as cumulative DAP or KAP, cumulative Air Kerma, and total fluoroscopy time following the completion of a case. These dose indicators may be captured in two ways:

Procedure log book: A format that contains dose indicator entries from multiple cases. The format can be paper or electronic.

Patient file or report: The dose indicators for a case are recorded into the individual patient's file or report. The format can be paper or electronic.

1. Inquire with department staff whether cumulative DAP (or KAP), cumulative Air Kerma, fluoroscopy time, or any other dose indicators are recorded after completion of cases. Indicate with "Y" or "N" in the first column of the table whether such values are recorded into a procedure log book or into patient files/reports. If you enter "N" into a cell for the first column, leave the remaining cells for that row blank.
2. Indicate in the second column of the table whether captured dose indicators are recorded in an electronic ("E") or paper ("P") format.
3. In the remaining columns indicate "Y" or "N" whether the dose indicator is captured. If the facility captures an additional dose indicator not listed (e.g. number of cine sequences), enter the name of the indicator in the top cell of the last column and complete the column entries.

EXAMPLE:

	Are one or more patient dose indicators collected? (Y/N)	Record Format: Electronic (E) or Paper (P)	Cumulative DAP or KAP (Y/N)	Cumulative Air Kerma (Y/N)	Fluoroscopic Irradiation Time (Y/N)	Other dose indicator (describe):
Procedure log book	<u>Y</u>	<u>E</u>	<u>Y</u>	<u>N</u>	<u>Y</u>	
Patient file or report	<u>N</u>					

24) Fluoroscopic Unit Annual Procedure Volume: Diagnostic Coronary Angiography

Consult with appropriate staff regarding the total number of adult and pediatric *diagnostic coronary angiography* procedures performed in the previous 12 months with the fluoroscopic unit. A pediatric patient is under the age of 18 years. You can request assisting staff to consult their department records or provide a good estimate of the procedure volumes.

Fluoroscopic unit annual procedure volume for Diagnostic Coronary Angiography

24a) Annual volume-
Adult:

24b) Annual volume-
Pediatric:

EXAMPLE

320

0

C. FLUOROSCOPIC UNIT CONFIGURATION FOR DIAGNOSTIC CORONARY ANGIOGRAPHY PROCEDURE (ITEMS 25 TO 27)

Inquire with assisting staff regarding the most frequently configured values for the following fluoroscopic unit parameters during a ***routine adult diagnostic coronary angiography procedure***. If assisting staff indicate that a value for a parameter varies, then request a range of values and indicate any additional details in the comments section on the data form.

- **Source-image distance (SID)** (*item 25*). Record the numerical value and the units of measurement (inches or centimeters).
- **Field-of-view (FOV) or Magnification Mode** (*item 26*). Record the numerical value and units (inches/centimeters).

Fluoroscopic dose mode (*item 27*). Record the display console label for the most frequently used fluoroscopy dose mode. Examples are “low dose” or “normal.”

D. PREPARATION FOR FLUOROSCOPIC IRRADIATION MEASUREMENTS

NOTE ON BI-PLANE UNITS

If the most frequently used fluoroscopic system for conducting diagnostic coronary angiography procedures is a bi-plane system, then determine which of the two x-ray tubes is used routinely for these procedures, and survey *ONLY THIS TUBE*.

You will need the following equipment for this portion of the survey:

1. NEXT fluoroscopy phantom
2. MDH meter with 10X5-6 chamber
3. Copper (two 0.8 mm and one 1.5 mm) and lead (3 mm) filters
4. Image quality test tool
5. 8 mm of aluminum in 1 or 2 mm increments for HVL determination
6. Tape

SAFETY FIRST!

You are encouraged to wear a lead apron during these survey procedures, and observe any state or other applicable requirements regarding radiation safety and protection, particularly with regard to shielding, protective garments, and radiation badging. You are also urged to stand at a shielded location if possible during fluoroscopy. Some systems allow for remote operation without the need to stand close to the primary beam path.

NOTE: You should request assistance from facility staff during the following survey procedures.

1. Have the assisting staff prepare the fluoroscopy unit for a NEW PATIENT examination. For the patient name fields enter the facility's name (first name) and state (last name). This step will permit the capture of survey image sequences into a DICOM record. Inform the staff that you would like to have two DICOM CD's of your survey file prepared upon completion of the survey. If the facility cannot provide the CD's before your departure, provide them with two pre-addressed mailers.
2. With assistance from facility staff, identify at the table-side control panel or main control console up to three routinely used fluoroscopy dose modes and the most frequently used cine mode that may be used during *routine diagnostic coronary angiography procedures*. You will collect exposure rate data for each of these modes of operation. Record on the surveyor data form as headers for the columns in Table 1 the control panel labels for the routine fluoroscopy dose modes and the routinely used cine mode you identified in step 2 above. For convenience it is suggested to sequence the dose mode column labels in Table 1 as they appear on the control panel. Figure 1 shows one vendor's table-side menu display of fluoroscopic dose modes.
3. Also record on the surveyor data form in the second row of Table 1, the pulse frequencies (pulses per second) for each fluoroscopy mode and for the cine mode (also indicated as "frames per second"). If the pulse frequency is not displayed on the control console for a mode of operation (fluoroscopy or cine) inquire with assisting staff. If a mode is not pulsed, then enter "CONTIN" in the appropriate cell. If you cannot determine the pulse frequency for a mode, enter "UNKN" in the appropriate cell.

E. PHANTOM SET-UP AND DATA COLLECTION PROCEDURES FOR FLUOROSCOPIC AND CINE EXPOSURE RATE MEASUREMENTS (ITEMS 28, 29, AND DATA ENTRY TABLE 1)

1. Clear the patient support table of any padding. Position the MDH at a location that is convenient to work from. Move a portable shield near the table such that you can operate the equipment (table-side control panel and foot switches) from behind it.
2. Adjust the SID of the fluoroscopic unit to the smallest available position.
3. Position the x-ray tube gantry in the A/P orientation. The image receptor will be above the table. Indicators of the gantry's angular orientation are typically displayed.
4. Lower the table so that there is room to position the phantom beneath the image receptor.
5. Assemble the phantom and attach the MDH chamber to the holder. Slide the phantom beneath the image receptor and center as best possible.
6. Raise the table top so that the clear plastic handle attached to the phantom is just off the image receptor cover plate. Avoid direct contact between the phantom and the image receptor. **Figure 2** shows the phantom set-up.
7. Initiate fluoroscopy and center the image of the phantom in the field of view. Four lead beads are embedded to aid in centering. Select the smallest field size that will permit visualization of the four lead beads embedded in the phantom. Collimate the field as necessary so that the four beads are just within the visible field.
8. Configure the MDH as follows:
 - Set the **function selector** to “MEASURE.”
 - Set the **mode selector** to “EXPOSURE RATE.”
9. **Record** on the surveyor data form (*items 28 and 29*) the SID (including units) and the FOV (including units) that are displayed on the viewing monitor.

Figure 1. Photograph of one vendor's table-side control panel. This system has three fluoroscopy dose modes (solid red), and can store fluoroscopy sequences (yellow dash).

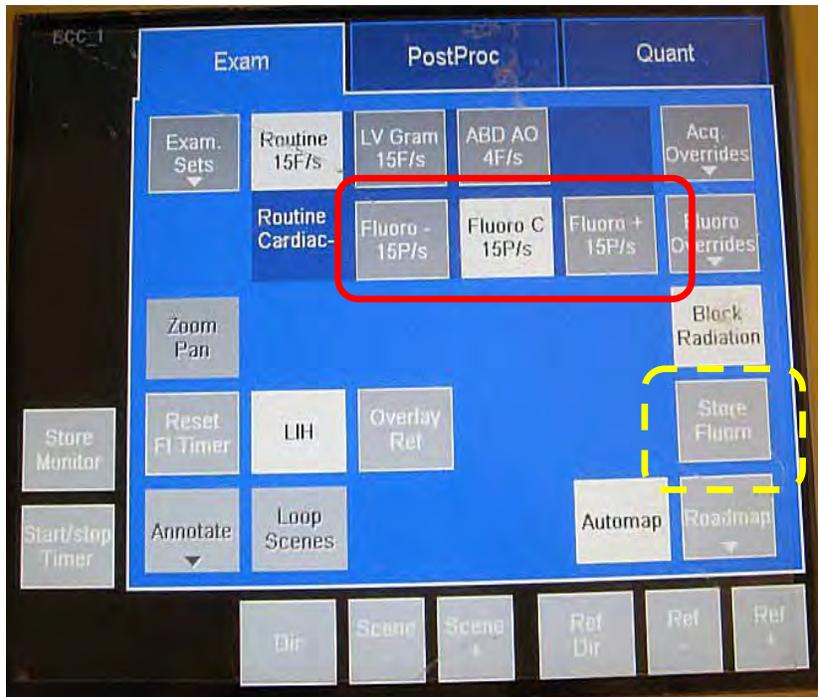


Figure 2. Phantom set-up for exposure rate measurements. Note the MDH cable is taped to the table top.



10. Place a couple pieces of tape on the table to locate the position of the phantom. This will assist you later when you need to remove the MDH and reposition the phantom for the image quality procedure.

11. Select the dose mode corresponding to the first data column in Table 1 and engage fluoroscopy. Depress the pedal briefly (about one second), and release. Engage a second time and hold for a fairly stable MDH reading. This process of engaging fluoroscopy twice will be referred to as “*double-clutching*”. It allows the fluoroscopy system to settle to an appropriate rate more quickly. Each time you change the attenuation in the beam it is suggested you double-clutch.

Also observe the kV and mA during fluoroscopy. **Record** in Table 1 in the appropriate cell the MDH reading (R/min), kV, and mA. NOTE: The red blinking light on the MDH readout panel indicates whether the displayed value for exposure rate is in **R/min** or **mR/min**. Always record your exposure rate entries in **R/min**.

12. Repeat the process in step 10 for all remaining fluoroscopy dose modes you identified in Table 1. Remember to double-clutch when you activate each fluoroscopy mode. For each mode, record the MDH exposure rate (R/min), kV, and mA on the surveyor data form.
13. Initiate a cine run using the mode you identified in Table 1, and observe the MDH display, kV and mA values after the MDH readout has stabilized. **Record** the exposure rate (R/min), kV, and mA on the data form.
14. Place one of the thin sheets (0.8 mm) of copper on the upper surface of the phantom.
15. Repeat exposure rate measurements for all identified fluoroscopy modes and for cine mode. For each mode **record** your values for exposure rate (R/min), kV, and mA.
16. Remove the thin copper sheet and replace it with the thicker (1.5 mm) copper sheet. Repeat exposure rate measurements for all identified fluoroscopy modes and for cine mode. For each mode **record** your values for exposure rate (R/min), kV, and mA.
17. Add one thin copper sheet to the phantom set-up (thick copper sheet is left in place). Repeat exposure rate measurements for all identified fluoroscopy modes and for cine mode. For each mode **record** your values for exposure rate (R/min), kV, and mA.
18. Add the second thin copper sheet to the phantom set-up. All three copper sheets should now be located on the upper surface of the phantom. Repeat exposure rate measurements for all identified fluoroscopy modes and for cine mode. For each mode **record** your values for exposure rate (R/min), kV, and mA.
19. Place the lead sheet on top of the copper sheets. Repeat exposure rate measurements for all identified fluoroscopy modes and for cine mode. For each mode **record** your values for exposure rate (R/min), kV, and mA.

NOTE: Some systems may not produce an output for this amount of attenuation. If this happens enter “X” into the cells for MDH exposure rate, kV, and mA. Make a note regarding this observation in the comments section of the data form.

F. IMAGE QUALITY EVALUATION WITH FLUOROSCOPY PHANTOM AND IMAGE QUALITY TEST TOOL (ITEMS 30 - 33).

1. Raise the image receptor to give clearance above the phantom. Remove the lead sheet and all copper sheets.
2. Remove the MDH probe from the phantom.
3. Reposition the phantom beneath the image receptor. Use the tape you placed on the table earlier to assist in re-positioning the phantom.
4. Place the test tool beneath the phantom and center as best possible.
5. Lower the image receptor so that it is just off the phantom handle plate.
6. Request staff to configure the position of the table-side viewing monitor and room light settings to those used for typical clinical cases.
7. Select the standard (e.g. “normal”) fluoroscopy dose mode and observe the image of the test tool. Some of the copper meshes may be partially cut off- this is fine as long as enough of each pattern is visible to determine a score. If needed, adjust the test tool for better visualization of the test objects. **Do NOT change the field-of-view. Do NOT adjust the test tool while fluoroscopy is ON.**
8. Engage fluoroscopy and score the test tool image on the viewing monitor **DURING** fluoroscopy. *Do not score the test tool from a last-image-hold view.* Count the number of mesh patterns visible and the number of low contrast holes visible, and **record** your scores on the surveyor data form (*items 30 and 31*). When scoring the low contrast holes do NOT include the center circle. If a mesh pattern shows interference fringes stop fluoroscopy and rotate the disk slightly. Re-engage fluoroscopy and continue scoring. NOTE: The fluoroscopy system may have a feature that can store a fluoroscopy sequence, similar to the way a cine sequence is captured. Refer to **Figure 1**.
9. Engage cine for approximately 3-4 seconds. Count the number of visible mesh patterns and low contrast holes during the cine playback loop and **record** your scores on the surveyor data form (*items 32 and 33*). The cine loop will typically replay automatically after the cine acquisition is terminated.

G. DETERMINATION OF FLUOROSCOPIC GANTRY ISO-CENTER

The remaining survey data collection procedures – half-value layer and reference-point dose/DAP measurements – will be performed with the C-arm positioned laterally and with the MDH chamber located at the gantry iso-center.

1. Remove the test tool from the phantom set-up.
2. Raise the image receptor to maximum SID.
3. Rotate the gantry to a lateral orientation – observe the gantry as you rotate it to ensure clearance with the table edges.
4. Lay the phantom on its side and tape a pen to the clear plastic phantom side plate. Tape it in a horizontal orientation and vertically centered on the plastic plate as best possible. Refer to **Figure 3**.

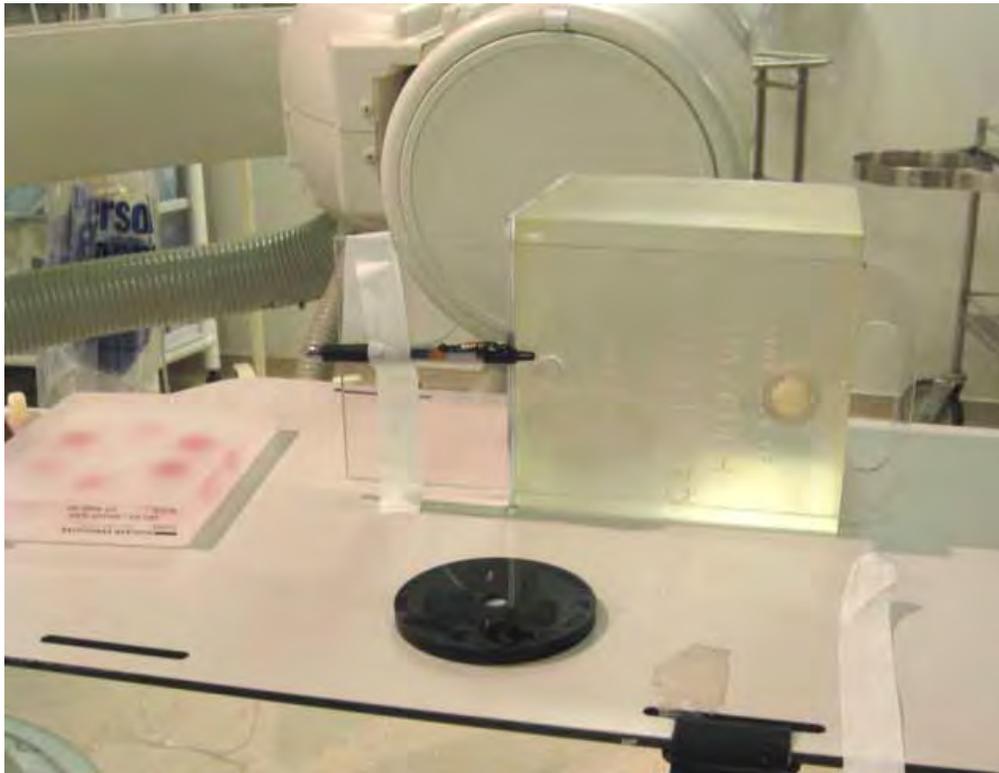
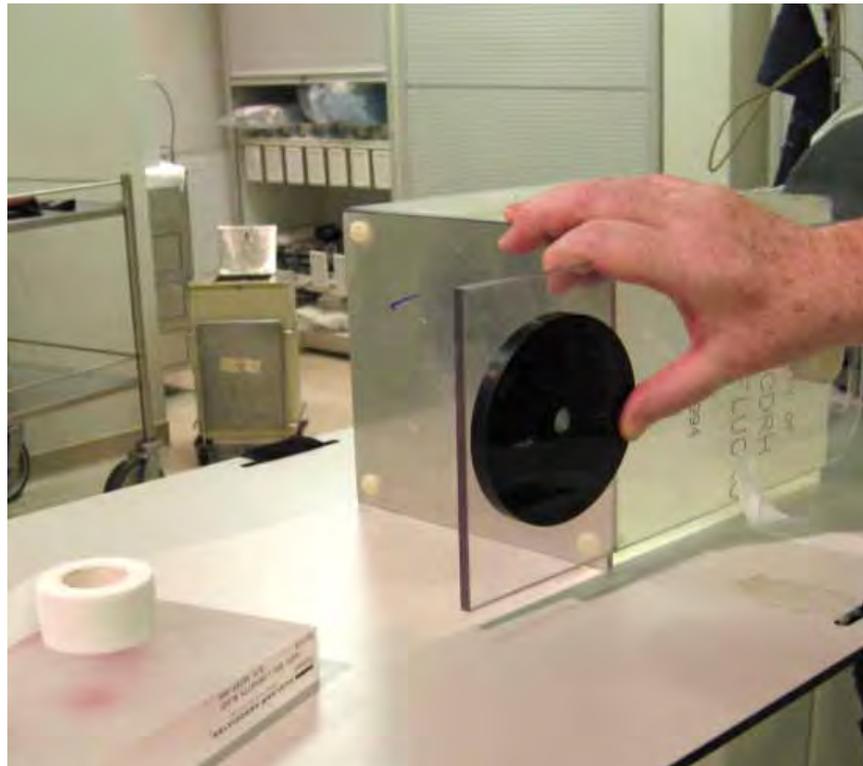


Figure 3. A pen is taped to the clear side plate. The phantom is then oriented so that the pen lies in the beam path.

5. Orient the phantom so that the pen is within the beam path.

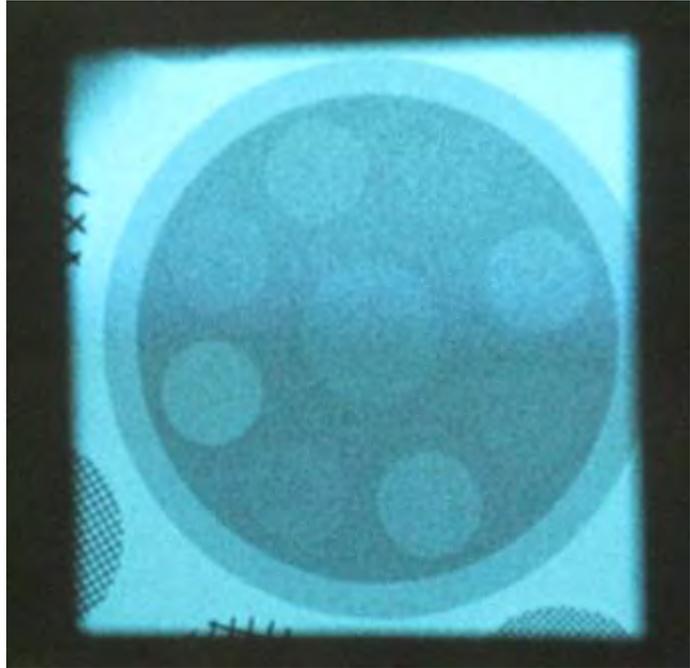
6. Select a dose mode and engage fluoroscopy. During fluoroscopy observe the position of the pen. Adjust the table position so that the pen is centered as best possible in the image. Collimate down approximately 50% on the left and right sides of the pen. This will aid in visualizing the shifting of the pen's location as the gantry is rotated.
7. Engage fluoroscopy and rotate the gantry to the vertical orientation- observe the image of the pen while the gantry is rotated. Any shifting of the pen to the left or right indicates that it is not located at the iso-center.
8. Engage fluoroscopy and adjust the table position to re-center the pen in the image.
9. Engage fluoroscopy and rotate the gantry back to the lateral orientation. If the pen is located at the iso-center then the image of the pen on the viewing monitor will shift very little during gantry rotation.
10. Once the pen is located at the iso-center make no changes to the position of the table. Do not move the phantom.
11. Place a piece of tape on the table directly beneath the clear plastic edge of the phantom side plate to mark its location in the event the phantom is inadvertently moved.
12. Remove the pen and in its place tape the image quality test tool. Center it vertically on the clear side plate as best possible. Refer to **Figure 4**.

Figure 4. The pen is removed and the test tool is taped to the plastic slide plate in the same location.



- Engage fluoroscopy and collimate the beam down to a square aperture defined by the space between the inner ring of low contrast circles and the mesh patterns. Refer to **Figure 5**. The ring circling the hole patterns does not need to be perfectly centered. Make no further changes to collimation for the duration of the equipment procedures once this step is completed.

Figure 5. The collimators are adjusted to a field slightly larger than the circular ring containing the low-contrast hole pattern. The test pattern does not need to be perfectly centered. Cine is briefly engaged to capture the image into the DICOM record for later data analysis.



- Make a brief (2-3 second) cine run to record the beam collimation into the DICOM record.
- Remove the test tool disk from the phantom side plate. Mount the MDH probe to the holder but inverted such that the chamber faces outward away from the phantom body. Refer to **Figure 6**.
- Position the chamber directly above the piece of tape on the table top that marks the iso-center location.
- Rotate the gantry 180 degrees while engaging fluoroscopy to verify that the probe is positioned at the iso-center. A slight amount of “wobble” of the chamber is acceptable. If necessary, make only minor adjustments to the table top position to correct the chamber position. The chamber does not need to be exactly centered in the image, but should not move very much as the gantry is rotated (**Figure 7**).
- Leave the MDH probe/phantom assembly and fluoroscopic unit as they are: the current set-up will be used for the remaining data collection procedures: half-value layer and reference-point dose/DAP measurements.

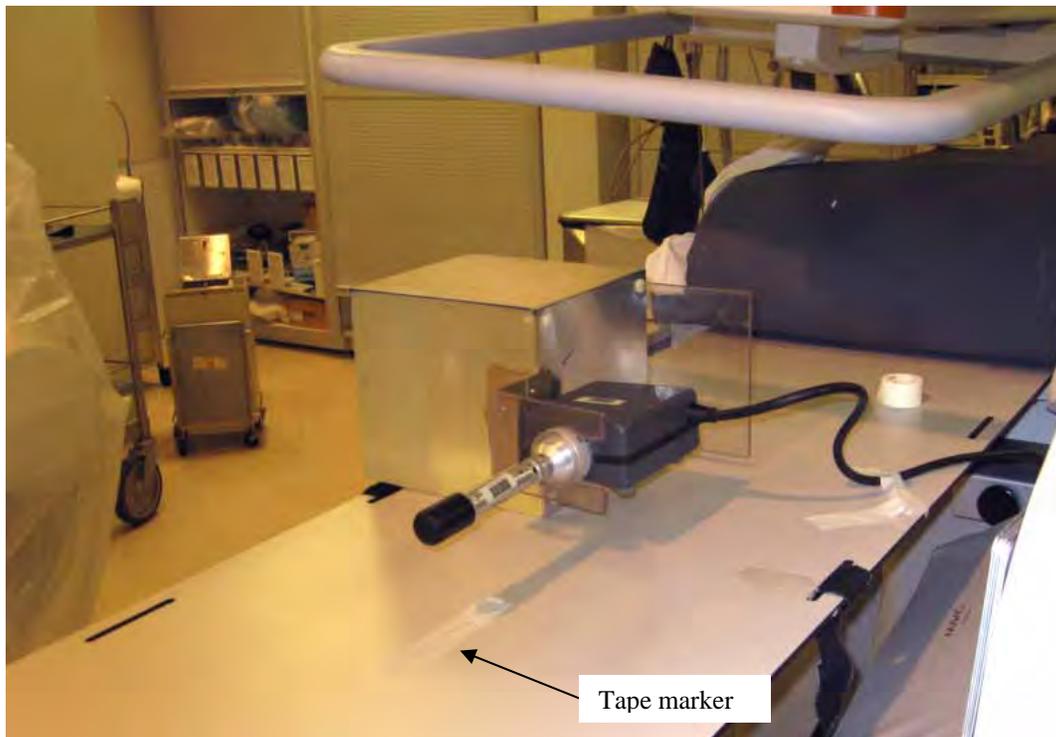
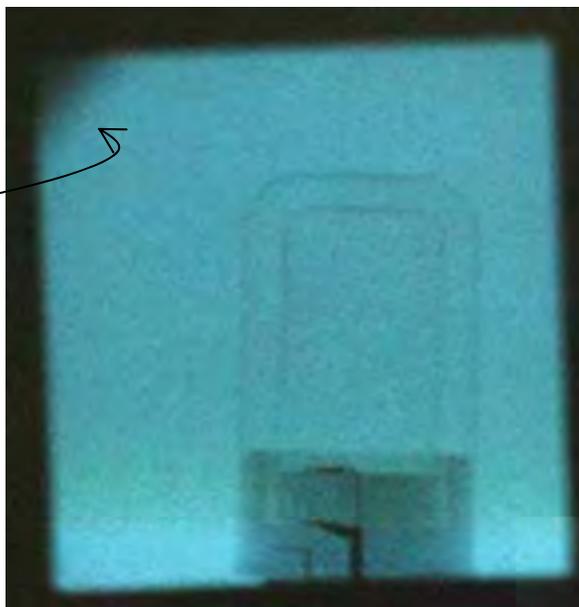


Figure 6. The image quality test tool is removed from the phantom and the MDH chamber is attached to the probe support piece backward, so that the chamber faces outward. The phantom is oriented so that the chamber is positioned where the test tool was previously located.

NOTE: Some systems may have edge collimation of the field. You should ensure that any edge collimation is fully OPEN to avoid unintended attenuation of the x-ray field.

Figure 7. MDH probe should be within the collimated field. Rotating the gantry will cause the probe to shift if it is not located at the iso-center, but a small amount of shifting is acceptable.



H. BEAM QUALITY (HALF-VALUE LAYER) DATA COLLECTION **(ITEMS 34 – 40)**

You will need 8 mm of aluminum for the following survey procedures. Since the majority of equipment cannot be operated in a manually configured mode, the data collection for half-value layer estimation will be done while maintaining a constant amount of aluminum in the beam. A combination of copper and aluminum will be used to drive the fluoroscopic system to a kV range of 70 kV to 75 kV.

1. Configure the MDH meter as follows:
 - Set the **function selector** to “**MEASURE.**”
 - Set the **mode selector** to “**EXPOSURE RATE.**”
2. Tape all three pieces of copper (2 x 0.8 mm + 1.5 mm) to the image receptor surface.
3. Tape 8 mm of aluminum over the copper.
4. Engage fluoroscopy using a *standard dose mode* and observe the kV reading. Data collection should be done for a kV value between 70 kv and 75 kV. If the kV does not lie within this range you can remove copper or adjust the SID as needed to adjust the kV. Verify that the copper and aluminum are secured to the image receptor when changing the SID.
5. **Record** on the data form the kV value for which you will collect HVL data (*item 34*) and the SID (*item 35*). Also enter the units for SID (inches/centimeters) in the space provided on the data form.
6. Engage fluoroscopy and observe the MDH display for exposure rate. **Record** this MDH display (R/min) value on the surveyor data form (*item 36*). This data entry is the “zero aluminum” reading (no aluminum lies between the MDH and the beam port).
7. Move 2 mm of aluminum from the image receptor to the x-ray beam port.
8. Engage fluoroscopy and observe the MDH display (R/min) for exposure rate. **Record** this reading on the surveyor data form as the ‘2-mm aluminum’ data value (*item 37*).
9. Continue to move aluminum from the image receptor to the beam port in 2 mm increments and **record** the MDH exposure rate (R/min) for these thicknesses of aluminum at the beam port: 4 mm, 6 mm and 8 mm (*items 38-40*).
10. Remove all aluminum from the beam port.

I. AIR KERMA AND DOSE-AREA PRODUCT (DAP) / KERMA-AREA PRODUCT MEASUREMENTS (ITEMS 41 - 50)

Overview

The majority of cardiac fluoroscopic systems now display to the equipment operator air kerma rate and cumulative air kerma. Systems that are compliant with the federal performance standard specified in 21 CFR 1020.32 (required for new fluoroscopy equipment manufactured after June 10, 2006) display air kerma rate and cumulative air kerma to a reference point in space as specified in the standard (typically a point that is near the skin entrance plane).

Dose-Area Product (DAP) or Kerma-Area Product (KAP) is a similar means of expressing the amount of radiation delivered, however DAP (or KAP) essentially integrates (sums) the amount of radiation contained in the entire beam by using a large-aperture ionization chamber that fully encompasses the beam. The output quantity of a DAP (or KAP) meter can be interpreted as the product of the air kerma with the beam area, and may be expressed for example in units of $Gy\text{-}cm^2$ or $\mu Gy\text{-}m^2$. For convenience the procedures below will refer to both DAP and KAP display devices simply as DAP.

1. If a system does not feature either DAP nor Air Kerma, then do not proceed with the following data collection procedures.
2. If the system you survey does not have one of the display modalities (e.g. the system does not display values for DAP) then leave those data entry fields for the display values blank.
3. The fluoroscopic gantry, phantom, and MDH probe are assumed to be set up as they were for the procedures in the previous section (*H. Beam quality (half-value layer) data collection*). All three copper filters should be taped to the image receptor surface.

The MDH probe should be positioned at the gantry iso-center.

If you removed any copper during the HVL procedures to adjust the kV, replace these on to the image receptor- *all three copper plates should be taped to the image receptor*.

4. Configure the MDH meter as follows:
 - Set the **function selector** to “**MEASURE.**”
 - Set the **mode selector** to “**EXPOSURE.**”

5. Identify and **record** on the surveyor data form the units of measure for Air Kerma and for DAP (*items 41 and 42*).
6. **Record** the current display values for Air Kerma (*item 43*) and DAP (*item 44*).
7. Configure the fluoroscopic unit for a standard or high fluoroscopy dose mode.
8. Zero the MDH display by briefly switching the function selector to “**HOLD**” and then back to “**MEASURE.**”
9. Initiate fluoroscopy and allow 5 R to build up on the MDH display. This will take approximately one minute depending on the output rate of the fluoroscopy unit. Observe the DAP display as the MDH reading increases. When approximately 5 R is obtained on the MDH display, disengage fluoroscopy. Do NOT reset the MDH meter.
10. Note the final DAP display reading. If the DAP display did not increase by at least 5 digits, then engage fluoroscopy and continue fluoroscopy until the DAP display reading changes by at least 5 digits. This may require a total build up of 10 R or more on the MDH meter. This will reduce the uncertainty associated with the low precision of the DAP display.
11. **Record** the display values for the Air Kerma (*item 45*), DAP (*item 46*), and the MDH display reading (R) (*item 47*). Read the NOTE below before proceeding to step 12.

NOTE: If you performed the additional exposure build up on the MDH as described in step 10 above, then **STOP HERE**. Do **NOT** proceed to the following steps. Do **NOT** record any data values for items 48, 49, and 50 on the surveyor data form. This completes the 2008-09 NEXT survey procedures on the fluoroscopic unit.

12. Zero the MDH display by briefly switching the **function selector** to “**HOLD**” and then back to “**MEASURE.**”
13. Engage cine and allow exposure to accumulate on the MDH for at least 5 seconds.
14. **Record** the display values for Air Kerma (*item 48*) and DAP (*item 49*). **Record** the MDH display value (R) (*item 50*). This completes the 2008-09 NEXT survey procedures on the fluoroscopic unit.

J. CLOSING THE SURVEY

1. Assist the staff with recording dose display indicators on the Clinical Dose Log form.
2. Return the room to its pre-survey configuration.
3. Collect the DICOM disks for your survey. If the facility cannot provide these before you leave, then provide two CD mailers they can use to send the disks.
4. Collect the medical physics survey report. Verify that it presents data regarding the same fluoroscopic unit that you surveyed.
5. Thank the facility for their participation.

APPENDIX A.

MEDICAL PHYSICS SURVEY REPORT CHECKLIST

Instructions

1. Obtain a copy of the report of the most recent medical physics survey for the fluoroscopy system you surveyed.
2. If possible prior to leaving the facility, review the report using the guidance items below. Make a photocopy for your records prior to mailing your survey package to FDA.

- The facility name and address should be identified on the report.
- The person/organization who conducted the medical physics survey should be identified.
- The date the medical physics survey was performed (as distinguished from the date the report was prepared/submitted) should be within 1 year of the NEXT survey.
- **IMPORTANT:** The medical physics survey report should identify the fluoroscopic unit by location/room number, manufacturer and model name. Please verify that this is the same unit you surveyed.

APPENDIX B.

LIST OF X-RAY EQUIPMENT MANUFACTURERS AND CODES FOR DATA ENTRY

Acoma (Aka Kram)	ACOM	Odelco	ODEL
Adtek	ADTK	Ohmic Ltd.	OHML
American Medical Imports Inc	AMII	Orion Corp	OTIC
Amrad Inc	AMRA	Philips Medical Systems Inc	PHMS
AR Custom Med. Products, Ltd.	AREM	Picker Corp	PICO
Ausonics Corp	AUSC	Planmeca	MECA
Bennett X-Ray Corp	BEXR	Planomed	PLAN
Belmont	BELM	Porta-Ray Inc	PORT
Berkley	BKLY	Profexray (Litton)	PROF
Castle	CSTL	Pfizer	PFIZ
CGR Medical Corp	CGRM	Radiation Sciences	RADS
Continental X-Ray Corp	CONX	Raytheon Medical Services	RAYT
Corometrics	CORO	Ritter	MORI
Del Medical Systems	DELM	Frank Scholz X-Ray Corp	FSXC
Diagnostic Inc	DIAG	Sankyo	SANK
Elscint Inc	ELSC	Shimadzu Co	SHIM
Elema-Schonander	ESCH	Siemens Medical Systems	SIEC
Fiad	FIAD	Spectrascan Inc	SPEC
Fischer Imaging Corp	HGFC	Soredex (A.k.a. Philips)	SORX
Franklin	FRNK	Standard X-Ray Corp	STAN
Gendex	GEND	Sybron	MORI
General Electric Medical systems	GEMS	Technomed	TECH
General X-Ray	GENX	Tokyo Emix Corp	TOEC
Giotto Ims (Mammo)	IMSE	Toshiba Corp	TOSE
Imaging Dynamics	IMAD	Transworld X-Ray Corp	TWXR
Italiensk Generay	ITAL	Thompson-CGR Medical Corp	TEGR
International Med. Systems Inc	IMSI	Trophy	TROP
Instrumentarium	INRU	TREX Medical Corp.	TREX
Keleket	KELE	TXR Tingle X-Ray Products	TXRI
Keystone	KYST	Unknown	UNKN
Kramex Corp	KRAM	Universal	UNIV
Litton Industries	LITT	Valmet	VALM
Lumix	LUMX	Varo Inc	VARE
Lorad Med. Systems Inc	LRAD	Velmet	VAIN
Machlett Laboratories Inc.	MALA	Versaview	MORI
Mattern	MATT	Weber	WEB R
Medicor Works Inc	MECO	Westinghouse	WEST
Midwest	MERI	S.S. White (A.k.a. Keystone)	WHCO
Min X-Ray Inc	MINX	Xerox Corp	XERO
J. Morita (A.k.a. Panex-E, Pan-Oral,		Xonics	XONI
Ora Tronix)	MORI	XRC Inc	XRCI
Moti Enterprises International	MOTI	Yoshida Co. (Distr. By Kaycor)	YOSH
Muller	MULL		

APPENDIX C.

Material from Excel Spreadsheets Provided to Surveyors

2008-09 Nationwide Evaluation of X-ray Trends Survey of Cardiac Catheterization Instructions

This questionnaire seeks information regarding your department's program of cardiac invasive fluoroscopy. In particular we request responses to questions regarding numbers of patients undergoing particular invasive diagnostic and interventional cardiac procedures, staffing levels, and aspects of your department's radiation safety program. This information will be used as part of the *Nationwide Evaluation of X-Ray Trends* (NEXT) survey to characterize practice and dose trends in Cardiac Catheterization facilities. Your facility was randomly selected for survey, and your participation is voluntary. All data that you provide will be treated confidentially and will be cited anonymously.

What you should expect to happen during the survey.

This survey has two components:

1) A NEXT surveyor will visit your facility to collect various data. The surveyor will request access to the fluoroscopy unit used most frequently at your facility for performing *diagnostic coronary angiography procedures*, and they will make radiation measurements from the unit. They will likely require the assistance of staff to operate the fluoroscopy unit, and data collection should require approximately 1 - 1+1/2 hours. The NEXT surveyor will also request your staff to record on a provided form for a period of one week the cumulative values for any dose display indicators following clinical procedures performed on the fluoroscopic unit.

2) Your facility is asked to complete a questionnaire that captures additional information regarding staffing levels, workloads of commonly performed cardiac procedures, and aspects of your department's radiation safety program. You are asked to please complete this form prior to the arrival of the NEXT surveyor. If your facility keeps a record of any dose indicators such as Dose-Area Product (DAP), air kerma, or fluoroscopy time following cases, you are also requested to provide these de-identified values of dose indicators on a separate form.

How to complete this questionnaire.

It is recommended that staff with good knowledge of the department's cardiac catheterization program provide responses to this questionnaire, including the Physician Medical Director, Cath Lab Manager, cardiovascular nurse, medical physicist, and radiation safety officer, as needed. It is not intended for staff to make extensive searches through department records and files to adequately answer the questions- good estimates are sufficient for the purposes of this survey.

If you require assistance regarding this form please contact the NEXT surveyor. Contact information is provided on the following page. You may also contact:

David Spelic, Food and Drug Administration
phone: 240-276-3312
email: david.spelic@fda.hhs.gov

Nationwide Evaluation of X-ray Trends
2008-09 Survey of Cardiac Catheterization Questionnaire

(1) Facility name: _____

Surveyor Information

(2) Surveyor name: _____ (3) State: _____

(4) Phone number: _____ (5) Email: _____

(6) Date of facility onsite visit (MM/DD/YYYY): _____

Survey participants please start here

NOTE: This questionnaire makes reference to the following terminology:

PROCEDURE refers to distinct invasive procedures such as LEFT HEART CATHETERIZATION

CASE refers to a single patient visit during which one or more **procedures** are performed.

(7) Facility staff completing this questionnaire:

NOTE: It is recommended that the *Physician Medical Director* and the *Cath Lab Manager* (or equivalent) contribute input to this questionnaire

Name: _____ Title or position: _____

Name: _____ Title or position: _____

Name: _____ Title or position: _____

(8) Your department (e.g. 'Cardiology'): _____

(9) Department Medical Director / Physician Director: _____

(10) Years of medical practice: _____ (11) Director's annual invasive procedure volume: _____

Types of Procedures Performed in the Department (item 12)

Indicate (Y/N) whether invasive diagnostic or interventional fluoroscopic procedures *other than cardiac* are performed in your department.

Procedures other than cardiac performed in department? (Y/N)

Department Staff (items 13 - 16)

Clinician Staff (item 13)

FOR THIS SPECIFIC DEPARTMENT Provide the **number of persons** (primary treating clinicians) performing CARDIAC invasive diagnostic or therapeutic fluoroscopic procedures. If entering a response for 'Other' treating clinician, provide the title of such persons.

Number of:

Cardiologists _____
Vascular/Cardio-
thoracic Surgeons _____
Interventional
Radiologists _____

Other _____ (provide titles
below)

Titles:

Non-clinician Staffing (item 14)

Provide the number of persons employed in your department in the following positions. You can indicate part-time positions as 1/2 of a full-time position (e.g., " 3.5 nurses").

Nurse (CV or other) _____
Cardiology/Cardiovascular
Technologist _____
Radiological Technologist _____

Other _____ (provide titles
below)

Titles:

Medical Physics Staff (item 15)

Indicate the **number** of medical physicists who:

are on staff and provide physics support ***exclusively*** to this department: _____

are on staff and provide physics support throughout the facility: _____

provide physics support on a contractual basis: _____

provide medical physics support via the following arrangement
(please describe below) : _____

Radiation Safety Staff (item 16)

Are radiation safety duties performed by a medical physicist, or by a person other than medical physicist who holds the title of Radiation Safety Officer? (check appropriate box)

medical
physicist

radiation
safety officer

Facility Annual Procedure Caseloads (items 17 -20)

Annual procedure caseload: Diagnostic Coronary Angiography (items 17 and 18).

Enter in the appropriate space below (item 17 for **hospitals**, item 18 for **all other facilities**) the total number of adult and pediatric **diagnostic coronary angiography procedures** performed in the previous twelve months at your facility. A PEDIATRIC procedure is one performed on a patient under the age of 18 years. A procedure should be counted whether it is performed as a stand-alone procedure or whether it is done in conjunction with additional fluoroscopic procedures during the same **case**. NOTE: You can consult your department records or provide a good estimate of your institution's annual procedure volume.

(item 17) HOSPITALS: Enter the number of Diagnostic Coronary Angiography procedures performed in previous 12 months:

(a) at the hospital site	<table><tr><td>Adult</td><td>Pediatric</td></tr><tr><td>_____</td><td>_____</td></tr></table>	Adult	Pediatric	_____	_____	b) at one or more outpatient locations as part of a program of patient care provided by this hospital	<table><tr><td>Adult</td><td>Pediatric</td></tr><tr><td>_____</td><td>_____</td></tr></table>	Adult	Pediatric	_____	_____
Adult	Pediatric										
_____	_____										
Adult	Pediatric										
_____	_____										

(item 18) FACILITIES OTHER THAN HOSPITALS: Enter the number of Diagnostic Coronary Angiography procedures performed in the previous 12 months:

a) On outpatients	<table><tr><td>Adult</td><td>Pediatric</td></tr><tr><td>_____</td><td>_____</td></tr></table>	Adult	Pediatric	_____	_____
Adult	Pediatric				
_____	_____				
b) As part of hospital-based patient care (inpatients)	<table><tr><td>Adult</td><td>Pediatric</td></tr><tr><td>_____</td><td>_____</td></tr></table>	Adult	Pediatric	_____	_____
Adult	Pediatric				
_____	_____				

TOTAL number of ALL invasive cardiac fluoroscopic cases for the department (item 19)

Provide estimates for the **TOTAL** number of **ALL INVASIVE CARDIAC FLUOROSCOPIC CASES** (diagnostic, therapeutic, or mix) for adult and pediatric (less than 18 years) patients in your department within the previous 12 months.

TOTAL number of <u>ALL INVASIVE CARDIAC FLUOROSCOPIC CASES</u> in this department in the previous 12 months:	<table><tr><td>Adult</td><td>Pediatric</td></tr><tr><td>_____</td><td>_____</td></tr></table>	Adult	Pediatric	_____	_____
Adult	Pediatric				
_____	_____				

Most Frequently Performed Invasive Cardiac Diagnostic and Interventional Fluoroscopy Procedures other than Diagnostic Coronary Angiography (item 20)

Enter the NAME/DESCRIPTION of the most frequently performed invasive cardiac diagnostic and therapeutic fluoroscopic procedures (other than diagnostic coronary angiography) performed in your department. Provide the *5 most frequent procedures* for adult patients and *3 most frequent* for pediatric patients. For each procedure you enter, provide the annual procedure caseload. A list of frequently performed procedures is provided below, **but may not be complete**. A procedure should be counted regardless of whether it is performed in conjunction with other procedures during a case.

NOTE: If you do not find a procedure your department routinely performs in the list below, enter the procedure name and workload.

Selected Invasive Diagnostic Cardiac Procedures:

- Left Heart Catheterization
- Right Heart Catheterization
- Myocardial Biopsy
- Electrophysiology studies

Selected Invasive Diagnostic Non-Cardiac/Extra-cardiac Procedures:

- Carotid Angiography
- Aortography
- Renal Angiography
- Femoral Angiography

Selected Interventional (therapeutic) Cardiac Procedures:

- Percutaneous Coronary intervention

Selected Interventional (therapeutic) Non-Cardiac/Extra-Cardiac Procedures:

- Carotid Stent
- Renal Stent
- Ileo-Femoral Stent
- Aortic Stent-Graft

Selected Structural Heart Disease Interventions:

- Aortic Valvuloplasty
- Mitral Valvuloplasty
- Closure of Patent Foramen Ovale (PFO)
- Closure of Atrial Septal Defect (ASD)

Selected Electrophysiologic Procedures:

- Pacemaker Implantation
- Intracardiac Defibrillator (ICD or BiV ICD) implant
- Ablation of Supraventricular Tachycardia (SVT), Atrial Flutter, Atrial Fibrillation, or Ventricular Tachycardia.

<u>ADULT PATIENTS:</u> Procedure name/description	Number of procedures performed in past 12 months
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____

<u>PEDIATRIC PATIENTS</u> : Procedure name/description	Number of procedures performed in past 12 months
1. _____	_____
2. _____	_____
3. _____	_____

Physician Credentialing and Training, Radiation Safety (item 21)

Check all that apply

_____ Currently our department does not have a formal credentialing program for fluoroscopy equipment operators.

_____ Our department has a formal credentialing program for fluoroscopy equipment operators. This program consists of the following requirements (check all that apply):

_____ Board certification in **interventional cardiology, interventional radiology**, or in a similar, appropriate radiological specialty.

_____ A probational period of close supervision by a senior clinician.

_____ One-time training provided by medical physics/radiation safety personnel who are (A) employed by our facility, or (B) contracted with our facility specifically to provide this training (enter A or B).

_____ Continuing education in topics on radiation safety by appropriate professional meeting/course attendance.

_____ encouraged attendance of in-house lectures featuring topics on radiation safety.

_____ Other:

Equipment (items 22 and 23)

(22) Please indicate the number of stationary fluoroscopic x-ray systems in your department that are used to perform invasive fluoroscopic procedures. Do NOT include fluoroscopy systems that are located in any other department (e.g. fluoroscopy systems located in Urology). **BI-PLANE configurations should be counted as one system.**

Total number of ALL stationary fluoroscopic systems in department _____

Number of stationary systems that are used exclusively to perform **cardiac** procedures _____

Number of stationary systems used exclusively for **NON-cardiac** interventional procedures _____

Number of stationary systems used for cardiac **AND** non-cardiac invasive procedures _____

(23) Specifically for those fluoroscopy units that are used for cardiac procedures please indicate the **number of units** that have the following features:

Flat panel (digital) fluoroscopy
image receptor _____

CT mode of operation (installed
AND used) _____

Display of Dose-Area Product
(DAP) or Kerma-Area Product
(KAP) (examples of units are
 $\mu\text{Gy-cm}^2$, cGy-cm^2 , Gy-cm^2) _____

Display of Air Kerma (examples
of units are mGy, cGy) _____

Patient Safety/Communication (items 24-32)

(24) For the three radiation dose parameters indicated below, indicate (Y/N) whether your department routinely maintains formal records of cumulative values following the completion of cases (e.g., in a cath lab logbook or in individual case files), and provide any *threshold values* for these dose parameters that your department uses as "*trigger levels*" of subsequent **action** in three areas: patient follow up, internal reporting within your institution, and mandatory incident reporting to an outside agency. For example, your department may initiate **patient follow-up** for the threshold, "cumulative air kerma exceeds 1500 mGy." If your department maintains record of an indicator for patient radiation dose that is not listed, provide responses in the space, "Other." If your department has no established trigger level for a dose indicator, indicate "NA" in the applicable columns to the right.

For each **action**, briefly describe your department's threshold values for the indicated dose parameters

	Are values recorded? (Y/N)	Patient Follow-up	Internal reporting within your institution	Mandatory reporting to an outside agency
Cumulative fluoroscopy time	<input type="text"/>			
Cumulative Dose-Area Product (DAP) or Kerma-area product (KAP)	<input type="text"/>			
Cumulative Air Kerma	<input type="text"/>			
Other:	<input type="text"/>			

(25) Does your department have procedures in place to minimize radiation dose specifically for patients who are either expected to undergo a procedure requiring extensive imaging or who have had a previous *interventional* fluoroscopic treatment session within the past 6 months (or similar time frame)? (Y/N). If so, briefly describe below.

Extensive Imaging (Y/N)	Previous Treatment (Y/N)
-------------------------	--------------------------

Extensive Imaging:

Previous Treatment:

--	--

If your department does not perform CARDIAC invasive fluoroscopic procedures on pediatric patients please proceed to item 27.

(26) Has your department implemented any procedures or equipment technologies for the particular goal of minimizing radiation exposure to pediatric patients? Check all that apply.

We do not have any specific procedures or equipment features for pediatric patients. _____

We provide training to equipment operators in the specific area of pediatric imaging with regard to radiation safety. _____

Fluoroscopic equipment in our department used for pediatric procedures have features or modifications (e.g. region-of-interest filters or spectral-shaping filters) that are designed to minimize radiation exposure to pediatric patients. _____

We have established recommended fluoroscopy protocols and procedures that can reduce radiation exposure to pediatric patients. _____

Other (Please describe below):

(27) Our department provides the patient with information/consultation on the possibilities of radiation injury during fluoroscopic procedures: **A=** Only prior to the exam, **B=** Only following the exam, **C=** Prior to, **AND** after the exam, **D =** varies, or not sure, **E =** Never (Enter A, B, C, D, or E) _____

(28) During the past 36 months, the number of patients in our department who presented with a CONFIRMED radiation injury is: **A=** zero, **B=** 1, **C=** 2-5, **D=** 5 - 10, **E=** more than 10 (Enter A, B, C, D or E) _____

(29) Select the response that best characterizes your facility's standard protocol, if any, for post-exam patient monitoring regarding the potential for radiation injury. (Enter A, B, C, D) _____

A. We rely on the patient to report any anomalous conditions/injuries.

B. We follow up with all patients at specified time intervals after the procedure.

C. We use an established threshold value for one or more dose indicators to determine whether to follow up with patients regarding potential radiation injury.

D. Other: Please describe:

(30) Does a medical physicist or other qualified staff person (e.g. Radiation Safety Officer) perform a radiation dose estimation as part of the investigative process for diagnosing a possible patient injury? (Y/N) _____

(31) Who is involved in the post-exam phase of patient care regarding a possible patient radiation injury? (check all that apply)

Treating physician _____	Nurse, Nurse Practitioner (NP), or Physician Assistant (PA) _____
Dermatologist _____	Physician Medical Director _____
Radiation Safety Officer _____	Patient's primary / referring physician _____
Other _____ => Title: _____	

If your facility is NOT accredited by the Joint Commission, please proceed to item 33.

(32) In 2006 the Joint Commission (JC) added the following as a reviewable sentinel event: the occurrence of fluoroscopy cumulative dose exceeding 1500 rad (15 Gy) to a single field. How has your facility responded to this added sentinel event? (Enter A or B) _____ (A or B)

A. We believe our current processes/x-ray equipment allows us to meet JC expectations.

B. We have made the following changes within our department in order to better meet JC expectations (briefly describe):

Quality-Control and Quality-Assurance (items 33-36)

The following items pertain exclusively to fluoroscopic equipment in your department that are used to perform cardiac invasive fluoroscopic procedures .

(33) How often is routine preventative maintenance performed on fluoroscopic equipment in your department? (A= annually, S=semi-annually, M= monthly, N= never, W=When needed, O = Other Frequency) _____

(34) How often is dose-display equipment calibrated? (A= annually, S=semi-annually, M= monthly, N= never, W=When needed, O = Other Frequency) _____

(35) How often is a medical physics survey performed on the fluoroscopy equipment? (A= annually, S=semi-annually, M= monthly, N= never, W=When needed, O = Other Frequency) _____

(36) Who performs medical physics surveys on the fluoroscopy equipment? (A= In-house medical physics staff, B= contracted medical physics services C= Other: (describe below) _____

Clinical Dose Log Data Form

How to complete this form

The NEXT surveyor will visit your department to perform radiation output measurements on one fluoroscopic unit in your department. We ask that you record on this form cumulative values for all dose parameters that are displayed by this same fluoroscopic equipment following clinical cases. Please Do Not include data that would indicate the name or identity of any individual patient or case. Prior to recording this anonymous dose-related information, please obtain appropriate approval.

Most fluoroscopic systems used for invasive fluoroscopic procedures now display one or more dose indicators during, and upon completion of a case.

For a period of one week following the NEXT surveyor's visit, please record on the provided form the cumulative value for every dose indicator displayed by the fluoroscopic unit the NEXT surveyor collects data from.

Following a case, indicate in the first column the date on which the case was performed. Next, enter the type of case performed using the NEXT procedure codes provided at the bottom of the form. Finally, record the displayed cumulative values for all dose indicators available on the fluoroscopic unit for the complete case. After the form has been filled in for the requested time period, please fax it back to the surveyor.

Your system may have dose indicators that are only recognized by the units of measure. For instance, your system may not have the text descriptor, "Dose-Area Product," but may only display the units, such as "mGy-cm2." The following descriptions of dose display indicators will assist you in identifying these dose display features on your equipment. Your equipment may or may not display every dose indicator listed on the form. If the fluoroscopic unit does not provide a particular dose indicator, leave that column empty.

NOTE: It is important to collect not only the values of the dose display features but also the units of measure. Please be sure to indicate the UNITS OF MEASURE your system uses by checking the appropriate boxes above the data entry columns. If your system does not display one of the indicated units, write the units in the provided space.

We request cumulative values for the following dosimetric indicators displayed by the fluoroscopic unit following clinical cases:

Total fluoroscopy time

The cumulative time of fluoroscopy during a case. This cumulative time is typically reported in *minutes*.

Number of digital acquisitions/cine runs

The total number of digital acquisitions or cine runs made during a case.

**Dose-Area Product (DAP) or
Kerma-Area Product (KAP)**

The fluoroscopic system to be surveyed may report cumulative values for Dose-Area Product (DAP) or Kerma-Area Product (KAP). DAP (or KAP) values may be expressed in any of the following units of measurement: milligray-centimeters (abbreviated mGy-cm²); or microgray-meters squared (abbreviated $\mu\text{Gy}\cdot\text{m}^2$ but sometimes written as uGy-m²); or gray-centimeters squared (abbreviated Gy-cm²). Your system may use any of these units of measurement, or it may report DAP (or KAP) in different units of measurement not listed among these examples. A single value of DAP (or KAP) for the entire case may be reported. It is also possible that values of DAP (or KAP) may be reported *respectively* for the fluoroscopic and digital acquisition (or cine) portions of the case. Spaces are provided on the form to report these respective values.

Air Kerma

The cumulative air kerma delivered during a case. A system may display this quantity by a different name such as "Dose," or "Exposure Dose." Air Kerma may be expressed in any of the following units of measurement: milligray (abbreviated mGy), centigray (abbreviated cGy), or gray (abbreviated Gy). Your system may use any of these units of measurement or it may report Air Kerma in different units of measurement not listed among these examples.

A single value for air kerma may be reported. Respective values of air kerma for the fluoroscopic and cine portions of a case may also be reported. Spaces are provided on the form to report these respective values.

If you have any questions or concerns regarding this form please contact your NEXT surveyor.

We appreciate your time and efforts with this survey!

2008-09 NEXT Cardiac Catheterization Surveyor Data Form

Surveyor Information (items 1-4) page 11

1) Surveyor name 2) Telephone number
3) Email address 4) Survey date
(MM/DD/YY)

Facility Information (items 5-10) page 11

5) Facility name
6) Facility ID number 7) State/Agency code
8) Facility type code 8a) Explain if 99
9) Practice specialty code 9a) Explain if 99
10a) Interviewee name (1) Title
10b) Interviewee name (2) Title

Fluoroscopic Unit Identification (items 11-16) page 13

Complete this section AFTER you have located the fluoroscopic unit that is typically used for Diagnostic Coronary Angiography.

11) Room number Location
(eg 'radiology dept' or 'cardiology dept')

12) Fluoro unit manufacturer: Name Code
(see list of equipment manufacturers in appendix B -page 36 of protocol)

13) Fluoro unit model name 14) Facility service / Site nmbr
15) Provider of service (O/I/T) 16) Date of assembly
MONTH YEAR

Features of the fluoroscopy unit being surveyed (items 17-20) page 15

17) Type of equipment? (C/B) 18) Fluoroscopic image receptor (I/D)
19) Grid used for fluroscopy? (Y/N) 19a) adult procedure 19b) pediatric procedure
20) Cineradiographic image acquisition equipment type (F/D)

21) Dose and fluoroscopy time display features (Y/N):

	DAP/KAP Rate and cumulative value	Air Kerma rate and cumulative value	Fluoroscopic irradiation time
Displayed at fluoroscopist's working location	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Displayed on the fluoroscopic system control console	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

22) Most recent calibration date of dose display equipment:

22a) DAP or KAP: MONTH YEAR 22b) Air Kerma: MONTH YEAR

23) Recording of patient dose display indicators:

	Patient Dose indicators collected? (Y/N)	Format: Electronic (E) or Paper (P)	Cummulative DAP or KAP (Y/N)	Cummulative Air Kerma (Y/N)	Fluoro irradiation time (Y/N)	Other dose indicator:
Procedure logbook	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient file or report	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24) Fluoroscopic Unit Annual Procedure Volume: Diagnostic Coronary Angiography.

24a) Annual volume - Adult: 24b) Annual volume - Pediatric:

25) Source-Image distance (SID) : UNITS (IN/CM) 26) Field-of-View (FOV) : UNITS (IN/CM)

27) Display console label for most frequently used fluoroscopy dose mode:

Comments:

28) Displayed Source-Image Distance: Enter units (IN / CM)

29) Displayed Field-of-View (magnification): Enter units (IN / CM)

Table 1: Fluoroscopic and cine exposure rate measurements.

		Fluoroscopy Modes			Cine
Control Panel Label					
Pulse Freq (pulses/sec)					
		↓	↓	↓	↓
Phantom only	Exposure Rate (R/min)				
	kVp				
	mA				
Phantom and 1 thin Copper	Exposure Rate (R/min)				
	kVp				
	mA				
Phantom and 1 thick Copper	Exposure Rate (R/min)				
	kVp				
	mA				
Phantom and 1 thick Copper and 1 thin Copper	Exposure Rate (R/min)				
	kVp				
	mA				
Phantom and 1 thick Copper and 2 thin Copper	Exposure Rate (R/min)				
	kVp				
	mA				
Phantom and all 3 Copper and 1 Lead	Exposure Rate (R/min)				
	kVp				
	mA				

Image quality evaluation (items 30-33) page 26

FLUORO MODE

CINE MODE

30) Number of visible meshes:

32) Number of visible meshes:

31) Number of visible holes:

33) Number of visible holes:

Beam quality data collection (items 34-40) page 31

34) kVp value used for HVL data collection:

35) SID:
UNITS

36) Exposure rate with no aluminum in the beam: R/min

(IN / CM)

37) Exposure rate with 2 mm aluminum in the beam: R/min

38) Exposure rate with 4 mm aluminum in the beam: R/min

39) Exposure rate with 6 mm aluminum in the beam: R/min

40) Exposure rate with 8 mm aluminum in the beam: R/min

NOTE: Record all exposure rates in R/min

Air Kerma and DAP measurements (items 41-50) page 32

	Air Kerma	DAP	MDH Display
41, 42) Enter units for Air Kerma and DAP →	<input type="text"/>	<input type="text"/>	Record MDH readings in 'R'
43,44) Initial Dose display values →	<input type="text"/>	<input type="text"/>	N/A
45,46,47) Dose display and MDH values after 5R built up on MDH →	<input type="text"/>	<input type="text"/>	<input type="text"/> R
48,49,50) Values after Cine run →	<input type="text"/>	<input type="text"/>	<input type="text"/> R

Comments: