

NEXT 2000
Protocol for Survey of Computed Tomography (CT)

December 18, 2000

Prepared by

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Food and Drug Administration (FDA)
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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.**

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Acknowledgment

We greatly appreciate the contributions, suggestions, and comments that have advanced the development of this protocol. Such contributions were provided by Robert M. Gagne, Frank Cerra, and Elizabeth Rodgers of the FDA Center for Devices and Radiological Health, Office of Science and Technology; Robert J. Slayton and Albert E. Moyal of the CDRH Office Health and Industry Programs; and Thomas Jakub and Henry Knox of the CDRH Office of Compliance. The thorough review and astute recommendations of Cynthia McCollough of the Mayo Clinic significantly enhanced the quality of the protocol, and we are grateful to her. Jim Deye and Jerry Galiatsatos of Fairfax Hospital opened their CT facility to us for protocol testing, and we thank them very much. We thank Diana Wozniak of the State of Connecticut for pilot testing the protocol. The CDRH Radiation Programs Branch staff and Lance J. Rakovan, on detail from the Nuclear Regulatory Commission, offered invaluable help in setting up and helping with the logistics of surveyor training sessions. We especially thank Mike Taylor and Doug Fletcher of the National Naval Medical Center for facilitating protocol testing and for making their CT facility available for surveyor training. Our particular thanks go to training lecturers Jerry Thomas (Uniformed Services University of the Health Sciences), Charles Finder (CDRH Office of Health and Industry Programs), and Robert M. Gagne (CDRH Office of Science and Technology). The American College of Radiology provided funding in support of travel by surveyors for training, and we thank them for their generous contribution.

NEXT Protocol for Computed Tomography

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Preface

The December 2000 version of the *NEXT 2000 Protocol for Survey of Computed Tomography* represents the final edition of survey instructions distributed to surveyors in previous versions and updates of March 8, March 15, March 31, May 22, and October 24, 2000. The December edition contains minor corrections and a few changes of format, but in content it is identical to the October 24 version.

The FDA Center for Devices and Radiological Health and the Conference of Radiation Control Program Directors NEXT Committee, with support of the American College of Radiology, provided surveyor training in March and April, 2000, to representatives of the following 43 States and to observers from Canada: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin. Surveys began in April 2000 and are continuing through April 2001.

NEXT 2000

Protocol for Survey of Computed Tomography (CT)

Introduction

This survey is intended to obtain information about CT system x-ray emissions, patterns of clinical application of CT technology, patient exposure, and quality assurance that would enable the analysis of individual and collective CT dose trends in the United States. Based on a random sampling of CT facilities nationwide, the survey is comprised of two parts, (i) concentrating in particular on routine examinations of the adult head and (ii) also covering in general a broad overview of CT practice. Surveyor measurements with the CDRH head phantom on-site at clinical facilities can be related to multiple scan average dose (MSAD) and to computed tomography dose index (CTDI), the common reference descriptors of patient dose and CT scanner radiation output.¹ For part (i) of the survey, the 2000 protocol has been extended from the one used in 1990² to include measurements of exposure facilitating estimation of air kerma free-in-air and skin-entrance dose. The latter is especially relevant to a mode of operation commonly called “CT fluoroscopy” or “dynamic scanning.” Another new feature of the protocol is that it incorporates queries related to helical scanning techniques. The more general survey instrument of part (ii) is a mail-in questionnaire based on an FDA³-inspired design of NRPB.⁴ It seeks clinical-practice, technique-protocol, frequency-distribution, patient-workload, and quality-assurance data for the most common kinds of CT examinations.⁵

We recognize the many other responsibilities of State surveyors participating in this project, and we highly value whatever contributions they and their offices make to the *NEXT* program. The program succeeds through their generous donations of effort.

¹ Thomas B. Shope, Robert M. Gagne, and Gordon C. Johnson, "A method for describing the doses delivered by transmission x-ray computed tomography," *Medical Physics* **8**, 488-495 (1981).

² Burton J. Conway, *NEXT Protocol for Computerized Tomography*, (unpublished, March 1990); Burton J. Conway, *Nationwide Evaluation of X-Ray Trends (NEXT). Summary of 1990 Computerized Tomography Survey and 1991 Fluoroscopy Survey*, CRCPD 94-2, Conference of Radiation Control Program Directors, Frankfort, Kentucky, January 1994.

³ J.L. McCrohan, J.F. Patterson, R.L. Burkhart, H.A. Goldstein, F.G. Shuman, and R.M. Gagne, *Computed Tomography Techniques and Quality Assurance Programs in the mid-1980s*, HHS (FDA) 86-8258, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, Maryland, 1986.

⁴ P.C. Shrimpton, D. Hart, M.C. Hillier, B.F. Wall, and K. Faulkner, *Survey of CT Practice in the UK. Part 1: Aspects of Examination Frequency and Quality Assurance*, NRPB-R248, National Radiological Protection Board, Chilton, Didcot, Oxon, United Kingdom, December 1991.

⁵ Brian R. Herts, John Perl II, Charles Seney, Mike L. Lieber, William J. Davros, Mark E. Baker, "Comparison of Examination Times Between CT Scanners: Are the Newer Scanners Faster?" *American Journal of Roentgenology* **170**, 13-18 (January 1998).

General Instructions

In an effort to expedite publication of survey results, we are seeking surveyor assistance with data entry. We realize that all States do not have access to the spreadsheet application *Excel 97*. For those that do, it would be greatly appreciated if in addition to providing completed handwritten forms, surveyors enter the data in *Excel* format according to the directions that follow.

The *surveyor worksheet* (Appendix D) and the *facility questionnaire* (Appendix E) have been developed as two different Microsoft *Excel 97* files. These files will be available on diskettes provided to surveyors: For *each* facility surveyed there will be a corresponding “*facility diskette*” in which the surveyor can enter surveyor-worksheet and facility-questionnaire results. After checking and making copies of filled-in files, surveyors can send *facility diskettes* to CDRH for data analysis.

Surveyors will be provided with *two* additional diskettes—one as a *master* diskette containing a repository of **blank** surveyor-worksheet and facility-questionnaire files. The second diskette (“*back-up diskette*”) is being made available to enable surveyors to make *back-up copies* of the *filled-in* surveyor worksheet and facility-questionnaire files completed for the facilities surveyed. We are asking surveyors to retain these two diskettes for safekeeping.

We encourage surveyors to transfer handwritten data from their worksheets and from facility questionnaires into electronic form (e.g., *Excel 97* format) to whatever extent may be practicable. Electronic data entry by many surveyors will save much time in getting final results out. If a surveyor has a spreadsheet application that is different from *Excel 97* and needs to convert the *Excel* forms to his or her application’s native format to enable data entry, then completed spreadsheets can be submitted in the alternate format. Of course, if it is not feasible or not convenient for surveyors to work with computer files, then they can submit to CDRH just the original, handwritten paper versions of worksheets and facility questionnaires as they are completed. *We appreciate surveyor efforts however the data are sent in!*

The filled-in *facility diskette* itself can be sent back to CDRH via U.S. mail after the surveyor has confirmed the accuracy of data entry and has made back-up copies of the filled-in surveyor-worksheet and facility-questionnaire files on the *back-up diskette*. If a surveyor finds it more convenient to attach files and transmit them to us via electronic mail, then we would be delighted to receive files that way in lieu of mailing a *facility diskette*. We would be grateful to receive either a *facility diskette* or electronic mail as soon as the work on that particular facility is completed; there is no need to wait until the entire allotment of surveys is done. For each facility surveyed, it would help our quality-assurance process to receive the original, handwritten paper versions of the surveyor worksheet and the facility questionnaire. *Please send in the handwritten paper versions of the surveyor worksheet and facility questionnaire **along with** the filled-in facility diskette.* It would be a good idea for surveyors to make copies of the original filled-in paper forms for their records in case files are lost in transmission.

Part of the survey protocol entails exposing and developing a ready-pack film. Please send the developed film along with the filled-in facility diskette (or e-mail) and paper forms to Stanley H. Stern, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs (HFZ-240), 1350 Piccard Drive Rockville, MD 20850 (e-mail: sas@cdrh.fda.gov; telephone: 301-827-0014; fax: 301-594-3306).

Instructions for the Facility Questionnaire

Surveyors are encouraged to contact a facility several weeks before the actual survey date and send facility staff a *facility questionnaire* form in advance. For the most part the *facility questionnaire* is a self-explanatory, self-contained package (Appendix E). At the facility, a paper copy of the questionnaire should be completed by (1) the radiologic technologist responsible for the CT unit and assisting with the on-site survey *and/or* (2) the medical physicist or other facility staff able to address the questions posed. Items **9-18** of the questionnaire refer to the *most frequently used CT unit* at the facility. **This unit should be the same one surveyed on site!**

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 Stanley Stern at CDRH (e-mail: sas@cdrh.fda.gov; telephone: 301-827-0014; fax: 301-594-3306) when there are problems that the surveyors may not feel comfortable addressing. If the facility can complete the questionnaire by the survey date, the surveyor can pick it up from them at that time.

The electronic version of the facility questionnaire is an *Excel 97* workbook file comprised of two spreadsheets—one spreadsheet for item nos. 1-12 and 15-18, the second spreadsheet for item nos. 13-14. It would speed the analysis of survey results if surveyors fill in the electronic version after they receive the completed paper form of the questionnaire from the facility.

Survey Scenario: Data Recording and File Transmission

What follows is one idea of how the survey process might work. We would value any other suggestions for facilitating surveys and transmission of results.

1. Several weeks in advance of a survey, the surveyor can send to an identified contact individual a *facility questionnaire* (Appendix E) and a request that it be completed by the survey date. The contact person may be the CT technologist (and/or medical physicist) who will assist with the survey.
2. On site at facility, the surveyor retrieves and reviews the filled-in *facility questionnaire* with the CT technologist (and/or medical physicist). Then, with the assistance of the facility staff, the surveyor performs measurements, exposes and develops a ready-pack

film, and obtains the additional information needed to fill in a paper copy of the *surveyor worksheet* (Appendix D).

3. Following the on-site survey, it would be helpful for the surveyor to transfer his or her handwritten information to a *surveyor-worksheet* file on the *facility diskette*. The surveyor could then electronically copy the filled-in *surveyor-worksheet* file to the surveyor's *backup diskette* and make a photocopy of the handwritten *surveyor worksheet* to retain for his or her records.
4. Also following the on-site survey, it would be helpful for the surveyor to transfer the facility staff's handwritten information from the filled-in *facility questionnaire* to the *facility-questionnaire* file on the *facility diskette*. The surveyor could then electronically copy the filled-in *facility-questionnaire* file to the surveyor's *backup diskette* and make a photocopy of the handwritten *facility questionnaire* to retain for his or her records.
5. The surveyor could then send to CDRH the *original filled-in paper forms*, the *filled-in* (if possible) *facility diskette*, and the *exposed and developed ready-pack film*. We greatly appreciate any effort made in filing electronic as well as paper versions of forms. If it is more convenient to send electronic files via e-mail in lieu of diskettes, the surveyor should do so.
6. The surveyor can follow the same or alternative procedures for each facility surveyed. The surveyor should retain the *master* and *backup* diskettes for a time pending confirmation of receipt of files and until completion of data analysis by CDRH. Note: If the disk space on the *backup diskette* becomes full as copies of files are being stored, the surveyor may need to use the *master diskette* as a place to store backup copies.

Instructions for the Surveyor Worksheet

(See Appendix C for a filled-in example, Appendix D for a blank surveyor worksheet.)

Whenever any piece of information pertinent to an entry is not known or cannot be confirmed, enter **UNKN** in the worksheet cell.

Surveyor, Survey, and Facility Identification (entries 1-12)

1) Surveyor name, 2) telephone number, 3) e-mail:

Enter your name, telephone number, and electronic-mail address in the respective shaded spaces.

4) Survey date: Enter the date on which the survey was done, e.g., **6/27/00**.

5) Facility name: Enter the name of the hospital, medical group, or corporation at which the x-ray CT system is located. If the CT system is located in a private office, enter the name of the physician.

6) Facility i.d. no.: Enter the unique number assigned to the facility by your State program. Letters or numbers may be used in any combination.

EXAMPLE Facility i.d. no.
23456B7C32

7) State/Agency code: Enter the appropriate two-letter or two-digit code from the Table of State and Agency Codes (Appendix A).

EXAMPLE State/Agency code
VA

8) Facility-type code: Determine the type of facility from the list below and enter the corresponding code. **8a) If code 99** ("other") is used, please explicitly describe the facility type in the space provided on the surveyor worksheet directly to the right of facility-type code 99.

EXAMPLE Facility-type code
01

The following codes and definitions apply to Facility Type:

01 = Private Practice: An individual practitioner or a group of practitioners engaged in the same specialty. This category includes a group of general practitioners.

02 = Hospital: A facility that has beds for overnight care of patients.

03 = Multiple Specialty Practice: A group of practitioners having different specialties. This category includes school infirmaries and clinics.

04 = **Mobile Unit**: A CT system transported by motor vehicle. If the van is not permanently affixed to the facility, i.e., it is located at a hospital temporarily while a permanent system is being installed, the **Facility type** should be coded "04" rather than "02."

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 directly to the right of "**8a) If code 99.**"

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 of Appendix B, and enter the appropriate code. If the entry **8) Facility-type code** is "02" (Hospital), enter the **9) Practice-specialty code** of the hospital *department* housing the CT unit being surveyed (e.g., **04** for RADIOLOGY, **25** for ONCOLOGY treatment planning for radiation therapy, **30** for EMERGENCY/SHOCK/TRAUMA, etc.) If entry **8) Facility-type code** is "03" or "04," enter **XX** for **9) Practice-specialty code**.

9a) If code 99 ("other") is used, 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

04

10) Patient workload per week:

Enter an estimate of the *total number* of routine patient examinations of the adult **head** *normally performed per week* with the CT unit being surveyed.

A routine CT examination of the adult head may be comprised of a variety of kinds of scanning. For example, a single examination may consist of (1) a series of axial scans exclusively without contrast media, or (2) a series exclusively with contrast media, or (3) two series, the first without and the second with contrast media, or (4) several series covering different anatomical ranges of the head, each series with or without contrast. A routine examination

may also use axial scanning or else helical scanning for different ranges, and each scanning mode may or may not be associated with different phases of contrast vs. non-contrast study. For the purpose of enumerating the patient workload, **one examination** of the head may be comprised of *any/all* of these scanning modalities and phases. The particular scanning protocols comprising a routine examination are recorded in a following section of this survey, *Radiological Protocols for a Routine Head Examination*.

11) Interviewee name & 12) Title/Position:

In the respectively labeled cells, enter the name and title/position of the facility staff person providing facility identification, patient workload, CT-system technical information, and/or assistance to you during the on-site measurements. If there is more than one facility staff person, please note that circumstance and identify the additional person or persons at the end of the worksheet, in the section dedicated to surveyor remarks.

X-ray CT Unit Identification and Capabilities (entries 13-23)

13) Manufacturer: Enter the name of the manufacturer specified on the certification and identification label located on the (back of the) **gantry** of the CT unit.

	<u>Manufacturer</u>
<u>EXAMPLE</u>	<u>Siemens Medical Systems, Inc.</u>

14) Serial number: Enter the serial number specified on the (back of the) **gantry** of the CT unit. Letters, numbers, hyphens, and leading blanks or zeros may be used in any combination. If there is more than one serial number on the gantry (referring, for example, to several components contained therein), then enter *any one* of those serial numbers into the worksheet, and note this circumstance in the section of the worksheet dedicated to surveyor remarks. If *no* serial number can be found on the gantry, enter the *room number* as a surrogate for the serial number, and note this circumstance as a surveyor remark.

	<u>Serial number</u>
<u>EXAMPLE</u>	<u>2B-85</u>

15) Date manufactured: Enter the month and year, e.g. **March-97**, that the CT *gantry* was manufactured as specified on the certification and identification label located on the (back of the) *gantry* of the CT unit.

16) Model name: Determine the model of the CT 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 *Synerview* (made by Picker) or *Somatom* (made by Siemens), followed by an alphanumeric qualifier, e.g., *Synerview 1200SX*, or *Somatom Plus*, or *Somatom Plus 4*. (Note that the *Somatom Plus 4* model-introduced in 1994-is different from the *Somatom Plus* model that was introduced in 1987.) Please enter the *entire* trade name (generic part plus qualifier) by which the model is commonly known.

Model name

EXAMPLE

Somatom Plus

Note: In the section of the surveyor worksheet reserved for remarks, please record what (if any) major *options* the model comes with, what major *upgrades* have been made to the system, and when such major upgrades were installed. Examples of major options or upgrades are (1) slip ring to allow helical scanning (in what might have been an axial scanner only), (2) solid-state detectors as an improvement over xenon (gas) detectors, (3) multi-slice capability, (4) CT fluoroscopy capability.

17) Model number: There may be an alphanumeric number used by the manufacturer as a unique identifier to distinguish this particular product from others made by the manufacturer. It is typically specified near the serial number on the certification and identification label located on the (back of the) *gantry* of the CT unit. This model number may be different from the commonly known model trade name. If you can identify a unique number associated with the model that may be different than the model trade name, enter the model number in the worksheet. If you cannot identify a unique model number, enter **UNKN** in the space provided for **Model number**.

Model number

EXAMPLE

174550-A

18) System pulsed?

Enter **Yes** if the CT unit is pulsed, **No** if it is not pulsed. Enter **UNKN** if unknown.

If the CT unit is not pulsed, or if it is not known whether the CT unit is pulsed, *do not enter data* for **19) Pulses per second** or **20) Duration (ms) of single pulse**.

19) Pulses per second:

If the CT unit is pulsed, enter the **Pulses per second** (i.e., the pulse rate) as the *number of pulses per second emitted by the x-ray tube as it is scanning*.

If the pulse rate can be selected or depends on the scanning mode used (e.g., axial scanning or helical scanning), enter the pulse rate most commonly used, and note the particular details of applicable scanning mode as well as additional pulse-rate values associated with the various modalities in the section of the surveyor worksheet dedicated to remarks.

If the CT unit refers to the pulse rate in terms of the *Number of pulses per scan*, obtain a value for the number of **Pulses per second** by dividing the number of pulses per single scan by the *Time (s) per single scan*:

$$\text{Number of **Pulses per second**} = \frac{\text{Number of pulses per scan}}{\text{Time (s) per scan}}$$

If the number of **Pulses per second** cannot be determined, enter **UNKN**.

Pulses per second

EXAMPLE

133

20) Duration (ms) of single pulse:

If the CT unit is pulsed, enter the duration of a single pulse in units of *milliseconds*.

If the pulse duration can be selected or depends on the scanning mode used (e.g., axial scanning or helical scanning), enter the pulse duration most commonly used, and note the particular details of applicable scanning mode as well as additional pulse-duration

values associated with the various modalities in the section of the surveyor worksheet dedicated to remarks.

If the **Duration (ms) of a single pulse** cannot be determined, enter **UNKN**.

EXAMPLE

Duration (ms) of single pulse

2.2

21) Helical scanning available on this unit?

Enter **Yes** if the CT unit being surveyed is capable of doing helical (also called "spiral") scanning. Enter **No** if the unit is not capable of doing helical scanning. This question refers to the availability of a helical scanning modality, not to whether helical scanning is actually used for a routine examination of the adult head.

Note: If the CT unit **cannot** do helical scanning, skip questions **34** through **43** in a following section of this survey.

22) "CT fluoroscopy" available on this unit?

This question refers to whether the CT unit being surveyed is *capable* of "CT fluoroscopy," not to whether such scanning is actually used for a routine examination of the adult head.

Enter **Yes** if the CT unit being surveyed is *capable* of scanning *any* part of the body in a mode variously referred to as "CT fluoroscopy," or "dynamic scanning," or "continuous scanning," or some other terminology defined by the manufacturer. Whatever the terminology, in this mode of operation, the source/detector array within the gantry rotates continuously around the patient multiple times (in some systems up to 200 revolutions of 360° each). In this mode table movement is not automated, but is controlled by the operator. Low-resolution CT images are acquired nearly in real time, at rates of 6 to 8 frames per second, and they are continuously reconstructed and displayed on a monitor typically located near the patient table. This mode is typically used to visualize interventional procedures involving biopsies or drainage. *In this mode there may also be added or special filtration as well as particular values of kV_p and mA.*

Enter **No** if the CT unit being surveyed is not capable of operating in a "fluoroscopic" mode. **Note:** If the CT unit cannot do "CT fluoroscopy," skip questions **22a** through **22h**. Ask how many CT units there are altogether at the facility and how many of these CT

units do “CT fluoroscopy.” Record the answers in the remarks sections of the surveyor worksheet.

CT fluoroscopy questions: head or body scanning, most typically-used settings

22a) patient workload per week (all patients—adults & pediatric; all exams)

22b) kV_p (most typical)

22c) mA (most typical)

22d) slice width (mm) (most typical)

22e) time (s) per 360° rotation (most typical)

22f) average “beam-on” time (s) for a procedure

22g) minimum “beam-on” time (s) for a procedure

22h) maximum “beam-on” time (s) for a procedure

If the CT unit being surveyed is *capable* of “CT fluoroscopy” for *any* part of the body, in worksheet cell **22a** estimate the patient workload as the *total number* of “CT fluoroscopy” patient procedures (**regardless of anatomical region of interest, for all patients including pediatrics**) *normally performed per week* with the CT unit being surveyed.

In cells **22b** through **22e** respectively enter the most typical **settings** associated with the most commonly used “CT fluoroscopy” protocol of the facility, *regardless of whether the procedures apply to the head or body*.

In cells **22f**, **g**, **h**, enter the total “beam-on” times (in units of *seconds*) that respectively characterize the average, the minimum, and the maximum times that the x-ray source would be activated and continuously rotating during CT fluoroscopy procedures.

Note: Ask how many CT units there are altogether at the facility and how many of these CT units do “CT fluoroscopy.” Record the answer in the remarks sections of the surveyor worksheet.

23a) Hard-copy output code and 23b) Image display/interpretation code:

In worksheet cell **23a**, enter one of the following *codes* for the kind of multifunction camera/printing system used with the CT unit being surveyed to produce *hard-copy films* of images. (If none of the following systems apply, enter the code **OTHR**, and describe the hard-copy output system in the section of the surveyor worksheet dedicated to remarks).

<u>Hard-copy output system</u>	<u>Code</u>
laser-based camera/automated chemical processor	LCHM
laser-based camera/dry printing	LAPR
video-based camera/automated chemical processor	VCHM
OTHER	OTHR

For routine examinations of the adult head, in worksheet cell **23b** enter one of the following *codes* for **the most common way** that images produced by the CT unit being surveyed are interpreted by radiologists. (If there is no single display method that predominates for interpretation, enter code letter **B**. If some other method is used that doesn't really fit as HC or SC, enter the code **OTHR**, and in the section of the surveyor worksheet dedicated to remarks, describe the most common way head images are displayed for interpretation). **Note:** Video-monitor as well as film display and interpretation may occur at a remote location, for example in a radiology reading room, and perhaps not in the CT room.

<u>Image display/interpretation</u>	<u>Code</u>
hard-copy films reviewed with light-box	HC
video-monitor display (with or without cine-interactive) review	SC
both video-monitor display and films	B
OTHER	OTHR

Radiological Protocols for a Routine Head Examination (entries 24-25)

Consult the person assisting with the survey (e.g., the operator of the CT system) to determine the particular physical filter (entry 24), scanning protocols (entry 25), and technique factors (entries 26-45) used by the facility for their *routine adult CT head procedure*. Some of the information sought will be found on one or more of the menus or screens that are displayed on the monitor at the operator's console or on the control panel indicators during the process of programming for scanning. Because of differences in nomenclature from system to system, especially for helical (also called "spiral") scanning modes, there may be differing terminology that actually refers to the same or similar physical parameters.

24) Selected physical filter:

If various filters (e.g., "bow-tie," "flat," etc.), and/or field-of-view (FOV) collimators, and/or FOV collimator positions *can be selected* by the operator, record the filter and/or collimator and/or collimator position used for the routine head procedure. Enter the same code, letters, or description (e.g., "head," or "body," or "Filter 2," etc.) that the CT unit uses to designate the filter on the CT system console. If the designation of collimator is made in terms of FOV, where FOV is the slice cross-section whose diameter might be specified in units of *millimeter* or *centimeter*, enter the collimator designator in terms field-of-view and its diameter. (**Note:** "Field of view" refers to the slice *cross section*. "Region of interest" refers to the range scanned axially or helically *along* the axis of rotation.)

If available, give a detailed description of the filter and/or collimator (e.g., thickness, design, material, etc.) Only record the physical filter used, not the mathematical reconstruction filter. If a filter/collimator cannot be selected by the operator, enter **NONE**. If you cannot determine whether such a selection can be made, enter **UNKN**.

Selected physical filter

EXAMPLE
EXAMPLE
EXAMPLE

"A"
"Filter no. 2"
"Head"

25) Scanning protocols: For worksheet cells **25a** through **25j**, obtain and enter estimates of the *frequency-of-use percentage* associated with each of the following scanning protocols. **Also, please describe the anatomical region of interest (ROI) briefly to the right of each**

percentage entered. (Note: “Region of interest” refers to the range scanned axially or helically *along* the axis of rotation. “Field of view” refers to the slice *cross section*.)

Each item corresponds either to an axial-scanning series, or to a helical scan, or to a scanning phase associated with injection of a contrast medium (or not), or to a combination of such series and phases that may comprise a routine examination of the adult head. The total frequency-of-use percentage should add up to 100%. Many of the items may be left blank if only one or two of the protocols are typically used by the facility for their routine CT examinations of the adult head. Item **25j** corresponds to any facility protocol not aptly described by the other entries; if there is such a protocol, please estimate its frequency of use in cell **25j** and provide a description of the protocol in cell **25k**.

Note: For the purpose of this question, the order of the scanning phases need not be considered: An axial (conventional) scanning series covering a particular anatomical ROI followed by a helical scan is dosimetrically equivalent to the helical scanning followed by the axial series.

	<u>Percentage</u>	<u>Protocol for a routine head exam</u>
<u>EXAMPLE</u>	25a) 50%	Axial scanning— <i>no contrast</i> .
<u>EXAMPLE</u>		ROI: From the top to the base of the skull.
	25b) ____	Axial scanning— <i>with contrast</i> .
	25c) ____	Axial scanning—2 phases: <i>partly no contrast, partly with contrast</i> .
<u>EXAMPLE</u>	25d) 30%	Axial scanning—2 phases: <i>wholly without contrast and wholly with contrast</i> .
<u>EXAMPLE</u>		ROI: From the foramen magnum to the suprasellar cistern in the brain.
<u>EXAMPLE</u>	25e) 20%	Helical scanning— <i>no contrast</i> .
<u>EXAMPLE</u>		ROI: From the top to the base of the skull.

- 25f) ____ Helical scanning—*with contrast*.
- 25g) ____ Helical scanning—2 phases: *partly no contrast, partly with contrast*.
- 25h) ____ Helical scanning—2 phases: *wholly without contrast and wholly with contrast*.
- 25i) ____ *One phase of axial scanning and one phase of helical scanning*. In the surveyor worksheet section for remarks, please indicate if a contrast medium is used and with which scanning phase(s).
- 25j) ____ **25k) Other:** If the facility uses a scanning protocol for the routine head examination that is not well represented by any of the preceding descriptions, enter an estimate for the percentage it is used in worksheet cell **25j**, and describe the protocol in the surveyor worksheet space to the right of the cell labeled "**25k) Other**."

Technique Factors used in Axial (Conventional) Scanning Mode (entries 26-33)

Entries 26a through 33 refer to CT unit operation with those *axial* (conventional) scanning techniques corresponding to the *most frequently used axial-scanning protocol* (see entry 25) for routine examination of the adult head. The terms “single scan,” “single axial scan,” or “scan” in this section refer to scanning done in *one* interval of x-ray exposure, i.e., during which time the x-ray source is activated.

26a) Which axial protocol?

From question 25, enter the letter code (a through d, i, or k) corresponding to the *most frequently used axial-scanning protocol* for routine examination of the adult head. Entries 26b through 33 should refer to this protocol.

Which axial protocol?

EXAMPLE

25a

26b) kV_p, 27) mA, and/or 28) mAs:

Enter the **kV_p** and **mA** typically selected with the most frequently used axial-scanning protocol. Depending on the CT unit, the quantity **mAs** (i.e., mAs per *single axial scan*) may or may not be able to be selected *before scanning* as an element of the technique set. If **mAs** cannot be selected before scanning, enter **NA** for **mAs** in the worksheet. If **mAs** can be selected before scanning but **mA** cannot be selected, enter the **value** usually selected for **mAs** and **NA** for **mA**. For a CT unit where a value is displayed for **mAs** *after scanning* even though the technique is set up through selection of **mA**, record the selected value of **mA** and the value of **mAs** that would be typically displayed for a single axial scan, and note in the section for surveyor remarks that the CT unit is set up through selection of **mA**.

kV_p

mA

mAs

EXAMPLE

120

250

500

29) Rotation angle (degrees) per single axial scan:

Enter the angle (in units of *degrees*) of source/detector rotation *per single axial scan*.

Rotation angle (degrees) per single axial scan

EXAMPLE

360

OR

EXAMPLE

214

OR

EXAMPLE

540

30) Time (s) per single axial scan:

Enter the time (in units of *seconds*) during which the x-ray source is activated during a *single axial scan*.

Time (s) per single axial scan

	<u>EXAMPLE</u>	<u>3.30</u>
OR	<u>EXAMPLE</u>	<u>1.00</u>
OR	<u>EXAMPLE</u>	<u>0.75</u>

31) Number of slices for 31a) non-contrast phase and/or 31b) contrast phase:

In surveyor worksheet cells **31a** and/or **31b**, enter the number of slices covering the anatomical region of interest scanned axially with the most frequently used axial-scanning protocol for a routine adult CT head examination without and/or with contrast, respectively. For this protocol, if the facility does *not* typically do scanning with contrast, or if it does *not* typically do scanning without contrast, enter NA in the corresponding cell. If there is a non-contrast phase and a contrast phase as well in the most frequently used axial-scanning protocol for a routine adult CT head exam, enter data in both cells. If the non-contrast and contrast phases correspond to different parts of the entire region of interest (e.g., see description for **25c**), make a notation in the remarks section of the worksheet.

	<u>No. slices (non-contrast)</u>	<u>No. slices (contrast)</u>
	<u>EXAMPLE</u>	<u>NA</u>
OR	<u>EXAMPLE</u>	<u>16</u>

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **number of individual slices** in cells **31a** and/or **31b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent axial-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), then record the number of slices used with the larger slice width in cells **31a** and/or **31b**. In the surveyor's remarks section of the worksheet, indicate that two values for slice width are used, and record the respective numbers of slices used with **each** width.

32) Slice width (mm) for 32a) non-contrast phase and/or 32b) contrast phase:

In surveyor worksheet cells **32a** and/or **32b**, enter the nominal values for the width (in units of *millimeters*) of the image slice respectively selected (via collimation) for non-contrast and/or contrast series as phases of the most frequently used axial-scanning protocol for a routine adult CT head examination. For the most frequently used axial scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

	<u>Slice width (mm)</u> (non-contrast)	<u>Slice width (mm)</u> (contrast)
OR	<u>EXAMPLE</u> 10	NA
	<u>EXAMPLE</u> 10	10

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **nominal width of an individual slice** in cells **32a** and/or **32b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent axial-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm slices from the top of the skull to the orbits and 5-mm slices from the orbits to the base of the skull), record the larger slice width in cells **32a** and/or **32b**. In

the section of the surveyor worksheet for remarks, indicate that two different values for slice width are used, and record the *slice-width value* of **each**.

33) Table increment (mm) for 33a) non-contrast phase and/or 33b) contrast phase:

In surveyor worksheet cells **33a** and/or **33b**, enter the *nominal* (i.e. the selected) **increment of the patient table** (in units of *millimeters*) per single axial scan used respectively for non-contrast and/or contrast series as phases of the most frequently used axial-scanning protocol for a routine adult CT head examination. For the most frequently used axial-scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

	<u>Table increment (mm)</u> (non-contrast)	<u>Table increment (mm)</u> (contrast)
OR	<u>EXAMPLE</u> <u>EXAMPLE</u>	<u>10</u> <u>20</u>
		<u>NA</u> <u>10</u>

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **actual table increment per single scan** in cells **33a** and/or **33b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent axial-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm slices from the top of the skull to the orbits and 5-mm slices from the orbits to the base of the skull), then record the table increment associated with the larger slice width in cells **33a** and/or **33b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the *table increment* associated with **each** width.

Technique Factors used in Helical (Spiral) Scanning Mode (entries 34-43)

Entries 34a through 43 refer to CT unit operation with those *helical* (spiral) scanning techniques corresponding to the *most frequently used helical-scanning protocol* (see entry 25) for routine examination of the adult head. The terms “single scan,” “single helical scan,” or “scan” in this section refer to scanning done in *one* interval of x-ray exposure, i.e., during which time the x-ray source is activated, and they may be associated with many rotations of the x-ray source/detector array. Please skip these entries if **none** of the routine head-examination protocols (entry 25) uses a helical-scanning modality.

34a) Which helical protocol?

From question **25**, enter the letter code (e through h, i, or k) corresponding to the *most frequently used helical-scanning protocol* for routine examination of the adult head. Entries 34b through 43 should refer to this protocol.

Which helical protocol?

EXAMPLE

25e

34b) kV_p, 35) mA, and/or 36) mAs:

Enter the **kV_p** and **mA** typically selected with the most frequently used helical-scanning protocol. In helical mode, **mAs** refers to the *entire* helically scanned region of interest (ROI), not just to one slice-width or to a single rotation of 360°. Depending on the CT unit, the quantity **mAs** may or may not be able to be selected *before scanning* as an element of the technique set. If **mAs** cannot be selected before scanning, enter **NA** for **mAs** in the worksheet. If **mAs** can be selected before scanning but **mA** cannot be selected, enter the **value** usually selected for **mAs** and **NA** for **mA**. For a CT unit where a value is displayed for **mAs** *after scanning* even though the technique is set up through selection of **mA**, record the selected value of **mA** and the value of **mAs** that would be typically displayed, and note in the section for surveyor remarks that the CT unit is set up through selection of **mA**.

kV_p

mA

mAs

EXAMPLE

120

50

5000

37) Time (s) per 360° rotation in helical mode:

Enter the time (in units of *seconds*) during which the x-ray source is activated *per 360° rotation* of the x-ray source/detector array.

Time (s) per 360° rotation in helical mode

	<u>EXAMPLE</u>	<u>1.00</u>
OR	<u>EXAMPLE</u>	<u>0.75</u>
OR	<u>EXAMPLE</u>	<u>0.50</u>

38) Number of revolutions (360° rotations) for 38a) non-contrast phase and/or 38b) contrast phase:

In surveyor worksheet cells **38a** and/or **38b**, enter the number of 360° rotations in which the anatomical region of interest (ROI) is scanned with the most frequently used helical-scanning protocol for a routine adult CT head examination without and/or with contrast, respectively. For this protocol, if the facility does *not* typically do scanning with contrast, or if it does *not* typically do scanning without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well in the most frequently used helical-scanning protocol for a routine adult CT head exam, enter data in both cells. If the non-contrast and contrast phases correspond to different parts of the entire region of interest (e.g., see description for **25g**), make a notation in the remarks section of the worksheet.

Note: Some CT units do not provide for selection or for display of the “number of revolutions” (360° rotations). In this case, enter **NA** in worksheet cell **38a** and in cell **38b**. In lieu of the “number of revolutions,” some CT units may provide for selection or display of an *ROI range (mm)* scanned helically. See question 39.

	<u>No. revs. (non-contrast)</u>	<u>No. revs. (contrast)</u>
	<u>EXAMPLE</u>	<u>NA</u>
OR	<u>EXAMPLE</u>	<u>80</u>
	<u>100</u>	<u>100</u>

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), record the number of revolutions used with the larger slice width in cells **38a** and/or **38b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the *number of revolutions* associated with **each** width.

39) **Region of Interest (ROI) range (mm) scanned helically for 39a) non-contrast phase and/or 39b) contrast phase:**

Note: In a helical mode, the range scanned corresponds to the distance that the table moves the patient—at a selected *table feed* (mm per 360° rotation) or *table speed* (mm/s)—during *multiple* 360° rotations of the x-ray source/detector-array within the gantry.

In surveyor worksheet cells **39a** and/or **39b**, enter the total range (in units of millimeters) scanned over the anatomical region of interest in the most frequently used helical-scanning protocol for a routine adult CT head examination without and/or with contrast, respectively. Such a range may be determined, for example, by the difference in selections of upper and lower z-coordinates (axial coordinates corresponding to upper and lower anatomical “levels”). For this protocol, if the facility does *not* typically do scanning with contrast, or if it does *not* typically do scanning without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well in the most frequently used helical-scanning protocol for a routine adult CT head exam, enter data in both cells. If the non-contrast and contrast phases correspond to different parts of the entire region of interest (e.g., see description for **25g**), make a notation in the remarks section of the worksheet.

Note: Some CT units do not provide for selection or for display of an “ROI range” (or, equivalently, z- or axial coordinates.) In this case, enter **NA** in worksheet cell **39a** and in cell **39b**. These CT units may provide for selection or display of a *number of revolutions (360° rotations)* in lieu of an “ROI range” (or z- or axial coordinates.) See question 38.

	<u>ROI range (mm)</u> (non-contrast)	<u>ROI range (mm)</u> (contrast)
OR	<u>EXAMPLE</u> 110	<u>EXAMPLE</u> NA
	<u>EXAMPLE</u> 110	<u>EXAMPLE</u> 80

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), then record the ROI range used with the larger slice width in cells **39a** and/or **39b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the ROI range associated with **each** width.

40) **Slice width (mm) for 40a) non-contrast phase and/or 40b) contrast phase:**

In surveyor worksheet cells **40a** and/or **40b**, enter the nominal values for the width (in units of *millimeters*) of the image slice respectively selected (via collimation) for non-contrast and/or contrast scanning as phases of the most frequently used helical-scanning protocol for a routine adult CT head examination. For the most frequently used helical scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

	<u>Slice width (mm)</u> <u>(non-contrast)</u>	<u>Slice width (mm)</u> <u>(contrast)</u>
OR	<u>EXAMPLE</u> <u>EXAMPLE</u>	<u>10</u> <u>10</u>
		<u>NA</u> <u>10</u>

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **nominal width of an individual slice** in cells **40a** and/or **40b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), record the larger slice width in cells **40a** and/or **40b**. In the section of the surveyor worksheet for remarks, indicate that two different values for slice width are used, and record the *slice-width value* of **each**.

41) **Table feed (mm) for 41a) non-contrast phase and/or 41b) contrast phase:**

In surveyor worksheet cells **41a** and/or **41b**, enter the *nominal* (i.e. the selected) **table feed** (in units of *millimeters*) *per 360° rotation* used respectively for non-contrast and/or contrast scanning as phases of the most frequently used helical-scanning protocol for a routine adult CT head examination. For the most frequently used helical-scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

Note: Some CT units do not provide for selection or for display of the table “feed.” In this case, enter **NA** in worksheet cell **41a** and in cell **41b**. These CT units may provide for selection or display of a *table speed* in lieu of table “feed.” See question 42.

	<u>Table feed (mm)</u> (non-contrast)	<u>Table feed (mm)</u> (contrast)
OR	<u>EXAMPLE</u> <u>EXAMPLE</u>	<u>10</u> <u>20</u>
		<u>NA</u> <u>10</u>

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **actual table feed per 360° rotation** in cells **41a** and/or **41b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), then record the table feed associated with the larger slice width in cells **41a** and/or **41b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the *table feed* associated with **each** width.

42) Table speed (mm/s) for 42a) non-contrast phase and/or 42b) contrast phase:

In surveyor worksheet cells **42a** and/or **42b**, enter the *nominal* (i.e. the selected) **table speed** (in units of *millimeters per second*) used respectively for non-contrast and/or contrast scanning as phases of the most frequently used helical-scanning protocol for a routine adult CT head examination. For the most frequently used helical-scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

Note: Some CT units do not provide for selection or for display of the table “speed.” In this case, enter **NA** in worksheet cell **42a** and in cell **42b**. These CT units may provide for selection or display of a *table feed* in lieu of table “speed.” See question 41.

	<u>Table speed (mm/s)</u> <u>(non-contrast)</u>	<u>Table speed (mm/s)</u> <u>(contrast)</u>
OR	<u>EXAMPLE</u> <u>EXAMPLE</u>	<u>10</u> <u>20</u>
		<u>NA</u> <u>10</u>

NOTE: Some CT systems acquire data two or four slices at a time. For such multiple-slice systems, record the **actual table speed** in cells **42a** and/or **42b** even though slices are acquired two or four at a time. Indicate in the worksheet section for surveyor remarks that the CT unit is a multiple-slice system and specify the number of slices acquired per scan.

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), record the table speed associated with the larger slice width in cells **42a** and/or **42b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the *table speed* associated with **each** width.

43) Pitch for 43a) non-contrast phase and/or 43b) contrast phase:

In surveyor worksheet cells **43a** and/or **43b**, enter the *nominal* (i.e. the selected) **pitch** used respectively for non-contrast and/or contrast scanning as phases of the most frequently used helical-scanning protocol for a routine adult CT head examination. For the most frequently used helical-scanning protocol, if the facility does *not* typically do a phase with contrast, or if it does *not* typically do a phase without contrast, enter **NA** in the corresponding cell. If there is a non-contrast phase and a contrast phase as well, enter data in both cells.

Note: The *pitch* is a dimensionless quantity. For many (but not all) CT systems, *pitch* is defined from other parameters in either of two ways—
(1) *table feed* divided by the nominal *scan width* set by the collimator or
(2) *table speed* times 360° -*rotation time* divided by the nominal *scan width*.⁶

⁶ For single-slice CT units, the scan width corresponds to the width of a single slice. For multi-slice CT units, the scan width corresponds to the *total* width of adjacent multiple slices. However, manufacturers of some multi-slice CT units have an alternative definition of “pitch” that does not refer to multiple-slice width at all: they define “pitch” as the ratio of the table feed to the *single-slice* width even for a multi-slice system. See discussions of Kenyon K. Kopecky, Kenneth A. Buckwalter, and Roman Sokiranski, “Multi-slice CT spirals past single-slice CT in diagnostic efficacy,” *Diagnostic Imaging*, Vol. 21, No. 4, pp. 36-42 (April 1999); and Cynthia H. McCollough and Frank E. Zink, “Performance evaluation of a multi-slice CT system,” *Medical Physics*, Vol. 26, No. 11, pp. 2223-2230 (November 1999).

$$\text{pitch} = \frac{\text{table feed}}{\text{scan width}} = \frac{\text{table speed} \times 360^\circ \text{-rotat. time}}{\text{scan width}}$$

Some CT units do not provide for selection or for display of the “pitch.” Some units enable a change of pitch by means of a change of “mode.” If **values** of pitch can be *selected*, or if they are *displayed*, then enter the **values** in cells 43a and/or 43b. However, if neither selection nor display of the *pitch* is available, **do not calculate** *pitch* from the other quantities that may be provided. Instead, enter **NA** in worksheet cell **43a** and in cell **43b**.

	<u>Pitch (non-contrast)</u>	<u>Pitch (contrast)</u>
OR	<u>EXAMPLE</u> <u>EXAMPLE</u>	<u>NA</u> <u>1</u>

Split-Technique Protocol: If the facility uses for its most frequent helical-scanning protocol (e.g., that you may describe in 25k) one slice width for one part of the head and a different slice width for the remainder of the head (e.g., 10-mm width from the top of the skull to the orbits and 5-mm width from the orbits to the base of the skull), record the *pitch* associated with the larger slice width in cells **43a** and/or **43b**. In the section of the surveyor worksheet for remarks, indicate that two values for slice width are used, and record the *pitch* associated with **each** width.

X-ray Exposure Measurements

Dosimetry phantom alignment (entries 44-46)

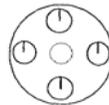
44a) Phantom model and 44b) serial number:

- In cell **44a** enter the names of the *manufacturer and model* (if any) of the head phantom being used in the survey. The phantom should be the 16-cm diameter, polymethyl methacrylate (PMMA) head phantom typically used to measure computed tomography dose index (CTDI). See Appendix F for a detailed description.
- In cell **44b** enter the serial number (if any). If there are no names, enter **NA**.

	<u>Phantom model</u>	<u>Phantom ser. no.</u>
<u>EXAMPLE</u>	<u>CDRH head, Mar 1990</u>	<u>CDRH 055</u>

- Position the head phantom directly on the patient table, fixing it in place with the facility’s foam wedges or—if needed—with masking tape after it is aligned.

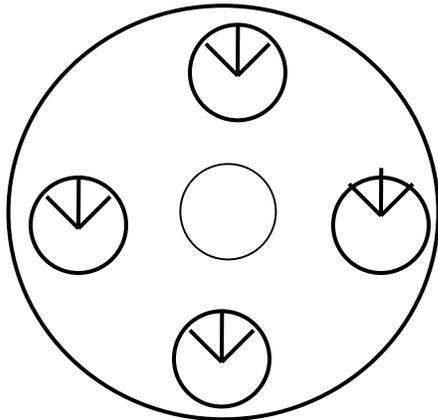
- Center the phantom in the gantry aperture so that you are facing the open holes at 12, 3, 6, and 9-o'clock positions at one end of the phantom. In this orientation, the phantom face with open holes lies in the direction of the long extent of the table, i.e., pointing away from the gantry and toward the “feet”-end of a patient lying on the table. The closed face of the phantom lies closer to the gantry aperture, i.e., toward the “head”-end of such a patient.
- Place alignment rods in the four holes near the phantom cylindrical surface. Be sure that the rods are fully inserted into the phantom. *Leave the center hole empty.* The alignment rods must be positioned in the phantom so that the small inscribed line on the end cap of each rod is vertical and extends *upward* from the center of each rod (see figure).



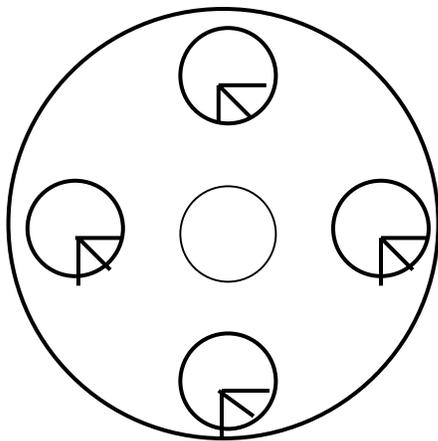
- **Position the gantry so that it is perpendicular to the plane of the patient table.** Use the CT unit alignment system (e.g., the CT unit laser-light system) and the “centerline” mark (i.e., the mark inscribed around the circumference of the phantom) to align the phantom for a single axial (conventional) scan that slices the phantom at a location *mid-way* along the phantom's length. Check to see that the phantom central axis of symmetry is aligned in the gantry along the axis of rotation of the CT unit, that the phantom is neither pitched up or down nor yawed left or right.

Find out from the CT operator whether the facility would ordinarily tilt the gantry for routine head exams. If the facility tilts the gantry, **record** the tilt angle in degrees in the remarks section of the surveyor worksheet. But please do **not** tilt the gantry for survey measurements!

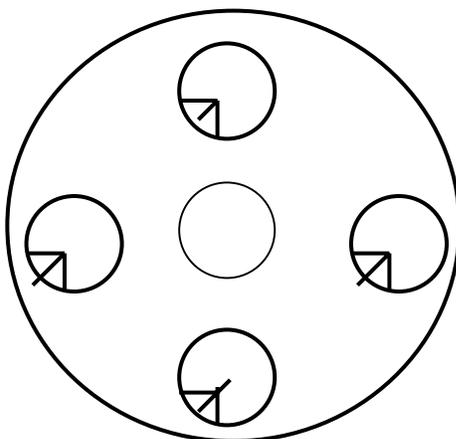
- For phantom alignment, ask the CT system operator to set the **slice width to 10 mm with no table incrementation.**
- Make a single scan (i.e., one slice) of the phantom. If the image of the phantom is not in the center of the reconstruction circle, adjust the table and/or phantom and make another scan. Repeat until the image of the phantom is within 10 mm of the center of the reconstruction circle.
- Examine the image of the phantom and observe the regions corresponding to the locations of the alignment rods. If the phantom is properly aligned with respect to the plane of the scan, then each alignment-rod pattern will appear as a group of three bars in the *upper* quadrants of the rod cross section: There will be a vertical middle bar adjacent to a pair of bars angled at ± 45 degrees from the vertical (see illustration).
- If these alignment-rod patterns are in the *lower* quadrants of the rod cross section, i.e., if the phantom is misaligned by ± 9 mm or more with respect to the head-to-feet location of the scan plane, then adjust the table position as indicated in the figure in order to correct the alignment. ***If the alignment-rod patterns lie within the upper quadrants or partially between upper and lower quadrants, i.e., the misalignment is less than ± 9 mm, then no adjustments are needed.***



Correct alignment



The phantom is located 9 mm too far toward the “feet”-direction with respect to the scan plane. Correct the alignment by moving the table or phantom 9 mm in the “head”-direction.



The phantom is located 9 mm too far toward the “head”-direction with respect to the scan plane. Correct the alignment by moving the table or phantom 9 mm in the “feet”-direction.

Sample Alignment Patterns

Radcal (“MDH”) Corporation radiation monitor/probe set-up

- Place the radiation monitor on the patient table, set the monitor *function* selector to **OFF**, and connect the probe (pencil ionization chamber) to the monitor.
- Set the radiation monitor *pulse-fraction threshold* to **0.5**, and the *mode* selector to **PULSE EXPOSURE**.

NOTE: Although PULSE EXPOSURE is the preferred mode of measurement, if you observe gross inconsistencies among any series of exposure values to be entered in cells 47, 48, or 49, then discard those values and do not use the PULSE EXPOSURE mode for the measurements. Instead, switch the *mode* selector to **EXPOSURE** and try to obtain consistent values in the **EXPOSURE** mode. *After recording any measured value of exposure* in the **EXPOSURE** mode, you will have to manually reset the *function* selector to **HOLD** in order to zero the radiation monitor for a subsequent measurement of exposure. After selecting **HOLD**, switch the *function* selector back to **MEASURE** to do the subsequent measurement. In the surveyor worksheet section for remarks, please indicate which measurements of cells 47, 48, or 49 were made in **EXPOSURE** mode rather than PULSE EXPOSURE mode. Also, if you cannot use the PULSE EXPOSURE mode for series 48 because you obtain grossly inconsistent values, then **do not** switch the mode selector to PULSE DURATION to measure values of *single-scan duration* sought in cells 48c, 48e, 48g.

45a) Monitor model, 45b) Monitor ser. no., 46a) Probe model, and 46b) Probe ser. no.:

- Enter the radiation monitor and probe model and serial numbers in the appropriate worksheet cells. The most commonly used monitor models are the **1015C** and **1515**. The *Radcal* pencil probe model number is **10X5-10.3CT**. See Appendix F.

Exposure-measurement series (three or six values), phantom central hole (entries 47):

- Carefully insert the pencil ionization-chamber probe in its *Plexiglas sleeve* into the central hole of the phantom. Be sure that the probe is fully inserted into the phantom and that each of the peripheral holes of phantom contains a plastic rod. You may have to tape the probe wire to the phantom to prevent the probe from moving out of its location.

For entries **47a-d**, if *axial scanning is used more frequently than helical scanning for a routine head procedure* (see entries **25a-k**), then without moving the gantry or table or otherwise disturbing the phantom alignment,

Ask the CT system operator to set up the unit for a *single scan* in a routine head procedure using the *same technique factors* recorded in worksheet cells **24, 26b, 27, 28** (if applicable), **29, 30**, and the *larger slice width* of either **32a** or **32b**.

Write in the remarks section that *axial* technique factors and not helical ones are being used for the exposure-measurement series to be recorded in worksheet cells **47a-d**.

Make sure that there is no table incrementation between scans.

For entries **47a-d**, if **helical** scanning is used more frequently than the axial scanning for a routine head procedure (see entries **25a-k**), then without moving the gantry or table or otherwise disturbing the phantom alignment,

Ask the CT system operator to set up the CT unit for a *single scan* using the *same helical technique factors* recorded in worksheet cells **24, 34b, 35, 37**, and the *larger slice width* of either **40a** or **40b**. **Note:** “Helical” technique factors here refer **only** to filtration, kV_p , mA, time per rotation, and slice width, **not to table movement!** In other words, the system shall **not** operate in a true “helical” mode: **For this series of measurements, the table is not to move during scanning. Each measurement shall correspond to a single 360° rotation without table movement.**

Write in the remarks section that *helical* technique factors and not axial ones are being used for the exposure-measurement series to be recorded in worksheet cells **47a-d**.

Make sure that there is no table incrementation between scans.

47a) Slice width (mm):

- Enter the slice width set up for exposure measurements 47b-d. (This value should be the larger value entered in cells 32a or 32b if axial scanning techniques are more frequently used or else the larger value entered cells 40a or 40b if helical scanning techniques are more frequently used.)

47b), c), and d) Exposure (mR), phantom *central hole*:

- Without making any changes in the techniques, and with the phantom and probe properly positioned, switch the radiation monitor *function* selector from **OFF** to **MEASURE**. For this first activation of the monitor, the display should indicate as follows: **-0.00** If any other reading is present, reset the radiation monitor by switching the *function* selector from **MEASURE** to **HOLD** and then back to **MEASURE**.
- Ask the CT operator to make the first *single scan* (one slice) of this measurement series.
- Enter the exposure value displayed by the radiation-monitor into worksheet cell **47b** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do **not** make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.

- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the phantom alignment, ask the operator to make the second *single scan* of this series.
- Enter the exposure value displayed by the radiation-monitor into worksheet cell **47c** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the phantom alignment, ask the operator to make the third *single scan* of this series.
- Enter the exposure value displayed by the radiation-monitor into worksheet cell **47d** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.

For entries **47e-g**, *except for slice width*, use the same technique factors that were used for measurements **47b-d**. **Note:** If the slice width entered in **47a** is 5 mm, skip measurements **47e-g**. If the slice width entered in **47a** is different from 5 mm, proceed with measurements **47e-g**.

47e), f), and g) Exposure (mR), 5-mm width, phantom *central* hole:

- Ask the CT operator to set the slice width to **5 mm**.
- **Make sure that there is no table incrementation between scans.**
- In the remarks section, write in whether *axial* or *helical* techniques are being used for entries **47e-g**.
- Without moving the gantry or table or otherwise disturbing the phantom alignment, perform a series of **three** *single-scan exposures* whose values in units of *mR* are to be entered respectively in cells **47e-g**. **If** the monitor displays any of the exposures in units of *roentgen*, convert the value to units of *milliroentgen* by multiplying the

roentgen value by a factor of 1000. **Note:** Except for ensuring that the exposure values are in units of *mR*, do not make any other correction to the values. Do **not** multiply the exposure values measured with the model 1015 radiation monitor by 2. CDRH will make this correction.

Slice width, exposure-measurement, and single-scan duration series, phantom *top* hole (entries 48):

For entries **48a-g**, if the CT unit is capable of “CT fluoroscopy” (see entry **22**), ask the CT operator to set up the CT unit for a *single scan* with the technique factors associated with CT fluoroscopy, recorded as worksheet entries **22b** through **22e**.

Note: Measurements for cells **48a-g** will be made with *single* axial scans of 360° each; do not use “continuous” scanning with multiple rotations as there would be in a true “CT fluoroscopic” mode.

In the section of the surveyor worksheet for remarks, record that the facility’s *CT-fluoroscopy* technique-set is being used for the series **48a-g** at the phantom top hole.

For entries **48a-g**, if the CT unit is **not** capable of “CT fluoroscopy” (or if *any* of the technique factors **22b** through **22e** is not known, **or if it is not possible to obtain a *single scan* in the CT fluoroscopic mode**), ask the CT operator to set up the CT unit for a *single scan* with the **same** technique factors that were used for exposure-measurement series **47a-d**, that is, those associated with the most frequently used modality for the routine CT head procedure.

Note: Measurements for cells **48a-g** will be made with *single* axial scans of 360° each; do not use “continuous” scanning with multiple rotations as there would be in a true “CT fluoroscopic” mode.

In the section of the surveyor worksheet for remarks, record that the *routine-head* technique-set is being used for the exposure-measurement series **48a-g** at the phantom top hole, and note whether this routine set is done with *axial* or *helical* technique factors.

- Without disturbing the alignment of the phantom in the gantry aperture, carefully *exchange* the alignment rod in the top hole of the phantom with the pencil ionization chamber in the central hole. You may have to tape the probe wire to the phantom to prevent the probe from moving out of its new location.

48a) Slice width (mm):

- Enter the slice width set up for exposure and single-scan duration measurements **48b-g**. (This value should be either the value entered in cell **22d** (if the CT unit has a CT fluoroscopic mode available) or else the value entered in cell **47a** (if the unit has no

CT fluoroscopy capability, or if any of the CT fluoroscopic technique factors is *not known*, or if it is not possible to obtain a single scan in the CT fluoroscopic mode.)

**48b-g) Exposure-measurement (mR) and single-scan duration (sec) series,
phantom *top hole*:**

- Make sure that there is no table incrementation between scans.
- Without making any changes in the techniques, and with the phantom and probe properly positioned, ask the CT operator to make the first *single scan* (one slice) of this measurement series.
- Enter the first single-scan exposure value displayed by the radiation-monitor into worksheet cell **48b** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- Switch the radiation monitor *mode* selector from PULSE EXPOSURE to **PULSE DURATION**.
- In worksheet cell **48c**, enter the time displayed for the single scan in *units of seconds*. **If** the radiation monitor displays the time in units of *milliseconds*, convert this value to units of *seconds* by dividing the *milliseconds* value by a factor of 1000.
- Switch the radiation monitor *mode* selector from PULSE DURATION back to **PULSE EXPOSURE**.
- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the phantom alignment, ask the operator make the second *single scan* (one slice) of this series.
- Enter the exposure value displayed by the radiation monitor into worksheet cell **48d** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- Switch the radiation monitor *mode* selector from PULSE EXPOSURE to **PULSE DURATION**.
- In worksheet cell **48e**, enter the time displayed for the single scan in *units of seconds*. **If** the radiation monitor displays the time in units of *milliseconds*, convert this value to units of *seconds* by dividing the *milliseconds* value by a factor of 1000.

- Switch the radiation monitor *mode* selector from PULSE DURATION back to **PULSE EXPOSURE**.
- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the phantom alignment, ask the operator make the third *single scan* (one slice) of this series.
- Enter the exposure value displayed by the radiation monitor into worksheet cell **48f** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- Switch the radiation monitor *mode* selector from PULSE EXPOSURE to **PULSE DURATION**.
- In worksheet cell **48g**, enter the time displayed for the single scan in *units of seconds*. **If** the radiation monitor displays the time in units of *milliseconds*, convert this value to units of *seconds* by dividing the *milliseconds* value by a factor of 1000.
- Switch the radiation monitor *mode* selector from PULSE DURATION back to **PULSE EXPOSURE**.
- Center a *ready-pack film* (supplied as Kodak X-Omat TL, 8 in X 10 in) on top of the phantom with the shorter dimension of the pack parallel to the axis of rotation. If the ready-pack film lies in a stable manner on the round surface of the phantom, there is no need to anchor it with tape. Anchor the film pack with tape if the pack doesn't stay put.

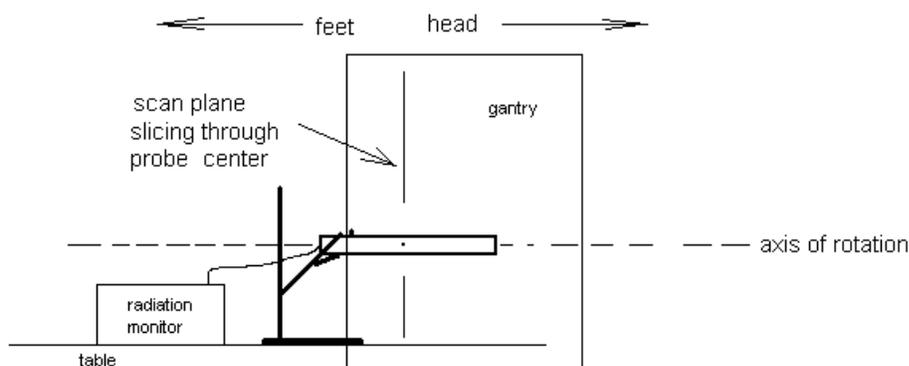
If the CT fluoroscopic technique factors were used for entries 48a-g, use those same techniques and expose the film in a single axial scan without any table incrementation.

If the routine head technique (not CT fluoroscopic) factors were used for entries 48a-g, use the same kVp and slice width but **reduce the mA and time for a single axial scan to yield the lowest possible mAs** and then expose the film without any table incrementation.

- In the remarks section of the Surveyor Worksheet, record the mAs, kVp, and milliroentgen (mR) for the film exposure.
- **After a single exposure, carefully remove the ready-pack film.** It should be exposed only once. Develop the film in the facility's processor after you have completed all other measurements.

Exposure-measurement series, *free-in-air on axis-of-rotation* (entries 49):

- Gently remove the pencil ionization-chamber probe from the head phantom and the head phantom from the gantry aperture.
- Set up the lab stand on the patient table by assembling the rod into the base and fixing the 3-prong extension clamp to the rod with the clamp holder.
- Secure the *base* of the pencil ionization-chamber probe in the 3-prong clamp, and make sure that the cables are kept out of the scan plane.
- Using the CT unit's alignment system, position the probe within the CT gantry so that 1) its *length lies on the CT axis-of-rotation* and 2) the *center* of the active volume (marked by a red line around the circumference in the middle of the probe) would be cut by a single tomographic slice at the scan plane:



Note: Please ensure that the table is low enough to accommodate the 18-inch height of the upright lab-stand rod if it needs to fit into the gantry opening. Alternatively, it may be possible to keep the lab-stand rod and lab-stand base out of the gantry altogether by fixing the probe (at the probe base) *parallel* to the extension arm and running the probe cables through the 3-prong clamp. Such a configuration extends the probe further away from the rod. In any case, please make sure that the scan plane intercepts no part of lab-stand base.

For entries **49a-d**, if *axial* scanning is used more frequently than helical scanning for a routine head procedure (see entries **25a-k**), then without moving the gantry or table or otherwise disturbing the probe alignment,

Ask the CT system operator to set up the unit for a *single scan* in a routine head procedure using the *same technique factors* recorded in worksheet cells **24**, **26b**, **27**, [and/or **28**], **29**, **30**, and the *larger* slice width of either **32a** or **32b**.

Write in the remarks section that *axial* technique factors and not helical ones are being used for the exposure-measurement series to be recorded in worksheet cells **49a-d**.

Make sure that there is no table incrementation between scans.

For entries **49a-d**, if **helical** scanning is used more frequently than the axial scanning for a routine head procedure (see entries **25a-k**), then without moving the gantry or table or otherwise disturbing the probe alignment,

Ask the CT system operator to set up the CT unit for a *single scan* using the *same helical technique factors* recorded in worksheet cells **24, 34b, 35, 37**, and the *larger* slice width of either **40a** or **40b**. **Note:** “Helical” technique factors here refer **only** to filtration, kV_p, mA, time per rotation, and slice width, **not to table movement!** In other words, the system shall **not** operate in a true “helical” mode: **For this series of measurements, the table is not to move during scanning. Each measurement shall correspond to a single 360° rotation without table movement.**

Write in the remarks section that *helical* technique factors and not axial ones are being used for the exposure-measurement series to be recorded in worksheet cells **49a-d**.

Make sure that there is no table incrementation between scans.

49a) Slice width (mm):

- Enter the slice width set up for exposure measurements 49b-d. (This value should be the larger value entered in cells 32a or 32b if axial scanning techniques are more frequently used or else the larger value entered in cells 40a or 40b if helical scanning techniques are more frequently used.)

49b), c), and d) Exposure (mR) free-in-air on axis of rotation:

- Without making any changes in the techniques, and with the probe properly positioned, ask the CT operator to make the first *single scan* (one slice) of this measurement series.
- Enter the exposure value displayed by the radiation-monitor into worksheet cell **49b** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the probe alignment, ask the operator to make the second *single scan* of this series.

- Enter the exposure value displayed by the radiation-monitor into worksheet cell **49c** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.
- **Make sure that there is no table incrementation between scans.**
- Without moving the gantry or table or otherwise disturbing the probe alignment, ask the operator to make the third *single scan* of this series.
- Enter the exposure value displayed by the radiation-monitor into worksheet cell **49d** in *units of milliroentgen*. **If** the monitor displays the exposure in units of *roentgen*, convert this value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure value is in units of *mR*, do not make any other correction to the value. Do **not** multiply the exposure value measured with the model 1015 radiation monitor by 2. CDRH will make this correction.

For entries **49e-g**, *except for filtration and possibly slice width*, use the same technique factors that were used for measurements **49b-d**.

49e), f), and g) Exposure (mR), body filter, 5-mm width, free-in-air on axis of rotation:

- Ask the CT operator to set up the unit with the most commonly used **body filter**. In the remarks section of the surveyor worksheet, record the name of the body filter used.
- Ask the CT operator to set the slice width to **5 mm**.
- **Make sure that there is no table incrementation between scans.**
- In the remarks section, record whether *axial* or *helical* techniques are being used for entries **49e-g**.
- Without moving the gantry or table or otherwise disturbing the probe alignment, perform a series of **three single-scan exposures** whose values in units of *mR* are to be entered respectively in cells **49e-g**. **If** the monitor displays any of the exposures in units of *roentgen*, convert the value to units of *milliroentgen* by multiplying the *roentgen* value by a factor of 1000. **Note:** Except for ensuring that the exposure

values are in units of mR , do not make any other correction to the values. Do **not** multiply the exposure values measured with the model 1015 radiation monitor by 2. CDRH will make this correction.

Please develop the ready-pack film in the facility's processor, identify the facility on the film, and return the developed film along with the facility diskette to CDRH following electronic filing of the surveyor worksheet and the facility questionnaire.

Please return the lab stand to CDRH after you have completed all of your surveys. Our goal is to have surveys completed by November 2000.

Many thanks for your efforts!

APPENDIX A

State and Agency Codes for NEXT Surveys

Alabama	AL	New York City	56
Alaska	AK	New York State	
Arizona	AZ	Dept. of Health	NY
Arkansas	AR	New York State	
California	CA	Dept. of Labor	55
Colorado	CO	North Carolina	NC
Connecticut	CT	North Dakota	ND
Delaware	DE	Ohio	OH
District of Columbia	DC	Oklahoma	OK
Florida	FL	Oregon	OR
Georgia	GA	Pennsylvania	PA
Guam	GU	Puerto Rico	PR
Hawaii	HI	Rhode Island	RI
Idaho	ID	South Carolina	SC
Illinois	IL	South Dakota	SD
Indiana	IN	Tennessee	TN
Iowa	IA	Texas	TX
Kansas	KS	Utah	UT
Kentucky	KY	Vermont	VT
Louisiana	LA	Virginia	VA
Maine	ME	Virgin Islands	VI
Maryland	MD	Washington	WA
Massachusetts	MA	West Virginia	WV
Michigan	MI	Wisconsin	WI
Minnesota	MN	Wyoming	WY
Mississippi	MS	Philadelphia	57
Missouri	MO	U.S. Coast Guard	59
Montana	MT	Bureau of Prisons	60
Nebraska	NE	U.S. Navy	61
Nevada	NV	U.S. Army	62
New Hampshire	NH	U.S. Air Force	63
New Jersey	NJ	Indian Health Service	65
New Mexico	NM		

APPENDIX B

Practice Specialty Codes

XX = Multiple Specialty Practice *or* Mobile Unit

01 = Dental (except orthodontics)

02 = Orthodontics

03 = Medical General Practice

04 = Radiology

05 = Internal Medicine

06 = Surgery

07 = Urology

08 = Pediatrics

09 = Orthopedics

10 = Gastroenterology

11 = Chiropractic

12 = Podiatry

13 = Osteopathy

14 = Obstetrics/Gynecology

15 = Cardiology

16 = Electrophysiology

17 = Endocrinology

18 = Geriatrics

19 = Hematology

20 = Immunology

21 = Infectious Diseases

22 = Nephrology

23 = Neurology

24 = Nuclear Medicine

25 = Oncology (including Radiation Therapy)

26 = Ophthalmology

27 = Otolaryngology

28 = Physical Medicine

29 = Pulmonary Medicine

30 = Emergency/Shock/Trauma Medicine

99 = Other

Radiological Protocols for a Routine Head Examination

24) Selected physical filter

"HEAD"

25) Scanning protocols		Frequency-of-use Percentage	Description of Anatomical Region-of-Interest (ROI)
Axial scanning—no contrast	25a)	50%	From the top to the base of the skull
Axial scanning—with contrast	25b)		
Axial scanning—2 phases: partly no contrast, partly with contrast	25c)		
Axial scanning—2 phases: wholly without contrast and wholly with contrast	25d)	30%	From the foramen magnum to the suprasellar cistern in the brain
Helical scanning—no contrast	25e)	20%	From the top to the base of the skull
Helical scanning—with contrast	25f)		
Helical scanning—2 phases: partly no contrast, partly with contrast	25g)		
Helical scanning—2 phases: wholly without contrast and wholly with contrast	25h)		
One phase of axial scanning and one phase of helical scanning	25i)		
25k) Other	25j)		
		sum = 100%	

Technique Factors used in Axial (Conventional) Scanning Mode

26a) Which axial protocol?	<u>25a</u>	26b) kV _p	<u>130</u>	27) mA	<u>100</u>	28) mAs	<u>400</u>
29) Rotation angle (degrees) per single axial scan	<u>360</u>			30) Time (s) per single axial scan	<u>4.00</u>		
31) Number of slices	a) non-contrast phase		<u>14</u>	b) contrast phase		<u>NA</u>	
32) Slice width (mm)	a) non-contrast phase		<u>10.0</u>	b) contrast phase		<u>NA</u>	
33) Table increm. (mm)	a) non-contrast phase		<u>10.0</u>	b) contrast phase		<u>NA</u>	

Technique Factors used in Helical (Spiral) Scanning Mode

34a) Which helical protocol?	<u>25e</u>	34b) kV _p	<u>130</u>	35) mA	<u>50</u>	36) mAs	<u>700</u>
37) Time (s) per 360° rotation in helical mode	<u>1.00</u>						
38) No. of revolutions (360° rotations)	a) non-contrast phase		<u>14</u>	b) contrast phase		<u>NA</u>	
39) ROI range (mm)	a) non-contrast phase		<u>NA</u>	b) contrast phase		<u>NA</u>	
40) Slice width (mm)	a) non-contrast phase		<u>10.0</u>	b) contrast phase		<u>NA</u>	
41) Table feed (mm)	a) non-contrast phase		<u>10.0</u>	b) contrast phase		<u>NA</u>	
42) Table speed (mm/s)	a) non-contrast phase		<u>NA</u>	b) contrast phase		<u>NA</u>	
43) Pitch	a) non-contrast phase		<u>NA</u>	b) contrast phase		<u>NA</u>	

X-ray Exposure Measurements (Note: Do **not** multiply exposure values by 2.)

44a) Phantom model	CDRH Head, Mar 1990	44b) Phantom serial no.	CDRH 055
45a) Monitor model	Radcal 1015C	45b) Monitor ser. no.	974
46a) Probe model	Radcal 10X5-10.3CT	46b) Probe serial no.	8519

47) Measurement series, phantom central hole:

a) slice width (mm)	10.0	Exposure (mR) b)	432	Exposure (mR) c)	431	Exposure (mR) d)	431
...& with 5-mm slice width:		Exposure (mR) e)	205	Exposure (mR) f)	204	Exposure (mR) g)	204

48) Measurement series, phantom top hole:

a) slice width (mm)	10.0	Exposure (mR) b)	484	Exposure (mR) d)	478	Exposure (mR) f)	479
single-scan duration (sec):		Duration (sec) c)	4.06	Duration (sec) e)	4.07	Duration (sec) g)	4.07

49) Measurement series, free in air:

a) slice width (mm)	10.0	Exposure (mR) b)	229	Exposure (mR) c)	225	Exposure (mR) d)	226
...& with body filter & 5-mm slice width:		Exposure (mR) e)	105	Exposure (mR) f)	104	Exposure (mR) g)	105

Surveyor Remarks

Tilt angle for most adults: 15°.

47a)-d): CT unit set-up with the axial scanning technique factors entered in cells 24), 26b)-30), & 32a).

47e)-g): CT unit set-up with the axial scanning technique factors entered in cells 24), 26b)-30), 5-mm slice width

48a)-g): Unknown whether CT unit capable of "CT fluoroscopy" mode. For entries 48, used routine head technique factors for axial scanning (entries 24, 26b-30, 32a). For film exposure, used 130 kVp, 50 mA, 1.00 s, 50 mAs. Observed 60 mR exposure when film was exposed.

49a)-d): CT unit set-up with the axial scanning technique factors entered in cells 24), 26b)-30), & 32a).

49e)-g): CT unit set-up with the axial scanning technique factors entered in cells 26b)-30), body filter "no. 1", and 5-mm slice width

APPENDIX D: Surveyor Worksheet

Surveyor, Survey, and Facility Identification

1) Surveyor name _____ 4) Survey date _____

2) Surveyor telephone no. _____ 3) Surveyor e-mail _____

5) Facility name _____

6) Facility i.d. no. _____ 7) State or Agency code _____

8) Facility-type code _____ 8a) If code 99: _____

9) Practice-specialty code _____ 9a) If code 99: _____

10) Patient workload per week _____

11) Interviewee name _____

12) Interviewee title/position _____

X-ray CT Unit Identification and Capabilities

13) Manufacturer _____ 14) Serial no. _____

15) Date manufactured _____

16) Model name _____ 17) Model no. _____

18) System pulsed? _____ 19) Pulses per second _____

20) Duration (ms) of single pulse _____ 21) Helical scanning available? _____

22) "CT fluoroscopy" available? _____ 22a) Patient workload per week _____

22b) kVp _____ 22c) mA _____ 22d) Slice width (mm) _____

22e) Time (s) per 360° rotation _____ 22f) Average "beam-on" time (s) _____ 22g) Minimum "beam-on" time (s) _____

22h) Maximum "beam-on" time (s) _____

23a) Hard-copy output code _____ 23b) Image display/interpretation code _____

Radiological Protocols for a Routine Head Examination

24) Selected physical filter

25) Scanning protocols	Frequency-of-use Percentage	Description of Anatomical Region-of-Interest (ROI)
Axial scanning—no contrast	25a)	
Axial scanning—with contrast	25b)	
Axial scanning—2 phases: partly no contrast, partly with contrast	25c)	
Axial scanning—2 phases: wholly without contrast and wholly with contrast	25d)	
Helical scanning—no contrast	25e)	
Helical scanning—with contrast	25f)	
Helical scanning—2 phases: partly no contrast, partly with contrast	25g)	
Helical scanning—2 phases: wholly without contrast and wholly with contrast	25h)	
One phase of axial scanning and one phase of helical scanning	25i)	
25k) Other _____	25j)	
sum = 100%		

Technique Factors used in Axial (Conventional) Scanning Mode

26a) Which axial protocol?	_____	26b) kV _p	_____	27) mA	_____	28) mAs	_____
29) Rotation angle (degrees) per single axial scan	_____			30) Time (s) per single axial scan	_____		
31) Number of slices	a) non-contrast phase		_____	b) contrast phase		_____	
32) Slice width (mm)	a) non-contrast phase		_____	b) contrast phase		_____	
33) Table increm. (mm)	a) non-contrast phase		_____	b) contrast phase		_____	

Technique Factors used in Helical (Spiral) Scanning Mode

34a) Which helical protocol?	_____	34b) kV _p	_____	35) mA	_____	36) mAs	_____
37) Time (s) per 360° rotation in helical mode	_____						
38) No. of revolutions (360° rotations)	a) non-contrast phase		_____	b) contrast phase		_____	
39) ROI range (mm)	a) non-contrast phase		_____	b) contrast phase		_____	
40) Slice width (mm)	a) non-contrast phase		_____	b) contrast phase		_____	
41) Table feed (mm)	a) non-contrast phase		_____	b) contrast phase		_____	
42) Table speed (mm/s)	a) non-contrast phase		_____	b) contrast phase		_____	
43) Pitch	a) non-contrast phase		_____	b) contrast phase		_____	

X-ray Exposure Measurements (Note: Do **not** multiply exposure values by 2.)

44a) Phantom model _____ 44b) Phantom serial no. _____

45a) Monitor model _____ 45b) Monitor ser. no. _____

46a) Probe model _____ 46b) Probe serial no. _____

47) Measurement series, phantom central hole:

a) slice width (mm)	_____	Exposure (mR) b)	_____	Exposure (mR) c)	_____	Exposure (mR) d)	_____
...& with 5-mm slice width:		Exposure (mR) e)	_____	Exposure (mR) f)	_____	Exposure (mR) g)	_____

48) Measurement series, phantom top hole:

a) slice width (mm)	_____	Exposure (mR) b)	_____	Exposure (mR) d)	_____	Exposure (mR) f)	_____
single-scan duration (sec):		Duration (sec) c)	_____	Duration (sec) e)	_____	Duration (sec) g)	_____

49) Measurement series, free in air:

a) slice width (mm)	_____	Exposure (mR) b)	_____	Exposure (mR) c)	_____	Exposure (mR) d)	_____
...& with body filter & 5-mm slice width:		Exposure (mR) e)	_____	Exposure (mR) f)	_____	Exposure (mR) g)	_____

Surveyor Remarks

APPENDIX E: Facility Questionnaire on CT Practice

This questionnaire seeks information primarily about the scanning protocols and typical weekly numbers of patients undergoing various routine x-ray CT examinations of the head *and* body. The information will be used as part of the *Nationwide Survey of X-Ray Trends (NEXT)* to characterize CT practice and dose trends. All data that you provide will be treated confidentially and will be cited anonymously.

The questionnaire should be completed by the radiologic technologist (*possibly assisted by the medical physicist or other knowledgeable individuals*) responsible for the CT unit that was/will be surveyed for the *NEXT* program.

The information sought here need not be retrieved from records! For the purpose of this survey, the data that you provide may be approximations estimated according to your judgment and experience. Please write "UNKN" when some piece of information is unknown.

It is anticipated that some of the categories and terminology used in the questionnaire may not correspond precisely to the practice and conditions at your facility. Nevertheless, please fill out the form to the best of your understanding, and make notations if you think they are warranted. If you have any questions or need clarification, please contact the *NEXT* surveyor who has visited or will visit your facility.

Please return this questionnaire to the *NEXT* surveyor at your earliest convenience. You may wish to make a photocopy for your records.

We thank you very much for your efforts and contributions to this project!

Instructions for items 11a) *Z-axis interpolation algorithm*, 11b) *Detector type*, and 11c) *Focal-spot to axis of rotation distance (mm)*

Items 11a and 11b may be addressed with the assistance of a medical physicist familiar with the most frequently used CT unit that was/will be surveyed for the *NEXT* program. **11a** applies only to CT units capable of helical scanning; **11b** and **11c** apply to all types of CT units.

For item **11a) *Z-axis interpolation algorithm***, please identify the algorithm used to do what may be called either "z-axis," or "slice," or "section" interpolation in the reconstruction of images from helical-scanning data. Examples of such algorithms are "360° linear interpolation," "180° linear interpolation," and "180° second-order interpolation." Enter "NA" if the CT unit cannot do helical scanning. Enter "UNKN" if the algorithm is not known.

For item **11b) *Detector type***, please identify whether the x-ray detectors for this CT unit are of the *gaseous (xenon)* type or *solid-state* type.

For item **11c) *Focal spot to axis-of-rotation distance***, please enter the **distance in millimeters** from the focal spot to the axis of rotation. If more than one distance is used, enter the one most commonly used.

Instructions for items 13 (Axial) and 14(Helical) Scanning Techniques and Workload:

For each examination conducted with the most frequently used CT unit in your facility (which was/will be surveyed for the *NEXT* program), please specify the *most frequently used set of technique factors for adults and adult-patient workload*. Under item **13**, please enter values associated with **axial-scanning protocols**. If **helical (spiral)** scanning is done for any of the listed examination categories, please count those exams and specify their associated technique factors *separately under item 14*.

Each row listed under either item **13** or **14** is intended to correspond to a unique category of examination for purposes of counting and identifying associated technique factors. As an example, if typically the *liver* is scanned *as part* of a broader anatomical region that ranges through the *abdomen and pelvis*, then this exam should be counted (and technique values entered) in the "**Abdomen & pelvis**" category, **not** in the "Liver" category. If the *liver* is typically studied *as part* of a scanning range that is even broader and includes the *chest as well as the abdomen and pelvis*, then the exam should be counted in the "**Chest, abdomen, & pelvis**" category, **not** in the "Liver" and **not** in the "Abdomen & pelvis" category. On the other hand, if the *liver* is scanned in an anatomical region of interest that is restricted to encompass the *liver principally*, then the exam should be counted in the "**Liver**" category.

For each category of examination, enter the number of "**scout**" views (also referred to as a "pilot scans," "scanograms," "topograms," "scan projection radiographs," etc.) done before CT scanning begins. Enter zero if none are done.

Entries in the column "**Selected physical filter**," where the filter can be selected before scanning, should indicate the specific head/body option or scanned field of view ("cm" or "mm") however the selection may be designated or named for the particular CT unit being surveyed.

For *each* row of item 13 and for each row of item 14, the entries in the **last 3 columns on the right** should *total* 100%. The last 3 column entries correspond to the following *different categories* of contrast use: (1) exams with *no contrast whatsoever*, (2) exams where scanning is done *exclusively with contrast*, and (3) exams with a no-contrast phase *and* with a contrast phase.

Particular instructions for item 14, Helical (Spiral) Scanning Techniques and Workload:

For each exam in the column "**Reconstruction increment**," please enter the increment (in units of *millimeters*) along the axis of rotation (i.e., the "z-axis") for which reconstructed single-slice images are available from helical-scanning data. Values of the reconstruction increment typically range from 0.1 to 7 mm.

The column "**Region of Interest (ROI) range spanned**" refers to the *helical scanning range* (in units of *millimeters*) along the z-axis which defines the extent of the region of interest for the exam in question. With some CT systems this range may be selected on the basis of a "scout" view, for example, as the *difference* between an operator-specified "stop-scanning" level and a "start-scanning" level. In other CT systems the scanning range for the exam may not be specified directly this way but rather in terms of a "number of revolutions" (or "360° rotations") from a starting level for a selected table feed per rotation. For each category of exam, please enter an estimate (in *millimeters*) of the "**ROI range spanned**" if your system is set up that way, and place an "X" in the box adjacent to "ROI range" at the bottom item 14. If your CT system is set up so that you must specify a "number of revolutions" to select the range for the exam in question, please enter the number of rotations in the column "ROI range s

In the column "**Table feed (mm) per 360° rotation**," please enter the selected table *feed* (in units of *millimeters* per 360° rotation), if your CT unit is set-up to allow such selection, and place an "X" in the box adjacent to "**Table feed (mm)**" at the bottom of item 14. If, however, your CT system provides for selection of table *speed* (mm per second) instead of table feed, for each exam enter the table *speed* (in units of mm/s) in the column and place an "X" in the box adjacent to "Table speed (mm/s)" at the bottom of item 14.

Identification and Workload

1) Facility name _____

2) State i.d. no. of facility _____ 3) State _____

4) How many *x-ray CT* units are currently used at the facility? _____

4a) How many of total are non-helical units? _____ 4b) How many of total are single-slice/detector helical units? _____

4c) How many of total are multi-slice/detector helical units? _____ 4d) How many of total are electron-beam CT (EBCT) units? _____

5) On average, approximately what's the *total number* of CT adult *and* pediatric patient examinations or procedures (*complete exams of any type--head exams or body exams*) done *weekly* on *all* CT units at the facility? _____

6) Person(s) completing this questionnaire: _____

a) Name _____ a) Title/position _____ a) Date _____

b) Name _____ b) Title/position _____ b) Date _____

c) Name _____ c) Title/position _____ c) Date _____

7) *NEXT* surveyor name _____ 8) Survey date _____

The following items **9** through **18** refer *exclusively* to the single most frequently used CT unit in your facility. If all units are equally used, pick the unit with which staff completing this form are most familiar. In any case, this particular CT unit should be the *same one* that was/will be surveyed for the *NEXT* program:

9a) Manufacturer _____ 9b) Model _____ 10) Room no. _____

11a) Z-axis interpolation algorithm (See page E-1.) _____ 11b) Detector type (See page E-1.) _____ 11c) Focal spot to axis-of-rotation distance (mm) (See page E-1.) _____

12) On average, approximately what's the *total number of complete* examinaton or procedures (of *all types--head or body*) done *weekly* with this CT unit?

Please break out the numbers entered for question 12 according to the following categories (12a-d):

	Adults	Pediatrics
12a) Weekly number of neuroradiological exams (e.g., head, brain, orbits, sinus, neurospine, etc.)		
12b) Weekly number of general-purpose radiological exams (e.g., chest, abdomen, pelvis, liver, orthopedic spine, etc.)		
12c) Weekly number of interventional procedures (e.g., biopsy, drainage)		
12d) Weekly number of exams for radiotherapy treatment planning		

13) Axial (Conventional) Scanning Techniques and Workload, Adult Patients

Please refer to the instructions on page E-2 in order to complete item no. 13!

= 100% for each row

Examination Category	How many "scout" views before exam?	Selected physical filter	kVp	mA	Rotation angle (°) per single slice	Time (s) per single slice	Number of slices	Slice width (mm)	Table increment (mm) per slice	Weekly number of exams	% exams with no contrast whatsoever		
											% exams exclusively with contrast	% exams with a no-contrast phase and a contrast phase	
Abdomen & pelvis													
Head													
Simple sinus													
Chest													
Chest, abdomen, & pelvis													
Skull (or facial bones, or orbits, or sella turcica, or complex sinuses)													
Spine (cervical, thoracic, or lumbar)													
Liver													
Kidneys													
Pancreas													
Abdomen													
Pelvis													
Other1 (describe):													
Other2 (describe):													

14) Helical (Spiral) Scanning Techniques and Workload, Adult Patients

Please refer to the instructions on page E-2 in order to complete item no. 14!											= 100% for each row		
Examination Category	How many "scout" views before exam?	Selected physical filter	kVp	mA	Reconstruction increment (mm)	Time (s) per 360° rotation	*ROI range scanned (mm)	Slice width (mm)	**Table feed (mm) per 360° rotation	Weekly number of exams	% exams with no contrast whatsoever	% exams exclusively with contrast	% exams with a no-contrast phase and a contrast phase
Abdomen & pelvis													
Head													
Simple sinus													
Chest													
Chest, abdomen, & pelvis													
Skull (or facial bones, or orbits, or sella turcica, or complex sinuses)													
Spine (cervical, thoracic, or lumbar)													
Liver													
Kidneys													
Pancreas													
Abdomen													
Pelvis													
Other1 (describe):													
Other2 (describe):													
*(See specific instructions on page E-2.) Please place an "X" in one of the following cells to indicate which values apply for the data entered in this column:							ROI range (mm)		No. of rotations for ROI range scanned				
**(See specific instructions on page E-2.) Please place an "X" in one of the following cells to indicate which values apply for the data entered in this column:							Table feed (mm)		Table speed (mm/s)				

APPENDIX F

Survey Phantoms and Measurement Instruments⁷

Phantoms

Over the years several different versions of the CT phantom required by the regulations have been manufactured by CDRH and commercially. They have some variations in their make-up that complicates attempts at correlating results. In a 1990 attempt to reduce those variations, CDRH modified all of the CDRH owned phantoms and sent one to each of the States for the NEXT CT study that year. The modified phantoms and inserts do not all look the same but are compatible with each other and with the NEXT test procedure. This is the first time since 1990 that NEXT will be looking at CT. It is possible that some incompatible phantoms and inserts still exist. In order to minimize confusion with different phantoms and to ensure that all inserts and probes fit properly, it is requested that all phantoms be checked for compatibility. A description of the proper phantom follows.

The proper CDRH CT phantom is engraved with "PROPERTY OF FDA ROCKVILLE, MD 20852 MARCH 1990." The body of the phantom is 6.3 inches (16 cm) in diameter with 5 holes from top to bottom. Because there are several different original body heights one or more plates may be glued to the body to correct the height. Each hole in the body is 0.5 inch in diameter with one on the central axis and 4 equally spaced on a 5.5-inch diameter (14 cm) circle about the center. There is a line inscribed around the circumference of the phantom to mark the center of alignment.

There are 4 alignment rods with the phantom that are used to position the phantom in the CT unit. These rods are 7 inches long and slightly under 0.5 inches in diameter. Some of the rods may have little buttons glued at one end, added to correct for rod length. Each rod has a series of 9 small holes drilled into the central axis of the rod. These small holes are spiraled about the center of the rods. One end of each rod has an engraved arrow in line with the central hole of the spiral group.

Some of the phantom versions that are not acceptable have different body heights, some are missing the engraved line around the body, some have a missing bottom plate, and some have holes with the wrong dimensions. Some of the holes are too small, so that rods will not easily fit into the phantom. Some of the alignment rods have only one or three spiral holes and no arrow or line engraved on the end of the rod. Some rods and probe sleeves are not properly centered on the phantom.

To assure that the correct phantom and rods are being used for the NEXT CT 2000 protocol please perform the following checks:

- 1) Check to see that the phantom has a centerline inscribed around its circumference.

⁷ Adapted from Robert Slayton and Frank Cerra, FDA Center for Devices and Radiological Health, December 1999.

- 2) There should be four alignment rods, each with nine holes in a spiral pattern.
- 3) There should be a back plate preventing rods to slide all the way through and out the other side of the phantom.
- 4) When inserted into the phantom, the center hole of the alignment rods should line up with the centerline on the phantom. The direction of this hole should be indicated by a mark at the visible end of the rod.
- 5) When the probe and sleeve are inserted into the phantom, the red line in the center of the probe should line up with the centerline on the phantom.
- 6) All the rods and probe sleeve should easily slide in and out of the phantom holes without resistance.

Measurement Instruments

The *Radcal ("MDH") Corporation* radiation monitor and CT ionization-chamber probe should have been calibrated within the last twelve months by CDRH. If the monitor has a recent calibration by CDRH (i.e. less than 6 months old) but the probe does not, it is possible to send the probe alone for recalibration. However, if a model 1515 monitor is used rather than a model 1015, the monitor should always accompany the CT probe when calibrated. Note that all 1015 readings must be multiplied by a correction factor of 2 when using the CT probe, and this correction will be made at CDRH after the raw survey data are submitted.