NEXT 2001 Protocol for the Survey of Adult Chest Radiography

July 30, 2002

Prepared by

David C. Spelic and Richard V. Kaczmarek

Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)

Rockville, Maryland

In association with

Committee H-4 on the *Nationwide Evaluation of X-Ray Trends (NEXT)* of the Conference of Radiation Control Program Directors (CRCPD), Inc.

Members

John Ferruolo* (Chair, Rhode Island), Jeanne Crosby* (California), Wayne Horowitz (Florida), Linda Plusquellic* (Maine), MaryAnn Spohrer[†] (Illinois), Robert Scott (Pennsylvania), Karen Farris (Massachusetts), Warren Freier (North Dakota)

FDA Liaison

John McCrohan (CDRH)

Resource Individuals

Ronald E. Bernacki (FDA/ORA), Jan Martensen (American Chiropractic College of Radiology), David C. Spelic (FDA/CDRH), Richard Kaczmarek (FDA/CDRH), Albert Moyal (FDA/CDRH), Keith Strauss (Children's Hospital, Boston, Massachusetts)

Advisors

Jennifer Elee (LA), Aaron Gantt (SC), Edward Gloor (CA), Beverly Hall (NC), June Hawkinson (MN), Josip Nosil (Capital Health Region, BC, Canada), Russell Takata (HI), Philip Thoma (FL), Bill Van Pelt (WA), Diana Wozniak (CT)

*Term of membership ending December 2000

[†]Chairmanship beginning January 2001

Contents

Address for Correspondence		
Acknowledgments	ii	
Introduction	3	
A. Surveyor information (<i>items 1-3</i>)	4	
B. Facility information (<i>items 4-9</i>)	4	
C. X-ray equipment information (items 10-16)	7	
D. Screen-film and digital image receptor information (<i>items 17-30</i>)	10	
E. Technique data (<i>items 31-38</i>)	13	
F. Exposure measurements and entrance skin exposure calculation		
(items 39-45)	17	
F.1 Screen-film x-ray systems	18	
F.2 Computed radiography x-ray systems	23	
F.3 Digital x-ray systems	28	
G. Beam quality determination at clinical kVp (<i>items 46-53</i>)	33	
H. Phantom-film background density and image quality scores (<i>items 54-59</i>)		
I. Darkroom-fog evaluation (<i>items 60-64</i>)		
J. Film processing information (<i>items 65-70</i>)		
K. Instructions for performing the STEP test (<i>items 71-78</i>)	44	
Appendix A: Phantom assembly and test-tool positioning	47	
Appendix B: Survey data form		
Appendix C: Facility questionnaire form		

Address for Correspondence

David Spelic, Ph.D. U.S. Food and Drug Administration Center for Devices and Radiological Health Office of Health and Industry Programs Division of Mammography Quality and Radiation Programs Radiation Programs Branch

1350 Piccard Drive (HFZ-240) Rockville, Maryland 20850

Tel: 301-594-3525 Fax: 301-594-3306 E-mail: david.spelic@fda.hhs.gov

Acknowledgments

We are first and foremost grateful to the participating state radiation control personnel for their time and efforts, without which this project would not have been possible. We wish to acknowledge Dr. Matthew Freedman from Georgetown University Hospital (Washington, DC) and Mike Taylor from the National Naval Medical Center (Bethesda, Maryland) for providing us access to their respective radiology departments. Dr. Freedman also provided valuable feedback on the sections devoted to digital x-ray systems, and we are thankful for this. We also thank Stanley Stern, Albert Moyal, and Orhan Suleiman of the FDA Division of Mammography Quality and Radiation Programs for their feedback on draft versions, and for their important roles they served in the surveyor training. We are grateful to Richard VanMetter of Eastman Kodak Co. for his helpful review and suggestions on draft versions of this document. We also wish to thank Frank Cerra, Elizabeth Rogers, Mary Walker and Bruce Fleharty of the FDA Office of Science and Technology for providing funds in support of travel by surveyors for training.

NEXT 2001 Protocol for the Survey of Adult Chest Radiography

Introduction

The purpose of this survey is to capture data and information which characterize patient exposure and image quality associated with the state of the practice of adult chest radiography. A NEXT survey of adult chest radiography was previously conducted in 1994, and the results have since been published.^{1,2} This protocol for the 2001 survey details procedures for capturing data and information on screen-film radiography systems, computed radiography (CR) systems and other digital-based x-ray imaging systems. Data can be captured on the following features of clinical chest radiography:

- Facility practice: number of tubes, patient workload and type of equipment.
- Clinical technique factors: tube potential, tube current, mAs, and exposure mode.
- Image-receptor information: film and screen data, and digital-imaging practice.
- Clinical exposure data using the CDRH adult chest phantom.
- Beam quality at the selected clinical technique.
- Image quality of the radiographic film- background optical density and test-tool evaluation.
- Presence of darkroom fog.
- Film processing quality.

If you have any questions, please contact the following CDRH staff:

David Spelic 301-594-3525 <u>david.spelic@fda.h</u>hs.gov

Richard Kaczmarek 301-594-0865 <u>richard.kaczmarek@fda.hhs.gov</u>

¹ Conference of Radiation Control Program Directors (1998) *Nationwide Evaluation of X-ray Trends (NEXT)*

Tabulation and Graphical Summary of Surveys 1994 Chest Survey. CRCPD Publication 98-2, Frankfort, Kentucky. ² RV Kaczmarek, BJ Conway, RJ Slayton, OH Suleiman. *Results of a Nationwide Survey of Chest Radiography: Comparison with results of a Previous Study.* Radiology 2000; 215: 891-896

An updated survey protocol

The survey protocol for 2001 has been modified from the protocol used during the 1994 survey. A separate questionnaire is now provided for the facility personnel to complete. This form requests information regarding their quality assurance and quality control programs as well as further details regarding their equipment and procedures. We ask that you mail or fax this separate form to the facility prior to your arrival. Advance transmission will give the facility personnel time to complete the form and also allow you to review and clarify their responses prior to leaving the facility after your survey.

Your state facility sample (State Radiation Control participants only)

If you are using this protocol in conjunction with the 2001 survey, then the number of facilities you are asked to survey is based on your state's population relative to the rest of the U.S. For each facility you are asked to survey, you will also be provided with two back-up facilities in the event the primary facility does not wish to participate. Please do not select the back-up facilities over the primary facility merely because it is convenient or near a desirable location because biased selections may compromise the integrity of the random sample. However, we do understand that the finite resources and time of your state program may preclude you from traveling to some facilities. If you have any questions regarding your facility sample, contact Dave Spelic or Rick Kaczmarek.

What you should do before conducting a survey

- *(State Radiation Control participants only)* Review your facility sample, you may be aware of facilities that no longer are in service, or there may be locations you cannot visit. Please advise us as soon as possible regarding these matters.
- Check the calibration of your MDH survey meter and probe. They should be calibrated **BY CDRH** annually. If you need to make arrangements for calibration, contact David Spelic.
- Check the calibration of your sensitometer and densitometer. These instruments also should be calibrated **by CDRH** annually. Contact Dave Spelic if they are near the end of their current calibration period. It is acceptable to use a MQSA-calibrated sensitometer and/or densitometer.
- Practice putting the adult chest phantom together. This will verify that you have all the components and that the phantom has no damage.

DO NOT CONFUSE THE ADULT CHEST PHANTOM WITH THE PEDIATRIC PHANTOM !!

They look similar, however the pediatric phantom will have the words 'Peds chest' engraved on one side panel and on the probe arm. A photograph of the adult chest phantom is given in Appendix A.

What to bring with yourself to the survey site

You will need the following equipment and supplies for each survey:

- 1. CDRH Adult chest phantom.
- 2. CDRH yellow image-quality test-tool.
- 3. Calibrated MDH model 1015 or 1515 survey meter with calibrated 10X5-6 probe.
- 4. Aluminum filters for HVL determination.
- 5. Calibrated sensitometer and densitometer.
- 6. One box of STEP test control film and appropriate STEP worksheet.
- 7. Fog folder or other similar darkroom fog test tool.
- 8. Stop watch or clock for indicating minutes.
- 9. Protocol and survey form (along with facility questionnaire, if appropriate)
- 10. NEXT trifolds for the facility.

What items you are asked to return to CDRH (State Radiation Control participants only)

In addition to the paper survey form, we are requesting that you also enter your data into an Excel Spreadsheet provided by CDRH. You will be provided one spreadsheet disk for each facility you are asked to survey. The paper forms are actually printed copies of the Excel spreadsheet files; hence you may print further paper copies from the provided disk(s).

For each survey, you are asked to return the following to CDRH:

- Completed paper survey form (MAKE A PHOTOCOPY OF YOUR ORIGINAL).
- Facility questionnaire.
- Phantom films.
- Fog film(s).
- STEP film and worksheet.
- HVL graph.
- Spreadsheet disk with completed survey and facility forms.

INSTRUCTIONS FOR COMPLETING THE SURVEYOR WORKSHEET

A. Surveyor Information (items 1-3)

1) Surveyor name, 2) State, and 3) Survey date

Enter your complete name, your state and the date the survey was performed. For your state, use the two letter abbreviation, e.g., **TX**. For the survey date, use the notation MM/DD/YY e.g., $\underline{06/23/01}$.

B. Facility Information (items 4-9)

4) Facility name

Write the name of the facility on the surveyor worksheet as it appears on your NEXT sample list. If the entry on your sample list is incomplete, then write the full name of the facility on the form.

Facility name

EXAMPLE Montgomery General Hospital

5) Facility ID number

Enter the unique alpha-numeric number your state uses to identify this particular facility. This can be any combination of numbers and/or letters.

Facility

EXAMPLE <u>A15972XX</u>

6) Facility type

Enter the appropriate Facility Type code from the list provided below.

Facility type codes (see also next page)

01 = Private Practice:	An individual practitioner or a group of
	practitioners engaged in the same specialty. This
	includes a group of general practitioners. If you
	select ' <u>01</u> ', then please fill in ' Private practice
	specialty' (item 7).

02 = Hospital:	A facility that has beds for overnight care of patients.
03 = Multiple Specialty Practice:	Group of practitioners having different specialties. This category includes school infirmaries and school clinics.
04 = Mobile Unit:	An establishment that provides x-ray machines transported by motor vehicle.
05 = School:	An educational institution such as university medical schools. School infirmaries or clinics are coded 03. Medical school hospitals are coded 02.
06 = Private Laboratory:	A commercial facility that takes diagnostic radiographs by prescription but is not involved in film interpretation.
07 = Health Agency:	Private (non-profit) and government health agencies that do not fall under any of the above categories.
08 = Industry:	A plant dispensary or first-aid station.
09 = Nursing Home:	A facility with provisions for long-term care of patients.
10 = Breast Clinic:	A facility specializing in mammography and breast disease.
99 = Other:	Enter a brief description on item 6a on the surveyor worksheet.
Facilit	<u>y Type</u>

EXAMPLE

<u>02</u>

7) Private Practice Specialty

If the Facility Type code from item $6 = \frac{01}{2}$ (Private Practice) then determine the appropriate Private Practice Specialty code from the following list. If the Facility Type code is not $\frac{01}{2}$ skip items 7 and 7a.

7a) If you code the specialty $\frac{99}{29}$ (Other) then write a brief description of the specialty on the surveyor worksheet in item 7a.

Private Practice specialty codes

01 = Dental (EXCEPT	18 = Geriatrics (diseases related to
ORTHODONTICS)	old age)
02 = Orthodontics	19 = Hematology (diseases of the
03 = Medical G.P.	blood)
04 = Radiology	20 = Immunology
05 = Internal Medicine	21 = Infectious Diseases
06 = Surgery	22 = Nephrology (diseases of the
07 = Urology	kidney)
08 = Pediatrics	23 = Neurology
09 = Orthopedics	24 = Nuclear Medicine
10 = Gastroenterology	25 = Oncology (including Radiation
11 = Chiropractic	Therapy)
12 = Podiatry	26 = Ophthalmology
13 = Osteopathy	27 = Otolaryngology
14 = OB/GYN	28 = Physical Medicine
15 = Cardiology	29 = Pulmonary Medicine
16 = Electrophysiology	30 = Emergency/Shock
17 = Endocrinology	/Trauma Medicine
	99 = Other

Private Practice Specialty

EXAMPLE

<mark>04</mark>

8) Number of x-ray units at facility

Enter the total number of x-ray tubes the facility *routinely* uses to **perform adult chest** x-ray exams. *This includes portable x-ray units.*

Number	of x-ray	units

EXAMPLE

Total facility weekly chest examination workload Enter the facility's best estimate of the total number of adult chest x-rathey routinely perform each week. NOTE: This item refers to the number of exams , <i>not the total number</i>		
Total facility weekly workload		
<u>EXAMPLE</u>	<u>310</u>	
	Total facility weekly chest ex Enter the facility's be they routinely perform NOTE: This item ref	

9a) Number of films for a typical routine adult chest examination

8

For each projection listed, enter the number of films taken by the facility during a routine adult chest exam.

	<u>PA</u>	<u>AP</u>	LAT	<u>OBL</u>
<u>EXAMPLE</u>	<u>1</u>	<u>0</u>	<u>1</u>	<u>0</u>

C. X-ray equipment information (items 10-16)

At this time determine the x-ray unit the facility routinely uses most often for adult chest exams. This is the x-ray unit you should survey. *This should be the same x-ray unit on which the facility based its responses to the facility questionnaire.*

10) Single x-ray unit weekly patient workload

For the particular tube you are surveying, enter the facility's best estimate of the total number of patients they routinely perform adult chest exams on each week.

Single x-ray unit weekly workload

EXAMPLE <u>90</u>

11) X-ray control manufacturer

Determine the manufacturer of the x-ray unit and write the name in the space provided. Also determine the appropriate code for the manufacturer from the list provided in the *NEXT* Supplement B.1, **'Standard x-ray control manufacturers'** and enter into the appropriate spaces. If there is no code listed, then leave the Code blank.

	X-ray control manufacturer name	Code
EXAMPLE	General Electric	GECO

12) X-ray unit- month and year of manufacture

Determine as best possible the month and year of manufacture for the x-ray unit being surveyed. The date of manufacture is often indicated by a label on the control unit.

NOTE: The x-ray tube may have been replaced since initial installation. (This information is captured on the facility questionnaire).

	X-ray unit date of manufacture		
EXAMPLE	month 09	year 96	

13) Type of x-ray unit

From the following list, determine which category best describes the particular x-ray unit you will survey.

IMPORTANT: Computed radiography (CR) and digital x-ray systems predominantly use conventional x-ray tube systems! A CR or digital x-ray suite will often resemble a conventional x-ray suite using screens and film. *First consult with the technologist if you are unsure what form of imaging the facility is using*.

S	=	Standard radiographic x-ray system using screen-film technology.
С	=	Computed Radiography (CR) system.
		This system uses cassettes called Image Plates (IP) which look similar to traditional x-ray screens but contain no film. Be certain that the facility is using CR before coding the type of equipment 'C'.
D	=	Completely digital format x-ray imaging system such as flat panel technology. Other terminology used is DR (for 'direct radiography'). This technology uses no screens nor cassettes.

Type of x-ray equipment

EXAMPLE

14) X-ray generator phase

Determine the phase of the x-ray generator you are surveying and enter the appropriate code from the list below. The following tips may help you to obtain this information.

a) Consult facility staff or any available user documentation.

C

- b) Many times the manufacturer will list the phase along with other electrical information on an identification plate attached to the high-voltage generator.
- c) Observe the time settings on the control panel. Single phase units will most frequently have time stages in increments of 1/120th of a second, s (i.e. 0.008 s, 0.016 s, 0.032 s, etc.) Three-phase and higher (or constant potential) will usually have exposure time stages in decimal increments (e.g. 5 ms, 10 ms, 20 ms, 30 ms, etc.)

Generator Codes

S	=	Single-phase	
Т	=	Three-phase (r	

- = Three-phase (**not** falling load)
- **F** = Three-phase falling load
- **D** = DC filtered or capacitor discharge
- C = Constant potential
- \mathbf{H} = High frequency
- U = Unknown

T

Generator phase

EXAMPLE

15) Scatter suppressor

Determine the method of scatter suppression used with the particular x-ray unit you are surveying and enter the corresponding code on the survey form using the list of codes provided below.

If you cannot determine what form of scatter suppression is used, enter ' \underline{U} ' for **unknown**. *Enter a value of* ' \underline{N} ' *only if the facility explicitly states that they do not use any form of scatter suppression for adult chest x-rays.*

NOTE: The facility may incorporate specific grids into the patient set-up depending on the type of exam, so request a response to this item that is specific to adult chest x-ray exams.

Scatter suppressor codes

	G A N U	= = =	Grid Air gap None Unknown
		Scatt	ter suppressor
<u>EXAMPLE</u>		<u>G</u>	

16) Grid Ratio

If the facility uses a grid for scatter suppression during adult chest x-ray exams, then determine the grid ratio. The grid ratio may be marked on the grid. Code the grid ratio (\underline{UU}) if you can not determine this value.

	<u>Grid ratio</u>	
EXAMPLE	<u>12</u> : 1	

D. Screen-film and digital image-receptor information (items 17 - 30)

NOTE: For computed radiography systems skip to item 24. For digital x-ray systems, skip to item 29.

D.1 Screen and Film Information

17-18) Film brand and type

Determine from the facility technologist the brand and type of film typically used for adult chest exams. Write the name of the brand and type on the surveyor worksheet. Refer to the *NEXT* Supplement section C, **'Film codes'** and determine the film brand and type codes, respectively. Enter these in the appropriate spaces on the surveyor worksheet. If the film brand or type code is not on the list, write the complete names of each product, and the name, address and telephone number of the supplier in the comment section, if such information is available.

Film brand code

Film brand name

EXAMPLE

EKCO

Kodak

	Film type code	Film type name
<u>EXAMPLE</u>	TML	T-Mat L

19-21) Film size

Enter the film size that the facility typically uses for adult chest exams in inches or centimeters. The **width** (item 19) is the dimension across the body (the shorter dimension.) The **length** (item 20) is the dimension along the length of the body (head to toe). Specify the units as inches (IN) or centimeters (CM) in *item 21*.

	Film size:	Width	Length	<u>Units</u>
EXAMPLE		<u>14</u>	<u>17</u>	IN

22-23) Screen brand and type

Determine from the facility technologist the brand and type of screens typically used for adult chest exams. Write the name of the brand and type on the surveyor worksheet. Refer to the *NEXT* Supplement section C, **'Screen codes'** and determine the screen brand and type codes, respectively. Enter these in the appropriate spaces on the surveyor worksheet. If the screen brand or type code is not on the list, write the complete names of each product, and the name, address and telephone number of the supplier in the comment section, if such information is available. **Skip** *items 24 through 30*.

	Screen brand code	Screen brand name
<u>EXAMPLE</u>	EKCO	Kodak
	Screen type code	Screen type name
<u>EXAMPLE</u>	LNM	Lanex Medium

D.2 Computed radiography and digital imaging information (items 24-30) Computed radiography: answer items 24-28. Other digital x-ray systems answer items 29 and 30.

24) CR System installation date

Determine the installation month and year for the CR system. This date may or may not be the same as the installation date for the x-ray system, so verify this date with facility personnel to be certain.

	CR system installation date:	month	<u>year</u>
<u>EXAMPLE</u>		<u>07</u>	<mark>99</mark>

25) CR Imaging plate manufacturer and plate size

Determine the true manufacturer (not vendor) of the CR system and write the name in the space provided. Determine also the size of the imaging plate used for routine adult chest exams and enter this along with the appropriate units.

	CR imaging plate manufacturer	Size: Width	Length	units
EXAMPLE	Fuji	<u>14</u>	<u>17</u>	IN

26) CR system vendor

Determine the vendor of the CR system. The vendor may be different from the actual manufacturer you identified in *item 25*. For instance Fuji CR systems are sold by vendors such as Philips, Siemens and Marconi, among others. Refer to the NEXT supplement section B.2 for a list of known vendors of CR and digital x-ray imaging equipment.

CR system vendor

EXAMPLE

Siemens

27) CR system speed

CR systems are typically configured to respond in a manner that may be characterized in terms of the traditional concept of screen-film combination speed. Determine from the technologist or other staff members the speed at which the CR system is configured to perform for adult chest radiographs. If you can not determine this enter <u>UNK</u>.

CR system speed

EXAMPLE 200

28) CR Dual-energy subtraction

Determine whether the facility does energy subtraction imaging using CR. In this method, two cassettes are used for a single x-ray projection, separated by a filter material (typically copper). Enter a ' \underline{Y} ' (Yes) or ' \underline{N} ' (No) on the surveyor worksheet. Skip to section E, *Technique Data* (next page).

29) Digital Radiography (DR) and other digital systems- vendor name and model

Determine the vendor (such as Siemens, GE, etc.) and model name of the DR system and write the names in the space provided on the surveyor worksheet.

Digital Radiography:

<u>EXAMPLE</u>	vendor:	General Electric
EXAMPLE	model:	GE-D5000R

30) Digital Radiography and other digital systems- image receptor manufacturer

Determine the actual manufacturer (not necessarily the same as the vendor) of the digital image receptor and write the name on the surveyor worksheet.

Digital Radiography- image receptor manufacturer

EXAMPLE

Direct Radiography

E. Technique Data (items 31-38)

This next section pertains specifically to the adult chest PA/AP projection. The *NEXT* chest phantom is equivalent to a human patient standing 5'8" tall, weighing 164 pounds and having a 23 cm PA chest. Provide this information to the facility technologist so that he or she can configure the x-ray equipment as they would for clinical exams.

At this time do the following:

- 1. Ask the facility technologist to configure the x-ray gantry for an adult chest exam. This includes positioning the x-ray tube, selecting the appropriate grid (if appropriate), and collimating the beam.
- 2. Request a loaded film cassette of the same film size and type you recorded *in item 17 and 18* for adult chest radiographs. *Use this same cassette for all measurements.*
- 31) Source-to-film distance (also referred to as 'Source-to-Image Distance' or SID) Measure and record in centimeters the source-to-film distance. The 'Source' is the x-ray tube focal spot location, and is usually indicated on the tube. You should insert a film cassette partially into the bucky/film holder in order to more accurately determine the location of the film.

NOTE: Centimeters = inches x 2.54

Source-to-film distance

EXAMPLE <u>190.0</u> cm

32) Source-to-patient support distance

EXAMPLE

Measure and record **in centimeters** the distance from the '**Source**' (tube focal spot) to the surface that the patient rests against during the exam. This is essentially the front plate of the wall bucky.

Source-to-patient support distance

EXAMPLE <u>178.5 cm</u>

33) Projection code

Facilities will typically take either an anterior-posterior (AP) film (patient faces toward the x-ray tube) or a posterior-anterior (PA) film (patient faces away from x-ray tube) as part of a complete chest x-ray exam. Determine which of these two projections the facility acquires and enter the appropriate two-letter code:

PA AP	=	Posterior-anterior exam Anterior-posterior exam
	<u>Proje</u>	ection code
	<u>PA</u>	

34) Exposure technique (manual or automatic exposure (AEC))

Determine whether the facility uses a manual technique or uses automatic exposure control (AEC) and record the appropriate code:

Μ	=	manual technique
Α	=	automatic exposure controlled technique

If the facility uses a manual technique then skip items 35 and 36.

Exposure technique

EXAMPLE A

35) AEC detector configuration (AEC technique only)

Refer to the following diagram and enter the code that represents the detector configuration the facility uses for automatic exposure controlled exams.

NOTE: If the unit has a detector configuration that does not appear like the one shown below, then enter '6' for the code and sketch on the surveyor worksheet a diagram of the configuration and indicate which cells are used.



36) Density setting (AEC technique only)

Ask the technologist what density control setting they typically use for an adult chest PA or AP exam. Remember that our NEXT patient is 5'8" tall, weighs 164 pounds, and has a 22.5-cm chest dimension in the AP or PA direction.

Density setting (AEC only)

EXAMPLE

+1

37) Technique Charts (manual and AEC modes)

Determine from the technologist if the facility maintains technique charts for the specific unit you are surveying. If the technologist claims that technique charts exist, but can not locate them, enter 'Y'. Enter 'N' only after verifying that they do not maintain technique charts for the x-ray unit you are surveying.

38) Technique factors for routine adult chest exam: kVp, mAs, tube current, and exposure time.

Ask the facility technologist to select at the console the technique factors for an adult chest PA/AP x-ray exam. Enter the **selected** factors on the worksheet in the appropriate spaces.

Ask the technologist to provide technique factors for all other possible projections (Lateral and Oblique) their facility use during the routine adult chest exam. If

they do not perform a particular projection, then enter 'NA' for the respective cells.

NOTE: Only those technique factors *selected at the console prior to exposure* should be entered into *items 38a through 38d*. Do not attempt to estimate the exposure time in 38d using the output from the MDH meter, for example.

38a)	kVp	38c)	Tube current (mA)
38b)	mAs (manual mode	38d)	Exposure time (in milliseconds-
	only)		manual mode)

EXAMPLE

	38a	38b	38c	38d
	kVp	mAs	Tube current (mA)	Exposure time (ms)
AP/PA	120	12	400	30
Lateral	140	20	400	50
Oblique	NA	NA	NA	NA

Technique factors for routine adult chest exam

F. Exposure measurements (items 39-45)

In this section you will set up the phantom and measure x-ray exposure and time measurements according to the facility's clinical technique. You will also acquire one or more films for image quality evaluation and for assessing darkroom fog, if applicable.

Watch your units! Record exposure values in **milliroentgens (mR)**, and record time measurements in **milliseconds (ms)**. NOTE: 1 Roentgen = 1000 milliroentgens, and 1 second = 1000 milliseconds.

Good example of MDH exposure entry:



Refer to the section corresponding to the type of imaging the facility does.

Screen-film systems:	Complete section F.1	below.
Computed radiography:	Complete section F.2	beginning on page 25.
Other digital systems:	Complete section F.3	beginning on page 30.

F.1 Screen-Film X-ray Systems (items 39-45)

39-45) X-ray Exposure and time measurements

Prepare the adult chest phantom- refer to Appendix A for details on assembly and proper placement of the image quality test tool.

You will acquire two films:

- 1. Phantom image including the test tool. This film will be used to obtain background optical density and to score the test tool image.
- 2. Darkroom fog film. This film will be taken with the last of the four exposures and used to measure levels of darkroom fog. *This film must have a background density of 1.0 or greater to be useful for the darkroom fog test.*

Procedure

1. Position the phantom so that it rests directly against the front plate of the wall bucky or the table top- refer to the diagram below. **Remember** the phantom simulates the radiation absorption and scatter properties presented by a real patient, so the phantom should rest against the same surface the patient would. Center the phantom transversely (across the patient, left to right). The technologist should already have positioned the tube and collimated the beam.

TIP: In facilities that do upright exams with a wall bucky, you may be able to move the tabletop close to the bucky to support the phantom.



- 2. Position the phantom vertically (head to foot) as follows, depending on the exposure mode:
 - > *Manual mode*: such that the phantom is approximately centered
 - ➤ AEC mode: such that all relevant AEC cells are covered. The phantom may thus not be centered vertically, but shifted up slightly in order to cover the detectors.
- 3. Place the *Radcal* MDH probe in the probe holder.
- 4. Set the mode selector to 'PULSE EXPOSURE'
- 5. Set the threshold thumbwheel to **0.2** for single phase units. For three phase and constant potential units, set the threshold to **0.5**.
- 6. Set the function selector to 'MEASURE'.

NOTE: If the x-ray tube has not been used for a period of time such that it is "cold," make a couple of exposures (with assistance from the technologist if needed) to warm the tube.

- 7. Obtain a loaded cassette of the appropriate film type and size (see *items 17-20*) and insert into the bucky / cassette holder.
- 8. VERIFY that the technique factors set at the console are those that you recorded in *items 38a 38d*.
 Verify that your cassette and film are consistent with your responses to items 19-24, the typical screen-film system used for routine adult chest radiography.
- 9. Make an exposure and record ONLY the MDH exposure (*item 39*). DO NOT record the time measurement from the MDH meter at this time. (This first exposure serves to initialize the MDH for subsequent exposures.) Record the value of the exposure in **milliroentgens (mR)**.
- 10. Remove the film cassette and process the film. Reload the cassette and use for the remaining exposures.
- 11. Measure the optical density of the film anywhere in the main body portion of the phantom image (refer to illustration in section H). Do not record this number on the surveyor worksheet, but keep in mind whether the number is ≥ 1.0 .

CHECK THE FILM NOW! Be certain the film was produced without problems. If the film is unusually light (background OD < 0.60) or very dark (background OD > 2.5), or has other features that suggest a problem with processing or other source, then:

- Check with the technologist, or check other clinical chest films, if available, for similar appearance/features.
- Verify your clinical technique factors and set-up.
- > Make certain you are using the correct film and/or cassette.
- Document your actions/findings in the comments section on the Surveyor Worksheet.
- 12. When you are satisfied the film is acceptable, label the processed film '*Phantom Film Evaluation*', and include the facility name and date on the film. Section H describes the methods for measuring background optical density and scoring the test tool image.
- 13. Make a second, and third exposure. No useful image is needed from this film, but it is important that there be film in the cassette. After each exposure :
 - \blacktriangleright Record the exposure in mR (*items 40 and 42*)
 - Switch the MDH selector to PULSE DURATION and record the exposure time in milliseconds (ms) (*items 41 and 43*). Switch the MDH selector back to PULSE EXPOSURE.

IF the background density of your phantom film is between 1.0 and 2.5 (from procedure step 11),

- *A.* Remove the cassette and discard the exposed film. Reload the cassette with a new piece of film and replace the cassette into the bucky/film holder.
- B. Make a fourth exposure and record the MDH exposure and time (*items 44 and 45*). Do NOT process this film yet! Put it aside for the darkroom fog test (section I).
- *C.* Proceed to section G and perform the HVL measurements.

IF the background density of your phantom film is less than 1.0 or greater than 2.5,

- *A.* Make a fourth and final exposure with the **same** cassette and same technique factors as before. Record the MDH exposure and time *(items 44 and 45)*.
- *B.* Remove the cassette, process or dispose of the exposed film (this film can be discarded), and reload the cassette with a new piece of film.

You will now need to adjust the x-ray technique factors to produce a film dark enough to use for the darkroom fog test.

- C. Using a **manual technique**, increase (or *decrease*, if your film was too dark) the exposure mAs (mainly the exposure time) by a factor of approximately **2** and make another exposure. This should be adequate to produce a phantom film having an acceptable background optical density. **Do NOT process this film yet!** Put the cassette aside for the darkroom fog test (section I).
- *D.* Perform the entrance skin exposure calculation (item 45a below) and then proceed to section G and perform the HVL measurements.

45a) Entrance skin exposure calculation

Use the procedure below to compute the entrance skin exposure. This is the entrance exposure that a standard patient with an AP chest dimension of 22.5 cm would receive using the same clinical factors and conditions you made your exposure measurements with.

- 1. Compute the average exposure resulting from your four exposure measurements from section F.
- 2. Refer back to item 32 (Source-to-patient support distance). Using this distance measurement and your mean exposure value from step 1 above, compute the entrance skin exposure to the standard NEXT patient (having a 22.5 cm AP chest dimension.).

IMPORTANT: Your value for *Source-to-patient support distance* should be expressed in centimeters, otherwise the below calculation will be incorrect.

$$ESE(mR) = \left(\frac{Source \text{ to patient support distance}(cm) - 50.9 \text{ cm}}{Source \text{ to patient support distance}(cm) - 22.5 \text{ cm}}\right)^2 x \text{ Average Exposure}(mR)$$

An example of this calculation is given on the following page.



Diagram of geometry used to calculate entrance skin exposure

EXAMPLE

Source-to-patient support distance = 68.5 inches. [Convert to cm : 68.5 in x 2.54 cm/in = 174.0 cm]

Exposure data = 33.5 mR, 33.2 mR, 32.9 mR, and 33.1 mR.

1. Average Exposure =
$$(33.5 + 33.2 + 32.9 + 33.1)$$
 mR = 33.2 mR
2. Entrance skin exposure = $(\frac{174.0 \text{ cm} - 50.9 \text{ cm}}{174.0 \text{ cm} - 22.5 \text{ cm}})^2 \times 33.2 \text{ mR}$
= $(\frac{123.1 \text{ cm}}{151.5 \text{ cm}})^2 \times 33.2 \text{ mR}$
= $0.8125^2 \times 33.2 \text{ mR}$
= 21.9 mR

NOTE: As a check of your results, the entrance exposure should be smaller than the average of your exposure measurements, because a 22.5 cm patient is further from the focal spot than the MDH probe.

F.2 Computed Radiography X-ray Systems (items 39-45)

39-45) X-ray Exposure and time measurements

Prepare the adult chest phantom- refer to Appendix A for details on assembly and proper placement of the image quality test tool.

You will acquire ONE film containing an image of the phantom + test tool. This film will be used to determine background optical density and to score the test tool image. If the facility maintains a darkroom, you will perform a darkroom fog test even though the facility may not typically handle clinical chest films there. You are asked to obtain a loaded standard film cassette for the darkroom fog test.

Procedure

1. Position the phantom so that it rests directly against the front plate of the wall bucky or the table top- refer to the diagram on the following page. **Remember**the phantom simulates the radiation absorption and scatter properties presented by a real patient, so the phantom should rest against the same surface the patient would. Center the phantom transversely (across the patient, left to right) using the light field. The technologist should already have positioned the tube and collimated the beam.

TIP: In facilities that do upright exams with a wall bucky, you may be able to move the tabletop close to the bucky to support the phantom.

- 2. Position the phantom vertically (head to foot) as follows, depending on the exposure mode:
 - > *Manual mode*: such that the phantom is approximately centered with the position indicators/light field.
 - AEC mode: such that all relevant AEC cells are covered. The phantom may thus not be centered vertically with the bucky surface, but shifted up slightly in order to cover the detectors. Adjust the x-ray tube position vertically as needed to recenter the phantom in the beam according to the light field.
- 3. Collimate the beam down to the edges of the phantom- refer to the following illustration.



- 4. Place the *Radcal* MDH probe into the probe holder.
- 5. Set the mode selector to 'PULSE EXPOSURE'
- 6. Set the threshold thumbwheel to **0.2** for single phase units. For three phase and constant potential units, set the threshold to **0.5**.
- 7. Set the function selector to 'MEASURE'.

NOTE: If the x-ray tube has not been used for a period of time so that it is "cold," make a couple of exposures (with assistance from the technologist if needed) to warm the tube, if possible.

- 8. Insert an unexposed CR imaging plate (IP) appropriate for adult chest exams into the bucky / cassette holder.
- 9. Verify that the technique factors set at the console are those you recorded in items 38a-38d.
- 10. Make an exposure and record ONLY the MDH exposure *(item 39)-* do NOT record the time measurement from the MDH meter at this time. This first exposure serves to initialize the MDH for subsequent exposures. Record your answer in **milliroentgens (mR)**.
- 11. Remove the CR cassette and process it as follows:

Ask the technologist to process the CR cassette using the menu option(s) the facility normally would use for an adult PA or AP chest radiograph. RECORD in the comments section a brief description of the specific imaging

processing that was performed. Retain the same CR plate for the remaining exposures after it has been processed.

Ask for a hardcopy film of the phantom image using a size they normally would use for adult clinical chest films. If the facility previews and manipulates the image on a computer monitor prior to printing, ask the appropriate person to follow normal procedures prior to printing the phantom film.

CHECK THE FILM! Be certain the film was produced without problems. If the film is unusually light (background < 0.60) or dark (background > 2.5) or has other features that suggest a problem with the laser film processor or other source, then check:

- > Other clinical chest films, if available, for similar appearance/features
- Your clinical technique factors
- The algorithm used: the facility usually has particular image processing routines for different exams that are applied to the image prior to producing a film.

Document your actions in the comments section on the Surveyor Worksheet.

- 12. Label the processed film "*Phantom Film Evaluation*" and include the facility name and date on the film. Section H describes the method for measuring background optical density and for scoring the test tool image.
- Replace the CR plate into the bucky/holder and make a second, third and fourth exposure without removing the cassette. No useful image is needed from these exposures, and the CR cassette can safely be exposed several times without being damaged. After each exposure:
 - Record the exposure in mR. (*items 40, 42, and 44*).
 - Switch the MDH selector to **PULSE DURATION** and record the exposure time in milliseconds (ms) *(items 41, 43, and 45)*. Switch the MDH selector back to **PULSE EXPOSURE**.
- 14. Process the CR cassette and the return it to the department's storage area.

This completes the exposure measurement procedure. You will now acquire a film for performing the darkroom fog test.

NOTE: If the facility's department is 'all digital' and does not routinely handle ANY standard radiographic film in their darkroom, then do not perform the darkroom fog test, and proceed directly to section G.

- 15. *Darkroom fog film*: Obtain a loaded standard *film* cassette from the technologist. Request a size that will adequately cover most if not the entire phantom (a suggested minimum size is 10 in x 12 in or 24 cm x 30 cm). The film type should be one the facility uses routinely for general purpose exams.
- 16. Configure the x-ray technique for a manual mode exposure. If the kVp is below 100, adjust the kVp to at least 100 kV. Select a combination of tube current and exposure time to obtain an exposure of 15-20 mAs. This technique should give a film with sufficient background density for performing the darkroom fog test. The phantom should still be positioned as it was for the exposure measurements.
- 17. Install the cassette into the bucky and make an exposure. Put this cassette aside until you are ready to perform the darkroom fog test.
- 18. Perform the entrance skin exposure calculation (item 45a below) and then proceed to section G and perform the HVL measurements.

45a) Entrance skin exposure calculation

Use the procedure below to compute the entrance skin exposure. This is the entrance exposure that a standard patient with an AP chest dimension of 22.5 cm would receive using the same clinical factors and conditions you made your exposure measurements with.

- 3. Compute the average exposure resulting from your four exposure measurements from section F.
- 4. Refer back to item 32 (Source-to-patient support distance). Using this distance measurement and your mean exposure value from step 1 above, compute the entrance skin exposure to the standard NEXT patient (having a 22.5 cm AP chest dimension.).

IMPORTANT: Your value for *Source-to-patient support distance* should be expressed in centimeters, otherwise the below calculation will be incorrect.

$$ESE(mR) = \left(\frac{Source \text{ to patient support distance}(cm) - 50.9 \text{ cm}}{Source \text{ to patient support distance}(cm) - 22.5 \text{ cm}}\right)^2 x \text{ Average Exposure}(mR)$$

An example of this calculation is given on the following page.



Diagram of geometry used to calculate entrance skin exposure

EXAMPLE

Source-to-patient support distance = 68.5 inches. [Convert to cm : 68.5 in x 2.54 cm/in = 174.0 cm]

Exposure data = 33.5 mR, 33.2 mR, 32.9 mR, and 33.1 mR.

3. Average Exposure =
$$\frac{(33.5 + 33.2 + 32.9 + 33.1)}{4}$$
 mR = 33.2 mR
4. Entrance skin exp osure = $\left(\frac{174.0 \text{ cm} - 50.9 \text{ cm}}{174.0 \text{ cm} - 22.5 \text{ cm}}\right)^2 x 33.2 \text{ mR}$
= $\left(\frac{123.1 \text{ cm}}{151.5 \text{ cm}}\right)^2 x 33.2 \text{ mR}$
= $0.8125^2 x 33.2 \text{ mR}$
= 21.9 mR

NOTE: As a check of your results, the entrance exposure should be smaller than the average of your exposure measurements, because a 22.5 cm patient is further from the focal spot than the MDH probe.

F.3 Digital X-ray Systems (items 39-45)

39-45) X-ray exposure and time measurements

This section describes procedures for measuring x-ray exposure and time on digital x-ray systems that have no removable form of image cassette. These systems may provide for laser film output (hard-copy) as well as for viewing of the image on a computer monitor (soft-copy).

You will acquire **one laser film** containing an image of the phantom + test tool. Inform the technologist of this intent prior to making exposures so that they can make appropriate arrangements if needed. This film will be used to determine background optical density and to score the test tool image. If the facility maintains a darkroom, you will perform a darkroom fog test even though the facility may not typically handle clinical chest films there. You are asked to obtain a loaded standard film cassette for performing the darkroom fog test.

At this time prepare the adult chest phantom- refer to Appendix A for details on assembly and proper placement of the image-quality test tool.

Procedure

1. Position the phantom so that it rests directly against the front plate of the upright image receptor or the table top. **Remember**- the phantom simulates the radiation absorption and scatter properties presented by a real patient, so the phantom should rest against the same surface the patient would. Center the phantom transversely (across the patient, left to right) using the light field. The technologist should already have positioned and collimated the tube housing.

TIP: In facilities that do upright exams with a wall bucky, you may be able to move the tabletop close to the bucky to support the phantom.

- 2. Position the phantom vertically (head to foot) as follows, depending on the exposure mode:
 - Manual mode: such that the phantom is approximately centered with the position indicators/light field.
 - AEC mode: such that all relevant AEC cells are covered. The phantom may thus not be centered vertically with the bucky surface, but shifted up slightly in order to cover the detectors. Adjust the x-ray tube position vertically as needed to recenter the phantom in the beam according to the light field.
- 3. Collimate the beam down to the edges of the phantom- refer to the following illustration.



- 4. Place the *Radcal* MDH probe into the probe holder.
- 5. Set the mode selector to 'PULSE EXPOSURE'
- 6. Set the threshold thumbwheel to **0.2** for single phase units. For three phase and constant potential units, set the threshold to **0.5**.
- 7. Set the function selector to 'MEASURE'.

NOTE: If the x-ray tube has not been used for a period of time such that it is cold, make a couple of exposures (with assistance from the technologist if needed) to warm the tube, if possible.

- 8. Ask the technologist to configure the control panel with the settings typically used to acquire an image of an adult PA chest. Verify that these are the same technique factors you recorded for *items 38a-38d*.
- 9. Make an exposure (you may need assistance with the control panel) and record ONLY the MDH exposure *(item 39)*. DO NOT record the time measurement from the MDH meter at this time. This first exposure serves to initialize the MDH for subsequent exposures. Record your answer in **milliroentgens (mR)**
- **10.** Ask the technologist to produce a hardcopy (film) using the menu option(s) the facility normally would use for an adult PA or AP chest radiograph. If the facility previews and manipulates the image on a computer monitor prior to printing, ask the appropriate person to follow normal procedures prior to printing the phantom film.

CHECK THE FILM! Be certain the film was produced without problems. If the film is unusually light (background OD > 0.6) or dark (background OD > 2.5) or has other features that suggest a problem with the laser film processor or other source, then check:

- > Other clinical chest films, if available, for similar appearance/features
- Your clinical technique factors
- The algorithm used: the facility may have particular image processing routines for different exams that are applied prior to producing a film.

Document your actions in the comments section on the Surveyor Worksheet.

- 11. Label the processed film *'Phantom Film Evaluation'*, and include the facility name and date on the film.
- 12. Return to the x-ray suite and make a second, third and fourth exposure. No useful image is needed from these exposures. After each exposure:
 - ▶ Record the exposure in mR. (*items 40, 42, and 44*).
 - Switch the MDH selector to PULSE DURATION and record the exposure time in milliseconds (ms) (*items 41, 43, and 45*). Switch the MDH selector back to PULSE EXPOSURE.

This step completes the exposure measurement procedure. You will now acquire a film for performing the darkroom fog test.

NOTE: If the facility's department is 'all digital' and does not routinely handle ANY standard radiographic film in their darkroom, then do not perform the darkroom fog test, and proceed directly to section G.

13. *Darkroom fog film*: Obtain a loaded standard *film* cassette from the technologistrequest a size that will adequately cover most if not the entire phantom (a suggested minimum size is 10 in x 12 in or 24 cm x 30 cm). The film type should be one the facility uses routinely for general purpose exams.

NOTE: The digital unit may or may not provide a means of exposing a standard film cassette. You may need to use the table top (if there is one), or ask to use an x-ray suite where a standard cassette can be exposed.

14. Configure the x-ray technique for a manual mode exposure.) If the kVp is below 100, adjust the kVp to at least 100 kV. Select a combination of tube current and exposure time to obtain an exposure of 15-20 mAs. This technique should give a

film with sufficient background density for performing the darkroom fog test. The phantom should still be positioned as it was for the exposure measurements.

- 15. Install the cassette into the bucky and make an exposure. Put this cassette aside until you are ready to perform the darkroom fog test.
- 16. Perform the entrance skin exposure calculation as described below and then proceed to section G and perform the HVL measurements.

45a) Entrance skin exposure calculation

Use the procedure below to compute the entrance skin exposure. This is the entrance exposure that a standard patient with an AP chest dimension of 22.5 cm would receive using the same clinical factors and conditions you made your exposure measurements with.

- 1. Compute the average exposure resulting from your four exposure measurements from section F.
- 2. Refer back to item 32 (Source-to-patient support distance). Using this distance measurement and your mean exposure value from step 1 above, compute the entrance skin exposure to the standard NEXT patient (having a 22.5 cm AP chest dimension.).

IMPORTANT: Your value for *Source-to-patient support distance* should be expressed in centimeters, otherwise the below calculation will be incorrect.

$$ESE(mR) = \left(\frac{Source to \ patient \ support \ distance(cm) - 50.9 \ cm}{Source to \ patient \ support \ distance(cm) - 22.5 \ cm}\right)^2 x \ Average \ Exposure(mR)$$

An example of this calculation is given on the following page.



Diagram of geometry used to calculate entrance skin exposure

EXAMPLE

Source-to-patient support distance = 68.5 inches. [Convert to cm : 68.5 in x 2.54 cm/in = 174.0 cm]

Exposure data = 33.5 mR, 33.2 mR, 32.9 mR, and 33.1 mR.

5. Average Exposure = (33.5 + 33.2 + 32.9 + 33.1) mR = 33.2 mR 6. Entrance skin exposure = $\left(\frac{174.0 \text{ cm} - 50.9 \text{ cm}}{174.0 \text{ cm} - 22.5 \text{ cm}}\right)^2 x 33.2 \text{ mR}$ = $\left(\frac{123.1 \text{ cm}}{151.5 \text{ cm}}\right)^2 x 33.2 \text{ mR}$ = $0.8125^2 x 33.2 \text{ mR}$

NOTE: As a check of your results, the entrance exposure should be smaller than the average of your exposure measurements, because a 22.5 cm patient is further from the focal spot than the MDH probe.

G. Beam Quality Determination at Clinical kVp (items 46-53)

46-52) Half-value layer (HVL) exposure measurements

Perform the half-value layer (HVL) exposures with the x-ray unit in the MANUAL mode. You should adjust the exposure (exposure time or mAs) such that an MDH exposure reading of at least 200 mR results. You can also move the phantom slightly closer to the x-ray tube to increase the exposure to the MDH probe with minimal increase in the technique.

1. Verify that the x-ray console is in the MANUAL mode and that the kVp selected is the same as the kVp setting used for the exposure measurements of section F.

It is very important that the kVp be the same as the kVp used for the exposure measurements of section F.

- 2. Adjust the phantom position such that the MDH probe is more centered in the xray beam.
- 3. Review your exposure values from section F (items 39-44) and estimate an exposure time or mAs that will provide a 'zero aluminum' exposure of at least 200 mR :

new exposure time (or mAs) = old exposure time (or mAs) $x \frac{200 \, mR}{MDH \, Exp}$ from section F

For example, if

- ➤ Your MDH exposure numbers are about 75 mR from section F.
- The facility selected a mAs (manual mode) of 10 mAs.
- > To determine HVL the mAs should be adjusted to about

 $10 mAs \ x \ \frac{200 mR}{75 mR} = 26.6 mAs$, or about 27 mAs.

Make an exposure with no aluminum filter in the beam (*item 46*), and verify that 4. an exposure of at least 200 mR results. Record this first exposure on the surveyor worksheet.

MDH Exposure (NO Al)

EXAMPLE 213

- 5. Securely attach 2.0 mm of aluminum to the collimator housing and verify using the light-field that the entire chamber volume of the MDH probe is covered.
- 6. Make an exposure and record the MDH reading *(item 47)* on the surveyor worksheet.
- 7. Make further exposures for additional **TOTAL** thicknesses of 3.0, 4.0, and 5.0 mm of aluminum *(items 48, 49, and 50)*. For each exposure record your MDH exposure on the worksheet. Your exposures should decrease with increasing aluminum in the beam- see the data table below for an example. If your exposures remain constant or increase, then the system may be in automatic exposure mode.
- 8. Verify that your final MDH exposure value with 5.0 mm of aluminum is beyond the half-value point (i.e. this last exposure should be less than ½ of the first exposure with no aluminum, item 46.)
- 9. If you need to add additional aluminum and make further exposures, add 1.0 mm increments and record both the exposure and the TOTAL aluminum thickness *(items 51 and 52)* in the appropriate space provided on the worksheet.
- 10. **CHECK YOUR DATA**. Prior to proceeding, inspect your numbers and verify that there is a general decreasing trend of your exposure values with increasing thickness of aluminum. If the values look suspect, verify that the x-ray unit was configured for a manual technique.

53) Procedure for plotting data and determining HVL

Review your exposure data to be certain it is valid for HVL determination (see example data on the following page) Do not proceed to graph your HVL data while you are at the facility- this task can be completed back at your office.

- 1. Using the provided semi-log graph paper, plot your exposure values on the vertical axis, and your aluminum TOTAL thicknesses on the horizontal axis. DO NOT PLOT THE FIRST (zero-aluminum) EXPOSURE (*item 46*).
- 2. Draw a straight line that best fits your plotted data points.
- 3. Divide your zero-aluminum exposure value *(item 46)* by 2, and then locate this number on the vertical axis of your graph. At this point on the vertical axis now draw a horizontal line over to the line you made in step 2 above.
- 4. Read off the x-axis value of this intersection point. This is your HVL- enter this number on the surveyor worksheet *(item 53)*. NOTE: Your units should be in mm of aluminum- refer to the example below.

Example: The table of HVL data shown on the following page results in a HVL of 2.6 mm Al.

HVL(mm Al) from data plot

EXAMPLE 2.6

500



Aluminum (mm)	Exposure (mR)
0	293
2	157
3	112
4	85
5	57

H. Phantom-Film Background Optical Density and Image Quality Scores (items 54-59)

This section describes measurement of optical densities of the phantom film and test-tool image scoring. You are also asked to report exactly which of the test-tool objects were visible to you.

Before proceeding, please check that your densitometer is in good agreement with an available calibration strip. If CDRH calibrated your densitometer recently, a calibration strip should have been provided when the unit was returned to you.

54) Number of meshes visible on the phantom film

- 1. Place the phantom film on a viewbox that the facility typically uses to view x-ray films. **IMPORTANT: Make sure the film is oriented as shown in the diagram on page 35**. The test tool image should be at the top with the circular edge toward the left. Mask the film to cut down on ambient light from the film and viewbox. Turn off neighboring viewbox panels if possible.
- 2. Count the number of copper mesh patterns you can visualize on the test tool image.
 - > Count a mesh square only if you can clearly see the checkerboard-like pattern
 - Do not count a mesh pattern if you can see interference with a stationary grid pattern. (This typically has the appearance of a series of either vertical or horizontal lines that are spaced widely compared with the spacing of the mesh pattern.)
- 3. Record your answer on the surveyor worksheet (*item 54*). Indicate with an 'X' exactly which meshes you could see using the diagram on the surveyor worksheet (see example below.)

55) Number of holes visible on the phantom film

- 1. Next score at the viewbox the number of holes visible on the film:
 - > Count a hole only if you can visualize the entire circular edge.
 - Include the center hole in your count.
- 2. Record your answer on the surveyor worksheet *(item 55)*. Using the diagram on the surveyor worksheet, indicate with an 'X' exactly which holes you could see.

	Number of meshes	Number of holes
EXAMPLE:	<u>5</u>	<u>4</u>



Test tool score form on the surveyor worksheet

DO NOT MARK YOUR SCORES ON THE PHANTOM FILM !!

- Make sure you orient your phantom film so that the test tool has the same orientation as shown above. (Test tool at top, circular edge of test tool toward the left.)
- Only mark your scores on the drawing on the surveyor worksheet.

56-59) Phantom film background optical density

1. Using your calibrated densitometer measure the background optical density of the phantom film in four locations marked with a \otimes as shown in the illustration below *(items 56-59)*. Be certain to zero your densitometer before making measurements.

NOTE: You may need to cut into the phantom film in order to reach the central region of the film- cutting is acceptable as long as you do NOT cut into the test-tool image. Suggested areas to cut are shown as a dotted boundaries on the following illustration.



I. Darkroom fog evaluation (items 60- 64)

The darkroom fog test should be performed in any facility that has a darkroom, regardless of the their imaging technology.

Conventional screen-film systems: start at item 60. CR and digital systems: If the facility has a darkroom then perform the darkroom fog test- start at item 61. It is assumed you have a pre-exposed film with which to do the test.

60) Darkroom / Daylight system

- 1. Indicate on the surveyor worksheet whether the facility has a conventional darkroom or uses a daylight loader *system for routine handling of adult chest x-ray films*.
 - C = Conventional darkroom

C

D = **D**aylight system

Darkroom /Daylight system

EXAMPLE:

2. If the facility has a darkroom then proceed with the fog test even if the facility uses a daylight loader system.

Take with you into the darkroom:

- > The cassette with pre-exposed film from section F.
- A timer/stop or watch for clocking two minutes of time.
- \succ The fog folder.

61-64) Fog border determination and optical density measurements

- 1. Inspect the darkroom for the area where clinical film is routinely handled. Make certain that any safelights that are routinely used are 'ON' during the test.
- 2. Open the cassette, and quickly insert the film into the fog folder with an orientation as shown below. Make certain that the folder edge lies flat against the film and does not lift up away from it (this would result in a fuzzy fog border.)

NOTE: If the facility uses single-sided emulsion film, be certain that the emulsion side of the film is facing upward.

3. Let the film sit for two minutes of exposure. Move back away from the film during the two minute exposure so that your body does not accidentally shade the film from sources of fog.

- 4. Quickly remove the film from the fog folder and process the film (if the facility uses a daylight processor, you will need to reload the film into the cassette.)
- 5. Using a viewbox, inspect the film for a fog border.

If you see NO visible border on the film:

1. Enter 'N' on the surveyor worksheet (*item 61*), 'Fog border visible?'.

Fog border visible?

EXAMPLE: N

Leave *items 62 and 63* blank and enter <u>'0.00'</u> for the net fog optical density (*item 64*). You are now done with the darkroom fog test.

If you DO see a visible border on the film:

1. Enter 'Y' on the surveyor worksheet (*item 61*) 'Fog border visible?'.

Fog border visible?

Y

EXAMPLE:

- 2. Locate an area near the center of the film and measure the optical density on either side of the fog border *(items 62 and 63)*. The following illustration shows where to measure (indicated by \otimes .)
 - NOTE: The darker side is the "**Fogged area OD**" (*item 62*), and the lighter side of the border is the "**Unfogged area OD**" (*item 63*). Record your measurements on the surveyor worksheet.
- 3. Subtract the smaller optical density value *(item 63)* from the larger optical density value *(item 62)*. This is the net fog density. Record this value *(item 64)* on the worksheet.

EXAMPLES:	Fogged area OD	Unfogged area OD
	<u>1.78</u>	<u>1.71</u>
EXAMPLE:	Net fog OD	
	<u>0.07</u>	



Diagram showing locations for making optical density measurements on the fog film.

J) Film processing information (items 65-70)

For **ALL** surveys (conventional screen-film, CR and digital) we ask that you perform a STEP test on the facility's *conventional* film processor if they have one.

CR and digital systems:

Please capture information about their digital (laser) film processor *(items 69 -70)* **and also** on their conventional film processor *(items 65-68)*, if one is available in the facility/department. Proceed to conduct the STEP processing test on this standard film processor.

Do not evaluate a conventional processor if the facility personnel in the department do not have routine access to it. For example, if there is a conventional film processor on another floor or in another section but it is mostly used for different applications such as mammography or therapy, do not complete *items 65-68*, and do not perform the STEP *test (items 71-78)*.

Screen-film systems:

Evaluate the film processor that the facility uses to routinely process chest films. This should be the same processor you used to process your phantom and fog films. Do not complete *items 69-70*.

65-66) Conventional film processor manufacturer and model

- 1. Determine the manufacturer *(item 65)* and model *(item 66)* for the conventional film processor the facility uses for routine standard film processing. Again, *for surveys of CR and digital systems*, please complete items 65-66 even if the facility uses a laser film printer for CR or digital x-ray chest films.
- 2. Write the information on the surveyor worksheet and then identify the corresponding codes from the *NEXT* Supplement section E, **'Film Processor codes'**. Enter the codes in the appropriate spaces on the worksheet. If you can not locate a code, enter 'X's in the spaces for that particular code.

Please provide as much information as you can about new processors you encounter. There is room on the surveyor worksheet in the comments section.

	Manufacturer code	Manufacturer name
EXAMPLE	EKCO	Kodak
	Model code	Model number / name
EXAMPLE	<u>480</u>	<u>RA 480</u>

67-68) Conventional processing chemistry brand and type

- 1. Determine the chemistry brand *(item 67)* and type *(item 68)* used with the processor and write this information on the surveyor worksheet.
- 2. Find the corresponding codes for chemistry brand/type in the *NEXT* Supplement section F, **'Processor chemistry codes'** and enter on the worksheet. If you can not locate a particular code, enter ' \underline{X} 's for that code. Skip *items 69-70* and proceed to *item 71*, Section K, and perform the STEP test.

Please provide as much information as you can about new chemistry brands/types you encounter. There is room on the surveyor worksheet in the comments section.

	Chemistry Brand code	Brand name
EXAMPLE	LOWX	Agfa
	Chemistry Type code	Chemistry type name
EXAMPLE	<u>GEV</u>	Gevmatic

69-70) Digital (Laser) film processor information (CR and digital systems only)

Determine the manufacturer (*item 69*) and model (*item 70*) for the laser film processor the facility routinely uses to generate adult chest films. Write the information on the surveyor worksheet and then identify the corresponding codes from the *NEXT* Supplement, **'CR and Digital- Film Processors'**. Enter the codes in the appropriate spaces on the worksheet. If you can not locate a code, enter **'X**'s in the spaces for that particular code.

	Manufacturer code	Manufacturer name
<u>EXAMPLE</u>	<u>EKCO</u>	Kodak
	Model code	Model number / name
<u>EXAMPLE</u>	<u>E21</u>	Ektascan 2180

K. Instructions for performing the STEP test (items 71-78).

Perform the STEP test if you completed items 65-68 for a <u>conventional film processor</u> which the department has routine access to. The STEP test should be performed even if the facility uses a digital x-ray imaging technology and prints laser films of patient exams.

FOR DAYLIGHT SYSTEMS: You should first verify that the film size provided to you for the STEP test (18 x 24 cm) can be processed in the daylight processor. If this is permitted by the facility, obtain an appropriate size cassette for transporting the exposed STEP film to the processor.

71) Reference STEP number for your control film

1. Enter on the surveyor worksheet the reference STEP number for your control film *(item 71)*. You will find this number on the label attached to your box of film as well as on the STEP worksheet (the reference number is the STEP number corresponding to a speed of 100- check the table on the worksheet).

Reference STEP no.(from film box)

EXAMPLE 9.6

72-78) Processing speed determination (Note that this procedure is also outlined on the STEP worksheet.)

- 1. Take with you into the darkroom your calibrated sensitometer and your box of control film. Verify that your sensitometer is configured for 'GREEN' mode.
- 2. Flash the sensitometer *once with NO film in it*. Next flash one piece of the control film with the sensitometer once on each edge of the film (total of 4 exposures).
- 3. Process this film normally as film from the x-ray unit surveyed would be processed.
- 4. Inspect the film for possible anomalies, and then label the film with the facility name and date of the survey. If the facility has more than one film processor, then test the one that they typically use for chest films. Indicate on the film which processor you are evaluating.
- 5. Zero the calibrated densitometer and measure the optical density (OD) of the **base plus fog** (near the center of the film). Record this value on the STEP worksheet and in the space provided on the surveyor worksheet *(item 72)*.

Base + fog OD

EXAMPLE: 0.13

6. Determine the speed density by adding 1.00 to the optical density of the baseplus-fog optical density. Record this optical density on the STEP worksheet.

EXAMPLE: If Base plus Fog = 0.13, then the speed density = 1.13.

- 7. Select the two steps that have optical densities lower and higher than the speed density and enter these values on the surveyor worksheet *(items 73 and 75)*. Read the optical density of each of these two steps (once on each of the four sensitometric strips on the film) and record the optical densities and their corresponding step numbers on the STEP worksheet. If one strip of densities is dramatically different from the remaining three sets, then discard the optical density values for this one 'bad' strip.
- 8. Average the four optical densities for both the lower step and upper step. For example, if you measured film densities from steps 9 and 10, then average the four optical densities for step 9 and average the four optical densities for step 10. Record these average values on the STEP form and on the surveyor worksheet *(items 74 and 76).*

	Lower-step number	Upper-step number
EXAMPLE:	<u>9</u>	<u>10</u>
	Lower step-average OD	Upper step- average OD
EXAMPLE:	<u>1.02</u>	<u>1.63</u>

- 9. On the STEP worksheet, plot the step number and the average optical density for the two steps you chose in step 7.
- 10. Connect these two points with a straight line.
- 11. Locate on the Y-axis the speed density (from step 4), and follow this value over horizontally to the straight line you drew in step 8 above. At this point of intersection, draw a line straight up to the x-axis and read the resulting step number for this point. NOTE THAT THIS WILL BE A FRACTIONAL STEP NUMBER, such as 9.7 or 12.3. Record this resulting STEP number on the surveyor worksheet (*item 77*).
- 12. Using the look-up table on the STEP worksheet, determine the resulting processing speed value. Record this value on the STEP form and on the worksheet *(item 78)*.
- 13. CHECK YOUR NUMBER!If you get an unusually high (greater than 130) or low (less than 70) processing speed then check your work!
 - > Review your numbers, where you measured your densities, etc.
 - Examine the exposures you obtained from section F- are they low (< 10 mR) or high (> 50 mR) as well for this particular exam? A facility may be

compensating for low processing (< 80) by increasing its technique (mA, exposure time or possibly kVp).

- Is your sensitometer configured to expose the STEP film in the 'green' mode?
- Repeat the test to be certain your results are correct.

Appendix A

Phantom assembly and test tool positioning

Assemble the chest phantom so that it appears as shown at the right. Refer to the diagram below.

Your phantom kit should have:

- 1. Two plexiglass side plates
- 2. One thick phantom plate
- 3. One thin phantom plate
- 4. One MDH probe holder.
- 5. Three plastic bolts
- 6. One yellow image quality test tool.

Three plastic screws are provided to attach the sides of the phantom and the MDH probe arm. The thinner plexiglass side is the Anterior side of the phantom (patient's chest). The thicker plexiglass side is the posterior side of the phantom (patient's back).

Refer to the following page for instructions on positioning the image quality test tool.



A fully assembled phantom



VIEW FROM ABOVE

Positioning of the image quality test tool

Position the yellow test tool with tape on the INNER surface of the thinner panel (anterior side) as shown. Position it so that the curved end is toward the left and the aluminum disk is visible.



Inside view of anterior (thinner) phantom plate showing proper location of image quality test tool.

Appendix B. Surveyor Data Form

All NEXT surveyors were provided an electronic spreadsheet with which to collect and submit their survey data results. The spreadsheet can be printed with minimal changes in formatting, and was originally developed for the Hewlett Packard brand of laser printers. Entrance skin exposure is calculated by the spreadsheet using the four exposure values and the source-to-patient support distance entered by the surveyor. The calculation is performed for a skin entrance plane 22.5 cm from the patient support surface (i.e. table-top or wall bucky surface). This spreadsheet was developed in Microsoft Excel 97 SR-2 (Microsoft Corporation, Redmond, WA). An electronic PDF version of this document is available on the CRCPD website. Electronic copies of this spreadsheet are also available from the Food and Drug Administration by sending an email request to dcs@cdrh.fda.gov.

Appendix C. Facility Questionnaire

Each facility that participated in the survey was asked to complete a questionnaire that requested detailed information regarding the facility's radiological practice including the types of diagnostic imaging modalities performed, number of staff members and their respective duties, details of the x-ray imaging equipment used for diagnostic chest imaging, and information regarding their quality assurance and quality control programs. The Excel form contains three sheets:

1.	READ ME	Contains brief instructions to the surveyor on the contents of this Excel file.
2.	INSTRUCTIONS	Information and instructions for the facility personnel.
3.	FORM	The questionnaire form to be completed by the facility.

This form was also developed in Microsoft Excel version 97 SR-2. The Microsoft Excel version and the PDF version are both available from the CRCPD website, and as well from the Food and Drug Administration by email: <u>dcs@cdrh.fda.gov</u>.