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Technical Manual NMCPHC TM-6470.1A

Navy Diagnostic Imaging Equipment Performance Survey Manual

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NMCPHC Technical Manual TM-6470.1, *Navy Diagnostic Imaging Equipment Performance Survey Manual,* dated June 2013, is hereby cancelled.

This manual may be accessed through the NMCPHC website:
http://www.med.navy.mil/sites/nmcphc/occupational-and-environmental-medicine/rhd/Pages/rsoep.aspx.

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TABLE OF ISSUANCE AND REVISIONS/CHANGES

NMCPHC Manual	Basic Issuance Date
6470.1	June 2013

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LIST OF FORMS AND REPORTS

1. Forms. The following Navy and Marine Corps Public Health Center (NMCPHC) forms are available electronically at: https://forms.documentservices.dla.mil/.

Form No.	Form Title
NMCPHC 6470/21	General Radiographic Unit Survey
NMCPHC 6470/22	Dental Radiographic Unit Survey
NMCPHC 6470/23	General Fluoroscopy Unit Survey
NMCPHC 6470/24	Computed Tomographic Unit Survey
NMCPHC 6470/25	Ultrasound Scanner System Survey
NMCPHC 6470/26	Magnetic Resonance Imaging Unit Survey
NMCPHC 6470/27	Nuclear Medicine Camera Survey
NMCPHC 6470/28	Direct Digital Radiographic System Survey
NMCPHC 6470/29	Computed Radiographic System Survey

2. Reports. The reporting requirements for this manual are exempt from reports control per SECNAV M-5214.1 of December 2005, Part IV, paragraph 7.j.

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LIST OF ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ABC	Automatic Brightness Control
ABHP	American Board of Health Physicists
ABR	American Board of Radiology
ACR	American College of Radiology
AEC	Automatic Exposure Control
AERC	Automatic Exposure Rate Control
AKR	Air Kerma Rate
ALARA	As Low As Reasonably Possible
AP	Anterior/Posterior
BB	Ball Bearing
BUMED	Bureau of Medicine and Surgery
BW	Bandwidth
CBCT	Cone Beam Computed Tomography
CFOV	Central Field Of View
CNR	Contrast to Noise Ratio
COR	Center Of Rotation
cov	coefficient of variation
CR	Computed Radiography
CRCPD	Conference of Radiation Control Program Directors
CRT	Cathode Ray Tube
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DC	Direct Current
DDR	Direct Digital Radiography
DICOM	Digital Imaging and Communications in Medicine
DQA	Delivery Quality Assurance
DR	Digital Radiography
DRMO	Defense Reutilization and Marketing Office
DSOV	Diameter of Spherical Volume
EPI	Electronic Portal Imaging
ESE	Entrance Skin Exposure
ESAK	Entrance Skin Air KERMA
ESAKR	Entrance Skin Air KERMA Rate

FDA	Food and Drug Administration
FOV	Field Of View
fps	frames per second
fc	foot candles
FWHM	Full Width at Half Maximum
GFI	General Fluoroscopic Units
GRE	Gradient Echo
HAZMAT	Hazardous Materials
HDR	High Dose Radiation
HLC	High Level Control
HU	Hounsfield units
HVL	Half Value Layer
ICRP	International Council on Radiation Protection
II	Image Intensifier
IMRT	Intensity Modulated Radiation Therapy
IRI	Interventional Radiology Imaging
JCAHO	Joint Commission for Accreditation of Healthcare Organizations
KERMA	Kinetic Energy Released in Material
keV	Kilo-electron volts
KVCT	Kilovoltage Computed Tomography
kVp	kilovolt peak
LINACs	Linear Accelerators
lp/cm	line pairs per centimeter
lp/mm	line pairs per millimeter
LR	Lower Right
LSF	Line Spread Function
LUT	Look-up Table
mA	milliamp
Mammo	Mammography
mAs	milliamp seconds
mGy	milligray
MHz	megahertz
MPAB	Medical Physics Advisory Board
MQSA	Mammography Quality Standards Act
mR	milliroentgen
mrem	millirem

MRI	Magnetic Resonance Imaging
MSAD	Multiple Scan Average Dose
msec	millisecond
MTF	Modulation Transfer Function
MVCT	MegaVoltage Computed Tomography
NAVMED	Navy Medicine
NCRP	National Council of Radiation Protection and Measurements
NMCPHC	Navy and Marine Corps Public Health Center
NME	Navy Medicine East
NMW	Navy Medicine West
Nuc Med	Nuclear Medicine
OBI	onboard imaging
OD	Optical Density
OID	Object to Image Distance
PACS	Picture Archiving and Communication System
PET	Photon Emission Tomography
PIU	Percent Image Uniformity
PMMA	Polymethyl Methacrylate
PMT	Photomultipler Tube
PQS	Personnel Qualification Standard
PSG	Percent Signal Ghosting
QA	Quality Assurance
QC	Quality Control
rad	Radiation Absorbed Dose
rem	Roentgen Equivalent Man
RF	Radiofrequency
ROI	Region Of Interest
SD	Shielding Design
SID	Source to Image Distance
SMPTE	Society of Motion Picture and Television Engineers
SNR	Signal to Noise Ratio
SPECT	Single Photon Emission Computed Tomography
SSD	Source to Skin Distance
STP	System Transfer Properties
TE	Echo Time
TFT	Thin Film Transistor

TG	Task Group
TGC	Time Gain Compensation
TM	Tissue Mimicking
TR	Repetition Time
UFOV	Useful Field Of View
UL	Upper Left
US	Ultrasound
USUHS	Uniformed Services University of the Health Science

Chapter 1. Introduction

A. *Background*

1. Per BUMEDINST 6470.22B, this manual has been prepared to provide the surveyor with standard procedures for acceptance and periodic testing of diagnostic imaging equipment throughout the Navy and Marine Corps. It provides a uniform methodology for testing equipment and reporting results. Standardized procedures ensure that required parameters are evaluated and are consistent throughout all naval medical facilities. Standardized formats and procedures also provide a means for comparing results between facilities, among surveyors, between manufacturers and among individual systems from a single manufacturer. Use of this manual will provide objective quality evidence that the radiographic unit has been evaluated and the result of the assessment. This will facilitate trending equipment performance, identifying equipment and training deficiencies, and other applications.

2. This manual establishes parameters to be measured during a diagnostic imaging equipment performance survey and suggested methods for performing survey measurements. This manual also establishes surveyor training and qualification standards and the process by which qualification is attained. The manual does not address therapeutic radiological systems. Navy radiation oncology services should establish local equipment performance programs aligned with nationally accepted protocols (e.g. American Association of Physicists in Medicine (AAPM)).

3. While this manual is intended for use by qualified surveyors and surveyors-in-training, it may also be of use to diagnostic radiologists and biomedical equipment repair technicians in the performance of their duties.

B. *Extent of Surveys*

1. Diagnostic imaging equipment must be surveyed after installation and prior to first clinical use (acceptance), after major repairs, and periodically at intervals defined by BUMEDINST 6470.22B. Invasive acceptance testing is complex and time-consuming since almost all combinations of variable settings are evaluated. Detailed acceptance testing procedures are not covered in this manual. Manufacturer’s technical specification and Federal Regulations should be consulted to ensure adequate acceptance testing. Non-invasive periodic testing is less rigorous and should cover the range of clinical use. Testing after repairs should be limited to those parameters potentially affected by the work performed unless more extensive testing is deemed necessary by qualified medical physics authority.

2. An effective equipment performance survey should include communication between clinicians, radiological technologists, repair technicians and surveyors. Equipment parameters, operational procedures, patient exposures, radiation safety practices, and related factors should be evaluated. Coordination with facility personnel prior to the survey is necessary to ensure equipment is operational and available for testing. Significant findings should be discussed with facility personnel responsible for ensuring equipment repairs are completed prior to leaving the facility.

C. *Radiation Protection*

1. X-ray producing machines are tested for technical performance and radiation safety. The objective of an effective x-ray survey program is to provide a safe diagnostic tool that benefits both the patient and the medical practitioner by providing acceptable image quality while simultaneously keeping patient radiation dose as low as reasonably achievable (ALARA).

2. Radiation dose received by patients may be decreased by eliminating unnecessary procedures and procedures of minimal value and using technical advances, such as digital image receptors and automatic exposure control, in clinical practice.

3. Radiation dose received by medical, dental, and allied health personnel should also be minimized. Fundamental methods to reduce staff dose include the provision of protective barriers, protective clothing, and the implementation of appropriate operational procedures. A well-managed dosimetry program for medical x-ray personnel is also very important. When performing radiological equipment surveys at Navy and Marine Corps activities, the individual should make themselves available to perform an annual external Radiation Health Program audit as required by NAVMED P-5055, Radiation Health Protection Manual.

4. After installation of imaging equipment or construction in rooms where ionizing radiation will be emitted, a qualified shielding expert must conduct a radiation protection survey to verify the adequacy of installed shielding. The survey is conducted prior to clinical use of the room.

D. *Training and Qualification*

1. Training guidelines for qualification as a surveyor for each modality are established by the Medical Physics Advisory Board (MPAB). Individuals applying to be designated as a qualified surveyor will complete and submit the appropriate Personnel Qualification Standard (PQS), included as Appendix A, to the Navy and Marine Corps Public Health Center (NMCPHC) via the applicable regional medical physicist. The MPAB will review completed PQS packages and forward the applications to the Bureau of Medicine and Surgery (BUMED) for final approval. Approved PQS packages will be maintained by NMCPHC to document the training of individual surveyors.

2. Senior qualified physicists at each Naval Medical Center and at the Uniformed Services University of the Health Sciences (USUHS) will mentor surveyors. Other personnel qualified as surveyors at the appropriate level may provide mentored training with prior approval from their regional medical physicist. Surveys by trainees should be reviewed and countersigned by the mentoring senior physicist.

3. All qualified surveyors will maintain continuing education hours and continuing experience as practicable in their current assignments. Per BUMEDINST 6470.22B, regional medical physicists must periodically review and evaluate qualified surveyor work product for appropriateness, completeness, and conformance with professional standards.

4. Any qualified surveyor performing surveys at a facility accredited by an accrediting body must meet all initial qualification and continuing education and experience requirements established by the accrediting body. This is in addition to all qualification requirements listed in this manual or any other applicable regulations.

E. *Qualification Levels*

1. Diagnostic imaging equipment surveyor qualification is separated into two categories: Basic and Advanced Diagnostic Imaging Equipment. Surveyors should complete qualification at the Basic Diagnostic Imaging Equipment level prior to qualification in Advanced Diagnostic Imaging Equipment modalities. Surveyors may qualify for individual Advanced Diagnostic Imaging Equipment modalities.

2. After qualification, Basic Diagnostic Imaging Equipment surveyors may perform surveys of A) general radiographic units, B) dental radiographic units, C) computed radiographic units and D) digital radiographic units. Basic surveyors may evaluate local quality control programs for these systems.

3. Advanced Diagnostic Imaging Equipment surveyors may perform surveys of any of the following modalities in which they are qualified: fixed and mobile General Fluoroscopic Imaging (GFI) systems, Interventional Radiology Imaging (IRI) systems, Ultrasound (US) systems, Magnetic Resonance Imaging (MRI) systems, Nuclear Medicine (NM) imaging systems, Mammography (Mammo) systems, and Computed Tomography (CT) systems. In addition, Advanced surveyors may qualify to perform Shielding Design (SD) evaluations for diagnostic imaging rooms. Diagnostic Imaging Equipment modality levels are listed in Table 1-1 below.

Table 1-1.—Diagnostic Imaging Equipment Surveyor Qualification Levels.

	Qualified Modalities
Basic Diagnostic Imaging Equipment[1]	1. General Radiographic Units 2. Dental Radiographic Units (IO, Pano/Ceph, CBCT) 3. Computer Radiographic Units 4. Digital Radiographic Units
Advanced Diagnostic Imaging Equipment[2,3,4]	1. General Fluoroscopic Imaging (GFI) 2. Interventional Radiology Imaging (IRI) 3. Ultrasound (US) 4. Magnetic Resonance Imaging (MRI) 5. Nuclear Medicine (NM) Imaging (SPECT) (PET) 6. Mammography (Mammo) Systems 7. Computer Tomography (CT) 8. Shielding Design (SD)

Notes:
1) Surveyors should be fully qualified as Basic Diagnostic Imaging Equipment Surveyor before progressing to Advanced Diagnostic Imaging Equipment Surveyor.
2) Surveyors may be qualified for sublevels (individual systems) within Advanced Diagnostic Imaging Equipment.
3) Surveyors may perform tests on equipment without being qualified; however, the senior qualified medical physicist must review and approve their survey report.
4) Mammography qualifications are performed in accordance with MQSA.

4. The Mammography Quality Standards Act (MQSA) of 1992 defines the qualification requirements for the physicist of record for facilities providing screening mammography

services. Individuals surveying mammography systems must meet all applicable requirements listed in MQSA. Once the individual has satisfied MQSA requirements, he or she should forward all documentation to NMCPHC and MPAB for review and verification of qualification.

5. Individuals certified by the ABR and ABMP in Diagnostic Radiological Physics are qualified by virtue of certification to perform testing of all modalities listed in this manual, except equipment covered by MQSA. The ABR or ABMP certification letter must be forwarded to NMCPHC for documentation of qualification.

6. The Joint Commission (TJC) established qualification requirements for diagnostic medical physicists surveying CT systems at TJC-accredited facilities. Individuals surveying such systems must meet all applicable requirements established by TJC. Once the individual has satisfied TJC requirements, he or she should forward all documentation to NMCPHC and MPAB for review and verification of qualification. Individuals who do not meet TJC requirements may qualify as CT Assistants (CT-A) and perform CT surveys under the general supervision of an individual who meets TJC requirements. The CT survey must be reviewed and countersigned by the TJC-qualified surveyor. An individual qualified as a CT-A may perform surveys of CT systems independently at non TJC-accredited facilities.

7. Qualifications are valid for a maximum of 5 years. After 5 years, the MPAB will review each surveyor's activity to determine if proficiency has been maintained. If the board determines the surveyor has not maintained proficiency, the surveyor must repeat initial qualifications to regain certification.

F. ***Reports***

1. Reports document the parameters of each piece of equipment evaluated during a survey. At a minimum, a unit survey summary sheet describing equipment discrepancies, recommended corrective actions, and specific unit information must be sent to the facility possessing the surveyed unit. Each discrepancy should be identified as minor or significant in the professional judgment of the surveyor. Significant discrepancies are conditions that impact patient/operator safety or image quality. The entire survey package need not be provided. However, the information contained in the survey package can be useful in performing subsequent surveys. If the entire package is not provided, the summary sheet should note where the package is filed. Survey reports must be provided to the facility within 30 days of completion of the survey.

2. If required, the facility should provide a corrective action report to the surveyor within 15 working days of receipt of the equipment performance survey report. The surveyor should track corrective actions for discrepancies found during equipment performance survey until actions are completed or verified. Any corrective action report that is delinquent greater than 60 days should be reported to the facility's respective regional command for further action. NMCPHC should also be notified of this delinquency.

G. ***How to Use This Manual.*** Each chapter in this manual lists the minimum required tests for each type of imaging system or procedure, and the frequency and tolerances to which they should be performed. The operating procedures are for general guidance and are subject to

change based on subsequent revisions to FDA, Joint Commission, or other regulatory standards and recommendations from national standards bodies such as the American College of Radiology, American Association of Physicists in Medicine, etc. The qualified surveyor may deviate from the steps of the procedures listed in this manual as long as the final outcome is in full compliance with the listed tolerance for each test. The level of training appropriate for the particular unit being surveyed and supplementary recommended references is also included. Surveyors should maintain proficiency and stay abreast of current issues regarding the modalities they are qualified to survey.

Chapter 2. General Radiographic Units (Fixed and Portable)

A. *Minimum Required Personnel Qualifications*

Basic Diagnostic Imaging Equipment Surveyor

B. *Testing Periodicity*

Facility	Frequency
Ashore Facilities	Annually
Afloat, Special Forces support, and "IN USE" War Reserve Materiel Units	Within 6 months of scheduled deployment, not to exceed 24 months between surveys.
Hospital Ships	Within 6 months of scheduled deployment, not to exceed 24 months between surveys.
Deployed Medical Units	Prior to Fielding
Veterinary Clinics	Every 24 Months
All Units	Upon Acceptance

Testing periodicity for units at Navy and Marine Corps activities is found in BUMEDINST 6470.22B. For units at other activities, follow applicable service or agency regulations.

C. *Equipment*

1. Ionization chamber/solid state detector
2. kVp meter
3. Light meter
4. Type 1100 10x10cm Al plates (9mm total, three 2mm, two 1mm, two 0.5mm thickness)
5. 1.0mm Copper plate (>10x10cm)
6. X-ray beam alignment test tool (if available)
7. Lead plate (at least 3.2mm x 20x20cm)
8. TO20 threshold contrast test object
9. Resolution test object (e.g. Huttner 18)
10. CR DIN Phantom

11. M1 geometry test object
12. Contact mesh
13. Tape measure
14. Tape
15. Level
16. Previous General Radiographic Unit Survey

D. *References*

1. AAPM Report 31, *Standardized Methods for Measuring Diagnostic X-ray Exposures,* 1990.
2. AAPM Report 60, *Instrumentation Requirements of Diagnostic Radiological Physicists,* 1998.
3. AAPM Report 74, *Quality Control in Diagnostic Radiology,* 2002.
4. Bushberg, J.T., Seibert, J.A., Leidholdt, E.M. Jr., Boone, J.M., *The Essential Physics of Medical Imaging*, Williams & Wilkins, 2011.
5. Code of Federal Regulations, Title 21.
6. Curry, T.S. III, Dowdey, J.E., Murry, R.C. Jr., *Christensen's Physics of Diagnostic Radiology*, Lea & Febiger, Philadelphia, 1990.
7. Fluke Biomedical, Nuclear Associates, 07-605-7777-1 Rev. 3, *EZ CR-DIN Phantoms, User's Manual,* May 2006.
8. KCARE *DDR Commissioning and Annual QA Protocol Draft 8.0,* 2005.
9. NCRP Report 99, *Quality Assurance for Diagnostic Imaging Equipment*, 1988.
10. National Council on Radiation Protection and Measurements (NCRP), Report 172, *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States*, September 2012.

E. *Performance Tests for General Radiographic Units*

1. Safety/Mechanical.

a. Purpose. Verify the presence and/or functionality of indications, labels, controls and interlocks.

b. Regulations. All the items listed below must be present and/or function properly (21CFR1020.30/31, AAPM 74, NCRP 99).

c. Equipment. Tape measure.

d. Procedure: Verify the presence and/or functionality of the following:

(1) Warning label on the control panel containing the main power switch:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operations instructions and maintenance schedules are observed."

(2) Visual indication of technique factors.

(3) Unit will not make an exposure with the timer set to 0 (if applicable).

(4) Ability to manually terminate an exposure of > 0.5 seconds at any time.

(5) A visual indication x-rays are being generated along with an audible signal when the exposure is terminated.

(6) Inspect the cables, tube head movement, stability, image receptors, etc. to identify any damage and ensure proper operation of all components.

(7) No modifications have been made to the unit that would cause it to fail any of the standards. If any modifications have been made, the details, including the date, are documented.

(8) Lead aprons available and in good condition, as required.

2. Radiation Exposure Reproducibility

a. Purpose. To ensure that exposure received for the same mA, time, and kVp is the same from exposure to exposure.

b. Regulations. Determination of reproducibility should be based on consecutive measurements within a time period of one hour, using the same technique factors. For acceptance testing, make 10 exposures at these settings. For periodic testing, only 4 exposures are required. For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposure should be no greater than 0.05. (21 CFR 1020.31)

c. The Coefficient of Variation (COV) is the ratio of the standard deviation to the mean value of a population of observations. (21 CFR 1020.30)

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{(X_i - \bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

Where:

s = Estimated standard deviation of the population
$\bar{X}$ = Mean value of observation in sample
X_i = ith observation sampled
n = Number of sampled observations

d. Equipment. Ionization chamber or solid state detector.

e. Procedure:

(1) Set the x-ray tube at 100 cm (40 inches) source-to-table distance, if possible. Solid state detectors shielded against backscatter (i.e. contain a lead or lead-equivalent backing material) may be placed directly on the tabletop and centered in the light field. Ionization chambers and unshielded solid state detectors should be placed 10 cm (4 inches) above the x-ray tabletop and centered in the light field. All solid state detectors should be oriented such that the long axis of the detector active area is perpendicular to the cathode-anode axis of the x-ray tube.

(2) Determine the distance from the focal spot to the center of the radiation detector.

(3) Collimate the light field to a narrow beam (e.g. 4 x 4 cm field), making sure to include the active area of the radiation detector.

(4) Make radiation exposures at the selected technique. For efficiency, the surveyor is reminded that some meters will read out both exposure and time, therefore, record both for future measurements.

f. Interpretation of Results. If the coefficients of variation deviate from the criteria listed in 1b, consult a qualified service engineer. Exposure reproducibility is critical as it directly influences image quality and patient dose.

3. Timer Reproducibility

a. Purpose. To ensure that the x-ray generator is producing exposure times that are the same from exposure to exposure.

b. Regulations. Determination of reproducibility should be based on consecutive measurements made within a time period of one hour, using the same technique

factors. For acceptance testing, make 10 exposures at these settings. For periodic testing, only 4 exposures are required. For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposure should be no greater than 0.05.

c. Equipment. Radiation detector with timer function.

d. Procedure:

(1) Utilize the procedure described for radiation exposure reproducibility measurements.

e. Interpretation of Results. If the COV deviates from the criteria listed in 2b, consult a qualified service engineer. Timer reproducibility is critical as it directly influences image quality and patient dose.

4. Timer Accuracy

a. Purpose. To ensure that the x-ray generator is producing the exposure time as set on the control panel.

b. Regulations. The accuracy of the timer should be within ±5% of the selected timer setting or ±1 ms for exposure times less than 10 ms or 1 pulse for exposure times less than 10 pulses.

c. Equipment. Radiation detector with timer function.

d. Procedure:

(1) Utilize the procedure described for reproducibility measurements.

(2) Measure and record the full range of clinically useful exposure times.

e. Interpretation of Results. Refer units deviating from the criteria in Table 2-1 for adjustment by a qualified service engineer. Timer accuracy is critical as it directly influences image quality and patient dose.

5. Linearity of mGy/mAs

a. Purpose. To ensure that the radiation output varies linearly with the tube current-time product (mAs).

b. Regulations. The average ratios of air kerma to the indicated mAs product (mGy/mAs) obtained at any two consecutive tube current settings should not differ by more than 0.10 times their sum.

$$|X_1 - X_2| \leq 0.10 \cdot (X_1 + X_2)$$

Where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive tube current settings. (21CFR1020.31)

c. Equipment. Ionization chamber or solid state detector.

d. Procedure:

(1) Utilize the setup described for reproducibility measurements. Measure and record the radiation output at 5 different mA settings while keeping kVp and time constant. With some x-ray units, the mA cannot be varied without varying time. In this instance, make measurements at 5 different mAs settings while keeping kVp constant.

(2) Divide the output by mAs setting, record mGy/mAs as calculated.

e. Interpretation of Results. If each of the average ratios between mA stations deviate from the criteria listed in 4.b, consult a qualified service engineer. Linearity of mGy/mAs is critical as it directly influences image quality and patient dose.

6. Kilovoltage Accuracy

a. Purpose. To ensure that the x-ray generator is producing the kVp as indicated on the control panel.

b. Regulations. The accuracy must be ± 5 % of the nominal control panel setting or within manufacture specifications.

c. Equipment. kVp meter.

d. Procedure:

(1) Place the kVp meter on the x-ray table top. Set the distance from the focal spot to the table top and orientation with respect to the tube axis as indicated in the kVp meter owner’s manual.

(2) Collimate the beam to the active area of the kVp meter. Set the desired starting kVp, mA, and time stations on the generator using the manufacturer's suggested techniques.

(3) For acceptance testing, evaluate kVp settings from 50 kV up to the maximum kV incrementing by 5 kV. During periodic evaluations, evaluate kVp settings from 60 kV to the maximum kV incrementing by 20 kV unless further measurements are necessary.

(4) Make an exposure and record the display value of the kVp meter.

e. Possible Pitfalls:

(1) The Half Value Layer (HVL) should always be measured after assuring the kVp is correct.

(2) The major cause of kVp variation is calibration. Some generators maintain their calibration well and others drift constantly. It is important to note that a change in kVp may not always show as a change in image density because changes in the mA will often compensate for the change in kVp.

(3) Since the kVp affects the radiographic contrast, it must be checked to assure that it is acceptable.

(4) Other major causes of variations in kVp are line voltage drops and electrical component failure.

f. Interpretation of Results. Refer units deviating from the criteria listed in 5b for adjustment by a qualified service engineer. Proper kVp calibration is critical as it directly influences image quality and patient dose.

7. Beam Quality

a. Purpose. To assure that the permanently installed filtration at the x-ray tube is maintained at an appropriate level to help minimize patient exposure.

b. Regulations. 21 CFR Part 1020.30 specifies the minimum beam quality (HVL) requirements for a range of tube potentials.

c. Equipment. 1100 aluminum alloy HVL sheets, radiation detector.

d. Procedure:

(1) If the detector is capable of measuring the HVL directly, beam quality can be evaluated during any of the previously completed tests and the remaining steps can be skipped.

(2) Place the radiation detector 5 cm above the table top (solid state detectors with lead backing do not need to be above the table). Collimate the light field to a narrow beam to include the radiation detector.

(3) Make an exposure without any Al sheets in the beam. An exposure made using 80 kVp, 125 msec and 320 mA to achieve an output of approximately 3 mGy will ensure that you have a high enough exposure to make the measurements accurately.

(4) Place an aluminum sheet between the radiation detector and the x-ray tube at a distance X/2, where X = source to detector distance. Make sure the Al sheets intercept the entire beam (light field). Make another exposure using the same technique settings. Continue to add Al sheets and make additional exposures until the air kerma is less than half of the original air kerma. Recommend using 2, 3, and 4 mm Al.

(5) Remove all Al sheets and make one exposure. If exposure is not within 2% of the initial exposure made with 0 mm of Al, repeat the measurement series ensuring that the technique and geometry selected remain the same throughout the procedure.

(6) Calculate HVL for the set kVp mathematically as follows:

$$HVL = \frac{T_2 \ln\left(\frac{2L}{A}\right) - T_1 \ln\left(\frac{2M}{A}\right)}{\ln\left(\frac{L}{M}\right)}$$

Where:

T_1 = Al thickness resulting in less than half the zero Al output rate
T_2 = Al thickness resulting in more than half the zero Al output rate
A = Output with no Al in beam
L = Output at T_1
M = Output at T_2

e. Possible Pitfalls.

(1) The entire radiation detector must be in the x-ray beam. When placing the sheets of Al in the beam, be sure that the entire beam is intercepted by the Al sheet. Once selected, the technique factors must not be altered for subsequent exposures.

(2) The kVp should be checked before measuring the HVL to ensure that it is within acceptable limits.

(3) The Al used for HVL measurements should be type 1100.

f. Interpretation of Results. Table 1 of 21CFR1020.30 lists minimum HVLs for various voltage potentials, reproduced in Appendix B of this manual. If the beam does not

meet the minimum standard, refer the unit for adjustment by a qualified service engineer. Insufficient filtration may lead to unnecessary patient dose. A unit with a hard beam need not be removed from service. However, a high HVL often indicates the presence of an older tube that may fail shortly thereafter.

8. Light Field Intensity

a. Purpose. To ensure that the light field intensity is adequate to illuminate the field.

b. Regulations. The light should provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or at the maximum Source Image Distance (SID), whichever is less. (21CFR1020.31)

c. Equipment. Light meter capable of providing either lux or foot candles.

d. Procedure:

(1) Place the light meter on the x-ray table top. Set the SID to 100 cm or the maximum available whichever is less.

(2) Set the ambient lighting in the x-ray room to the level used clinically.

(3) Collimate the x-ray beam to a 25 x 30 cm field. Illuminate the field.

(4) Measure and record the illumination in the 4 quadrants then calculate the average.

e. Interpretation of Results. Consult a qualified service engineer if the alignment deviates from the criteria listed in 7b.

9. Light Field/X-Ray Beam Alignment

a. Purpose. To ensure that the x-ray field and the light field are congruent.

b. Regulations. The light field/x-ray field alignment should be within ± 2% of the SID (21CFR1020.31).

c. Equipment. Digital x-ray rulers, radiochromic film, or x-ray beam alignment tool (use with CR/DR detector).

d. Procedure

(1) If using digital x-ray rulers, place rulers at edge of light field and expose according to manufacturer's directions.

(2) If using film, mark the edge of the light field on the film and expose and measure distance from edge of exposed area to mark on film.

(3) If using the x-ray beam alignment tool (etched brass plate and acrylic cylinder with BBs):

(a) Place the tool on a CR/DR detector or other x-ray recording media. Center the tool and detector in the light field and align the axes of the tool with the axes of the light field. Place the acrylic cylinder with bottom BB at the center of the brass plate.

(b) Collimate the field to a size within the measurement area of the brass plate (usually 7 x 14 cm).

(c) Make an exposure at 50-60 kVp and 2-3 mAs.

(d) Process the detector, if needed, and measure the size the resulting x-ray field image. Compare to the light field size to determine the misalignment.

e. Interpretation of Results. Consult a qualified service engineer if the alignment deviates from the criteria in 8b.

10. X-ray Field Size - Indicated vs. Actual

a. Purpose. To ensure that the actual and indicated X-ray field are congruent.

b. Regulations. The indicated vs. actual x-ray field should be within ± 2% of the SID. (21CFR1020.31)

c. Equipment. Digital x-ray rulers, radiochromic film, or x-ray beam alignment tool (use with CR/DR detector).

d. Procedure: Measure the deviation between the x-ray field size displayed on the x-ray equipment and the actual x-ray field. If the actual x-ray field size was not measured in the Light Field/X-Ray Beam Alignment test, then add or subtract the light field misalignment values from the light field size to determine the actual x-ray field size. Light field size may be measured by placing a ruler across the light field axes.

e. Interpretation of Results. Consult a qualified service engineer if the alignment deviates from the criteria in 9b.

11. Central Beam Alignment

a. Purpose. To ensure that the central x-ray beam is perpendicular to the table for stationary general purpose x-ray equipment. This test is not required for mobile or portable units.

b. Regulations. The perpendicularity of the central beam should be within ± 2% of the SID.

c. Equipment. X-ray beam alignment tool.

d. Procedure

(1) If the x-ray beam alignment tool was used in previous tests, measure the deviation between the upper (magnified) BB and the lower BB.

(2) If not, place the tool on a CR/DR detector or other x-ray recording media. Center the tool and detector in the light field and align the axes of the tool with the axes of the light field. Place the acrylic cylinder with bottom BB at the center of the brass plate.

(3) Collimate the field to a size within the measurement area of the brass plate (usually 7 x 14 cm).

(4) Make an exposure at 50-60 kVp and 2-3 mAs.

(5) Process the detector, if needed, and measure the deviation between the upper (magnified) BB and the lower BB.

e. Interpretation of Results. Consult a qualified service engineer if the perpendicularity measured deviates from the criteria in 10b.

12. Indicated Source to Image Distance (SID)

a. Purpose. To ensure the actual SID distance and the indicated SID are congruent.

b. Regulations. The actual SID should be within ± 2% of the indicated SID.

c. Equipment. Tape measure.

d. Procedure:

(1) Position the tube assembly at 100 cm (40 inches) from the image receptor. Measure the SID.

(2) If automatic detent is available, position the assembly utilizing the detent. Measure the SID.

e. Interpretation of Results. Consult a qualified service engineer if the measurement deviates from the criteria in Table 2-1.

13. Automatic Exposure Control (AEC) System (if applicable)

a. Purpose. To ensure that the Automatic Exposure Control (AEC) system is responding adequately. The system compensates for variations in technique factors and patient thickness such that resulting films appear with constant, optimal densities. The following AEC parameters should be evaluated during testing: reproducibility, balance, maximum exposure time, kVp compensation, thickness compensation and density control tracking (if available).

b. Regulations. For each AEC cell (phototimer) measurement, the reproducibility should be within ± 5%. Back up timer should terminate the exposure before the product of kVp and mAs reaches 60 kilowatt-seconds (kWs) or before 600 mAs. For kVp settings less than 51 kVp, the limit is 2000 mAs.

c. Equipment. 20 cm Acrylic or 4 cm Al phantom, 1.6 mm Lead (Pb) plate, radiation detector

d. Procedure: For a radiographic system, set the x-ray tube at an SID of100 cm (40 in) for tabletop systems and 180 cm (72 in) for chest systems and center to the bucky. Set selector such that only one phototimer is activated. To determine the location of the phototimer(s) look at the chest unit pattern of rectangles on the chest board surface. Use the same layout for the table, noting that the center chamber is usually located at the lateral center of the table when the tube and bucky are aligned. If using a Computed Radiography (CR) machine, place a cassette in the bucky tray (not necessary for digital). Place the Acrylic or Al phantom in the beam. Ensure that the phantom covers all the AEC detector cells. Set the system in the AEC mode, 80 kVp, and select the detector to be checked (e.g. table, center, left or right chamber). If using a CR system, a single cassette should be used for all testing, to reduce variability. This will require processing the cassette after each exposure.

(1) Output Reproducibility. Place the radiation detector along the beam central axis at the phantom beam entrance surface, being careful not to cover the phototimer cells. Set the technique at 80 kVp, 200 mA (if applicable), and AEC density control setting to neutral (0). If using a CR machine, ensure you have a clean cassette for this test. Perform three exposures, record the readings and calculate their mean. All three readings should be within ± 5% of their mean. Repeat for each AEC detector.

(2) Back-up Timer. Place the lead sheet (or several lead aprons) in the beam so as to cover all of the AEC detector fields so that no radiation reached them. Set the technique at 80 kVp, 200 mA (if applicable), and AEC density control setting to neutral (0). Record the elapsed mAs. The beam should terminate before the product of kVp and mAs reaches 60 kilowatt-seconds (kWs) or before 600 mAs. For kVp settings less than 51 kVp, the limit is 2000 mAs. Perform this test for each AEC cell individually and with all cells together.

(3) Phototimer Balance. Using the measurements from 12d(1), ensure that the mean output for the left and right cells does differ from the mean output of the center cell by more than ± 20 %.

(4) Patient Thickness Compensation. Use the setup described previously in 12d. Set the technique at 80 kVp, 200 mA (if applicable), AEC density control setting to neutral (0), and all cells active. Make exposures using at least 3 phantom thicknesses. Record the elapsed mAs for each exposure. The mAs should increase with increasing phantom thickness.

(5) kVp Compensation. Use the setup previously described. Set the technique at 80 kVp, 200 mA (if applicable), AEC density control setting to neutral (0), and all cells active. Vary the kVp over the clinically used range 60, 80, and 100 and record the elapsed mAs. The mAs should decrease with increasing kVp.

(6) Density Control Tracking (if available). Use the setup previously described. Set the technique at 80 kVp, 200 mA (if applicable), and all cells active. Vary the AEC density control setting over the range of available positive and negative settings, making at least 5 exposures. Record the elapsed mAs. The mAs should increase with increasing density control levels.

14. Entrance Skin Air Kerma (ESAK) Measurements

a. Purpose: To ensure that ESK also formally known as entrance skin exposure for standard radiographic techniques is within standards.

b. Procedure

(1) Manual Mode

(a) Set the clinically used SID. Center the radiation detector in the x-ray field. If using a lead-backed detector, it may be placed on the tabletop. Otherwise, place it at approximately 23 cm above the tabletop to minimize backscatter. Record the distance from the source to the center of the radiation detector (SDD).

(b) Collimate the light field on the radiation detector using a narrow beam.

(c) Set the desired technique factors at the control panel.

(d) Make an exposure. Measure and record the SDD, SID, and the air kerma.

(e) Repeat as necessary for other commonly used projections and technique factors.

(2) Automatic Exposure Control Mode.

(a) Place the patient-equivalent phantom over the desired AEC detectors.

(b) Set the clinically used SID. Center the radiation detector in the x-ray field. If using a lead-backed detector, it may be placed on the phantom. Otherwise, place it at approximately 23 cm above the phantom to minimize backscatter. Ensure that the detector does not cover the AEC sensor. Record the distance from the source to the center of the radiation detector (SDD).

(c) Select a commonly used projection such as an abdomen x-ray.

(d) Make an exposure. Measure and record the SDD, SID, and the air kerma.

(e) Repeat as necessary for other commonly used projections and technique factors.

(3) Calculate the entrance skin air kerma for each projection using the patient thickness guidelines in Table 2 of HHS Publication (FDA) 89-8031 and the inverse square law. The inverse square calculation is as follows:

$$ESAK = \left(\frac{SDD}{SSD}\right)^2 \cdot K$$

Where:

ESAK = corrected x-ray air kerma at the skin entrance without backscatter
SDD = source to center of radiation detector distance
SSD = distance from the source to the surface of the skin (approximately SID minus the patient thickness)
K = measured air kerma

NOTE: Air kerma (mGy) may be converted to exposure (mR) by dividing by 0.00876 mGy/mR.

c. Interpretation of Results. Compare exposures received for standard techniques with the reference levels published in Reference 10 and rate as satisfactory or unsatisfactory. If exposures are not within recommended ranges, an evaluation of image quality should be conducted in consultation with the clinical staff. Factors that can cause variations are backscatter, collimation, phantom material, location of ion chamber, x-ray beam, etc. A qualified service engineer should be consulted for equipment adjustment.

15. Survey Procedures for Portable and Mobile Radiographic Equipment

The following modifications of quality control procedures and acceptance parameters from fixed x-ray units apply for portable and mobile units:

a. The minimum source to skin distance must be no less than 30 cm (12 inches). This can be measured directly with a tape measure provided the location of the focal spot is known.

b. The operator must be able to stand at least six feet away from the x-ray tube during the actual exposure. This is normally accomplished by attaching the exposure switch to the unit with at least a six foot long cord.

c. Each portable unit should be supplied with at least two lead aprons.

General Radiographic Unit Survey Requirements

Table 2-1—General Radiography System Survey Requirements (Fixed, Portable, Digital).

Test	Frequency	Measurements	Tolerance
Exposure Reproducibility	A	10 repeat measurements	COV ≤ 0.05
	P	4 repeat measurements	COV ≤ 0.05, if COV>0.05, do 4 more
Timer Reproducibility	A	10 repeat measurements	COV ≤ 0.05
	P	4 repeat measurements	COV ≤ 0.05, if COV>0.05, do 4 more
Timer Accuracy	A	From 1 second to the minimum timer setting in increments of decreasing time of 50%.	± 5% of nominal setting or ± 1 ms for times ≤ 10 ms or ± 1 pulse for times ≤ 10 pulses
	P	Minimum and 1 second plus 3 others evenly spaced between.	± 5% of nominal setting or ± 1 ms for times < 10 ms or ± 1 pulse for times < 10 pulses
Linearity of mGy/mAs	A	All focal spots, all mA stations. If continuous, in 100 mA increments from min to max	magnitude of the difference between measurements at adjacent mA stations ≤ 10 % of their sum
	P	5 adjacent mA stations over range of clinical use	Same as acceptance
kVp Accuracy	A	for each generator: from 50 up to the maximum kVp setting by 5's	±5% of nominal setting or manufacturer's spec
	P	for each generator: from 60 up to the maximum kVp setting by 20's	±5% of nominal setting or manufacturer's spec
Beam Quality	A/P	Measured or calculated HVL	Must exceed the minimum value in Appendix B for the specified kVp.
Light Field Intensity	A/P	Average of 4 quadrants of 25 x 30 cm light field	average illuminance ≥ 160 lux (15 fc) at 100 cm or at the max SID whichever is less

Test	Frequency	Measurements	Tolerance
Light Field/x-ray beam alignment	A/P	Set any clinically used field size (e.g. 18 x 24 cm)	total misalignment of edges of light field vs x-ray field not to exceed 2% of SID along either length or width
X-ray field size (Indicated vs. Actual)	A/P	Set any clinically used field size (e.g. 18 x 24 cm)	± 2% SID
Central Beam Alignment	A/P	Measurement of perpendicularity of central beam	± 2% SID
Indicated SID	A/P	Measuring tape vs indicated distance	± 2% SID
AEC	A/P	Table and Wall	
Reproducibility		3 exposures each detector	All ≤ ± 5% of mean
Back-up timer		Max exposure time w/ Pb over all detectors, measured for each detector and all at once	Elapsed ≤ 60 kWs or ≤ 600 mAs; ≤ 2000 mAs for tube potentials < 51 kV
Thickness Compensation		At least three phantom thicknesses	mAs Increase with increasing thickness
kVp compensation		60, 80, 100 kVp	mAs Decrease with increasing kVp
DCF tracking		5 exposures over the range of density settings	mAs Increase with increasing density

Abbreviations: A: acceptance, P: periodic, COV: coefficient of variation, HVL: Half Value Layer, kWs: kilowatt-seconds, kVp: kilovolt peak, mA: milliamp, mAs: milliamp seconds, fc: foot candles SID: Source to Image Distance, Pb: Lead.

General Radiographic Unit Survey Summary

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	
Model Number:	Tube Serial Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Safety Equipment/ Mechanical Checks				
Radiation Exposure Reproducibility				
Timer Reproducibility				
Timer Accuracy				
Linearity of mGy/mAs				
Kilovoltage Accuracy				
Beam Quality				
Light Field Intensity				
Light Field/X-ray Beam Alignment				
X-ray Field Size - Indicated vs. Actual				
Central Beam Alignment				
Indicated Source to Image Distance (SID)				
Automatic Exposure Control (AEC)				
Entrance Skin Air Kerma				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 3. Dental Radiographic Units
Intraoral, Panoramic, & Cone Beam Computed Tomography

A. *Minimum Required Personnel Qualifications*

1. Basic Diagnostic Imaging Equipment Surveyor.

B. *Introduction*

1. Intraoral (IO)

a. These units are the simplest x-ray machines to evaluate.

b. The relatively low output is the biggest obstacle to performing a survey. However, this can be overcome by increasing exposure time or decreasing the target to chamber distance.

c. Record the settings of all variable controls on the control console and return to these settings at the end of the survey.

2. Panoramic/Cephalometric (Pano/Ceph)

a. Panoramic dental x-ray units pose a challenge for even the most experienced surveyors. The arcing motion of the tube head during exposure, thinly collimated beam, cowling hiding tube and image receptor, and lack of x-ray field location indication make positioning of radiation detectors (particularly solid state devices) difficult. As a result, measurement of tube output and other parameters is highly error prone and can lead to an incorrect evaluation of equipment performance. The use of x-ray fluorescent screens or gafchromic film to determine x-ray field location can greatly ease the testing process.

b. Some digital panoramic machines have the ability to operate in a testing mode. In this mode, the tube is typically stationary and technique settings such as kVp, mA, and time are variable. Use of this mode is highly recommended for tests that do not require full tube rotation.

c. Cephalometric imaging is usually performed by panoramic equipment or as an add-on device to a panoramic or CBCT unit. Testing is completed in the same manner as a panoramic unit.

3. Cone Beam Computed Tomography (CBCT)

a. The CBCT systems represent an unconventional imaging modality that does not lend itself well to performance testing under the CT paradigm.

b. The CBCT characteristic features of a widely collimated longitudinal beam and single rotation data acquisition (vice gapless multiple sequential or helical scans) pose difficulties in defining and assessing dose using conventional 10 cm pencil chamber and Computed Tomography Dose Index (CTDI) phantom techniques. Additionally, use of a single flat panel detector vice a multiple detector element matrix creates different image quality performance levels compared to conventional CT used for similar purposes and tested with established phantoms.

c. However, the equipment's similarity in design and geometry lends itself to testing in a manner similar to a panoramic dental x-ray unit. Additional tests evaluate the dose and image quality performance of the system.

4. Hybrid Systems

a. Some systems perform imaging in multiple modes (panoramic, cephalometric, and/or CBCT) or incorporate multiple tubes/detectors. If the same x-ray tube and detector system is used for these imaging modes, tests common to all modes need only be performed once for the unit (e.g. exposure reproducibility). The qualified surveyor shall perform all applicable tests for imaging modes that utilize a separate tube and/or detector. In all cases, dose metrics shall be evaluated for all imaging modes.

C. *Testing Periodicity*

Facility	Frequency
Intraoral units	Every 36 months, upon acceptance and after major repairs
Panoramic, Cephalometric, and CBCT	Every 24 months, upon acceptance and after major repairs

Testing periodicity for units at Navy and Marine Corps activities is found in BUMEDINST 6470.22B. For units at other activities, follow applicable service or agency regulations.

D. *Equipment*

1. Ion chamber or solid state radiation detector

2. kVp meter

3. Pulse counter

4. Type 1100 10 x 10 cm Al plates (varying thicknesses; at least 5mm total)

5. Stopwatch
6. Tape measure
7. Cardboard cassette or ready pack film
8. Surgical adhesive tape
9. Fluorescent screen or bitewing film
10. Optional: BRH test stand
11. Optional: Acrylic Ball and Pin Phantom
12. Dental Radiographic Unit Survey (found in Appendix B)

E. *References*

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4. Gray, J.E., Winkler, N.T., Stears, J., Frank, E.D. *Quality Control in Diagnostic Imaging*; University Park Press, Baltimore, 1983.
5. HPA Report HPA-CRCE-010, *Guidance on the Safe Use of Dental Cone Beam CT Equipment*. November 2010.
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9. National Council on Radiation Protection and Measurements (NCRP), Report 99, *Quality Assurance for Diagnostic Imaging*, February 1995.

10. American Association of Physicists in Medicine (AAPM), Report 175, *Acceptance Testing and Quality Control of Dental Imaging Equipment, Report of Task Group 175*, September 2016.

11. National Council on Radiation Protection and Measurements (NCRP), Report 172, *Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States*, September 2012.

F. *Performance Test Requirements for Intraoral Dental Units*

1. Safety/Mechanical.

a. Purpose. Verify the presence and/or functionality of indications, labels, controls and interlocks.

b. Regulations. All the items listed below must be present and/or function properly (21CFR1020.30/31, AAPM 74, NCRP 99).

c. Equipment. Tape measure.

d. Procedure: Verify the presence and/or functionality of the following:

(1) Warning label on the control panel containing the main power switch:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operations instructions and maintenance schedules are observed."

(2) Visual indication of technique factors.

(3) Unit will not make an exposure with the timer set to 0 (if applicable).

(4) Ability to manually terminate an exposure of > 0.5 seconds at any time.

(5) A visual indication x-rays are being generated along with an audible signal when the exposure is terminated.

(6) Inspect the cables, tube head movement, stability, chin rest and head alignment pieces, etc. to identify any damage and ensure proper operation of all components.

(7) No modifications have been made to the unit that would cause it to fail any of the standards. If any modifications have been made, the details, including the date, are documented.

(8) Lead aprons available and in good condition, as required.

2. Exposure and Timer Reproducibility

a. Purpose. To ensure that exposure received for the same mA, time, and kVp is the same from exposure to exposure.

b. Regulations. Determination of reproducibility is based on five consecutive measurements within a time period of thirty minutes, using the same technique factors. The exposures must have a COV less than 5%. Reference: 21 CFR 1020.31(b)(1).

c. Equipment. Radiation detector.

d. Procedure:

(1) Place the probe 10 in from the focal spot as marked on the tube head.

(2) Visually center the probe in the beam, checking from the front and the sides to ensure that the beam will strike the probe. Once established, this set up should not be varied during this test.

(3) Select the most commonly used patient technique and make five exposures, rotating all dial settings between exposures. Always wait at least 30 seconds between exposures so as not to overheat the tube.

(4) Record the radiation output and the exposure duration.

(5) Interpretation of Results. The exposures must have a COV less than 5%. The COV is the ratio of the standard deviation to the mean value of a population of observations, calculated as follows:

$$COV = \frac{s}{\bar{\bar{X}}} = \frac{1}{\bar{\bar{X}}}\left[\sum_{i=1}^{n}\frac{(X_i - \bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

Where:

s = Estimated standard deviation of the population
$\bar{X}$ = Mean value of observation in sample
X_i = ith observation sampled
n = Number of observations sampled

3. Timer Accuracy

a. Purpose. To ensure that the x-ray generator is producing the exposure time as set on the control panel.

b. Regulations. The accuracy of the timer should be within 10% of the selected setting.

c. Equipment. Same as above

d. Procedure:

(1) Keep the same set-up as for reproducibility, holding kVp and mA constant.

(2) Select three commonly used patient timer settings by consulting either the technician or the technique chart.

(3) Make an exposure at each setting, recording mR and msec.

e. Interpretation of Results. Pulse duration measured should be within 10% of the nominal setting or as specified by the manufacturer. Also, pulse exposure should increase linearly with time, i.e., exposure should increase by approximately the same percentage as the time is increased.

4. Linearity of mGy/mAs

NOTE: This test cannot be performed on fixed mA units.

a. Purpose. To ensure that similar exposures are obtained for the mAs and kVp regardless of the exposure time and mA.

b. Regulations. The average ratios of air kerma to indicated mAs (mGy / mAs) obtained at two tube current settings should not differ by more than 0.10 times their sum.

c. Equipment. Same as above

d. Procedure:

(1) With the equipment in the same set-up as above, record one of the reproducibility results as the first reading.

(2) Switch to another mA station if one exists while holding kVp and timer settings constant.

(3) Make an exposure and record radiation output, then divide output by mAs setting.

(4) Record this mGy/mAs as calculated.

e. Interpretation of Results. These two mGy/mAs results should be similar, specifically the difference between the two divided by sum of the two should not exceed ± 0.10.

5. Kilovoltage Accuracy

a. Purpose. To ensure that the x-ray generator is producing the kVp as indicated on the control panel.

b. Regulations. The accuracy must be within ±5 % of the control panel setting (fixed kVp units must be within 5 kVp of that value).

c. Equipment. kVp meter

d. Procedure:

(1) Select the proper phase switch on the kVp meter (many dental units are single phase).

(2) Center the end of the IO tube cone on the kVp meter so that the x-ray field will cover the required area of the kVp meter.

(3) Make an exposure and record the kVp. The output rate of IO units is typically low and may cause kVp meters to give inaccurate readings over short exposure times. If this occurs, repeat the exposure using an exposure time of one second or 60 pulses.

(4) If multiple kVp settings are available, make measurements at 3 other kVp settings or the maximum number of settings available, whichever is smaller.

e. Interpretation of Results. The meter reading should be within 5 kVp of each setting.

6. Beam Quality

a. Purpose. To assure that the permanently installed filtration at the x-ray tube is maintained at an appropriate level to help minimize patient exposure.

b. Regulations. The minimum value of the HVL should be as stated in Appendix B for the actual kVp determined above.

c. Equipment. Radiation detector, sheets of type 1100 alloy Al

d. Procedure:

(1) If the detector is capable of measuring the HVL directly, beam quality can be evaluated during any of the previously completed tests and the remaining steps can be skipped.

(2) Set the tube voltage potential to 80 kVp, if the unit has variable kVp.

(3) Take an exposure using the reproducibility test set-up.

(4) Measure the air kerma and record the value as the exposure with no filtration added.

(5) Tape 1 mm Al (use tape which does not leave marks, such as paper surgical tape, or whatever is conveniently available) on the end of the cone and take a reading at the same settings, recording this for 1 mm Al added. Maintain good beam geometry.

(6) Repeat with an increased thickness of Al (add 1mm for each shot) until the measurement is reduced by half of the initial reading recorded for the 0 mm Al exposure.

(7) Finally, remove all Al and take one last reading with no filtration. If the final exposure is not within 2% of the initial exposure made with no filtration, repeat the measurement series ensuring that the technique and geometry selected remain the same throughout the procedure.

e. Interpretation of Results:

(1) Use the average of the unfiltered readings as the non-attenuated value.

(2) Calculate HVL for the set kVp mathematically as follows:

$$HVL = \frac{T_2 \ln\left(\frac{2L}{A}\right) - T_1 \ln\left(\frac{2M}{A}\right)}{\ln\left(\frac{L}{M}\right)}$$

Where:

T_1 = Al thickness resulting in less than half the zero Al output rate
T_2 = Al thickness resulting in more than half the zero Al output rate
A = Output with no Al in beam
L = Output at T_1
M = Output at T_2

(3) The HVL must meet Food and Drug Administration (FDA) standards for the actual kVp used which was determined above. FDA standards for dental unit HVLs are included in Appendix B.

7. Source to Skin Distance and X-Ray Field Size/Cone Alignment

a. Purpose. To determine the minimum source to patient skin distance (SSD) and field size alignment.

b. Regulation. The SSD and field size should be as stated in 21 CFR 1020.31(f) & (h).

c. Equipment. Measuring tape and x-ray recording media (phosphorescent screen, gafchromic film, CR plate, etc).

d. Procedure:

(1) Measure and record the length of the removable cone, the distance between the focal spot and end of the cone and the inner diameter of the cone.

(2) Use the x-ray recording media to ensure the x-ray beam at the end of the cone is the same size as the cone.

e. Interpretation of Results:

(1) The SSD must not be less than 18 cm if operable above 50 kVp or 10 cm if not operable above 50 kVp.

(2) The x-ray field at the minimum SSD must be containable in a circle no greater than 7 cm for SSD ≥ 18 cm and no greater than 6 cm for SSD < 18 cm.

8. Entrance Skin Air Kerma (ESAK)

a. Purpose: To ensure that ESAK (formerly known as entrance skin exposure) for standard radiographic techniques is within standards.

b. Procedure

(1) Place the probe at the end of cone.

(2) Use a technique commonly used on the dental unit to make an exposure. This is the ESAK which should be recorded along with all settings used and the source to detector distance (SDD).

(3) Calculate the entrance skin air kerma using the inverse square law. The inverse square calculation is as follows:

$$ESAK = \left(\frac{SDD}{SSD}\right)^2 \cdot K$$

Where:

ESAK = corrected x-ray air kerma at the skin entrance without backscatter
SDD = source to center of radiation detector distance
SSD = distance from the source to the surface of the skin (approximately SID minus the patient thickness)
K = measured air kerma

NOTE: Air kerma (mGy) may be converted to exposure (mR) by dividing by 0.00876 mGy/mR.

c. Interpretation of Results. Compare exposures received for standard techniques with the reference levels published in Reference 11 and rate as satisfactory or unsatisfactory. If exposures are not within recommended ranges, an evaluation of image quality should be conducted in consultation with the clinical staff.

G. *Performance Test Requirements for Dental Panoramic Units*

1. Safety/Mechanical.

a. Purpose. Verify the presence and/or functionality of indications, labels, controls and interlocks.

b. Regulations. All the items listed below must be present and/or function properly (21CFR1020.30/31, AAPM 74, NCRP 99).

c. Equipment. Tape measure.

d. Procedure: Verify the presence and/or functionality of the following:

(1) Warning label on the control panel containing the main power switch:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operations instructions and maintenance schedules are observed."

(2) Visual indication of technique factors.

(3) Unit will not make an exposure with the timer set to 0 (if applicable).

(4) Ability to manually terminate an exposure of > 0.5 seconds at any time.

(5) A visual indication x-rays are being generated along with an audible signal when the exposure is terminated.

(6) Inspect the cables, tube head movement, stability, chin rest and head alignment pieces, etc. to identify any damage and ensure proper operation of all components.

(7) No modifications have been made to the unit that would cause it to fail any of the standards. If any modifications have been made, the details, including the date, are documented.

(8) Lead aprons available and in good condition, as required.

2. Exposure and Timer Reproducibility

a. Procedure: (Same as for the dental intraoral unit.) The radiation detector must be secured in a location in which the active area of the detector fully intercepts the x-ray field for measurements to be taken. This can be challenging due to the narrow collimation of most panoramic units.

3. Duration of Exposure Cycle

a. Purpose. To ensure that the x-ray generator is producing the exposure time set by the manufacturer.

b. Regulations. The accuracy of the timer should be as stated by the manufacturer.

c. Equipment. Radiation detector.

d. Procedure:

(1) Select the most commonly used clinical technique. Make one exposure at this setting.

(2) (3)Record the exposure duration from the radiation detector in seconds.

(4) If the radiation detector used is unable to accurately measure the exposure duration, a stopwatch may be used.

4. Linearity of mGy/mAs

Same as for dental intraoral units.

5. Beam Quality

Same as for intraoral dental units. If the aluminum sheet method is used to calculate the HVL, care must be taken to ensure the aluminum plates remain securely in position during rotation of the system.

6. X-Ray Beam/Image Detector Slit Alignment (if applicable)

a. Purpose. To ensure that the x-ray beam and image receptor (e.g. film) slit are in alignment. Note: many newer units do not have a visibly indicated image receptor slit. This test is not applicable for such units.

b. Regulations. The beam dimensions should not exceed the slit opening.

c. Equipment. Fluorescent/phosphorescent screen or intraoral/gafchromic film and tape

d. Procedure:

(1) This test may be performed in real time by using a piece of fluorescent or phosphorescent screen taped to the image receptor holder covering the slit. Mark the outline of the slit on the screen. Dim the room lighting and position yourself so as to be able to see the screen. Make an exposure and watch for the slit area to glow.

(2) The slit alignment may also be recorded on film for documentation as follows:

(a) Tape two pieces of intraoral or gafchromic film diagonally across the slit, one at the top and one at the bottom of the slit, or place a piece of ready pack film across the film holder.

(b) Mark the slit location using a pin to prick the film at the edge of the slit opening and make an exposure only a few seconds in duration.

(c) Develop the film.

e. Interpretation of Results.

(1) Fluorescent screen: The entire slit should be seen.

(2) For film, a diagonal line should be seen across each film from corner to corner or between pin marks.

7. Entrance Skin Air Kerma (ESAK)

a. Purpose: To ensure that ESAK (formerly known as entrance skin exposure) for standard radiographic techniques is within standards.

b. Procedure

(1) Position the radiation detector as in the Exposure and Timer Reproducibility tests.

(2) Use a technique commonly used on the dental unit to make an exposure. This is the air kerma which should be recorded along with all settings used and the source to detector distance (SDD).

(3) Calculate the entrance skin air kerma using the inverse square law. The inverse square calculation is as follows:

$$ESAK = \left(\frac{2 \cdot SDD}{SID - 15}\right)^2 \cdot K$$

Where:

ESAK = corrected x-ray air kerma at the skin entrance without backscatter
SDD = source to center of radiation detector distance
SID = distance from the source to the image
K = measured air kerma

NOTE: Air kerma (mGy) may be converted to exposure (mR) by dividing by 0.00876 mGy/mR.

c. Interpretation of Results. Compare exposures received for standard techniques with the reference levels published in Reference 11 and rate as satisfactory or unsatisfactory. If exposures are not within recommended ranges, an evaluation of image quality should be conducted in consultation with the clinical staff.

H. *Performance Test Requirements for Dental Cone Beam Computed Tomography (CBCT)*

1. Safety/Mechanical.

a. Purpose. Verify the presence and/or functionality of indications, labels, controls and interlocks.

b. Regulations. All the items listed below must be present and/or function properly (21CFR1020.30/31, AAPM 74, NCRP 99).

c. Equipment. Tape measure.

d. Procedure: Verify the presence and/or functionality of the following:

(1) Warning label on the control panel containing the main power switch:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operations instructions and maintenance schedules are observed."

(2) Visual indication of technique factors.

(3) Unit will not make an exposure with the timer set to 0 (if applicable).

(4) Ability to manually terminate an exposure of > 0.5 seconds at any time.

(5) A visual indication x-rays are being generated along with an audible signal when the exposure is terminated.

(6) Inspect the cables, tube head movement, stability, chin rest and head alignment pieces, etc. to identify any damage and ensure proper operation of all components.

(7) No modifications have been made to the unit that would cause it to fail any of the standards. If any modifications have been made, the details, including the date, are documented.

(8) Lead aprons available and in good condition, as required.

2. Exposure and Timer Reproducibility

a. Purpose. Verify that the radiation exposure for a given mA, time, and kVp is the same from exposure to exposure.

b. Regulations.

(1) For any combination of technique factors, the coefficient of variation (COV), defined below, shall be ≤0.05 (21CFR1020.31).

(2) The COV is the ratio of the standard deviation to the mean value of a population of observations.

$$COV = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i - \bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

Where:

s = Estimated standard deviation of the population
$\bar{X}$ = Mean value of observation in sample
X_i = i^{th} observation sampled
n = Number of observations sampled

c. Equipment. Detector that measures exposure.

d. Procedure:

(1) Attach the detector to the image receptor, facing the tube head and centered in the field of view (FOV). If service mode is available, disable tube head motion. Use of shorter exposure times, if possible, will minimize tube heating.

(2) Select the most commonly used patient technique.

(3) For acceptance testing, make 10 exposures at these settings. For periodic testing, only 4 exposures are required.

(4) Record both the exposure and time values and calculate COVs for each.

e. Interpretation of Results. Refer failing units to a qualified service engineer for adjustment.

3. Duration of Exposure Cycle

a. Purpose. Verify that the actual exposure time matches the indicated exposure time on the control panel.

b. Regulations. The cycle duration will be within 1 sec of the nominal value or as stated by the manufacturer (21 CFR 1020.31).

c. Equipment. Stopwatch or detector capable of reading exposure time.

d. Procedure:

(1) Select the desired technique setting. Make one exposure at this setting.

(2) If using a stopwatch, start and stop the stopwatch based on the visual and/or audible indications of radiation production.

(3) If using a detector, use the same setup as with Exposure and Timer Reproducibility. Be aware that units with pulsed output can result in time measurements longer than the timer setting.

e. Interpretation of Results. If the measured values are outside the allowable error, but within manufacturer's specifications, then they are acceptable. If the values are outside manufacturer's specifications, refer the unit to a qualified service engineer for adjustment.

4. Kilovoltage Accuracy

a. Purpose. Verify that the actual kVp matches the indicated kVp on the control panel.

b. Regulations. The kVp must be accurate to within ± 5% of the indicated value or as stated by the manufacturer (21CFR1020.31, AAPM 74, NCRP 99).

c. Equipment. kVp meter.

d. Procedure:

(1) Utilize the same setup as Exposure and Timer Reproducibility.

(2) For acceptance testing, evaluate kVp settings from the minimum up to the maximum kVp in increments of 5 kVp at a constant, clinically used mA values.

(3) For periodic testing, evaluate kVp settings from 60 kVp to the maximum kVp in increments of 10 kVp at a constant, clinically used mA value.

e. Interpretation of Results. If the measured values are outside the allowable error, but within manufacturer's specifications, then they are acceptable. If the values are outside manufacturer's specifications, refer the unit to a qualified service engineer for adjustment.

5. Linearity of mGy/mAs

a. Purpose. Verify that the radiation exposure increases linearly with mAs for a given kVp.

b. Regulations. The average ratio of exposure (in mGy or mR) to mAs at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X1 - X2 < 0.10(X1 + X2)$$

Where *X1* and *X2* are the average ratios obtained at each of two adjacent tube current settings (21 CFR 1020.31, AAPM 74, NCRP 99).

c. Equipment. Detector that measures exposure.

d. Procedure:

(1) Utilize the same setup as Exposure and Timer Reproducibility.

(2) For acceptance testing, measure and record the radiation exposure at every mA setting at a constant kVp and exposure time. Calculate the exposure to mAs ratios.

(3) For periodic testing, measure and record the radiation exposure at 5 adjacent mA settings at a constant kVp and exposure time. Select settings in the range of clinical use. Calculate the exposure to mAs ratios.

e. Interpretation of Results. Refer failing units to a qualified service engineer for adjustment.

6. Beam Quality

a. Purpose. Verify that the permanently installed filtration in the source assembly is sufficient to attenuate low energy x-rays and therefore reduce patient dose.

b. Regulations. Federal regulations specify the minimum require half-value layer (HVL) for a given kVp (21 CFR 1020.30). Appendix B lists these minimum values.

c. Equipment. Exposure meter, four 1 mm Al sheets (or various thicknesses as required).

d. Procedure:

(1) Utilize the same setup as Exposure and Timer Reproducibility.

(2) If the detector is capable of measuring HVL directly, beam quality can be evaluated during previous test. Otherwise, follow the procedure below.

(a) Make one exposure without any Al in the beam.

(b) Insert one sheet of Al and make another exposure, ensuring the sheet intercepts the entire beam and that the setup does not otherwise change.

(c) Repeat until an exposure equal to half of the initial exposure is achieved.

(d) Remove the Al sheets and make another exposure. If the exposure is not within 2% of the initial exposure, repeat the measurement series, ensuring that the techniques and geometry remain the same throughout the Procedure:

(e) Calculate the HVL:

$$HVL = \frac{T_2 \ln\left(\frac{2L}{A}\right) - T_1 \ln\left(\frac{2M}{A}\right)}{\ln\left(\frac{L}{M}\right)}$$

Where:

T_1 = Al thickness resulting in < half the original exposure
T_2 = Al thickness resulting in > half the original exposure
A = Exposure with no Al in beam
L = Exposure at T_1
M = Exposure at T_2

e. Interpretation of Results. Refer failing units to a qualified service engineer for adjustment.

7. Dose-Area Product (DAP)

a. Purpose. Verify the accuracy of the dose-area product (DAP) reading provided on the image display, if applicable.

b. Regulations. The DAP must be within 20% of displayed value and 10% of previous measurements.

c. Equipment. Exposure meter.

d. Procedure:

(1) Utilize the same setup as Exposure and Timer Reproducibility.

(2) Measure air kerma for most commonly used scan programs.

(3) Correct the results from the source to detector distance to the distance from the source at which the field of view (FOV) is defined:

$$K' = \left(\frac{SDD}{SFD}\right)^2 \cdot K$$

Where:

K' = corrected x-ray air kerma at the FOV distance
SDD = source to center of radiation detector distance
SFD = distance from the source to the distance at which the FOV is defined (typically the SID)
K = measured air kerma

(4) Multiply the distance-corrected exposure by the scan program's FOV area to determine DAP.

e. Interpretation of Results. If the measured values are outside the allowable error, but within manufacturer's specifications, then they are acceptable. If the values are outside manufacturer's specifications, refer the unit to a qualified service engineer for adjustment.

8. Dose Indices (if applicable)

a. Purpose. Verify the accuracy of the dose indices, such as CTDI, provided on the image display, if applicable.

b. Regulations. Dose indices provided must meet manufacturer's specifications.

c. Equipment. Pencil ion chamber, appropriate phantom.

d. Procedure:

(1) Defer to manufacturer instructions for measurement, if provided.

(2) Measure dose indices for the same programs as DAP above.

e. Interpretation of Results. If the values are outside manufacturer's specifications, refer the unit to a qualified service engineer for adjustment.

9. Image Quality

a. Purpose. Verify that CBCT images produced are of acceptable diagnostic quality.

b. Regulations. Manufacturer's image quality tests are the preferred method of evaluation. Each test has its own specification. If a manufacturer-provided test protocol does not exist, guidance on performing image quality tests can be found in the above references.

c. Equipment. Manufacturer's image quality phantom.

d. Procedure: As prescribed by manufacturer's test protocol.

e. Interpretation of Results. Refer failing units to a qualified service engineer for adjustment.

10. Acquisition Display Monitor Performance

a. Purpose. Verify that the performance of the acquisition display monitor meets minimum levels using a standard test pattern.

b. Regulations:

(1) There must be an even progression of gray levels around the ring of gray level patches.

(2) The 5% patch must be visible in the 0/5% patch; the 95% patch must be visible in the 95/100% patch.

(3) The finest line pair pattern can be visualized in the center and at each of the 4 corners.

(4) There must not be visible bleed-through in either direction of all black-white transitions. All high-contrast borders must be straight, not jagged.

(5) There must not be scalloping of the gray scale. There must not be geometric distortion in the image.

c. Equipment. SMPTE pattern or equivalent.

d. Procedure:

(1) Display the test pattern on the acquisition display monitor.

(2) Visually examine the pattern to confirm that the gray level display on the monitor is subjectively correct.

(a) Review the line pair patterns in the center and at each of the corners.

(b) Review each black-white transition.

(c) Look for any evidence of scalloping or geometric distortion.

e. Interpretation of Results. Refer failing units to a qualified service engineer for adjustment.

Dental Radiographic Unit Survey Requirements

Table 3-1.—Dental Intraoral Unit Survey Requirements.

	Test	Frequency	Measurements	Tolerance
1.	**Exposure Reproducibility**	A	10 repeat measurements	cov< 0.05
		P	4 repeat measurements	if cov>0.05, do 4 more
2.	**Timer Reproducibility**	A	10 repeat measurements	cov< 0.05
		P	4 repeat measurements (all at 100mSec)	if cov>0.05, do 4 more
3.	**Timer Accuracy**	A	From 1 second to the minimum timer setting in 50% decreasing time increments	± 5% of nominal setting
		P	Minimum and 1 second plus 3 others evenly spaced between.	± 5% of nominal setting
4.	**Linearity of mA/mAs**	A	All focal spots, all mA stations. If continuous, in 100 mA increments from min to max	change <0.1 of the sum of measurements at adjacent mA stations
		P	5 adjacent mA stations over range of clinical use	
5.	**kVp Accuracy**	A	for each generator: from 50 up to the maximum kVp setting by 5's	±5% of nominal setting
		P	for each generator: from 60 up to the maximum kVp setting by 20's	±5% of nominal setting
6.	**X-ray Beam Quality**	A/P	@ 80 kVp, 1st HVL	Greater than minimum value found in Appendix B.
7.	**Minimum SSD**	A	SSD ≥ 18 cm	Diameter of x-ray field ≤ 7 cm
		P	SSD < 18 cm	Diameter of x-ray field ≤ 6 cm
8.	**X-ray field size/cone alignment**	A/P	Measure x-ray beam alignment with end of cone	x-ray field size of 2.5 cm Beam aligns with cone
9.	**Entrance Skin Air Kerma (ESAK)**	A/P	Measure x-ray output for a standard intraoral exam	Less than DRL

Abbreviations: A: acceptance, P: periodic, HVL: Half Value Layer, kVp: kilovolt peak, mA: milliamp, mAs: milliamp seconds, SSD: Source to Skin Distance

Table 3-2.—Dental Panoramic Unit Survey Requirements.

	Test	Frequency	Measurements	Tolerance
1.	**Exposure Reproducibility**	A	10 repeat measurements	cov< 0.05
		P	4 repeat measurements	if cov>0.05, do 4 more
2.	**Duration of Exposure Cycle**	A/P	Measure during exposure reproducibility	± 1 Second
3.	**mAs Linearity**	A/P	Measure at 2 mA stations if available	< 0.1 of the sum of the measurements of adjacent mA stations
4.	**X-ray Beam Quality**	A/P	@ 80 kVp, 1st HVL	Greater than minimum value found in Appendix B.
5.	**X-ray Beam/Image Receptor Slit Alignment**	A	-View beam slit fluorescence using fluorescent screen or	-View of entire image receptor slit
		P	-Expose 2 pieces of intraoral film taped diagonally across beam slit or use ready pack	-Diagonal line across each film from corner to corner -Mark slit on film
6.	**Entrance Skin Air Kerma (ESAK)**	A/P	Measure x-ray output for a standard intraoral exam	Less than DRL

Abbreviations: A: acceptance, P: periodic, cov: coefficient of variation, HVL: Half Value Layer, kVp: kilovolt peak, mA: milliamp, mAs: milliamp seconds

Table 3-3.—Dental Cone Beam CT Unit Survey Requirements.

	Test	Frequency	Measurements	Tolerance
1.	**Exposure and Timer Reproducibility**	A	10 repeat measurements	COV < 0.05
		P	4 repeat measurements	If COV > 0.05, do 4 more.
2.	**Duration of Exposure Cycle**	A	All available timer settings.	± 5% of nominal setting
		P	Clinically used timer settings.	± 5% of nominal setting
3.	**kVp Accuracy**	A	From minimum up to the maximum kVp setting by 5s	± 5% of nominal setting
		P	From 60 up to the maximum kVp setting by 10s	± 5% of nominal setting
4.	**Radiation Output Linearity**	A	All focal spots, all mA stations.	Difference < 10% of sum of measurements between mA stations.
		P	5 adjacent mA stations over range of clinical use.	Difference < 10% of sum of measurements between mA stations.
5.	**X-ray Beam Quality**	A/P	Measure while performing kVp Accuracy	Greater than minimum value found in Appendix B.
6.	**Dose-Area Product**	A/P	Product of measured dose at center of FOV and FOV area for clinically used FOVs	± 20% of displayed value and ±10% of previous measurements.
7.	**Dose Indices**	A/P	Measured IAW manufacturer's specifications, if provided.	Within manufacturer's specifications
8.	**Image Quality**	A/P	Measured using manufacturer's QC program	Within manufacturer's specifications
9.	**Acquisition Display Monitor Performance**	A/P	SMPTE pattern or equivalent	Even gray scale progression, 5% and 95% patches and resolution patterns visible, no scalloping or geometric distortion

Abbreviations: A: acceptance, P: periodic, COV: coefficient of variation, HVL: Half Value Layer, kVp: kilovolt peak, mA: milliamp, mAs: milliamp seconds, FOV: field of view.

Dental Radiographic Unit Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	Type:
Model Number:	Tube Serial Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Safety Equipment/ Mechanical Checks				
Exposure Reproducibility				
Timer Reproducibility				
Timer Accuracy (IO)/ Duration of Exposure Cycle (Pano/CBCT)				
Linearity of mGy/mAs				
kVp Accuracy				
Beam Quality				
Minimum SSD				
X-Ray Field Size/ Cone Alignment				
X-Ray Beam/Slit Alignment				
Entrance Skin Air Kerma/Dose Area Product/Dose Indicies				
Image Quality				
Acquisition Display Monitor Performance				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 4. Fluoroscopy

A. *Introduction*

1. Fluoroscopic systems are not only used in the radiology department but also outside radiology, for example in the operating theater. The systems can be simple and used for limited purposes but can also be very complex for angiography examinations or cardiac catheterization. Especially in complex interventional procedures, the state and the clinical settings of the unit play a major role. Interventional radiology and cardiology procedures are so sophisticated or ambitious that they are often, especially in obese patients, characterized by long exposure times which implies a real chance of deterministic radiation effects at the level of the skin. Justification of these examinations implies that not only the device but also the adjustments of the device meet the standards. The link between the dose to the patient and the radiation exposure to the operator is an extra motivation for a careful assessment of fluoroscopic systems.

2. Each fluoroscopic system needs to be tested for its intended use. Interaction with the staff in the department is essential to understanding how the system is used.

3. Fluoroscopy devices can be classified according to function and geometry:

4. According to function:

    a. Radiography/fluoroscopy systems with a movable table for barium studies, iodine contrast studies, or classical recordings in which positioning is done using fluoroscopy.

    b. Mobile image intensifier or flat panel image receptor with C-arm used for use during surgery.

    c. C-arm for vascular diagnostic and therapeutic studies.

    d. Angiography systems for cardiac applications (single or biplane configurations).

    e. Systems for specific applications, such as lithotripsy, urology, etc.

5. According to geometry:

    a. Under table configuration in which the x-ray tube housing assembly is below the table and the image receptor is above.

    b. Over table configuration in which the x-ray tube housing assembly is above the table and the image receptor is below.

    c. C-arm type fluoroscope in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship.

d. Lateral type fluoroscope in which the x-ray tube housing assembly and the image receptor are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table. This is typically seen in a biplane system, dedicated to the lateral projection.

B. ***Minimum Required Personnel Qualifications***

1. For fixed and mobile general and urologic fluoroscopy systems: Advanced Radiological Systems (GFI)

2. For interventional radiology and cardiac catheterization systems: Advanced Radiological Systems (IFI)

C. ***Testing Periodicity***

Upon acceptance, annually, and after major repairs, per BUMEDINST 6470.22B.

D. ***Equipment***

1. Ionization chamber/solid state detector

2. kVp meter

3. Acrylic phantom (~20 cm total thickness, 5 cm for mini C-arms)

4. Lead plate (20 cm x 20 cm x 1.6 mm)

5. High resolution test patterns (mesh, line-pair, or other with minimum resolution of 1.0 lp/mm)

6. Low contrast test object (must have at least 2% contrast targets)

7. 1100 aluminum (Al) alloy sheets (10 cm x 10 cm) (varying thicknesses; at least 8 mm total)

8. Collimator/beam alignment test tool

    a. Etched plate (25 cm x 20 cm x 1.5 mm)

    b. Plastic cylinder with imbedded steel balls

9. Tape measure

10. Optional

a. CR cassette (14” x 17”, 35 cm x 43 cm)

b. Contact mesh

c. Al plates (4 cm total thickness)

d. Copper (Cu) plates (3 mm total thickness)

E. ***References***

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4. Bushberg, J.T., Seibert, J.A., Leidholdt, E.M. Jr., Boone, J.M., The Essential Physics of Medical Imaging. Williams & Wilkins, 2011.

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6. Code of Federal Regulations, Title 21, Chapter 1, Sections 1020.30, 1020.31, and 1020.32.

7. Curry, T.S. III, Dowdey J.E., Murry, R.C. Jr., Christensen's Physics of Diagnostic Radiology, Fourth Edition, Lea & Febiger, Philadelphia, 1990.

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9. The Joint Commission. Standards for the Accreditation of Ambulatory Care Clinics.

10. Anderson, J.A., Wang, J., Clarke, G.D. Choice of phantom material and test protocols to determine radiation exposure rates for fluoroscopy. RadioGraphics 2000; 20:1033–1042.

F. ***Performance Tests for Fluoroscopy***

1. Safety/Mechanical.

a Purpose. Verify the presence and/or functionality of indications, labels, controls and interlocks.

b Regulations. All the items listed below must be present and/or function properly (21CFR1020.30/31, AAPM 74, NCRP 99).

c Equipment. Tape measure.

d Procedure: Verify the presence and/or functionality of the following:

(1) Warning label on the control panel containing the main power switch:

> "Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operations instructions and maintenance schedules are observed."

(2) Visual indication of technique factors.

(3) Unit will not make an exposure with the timer set to 0 (if applicable).

(4) Ability to manually terminate an exposure of > 0.5 seconds at any time.

(5) A visual indication x-rays are being generated along with an audible signal when the exposure is terminated.

(6) Inspect the cables, tube head movement, stability, image receptor, etc. to identify any damage and ensure proper operation of all components.

(7) No modifications have been made to the unit that would cause it to fail any of the standards. If any modifications have been made, the details, including the date, are documented.

(8) Lead aprons available and in good condition, as required.

2. Kilovoltage Accuracy

a Purpose. To verify that tube voltage potential accurately tracks the nominal generator setting.

b Equipment. kVp meter.

c Procedure:

(1) Follow the meter manufacturer's instructions.

(2) For units with manual kVp control, measurements shall be made from 50 kVp to the maximum setting in increments of 5 kVp for acceptance and 10 kVp for periodic evaluations.

(3) For units without manual kVp control, measurements shall be made at a minimum of three (3) kVp settings provided by the automatic brightness control (ABC) or automatic exposure rate control (AERC) systems. This can be accomplished by placing varying thicknesses or types of attenuating materials in the beam and measuring the resulting kVp.

d Interpretation of Results. Refer units deviating from the criteria in Table 4-1 for adjustment by a qualified service engineer.

3. Air Kerma Rate (AKR) Measurements

a Purpose:

(1) To establish AKR for varying protocols.

(2) To verify long term AKR consistency.

(3) To verify proper automatic brightness control of exposure rate with varying image receptor field size.

b Equipment

(1) Radiation detector (solid state detector or ion chamber with exposure meter)

c Appropriate phantom (acrylic [also known to as PMMA, Plexiglas, Lucite, etc.] phantoms provide the best approximation of patient scatter and beam hardening characteristics. However, aluminum alloy or copper phantoms are acceptable in situations where PMMA phantoms are not practical. Refer to reference 10 for help in determining equivalent non-standard phantom thicknesses.)

d Procedure:

(1) Typical and maximum AKR measurements can be made with the same equipment arrangement.

(2) Place the solid state detector or ion chamber at the reference location indicated below. If this is not possible, inverse-square law corrections may be used to recalculate measured values to values at the reference location.

(a) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

(b) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the collimator or spacer positioned as closely as possible to the point of measurement.

(c) In a C-arm type fluoroscope with an SID greater than or equal to 45 cm, the AKR shall be measured at 30 cm from the input surface of the image receptor, with the source positioned at any available SID, provided that the end of the collimator or spacer is no closer than 30 cm from the input surface of the image receptor.

(d) In a C-arm type fluoroscope with an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(e) In a lateral type fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the collimator or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the collimator or spacer no closer than 15 cm to the centerline of the x-ray table.

(3) Note: For easier phantom placement, C-arms may be inverted for testing. Use caution when placing objects on or suspending objects above the image receptor input surface.

(4) Note: Treat lithotripsy systems as standard/C-arm hybrids (i.e. meet both conditions).

(5) Place the phantom in the radiation beam between the image receptor and radiation detector, close to the image receptor. The image receptor is very sensitive; ensure that it is always shielded by the phantom.

(6) If using an ion chamber radiation detector, make sure that there is enough distance between the phantom and detector to minimize backscatter. A phantom to chamber distance of approximately 8 cm should be sufficient. Very large image receptors may require that the phantom be placed closer to the ion chamber in order to ensure full coverage of the receptor.

(7) Place the scatter grid in the beam path.

(8) Collimate the field to the phantom ensuring the radiation detector is in the FOV.

(9) Maintain consistent positioning of the radiation detector, phantom, and image receptor to assure reproducibility.

e Measurement Considerations.

(1) For acceptance evaluations, all available clinical protocols shall be evaluated. AKR measurements shall be made in all dose/output modes (including manual, pulse, cine, and digital spot modes, if available) and image receptor size combinations. For manual mode, adjust kVp and mA to provide a monitor image brightness equal to that of ABC/AERC normal mode. A clinic-provided technique chart may also be used to determine manual mode settings.

(2) For periodic evaluations, frequently used clinical protocols (identified by the clinic) shall be evaluated as above in all applicable output modes. Include digital spot mode if used clinically.

(3) Record the clinical mode, operating parameters (i.e. kVp, mA, pulse rate, etc.), and the measured AKR (air kerma for digital spot mode).

(4) Make AKR measurements with and without the grid in place, as warranted. The grid generally remains in the beam but may be removed if no-grid studies are performed.

(5) Use minimal “beam - on” time to prevent unnecessary x-ray tube wear.

(6) If the unit is equipped with high level control (HLC), a distinct tone must be heard when HLC is active.

f Interpretation of Results: Typical AKR values should be significantly lower than their maximum output rate counterparts. AKR values should increase with decreasing image receptor size and pulse rate. Use acceptance inspection values to set baselines for future reference. Subsequent annual evaluation results should agree reasonably well with original levels (e.g. ± 10 %).

4. Maximum Air Kerma Rate

a Purpose.

(1) To prevent excessive exposure to patients subjected to fluoroscopic examinations by verifying that the maximum AKR conforms to the limits of 21 CFR 1020.32.

(2) To verify that measured and displayed AKR are within ±35 percent.

b Regulations. 21 CFR 1020.32 specifies maximum exposure rates allowed for fluoroscopic equipment.

c Equipment. Same as typical AKR measurement with the addition of a 1.6 mm lead plate.

d Procedure.

(1) Set up the fluoroscopy unit, phantom, and radiation detector as for typical AKR measurements.

(2) Place the lead sheet on top of the phantom between the radiation detector and image receptor.

(3) Ensure that proper radiation detector, lead/phantom, and image receptor distances are maintained. When using an ion chamber, maximum AKR measurements may be unduly influenced (10 to 15 % above equivalent free in air measurements) by backscatter from the lead sheet if it is too close to the phantom/lead assembly.

(4) Evaluate the same clinical protocols evaluated in the typical AKR evaluation and in the same manner.

(5) Record the clinical mode, operating parameters (i.e. kVp, mA, pulse rate, etc.), and the measured AKR (air kerma for digital spot mode).

(6) For at least one clinical protocol, record the measured and displayed cumulative air kerma (CAK) and AKR to determine the accuracy of the displayed values.

(7) **NOTE:** the reference point for displayed CAK and AKR for C-arm systems is 15 cm from isocenter towards the x-ray tube assembly. This is not always the same location as the maximum AKR reference location. Inverse-square correction of measured values may be used for displayed value accuracy determination. In addition, manufacturers may define alternative reference locations. Consult the system documentation when in doubt.

(8) Maximum AKR measurements need only be made at the smallest image receptor size.

(9) Radiation streaming around the lead plate should not be visible during testing.

WARNING: Image intensifiers may be irreparably damaged if exposed to unattenuated high energy x-ray beams for extended periods.

e Interpretation of Results. Maximum AKR and displayed CAK and AKR accuracy shall not exceed the limits set in 21CFR 1020.32. Limits for the most common systems are listed in Table 4-1. Limits do not apply to recorded images (i.e. cine, digital spots). If a limit is exceeded, the unit shall be removed from patient use and recalibrated by a qualified service engineer as soon as possible.

5. Transmission Through Primary Barrier

a Purpose. To verify that the radiation attenuation provided by the image receptor housing is adequate.

b Regulations. 21 CFR Part 1020.32 specifies the maximum transmission through the primary barrier.

c Equipment. Same as maximum AKR rate measurement except a radiation detector sensitive to scatter radiation shall be used.

d Procedure.

(1) Arrange the fluoroscopy unit, phantom, and Pb sheet in the same manner as for evaluating maximum AKR.

(2) Place the scatter radiation detector 10 cm beyond the rear surface of the primary barrier (image receptor housing) with the largest active area of the detector perpendicular to the beam axis.

(3) Irradiate the phantom using the maximum AKR technique. Record the radiation level and compare it with the maximum AKR recorded previously.

e Interpretation of Results. Radiation levels at 10 cm beyond the image receptor housing shall not exceed the limit in 21 CFR 1020.32 (detailed in Table 4-1). Refer units showing excessive radiation transmission for repair by a qualified service engineer.

6. Beam Quality (Half Value Layer)

a Purpose. To assure that the permanently installed filtration at the x-ray tube is maintained at an appropriate level to help minimize patient exposure.

b Regulations. 21 CFR Part 1020.30 specifies the minimum beam quality (HVL) requirements for a range of tube potentials.

c Equipment. 1100 aluminum alloy HVL sheets, radiation detector, and appropriate phantom.

d Procedure:

(1) If the detector is capable of measuring the HVL directly, beam quality can be evaluated during any of the previously completed tests and the remaining steps can be skipped.

(2) Set up the fluoroscopy unit, phantom, and solid state detector/ion chamber as for typical AKR measurements.

(3) If the unit allows manual kVp and mA control, use the following procedure:

(a) Manually set kVp to 90.

(b) Place the phantom between the radiation detector and image receptor. Allow some separation between the two to minimize the effect of backscatter, if needed.

(c) Under fluoroscopy, collimate the beam to an area just larger than the radiation detector active area. Ensure that the phantom always intercepts the beam. Failure to do so may damage the image receptor.

(d) Set mA to produce an output rate between 2.5 and 4.5 mGy/min. Record settings and measured output rate.

(e) Measure the output rate without any Al sheets between the tube and radiation detector. Repeat the measurement, adding 1 mm Al between the tube and radiation detector at a time, until the output rate is reduced to one half of the zero Al output rate.

(f) Repeat and record measured output for 0 mm Al shot to verify good beam geometry.

(4) If the unit does not permit manual technique control (i.e. ABC/AERC only), use the following procedure:

(a) Place the phantom and collimate the beam as per steps 5.d (2) (b) and (c).

(b) Place all 8 mm Al sheets between the radiation detector and image receptor (e.g. above the phantom). Ensure Al intercepts the entire beam.

(c) Measure the output rate without any Al sheets between the tube and radiation detector, allowing ABC/AERC to set kVp for all the aluminum in the beam (i.e. phantom + sheets).

(d) Repeat the measurement, moving 1 mm Al sheet from behind the radiation detector to in front of it at a time, until the output rate is reduced to one half of the zero Al output rate. **A constant Al thickness must remain in the beam throughout the procedure to prevent ABC/AERC from changing technique factors. Varying factors will lead to erroneous readings.**

(e) Repeat and record measured output for 0 mm Al shot to verify good beam geometry.

(5) Calculate HVL for the appropriate voltage potential (set manually or obtained through ABC/AERC) mathematically as follows:

$$HVL = \frac{T_2 \ln\left(\frac{2L}{A}\right) - T_1 \ln\left(\frac{2M}{A}\right)}{\ln\left(\frac{L}{M}\right)}$$

Where:

T_1 = Al thickness resulting in less than half the zero Al output rate

T_2 = Al thickness resulting in more than half the zero Al output rate

A = Output rate with no Al in beam

L = Output rate at T_1

M = Output rate at T_2

e Interpretation of Results. Table 1 of 21CFR1020.30 lists minimum HVLs for various voltage potentials, reproduced in Appendix B of this manual. If the beam does not meet the minimum standard, refer the unit for adjustment by a qualified service engineer. Insufficient filtration may lead to unnecessary patient dose. A unit with a hard beam need not be removed from service. However, a high HVL often indicates the presence of an older tube that may fail shortly thereafter.

7. Minimum Source to Skin Distance (SSD)

a Purpose. To prevent unnecessary patient exposure resulting from an unduly short source to skin distance (SSD).

b Regulations. 21 CFR Part 1020.32 specifies the minimum source to skin distance requirements based on fluoroscopy unit mobility and application.

c Equipment. Tape measure, etched brass plate.

d Procedure.

(1) For over-table tube or C-arm systems, determine minimum SSD using a tape measure. Measure from the external target position mark to the end of the collimator assembly or spacing cone if permanently installed.

(2) For under-table tube systems that allow tube access, measure minimum SSD using a tape measure as the distance from the target mark to the tabletop. For systems with variable SSD, set the target to table distance to minimum before measuring.

(3) For under-table systems without tube access, measure minimum SSD using triangulation. Place the brass plate on the tabletop and measure the distance from the plate to the image receptor face. Make an exposure at low kVp and mA (just enough to

make an image of the brass plate). In the image, measure the length of one etched measurement division (e.g. 1 cm). Calculate SSD as:

$$SSD = \frac{OID}{(w_2/w_1) - 1}$$

Where:

OID = Brass plate to image receptor distance
w_2 = Division length in image
w_1 = Division length on the plate

e Interpretation of Results. Minimum SSD for various systems are listed in Table 4-1. If the source to skin distance is less than required, refer the unit for adjustment by a qualified service engineer.

8. Minimum Fluoroscopic Image Size (Beam Limitation Devices)

a Purpose. To verify that the fluoroscopic imaging system displays the geometrically appropriate anatomical area of interest.

b Regulations. 21 CFR 1020.32 specifies that, for systems with stepless adjustment of the field size, the minimum radiation field size at maximum SID shall be contained within a square of 5 cm by 5 cm. For systems without stepless adjustment of the field size, the minimum radiation field size shall not exceed 125 square cm.

c Equipment. Etched brass plate.

d Procedure.

(1) Arrange the unit for maximum SID and grid in the beam. If a collimator is present, use the largest available field of view and collimate to the smallest field size possible. If no collimator is present, use the smallest field of view available.

(2) Position or affix the brass plate centered on the image receptor. If the brass plate does not intercept the entire x-ray field, position the plate at a distance from the image receptor surface that allows for interception of the entire field.

(3) Expose the plate at a low technique sufficient to visualize the markings on the brass plate (50-60 kVp at 1 mA).

(4) Using the markings on the brass plate, measure the x-ray field size. If the plate is positioned some distance from image receptor surface, correct the measurements for the magnification present using the following:

$$w_2 = w_1 \frac{SID}{SID - OID}$$

Where:

w_2 = Division length in the image
w_1 = Division length on the plate
SID = X-ray source to image receptor distance
OID = Brass plate to image receptor distance

e Interpretation of Results. If the minimum field size dimensions exceed tolerance limits, recommend that a qualified service engineer recalibrate the collimators.

9. Fluoroscopy Display Field Alignment

a Purpose. To verify that the fluoroscopy beam is properly collimated so that only the tissue volume corresponding to the active entrance area of the II is irradiated, & that the same volume is presented on the monitor.

b Regulations. 21 CFR 1020.32 specifies that, for systems with stepless adjustment of the field size, the minimum radiation field size at maximum SID shall be contained within a square of 5 cm by 5 cm. For systems without stepless adjustment of the field size, the minimum radiation field size shall not exceed 125 square cm.

c Equipment. Etched brass plate, plastic cylinder with stacked steel balls, 14” x 17” (35 cm x 43 cm) CR cassette, gafchromic film, or other external x-ray recording media.

d Procedure.

(1) Fluoroscopic units with variable collimators should calibrate the collimator shutters so that they are just visible along the edges of the live image at maximum field size.

(2) Arrange the system for minimum SID, largest available field of view, grid in the beam, and collimators fully open.

(3) Position the brass plate to obtain an object to image distance (OID) of approx. 30 cm. Place the plastic cylinder at the center of the plate and center the cylinder and plate in

the x-ray beam. The tools are centered when the images of the steel balls completely overlap.

(4) Expose the plate at a low technique sufficient to visualize the markings on the brass plate (50-60 kVp at 1 mA). If the system has a variable collimator calibrated as above and all shutter edges are visible, this test is complete. Otherwise, continue with the steps below.

(5) Place the x-ray recording media as close to the image receptor face as possible with the x-ray sensitive side facing the tube. Center the x-ray recording media over the image receptor housing assembly.

(6) Expose the setup using normal fluoroscopy using techniques sufficient for the x-ray recording media used.

(7) On both the monitor and recorded images, determine the indicated distance between opposing edges of the viewing field (monitor) or radiation field (recorded) along two axes through the center of the images. For circular image receptors, one of these axes shall be in the direction of the greatest misalignment.

(8) Compare the axis lengths in the monitor and recorded images, making sure to account for magnification in the images as in the previous test. If the recorded image axis lengths are less than or equal to the monitor image axis lengths, this test is complete. Otherwise, determine the excess length by subtracting the monitor image axis length from the recorded image axis length.

(9) If the unit allows, increase SID to maximum and repeat steps (5) and (6) during acceptance testing. In a properly functioning unit, collimation should track automatically with changing SID.

e Interpretation of Results. See Table 4-1 for limits on the excess x-ray field. Refer systems that exceed limits for recalibration by a qualified service engineer.

10. Beam Central Alignment

a Purpose. To verify that the fluoroscopy beam central axis is properly aligned with the center of the image intensifier.

b Equipment. Etched brass plate, plastic cylinder with stacked steel balls.

c Procedure.

(1) Complete steps (1) through (4) of the Fluoroscopy Display Field Alignment procedure.

(2) Measure the distance along each axis from the center of the plate to the edges of the visible field. If the fluoroscopy beam and image receptor are properly aligned, these distances will be equal.

(3) If they are not equal, calculate the central misalignment as:

$$c = \frac{\sqrt{(l_2 - l_1)^2 + (w_2 - w_1)^2}}{2}$$

Where:

$l_{1,2}$ = Misalignment in one direction along the length axis

$w_{1,2}$ = Misalignment in one direction along the width axis

d Interpretation of Results. If the central misalignment exceeds the limit in Table 4-1, refer the system for adjustment by a qualified service engineer.

11. Pin-cushion and "S-ing' Distortion

a Purpose. To verify that the fluoroscopic image contains minimal spatial distortion and artifacts. This test only applies to fluoroscopic systems with an image intensifier (II).

(1) It is difficult to quantify an amount of acceptable distortion. However, any distortion should be horizontally and vertically symmetrical. It should also be visibly similar for fluoroscopic, cine, and digital spot images produced using the same II.

(2) Two major forms of spatial distortion are pincushion distortion and S-ing. Pincushion is characterized by bowing of peripheral chords into the center of the image. S-ing is characterized by warping of straight lines passing through the center of the image into "S" shapes in the central quarter to third of the image.

b Equipment. Contact Mesh

c Procedure.

(1) Verify that the unit meets the standards for fluoroscopy display field and beam central alignment.

(2) Place contact mesh on II and take image with fluoroscopy.

(3) Observe the image, paying special attention to the effects of excessive spatial distortion.

(4) For adjustable units, move the imaging chain through its full SID range noting changes in the level of distortion with changing SID.

d Interpretation of Results. If the amounts of pincushion distortion or S-ing exceed the levels prescribed in Table 4-1, refer the system for adjustment by a qualified service engineer. Due to the subjectivity of this test, archived soft or hard copy reference images showing the level of distortion during acceptance may be invaluable during subsequent periodic testing.

12. High Contrast Resolution

a Purpose. To verify the system's ability to resolve high contrast objects under variable operating conditions and using multiple recording modes.

b Equipment. High resolution test patterns.

c Procedure.

(1) Follow the set-up and procedure specified by the test object manufacturer, if available. Otherwise, use the following:

(2)

(a) Arrange the unit for maximum SID, largest available image receptor size, grid & compression cone out of the beam, and all collimators open.

(b) Attach the test pattern as close to the image receptor face as possible.

(c) For manual modes, use 60 kVp and adjust mA for image brightness that provides the best viewing. For ABC/AERC modes, place a 1 mm Cu plate in the beam as close to the tube as possible (the plate must fully intercept the x-ray beam). Use the kVp and mA provided by the unit for 1 mm Cu and test pattern in the beam. For mini C-arms, the Cu plate is not needed.

(3) Determine the highest spatial resolution visible at the image center and periphery. For mesh-based test objects, a resolvable mesh should clearly show bright wires separated by dark spaces and be free of Moiré patterns. For line-pair based test objects, a resolvable line-pair is one in which there is no blur across the length of the lines, no phase shifts (bright lines shift to dark and vice versa), and no aliasing (fewer bars are visualized).

(4) For acceptance evaluations, all available clinical protocols shall be evaluated. High contrast resolution measurements shall be made in all dose/output modes (including manual, pulse, cine, and digital spot modes, if available) and image receptor size combinations.

(5) For periodic evaluations, frequently used clinical protocols shall be evaluated as above in all applicable output modes. Include digital spot mode if used clinically.

(6) Record the clinical mode, operating parameters (i.e. kVp, mA, pulse rate, etc.), and the measured high contrast resolution.

d Interpretation of Results. Refer to Table 4-1 and system manufacturer's recommendations.

13. Low Contrast Sensitivity

a Purpose. To verify the system's ability to display low contrast information.

b Equipment. 4 cm Al phantom, multi-perforated Al sheet.

c Procedure.

(1) Follow the set-up and procedure specified by the test object manufacturer, if available. Otherwise, use the following:

(a) Arrange the fluoroscopy unit in the same manner as for making AKR measurements, with largest available II size and grid in the beam.

(b) Place the test object in the middle of the phantom. If this is not possible, place the test object between the tube and the phantom. For units with attached tables, place the combination phantom on the tabletop. For C-arms, place the combination phantom at the same location as for AKR measurements.

(c) Collimate the field to the periphery of the phantom, ensuring that all low-contrast targets are within the image.

(d) For manual modes, use 85 – 90 kVp and adjust mA for image brightness that provides best viewing. During contrast sensitivity viewing, ensure that enough tube current is applied to prevent the brightness difference from being lost in the image noise. For ABC/AERC modes, use the kVp and mA provided by the system for the combination phantom in the beam.

(2) Determine the lowest contrast target(s) visible with the unaided eye during live fluoroscopy. To count a given target, it should be clearly visible against the phantom background. Ambient lighting levels should be the same as those used during clinical operation of the unit.

(3) For acceptance evaluations, all available clinical protocols shall be evaluated. Low contrast sensitivity measurements shall be made in all dose/output modes (including

manual, pulse, cine, and digital spot modes, if available) and image receptor size combinations.

(4) For periodic evaluations, frequently used clinical protocols shall be evaluated as above in all applicable output modes. Include digital spot mode if used clinically.

(5) Record the clinical mode, operating parameters (i.e. kVp, mA, pulse rate, etc.), and the measured low contrast sensitivity.

d Interpretation of Results. Refer to Table 4-1 and system manufacturer's recommendations.

Fluoroscopic System Survey Requirements

Table 4-1.—Fluoroscopy Survey Requirements.

	Test	Freq	Measurements	Tolerance
1.	kVp Accuracy	A	50 kVp to max in 5 kVp increments*	± 5% of indicated value or suggested manufacturer recommendations.
		P	50 kVp to max in 10 kVp increments* **If manual kVp control isn't available, use 3 ABC/AERC provided voltages.*	Same as acceptance
2.	Air Kerma Rate (AKR)	A	All available clinical protocols in all output modes [manual, ABC/AERC (NL & HLC), pulse, cine, digital spot] at each available FOV.	Less than max AKR (88 mGy/min, 176 mGy/min HLC for most systems)
		P	Most frequently used clinical protocols in all applicable output modes [manual, ABC/AERC (NL & HLC), pulse, cine, digital spot] at each available FOV.	No sig change from acceptance (± 10 %)
3.	Maximum AKR (Max AKR)	A/P	Same as above except only at the smallest FOV (maximum magnification).	Cannot exceed 88 mGy/min if no HLC and 176 mGy/min for HLC (for most systems)
4.	Transmission Through Primary Barrier	A/P	Max AKR technique from above.	Not to exceed 3.34×10^{-3} percent of entrance AKR at 10 cm from primary barrier rear surface.
5.	Beam Quality (HVL)	A/P	Measured or calculated HVL	Must exceed the minimum value in Appendix B for the specified kVp.
6.	Minimum SSD	A/P	Directly using tape measure or indirectly through triangulation	≥ 38 cm (stationary) ≥ 30 cm (conv C-arm) ≥ 20 cm (surg C-arm) ≥ 19 cm (mini C-arm) ≥ 10 cm (surg mini C-arm)

	Test	Freq	Measurements	Tolerance
7.	Beam Limitation (Minimum Field Size)	A/P	Minimum x-ray field size at max SID and FOV	For systems with stepless adjustment of field size, field size contained within 5 cm by 5 cm square. For systems without stepless adjustment, field size ≤ 125 cm^2.
8.	Fluoro Display Field Alignment	A	Visibility of collimator shutters or x-ray field size at largest FOV For variable SID units: determine at minimum and maximum SID	All collimator shutter edges visible OR Excess x-ray field X or Y axis lengths ≤ 3% of SID and sum of X & Y axis diff ≤ 4% of SID OR Max excess x-ray field ≤ 12% of FOV (circular image receptor manu. after 10 Jun 2006, FOV ≤ 34 cm) OR Excess x-ray field in direction of max misalignment ≤ 2 cm (circular image receptor manu. after 10 Jun 2006, FOV > 34 cm). Collimator tracks with changing SID.
		P	Test at largest FOV, min SID only	Same as acceptance
9.	Beam Central Alignment	A/P	Minimum SID, max FOV, widest collimation	≤ 3% of SID
10.	Pin-Cushion Distortion	A/P	Manual or ABC (NL) mode at largest II size	Spatial linearity visually uniform over center 75 % of FOV
	"S-ing" Distortion	A/P	Manual or ABC (NL) mode at largest II size	Etched plate lines visually linear along X & Y axes in center 75 % of FOV
11.	High Contrast Resolution	A	All available clinical protocols in all output modes [manual, ABC/AERC (normal & HLC), pulse, cine] at each available FOV.	≥ 1.2 lp/mm (30 lp/in) for 23 cm (9 in.) FOV or manufacturer's suggested values.
		P	Most frequently used clinical protocols in all applicable output modes [manual, ABC/AERC (normal & HLC), pulse, cine] at each available FOV.	Same as acceptance

	Test	Freq	Measurements	Tolerance
12.	Low Contrast Sensitivity	A	All available clinical protocols in all output modes [manual, ABC/AERC (normal & HLC), pulse, cine] at each available FOV.	≤ 4% contrast or manufacturer's suggested values (for non-pulsed fluoro modes).
		P	Most frequently used clinical protocols in all applicable output modes [manual, ABC/AERC (normal & HLC), pulse, cine] at each available FOV.	Same as acceptance

Abbreviations: A: acceptance, P: periodic, kVp: kilovolt peak, HVL: half value layer, cm: centimeters, ABC: automatic brightness control, AERC: automatic exposure rate control, AKR: air kerma rate, NL: Normal, HLC: High level control, FOV: field of view, SSD: source-to-skin distance, SID: source-to-image distance, II: image intensifier, in: inches.

General Fluoroscopy Unit Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	Manufactured Date:
Model Number:	Tube Serial Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Safety Equipment & Mechanical Checks				
kVp Accuracy				
Air Kerma Rate (AKR)				
Maximum AKR				
Transmission Through Primary Barrier				
Beam Quality (HVL)				
Minimum SSD				
Minimum Field Size				
Fluoro Display Field Alignment				
Beam Central Alignment				
Pin-Cushion / “S ing” Distortion				
High Contrast Resolution				
Low Contrast Sensitivity				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 5. Computed Tomography Units

A. *Introduction*

This section is designed to assist Navy medical physicists and qualified surveyors at medical treatment facilities in testing and maintaining diagnostic computed tomography (CT) equipment in accordance with The Joint Commission (JC) standards. This section follows the procedures delineated in the 2017 ACR CT Quality Control Manual and ACR Phantom Test Procedures. This section does not cover dental/maxillofacial cone-beam CT equipment or radiation oncology CT simulation equipment. The recommended tests, performance criteria, and operating procedures are for general guidance, and are subject to change based on subsequent revisions to JC and/or ACR performance test standards. The user should refer to the ACR CT QC Manual for detailed discussions on theory and concepts used for each test protocol.

Many CT manufacturers provide phantoms and software to automate performance of many of the tests listed below. Use of such programs is acceptable during the annual performance evaluations provided that these tests have been independently verified at, or subsequent to, acceptance. In addition, phantoms other than the ACR or manufacturer's phantoms (e.g. Catphan) may be used. In such cases, the phantom manufacturer's test conditions and limit criteria shall be used.

Due to the potential complexity of CT scanner operation, a radiological technologist, trained and experienced on the CT scanner being evaluated should be present during testing. The technologist should operate the scanner while the physicist performs the tests.

B. *Minimum Required Personnel Qualifications*

Diagnostic medical physicists who support CT services at Joint Commission-accredited facilities must meet Joint Commission qualification requirements. They may be assisted by Navy Surveyors qualified as CT Assistants. CT Assistants may survey CT systems at non-Joint Commission-accredited facilities.

C. *Testing Periodicity*

Upon acceptance, annually, and after major repairs, per BUMEDINST 6470.22B.

D. *Equipment*

1. Electrometer with 10 cm CT and large (180 cc) volume ion chambers
2. Manufacturer's QC Phantoms
3. ACR, AAPM or Catphan performance phantom
4. CTDI phantoms (16 cm diameter-head and 32 cm diameter-body)

5. External radiation detector (CR plate, self-developing film, OSL strip, electronic test tool)
6. Flat radiation attenuator (1/8-in thick lead or 15-cm thick acrylic)
7. Computed Tomography Unit Survey (found in Appendix D)

E. ***Minimum Evaluation***

1. Review of clinical protocols
2. Alignment light accuracy
3. Scout prescription accuracy
4. Table travel accuracy
5. Radiation beam width
6. Low-contrast performance
7. Spatial resolution
8. CT number accuracy
9. Artifact evaluation
10. CT number uniformity
11. Geometric or distance accuracy
12. Radiation Dosimetry ($CTDI_{vol}$)
13. Scatter Radiation
14. CT Scanner Display Calibration
15. CT Technologist Quality Control Program Review

F. ***Optional Evaluation***

Optional and alternative tests may be performed at the discretion of the medical physicist. Occasions when this may be desirable include upon acceptance and when an incorrect calibration is suspected. Such tests are described in many resources, most notably AAPM Report 39 (Specification and Acceptance Testing of Computed Tomography Scanners).

G. *Performance Tests for Computed Tomographic Units*

1. Review of Clinical Protocols

a. Purpose.

(1) To ensure that a selection of clinical protocols appropriately utilizes the scanner features, including kV, mAs, detector configuration, reconstructed scan width, pitch, reconstruction algorithm, and other features such as dose reduction options, including automatic exposure controls, iterative reconstruction techniques, etc.

(2) To ensure that these protocols provide the diagnostic image quality required for the CT exam while minimizing radiation dose to the patient.

b. Criteria. Protocols are reviewed and kept current with input from an interpreting radiologist, medical physicist, and lead imaging technologist to make certain that they adhere to current standards of practice and account for changes in CT imaging equipment. Protocols should be designed to optimize dose and image quality. The ACR standards must be met when applicable.

c. Equipment. None.

d. Procedure:

(1) A CT Protocol Review and Management Team, consisting at minimum of a radiologist, CT technologist, and medical physicist, must be responsible for development and review of all protocol parameter settings.

(2) The CT Protocol Review and Management team develops and reviews all new or modified protocol settings for existing and new scanners to ensure that both image quality and radiation dose are appropriate.

(3) The physicist need not be physically present at CT Protocol Review and Management Team meetings, but should be actively involved in the review process.

(4) For specific protocol review guidance, refer to the ACR CT Accreditation Program, AAPM CT Protocols, or other available references.

(5) After a new protocol is reviewed and pre-approved, the initial clinical scans should be reviewed, one case at a time, for:

(a) Acceptable image quality for the diagnostic task required.

(b) CTDI and/or DLP values should be checked and verified against expected values on patient images (or dose report) following initial scans.

(c) Appropriate centering, especially for automatic exposure control (AEC) and pediatric patients.

2. Alignment Light and Scout Prescription Accuracy

a. Purpose. To verify that the incorporated alignment lights correctly indicate the scan position and that the scout image prescription correctly identifies the scan position.

b. Criteria. The location of scans positioned either with the alignment lights or with the scout prescription should be accurate to within 2 mm.

c. Equipment. A phantom that incorporates externally visible radiopaque fiducial markers or an image-center indication (e.g. ACR CT Phantom Module 1).

d. Procedure:

(1) Using the alignment lights, carefully position the phantom to the radiopaque markers in all 3 orthogonal planes.

(2) Zero the table location indication.

(3) Scan the phantom in axial mode using a reconstructed scan width less than 2 mm or as thin as the scanner can produce in axial mode at the zero position. Use a technique appropriate to the phantom to allow accurate visualization of the fiducial markers; for most phantoms, the Adult Abdomen technique is adequate.

(4) Scan the entire phantom in scout mode.

(5) Magnify the image, if possible, and position a single slice at the location of the radiopaque fiducial markers.

(6) Perform an axial scan using a reconstructed scan width less than 2 mm or as thin as the scanner can produce in axial mode.

e. Interpretation of Results.

(1) Alignment Light Accuracy.

(a) View the image(s) collected in Step 3 above.

(b) Verify that the visible radiopaque markers are visible in the reconstructed image. If multiple scans were performed, identify the image in which the markers are best visualized. The image position reported by the scanner is the axial misalignment.

(2) Scout Prescription Accuracy.

(a) View the image(s) collected in Step 2.d(6) above.

(b) Verify that the visible radiopaque markers are visible in the reconstructed image. If multiple scans were performed, identify the image in which the markers are best visualized. If the initial position was set to zero, then the image position reported by the scanner is the axial misalignment. Otherwise, the difference between the scout position and the axial scan position is the axial misalignment.

3. Table Travel Accuracy

a. Purpose. To verify that the patient table translates as indicated.

b. Criteria. The table translation accuracy and return to a fixed position should be accurate to within 2 mm or manufacturer's specifications.

c. Equipment. A phantom that incorporates externally visible radiopaque fiducial markers or an image-center indication (e.g. ACR CT Phantom Module 1).

d. Procedure:

(1) If possible, add weight to the tabletop to simulate the weight of an average patient.

(2) Using the alignment light, carefully position the phantom such that the first set of fiducial markers is in the axial plane.

(3) Zero the table position indication.

(4) Move the table to the second set of external fiducial markers.

(5) Record the table position.

(6) Translate the table to full extension and return to the first set of fiducial markers.

(7) Record the new table position.

e. Interpretation of Results.

(1) Compare the distance between the fiducial markers as determined by the table travel to the known distance.

(2) Compare the first fiducial marker table position to the new position recorded after the table extension and return.

4. Radiation Beam Width

a. Purpose. To measure the radiation beam width and to assess its relationship to the nominal collimated beam width.

b. Criteria. Manufacturer's specifications or ACR recommended criteria of ± 3 mm or 30% of the total nominal collimated beam width (N × T), whichever is greater.

c. Equipment.

(1) External radiation detector (CR plate, self-developing film, OSL strip, electronic test tool).

(2) Flat radiation attenuator (1/8-in thick lead or 15-cm thick acrylic).

d. Procedure:

(1) Place the radiation attenuator on the table unless contraindicated by the test device being used.

(2) Place the external radiation detector on the flat attenuator.

(3) Adjust the table height so that the external radiation detector is at the isocenter. Each unique N × T product that is used clinically should be measured, adjusting table position as appropriate for the detector being used.

e. Interpretation of Results. Using a method appropriate for the external radiation detector used, determine the actual radiation beam width for each unique N × T product (for a scanner with multiple N × T producing the same beam width, each beam width need only be tested once). For film, OSL, and CR-based measurements, determination should be made at the full width at half maximum (FWHM).

5. Low Contrast Performance

a. Purpose. To verify that the low-contrast performance of clinical protocols is adequate for diagnosis.

b. Criteria. For the ACR phantom, CNR performance should meet the following standards:

Scan protocol	CNR
Adult Head	1.0
Adult Abdomen	1.0
Pediatric Head (1 yr)	0.7

Pediatric Abdomen (5 yr, 40-50 lb)	0.4

c. Equipment. A phantom that incorporates low-contrast targets of known contrast (Module 2 of the ACR CT Phantom).

d. Procedure:

(1) Perform clinical scans covering the low-contrast section of the phantom. Any Auto mA feature must be disabled; use a mAs value appropriate for an average-sized patient. At a minimum, the scans performed should include the Adult Head (average), Adult Abdomen (70 kg), Pediatric Head (1 year old), and Pediatric Abdomen (5 years old; 40–50 lb., approx. 20 kg).

(2) View the best image located in Module 2 using a WW = 100 and a WL = 100.

(3) Place Regions of Interest (ROIs) (≈ 100 mm^2) over the large (25-mm diameter) cylinder and between the large cylinder and the 6 mm cylinders.

(4) Figure 5-1 shows low contrast resolution image at WW = 100 and WL = 100 with ROI placements.

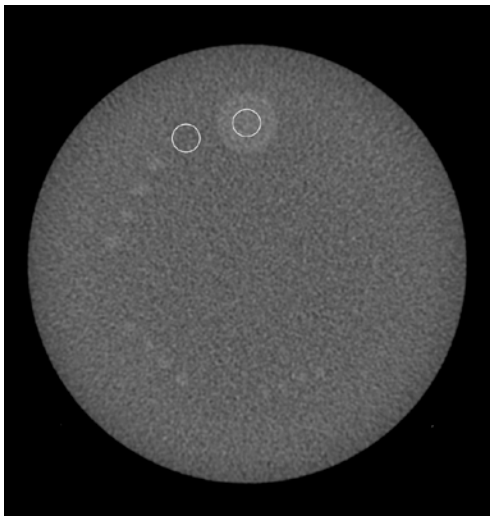


Figure 5-1.

(5) Record the mean signal in the ROI inside the 25mm rod (A), the mean signal in the ROI outside the 25 mm rod (B), and the Standard Deviation (SD) from the ROI outside the 25 mm rod for your records.

e. Interpretation of Results.

(6) Use the following formula to calculate the Contrast to Noise Ratio (CNR):

$$CNR = \frac{|A - B|}{SD}$$

6. Spatial Resolution

a. Purpose. To verify that the spatial resolution performance of clinical protocols is adequate for diagnosis.

b. Criteria. Manufacturer's specification or ACR recommended standards:

(1) ACR recommends that the CT system should be capable of resolving 6 lp/cm using the facility's adult abdomen protocol, and 8 lp/cm for high resolution (edge enhanced) adult chest protocol.

c. Equipment. A phantom that incorporates high-contrast targets of known resolution (Module 4 of the ACR CT Phantom).

d. Procedure:

(1) Perform clinical scans covering the spatial resolution section of the phantom. Any Auto mA feature must be disabled; use a mAs value appropriate for an average-sized patient. At a minimum, the scans performed should include the Adult Abdomen (70 kg) and High-Resolution Chest protocols.

(2) View the images in Module 4 (high contrast resolution) with a WW $\simeq$ 100 and a WL $\simeq$ 1100. Carefully view the image with the room light lowered and, determine the highest spatial frequency for which the bars and spaces are distinctly visualized.

(3) Figure 5-2 shows Module 4 of the ACR CT phantom and its eight bar resolution patterns in line pairs per centimeter (lp/cm).

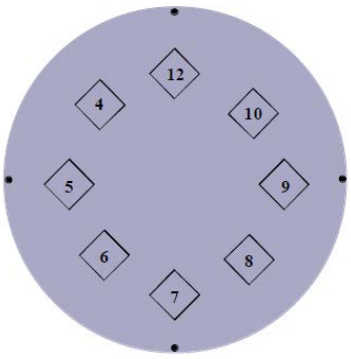


Figure 5-2.

e. Interpretation of Results. A higher resolution (8 lp/cm) should be seen for the high resolution (edge enhanced) adult chest protocol compared to the adult abdomen protocol (6 lp/cm).

7. CT Number Accuracy

a. Purpose. To verify that the CT numbers reported by the CT scanner are acceptably accurate and vary as expected.

b. Criteria. For the ACR phantom, the below standards should be met for all protocols using 120 kV (or 130 kV if 120 is not available). For other kV settings, only water and air ranges must be met:

Material	CT Number Range
Water	-7 to +7
Air	-1005 to -970
Teflon (Bone)	+850 to +970
Polyethylene	-107 to -84
Acrylic	+110 to +135

NOTE: Manufacturer's criteria for water and air CT numbers may differ from the ACR standards. In this case if the facility is not applying for or under ACR Accreditation status, the results should meet the manufacturer's specification.

c. Equipment. A phantom that incorporates targets that provide at least three different known CT number values. These must include a water (or water-equivalent material) and an air value (ACR CT Phantom Module 1).

d. Procedure:

(1) Perform clinical scans covering the CT number accuracy section of the phantom. Any Auto mA feature must be disabled; use a mAs value appropriate for an average-sized patient. At a minimum, the scans performed should include the Adult Head (average), Adult Abdomen (70 kg), Pediatric Head (1 year old), and Pediatric Abdomen (5 years old; 40–50 lb., approx. 20 kg).

(2) Perform scans of the CT number accuracy section of the phantom with each kV setting available on the scanner using the adult abdomen protocol.

(3) For each scan, select the image most central to the module containing the CT number accuracy targets.

(4) Adjust the window width/ level to optimize visibility of the targets. On the ACR CT Phantom, this is approximately WW=400 and WL=0.

(5) Place a circular ROI, approximately 80% of the size of the target, in each target. On the ACR CT Phantom, this is approximately 200 mm^2.

(6) Record the measured CT number mean for each target.

(7) Figure 5-3 shows ACR CT Phantom Module 1 ROI placement for each material and for the water-equivalent background material.

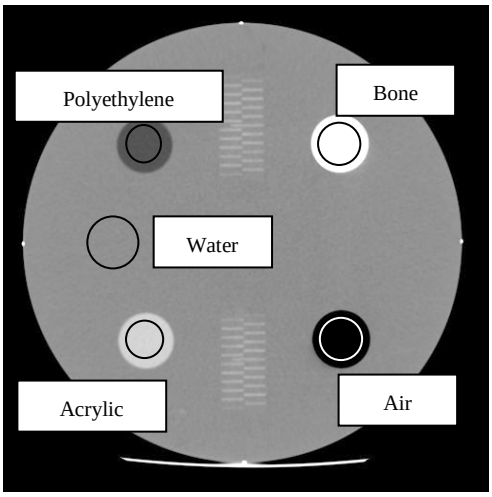


Figure 5-3.

e. Interpretation of Results. If the CT numbers do not meet the criteria, scanner calibrations should be run, if available, and the test repeated. If the values remain outside the ranges, consult a qualified service engineer.

8. Artifact Evaluation

a. Purpose. To identify and correct artifacts in images of a uniform test phantom before they become severe enough to be detected in patient images.

b. Criteria. Rings or streaks that are considered clinically significant.

c. Equipment. The water phantom provided by the scanner manufacturer or the ACR CT Phantom (Module 3).

d. Procedure:

(1) Scan the phantom using a typical patient technique for kV, mA, and rotation time. It is recommended to use the preprogrammed QC protocol set up for the technologist's artifact analysis test. Tube current modulation features must be disabled.

(2) The reconstructed images being evaluated for artifacts should be the thinnest axial images possible on the scanner and should span the z-axis of the detector array on the scanner.

e. Interpretation of Results. With all graphics turned off, view the same image carefully with the room lighting reduced. Examine the image for artifacts such as rings or streaks and record the presence and appearance of any artifacts. If artifacts are present, consult a qualified service engineer to investigate.

9. CT Number Uniformity and Distance Accuracy

a. Purpose. To identify and correct non-uniformities in the CT numbers in images of a uniform test phantom before they become severe enough to impact patient diagnosis and to verify the accuracy of in-plane distance measurements.

b. Criteria.

(1) Uniformity. The difference between the mean CT value of each peripheral ROI and the center ROI should not exceed 5 Hounsfield Units (HU), and must not exceed 7 HU.

(2) Distance Accuracy. The measured distance should be within 10% of the nominal distance (100 mm).

c. Equipment. The water phantom provided by the scanner manufacturer (uniformity only) or the ACR CT Phantom (Module 3).

d. Procedure:

(1) Scan the phantom using the same protocol used for Artifact Evaluation.

(2) Reconstruct the images to a clinically relevant image thickness and reconstruction algorithm.

(3) In the centrally located image, place an ROI with an area equal to approximately 1% of the phantom area (for the ACR phantom, this is 400 mm^2) at the center and at 3, 6, 9, and 12 o'clock positions around the periphery of the phantom, leaving approximately one ROI diameter between the outer edge of the ROI and phantom border.

(4) Record the mean of all five ROIs.

(5) Determine the difference between the mean value of each peripheral ROI and the central ROI.

(6) Using the scanner's linear measurement tool, measure the distance between the two very small BBs to assess the accuracy of in-plane distance measurements.

(7) Figure 5-4 on the following page shows ACR CT Phantom Module 3 ROI placement.

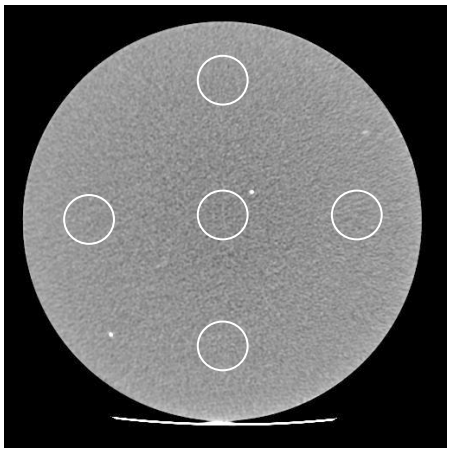


Figure 5-4.

e. Interpretation of Results.

(1) Uniformity. If the difference between the peripheral ROIs and the center ROI exceeds the criteria, consult a qualified service engineer.

(2) Geometric Accuracy. Consult a qualified service engineer if measured distance is outside 10% of the nominal distance.

10. Radiation Dosimetry ($CTDI_{vol}$)

a. Purpose. To measure doses for verification of scanner performance and to allow for calculation of dosimetric quantities relevant to patient exam estimates.

b. Criteria. Dose index measurements should not exceed the values in Table 5-1 below, should be within 20% of the values reported by the scanner, and should not differ by more than 5% year-to-year.

Examination	Pass/Fail Criteria	Reference Value
	$CTDI_{vol}$ (mGy)	$CTDI_{vol}$ (mGy)
Adult Head	80	75
Adult Abdomen	30	25
Pediatric Head (1 yr)	40	35
Pediatric Abdomen (5 yr, 40-50 lb)	20	15

Table 5-1. $CTDI_{vol}$ limits and reference values.

c. Equipment.

(1) Phantom Data Form, with average facility protocols for adult head and body, and pediatric head (1 year old) and body (5 year old, 40-50 lbs).

(2) Calibrated CTDI (pencil) ionization chamber (typically 10 cm in length).

(3) Calibrated electrometer.

(4) Acrylic (PMMA) cylindrical phantoms, having cylindrical holes at 1 cm from the edge, and one at the center (Figure 5-5):

(a) Head CTDI phantom: 16 cm diameter.

(b) Body CTDI phantom: 32 cm diameter.

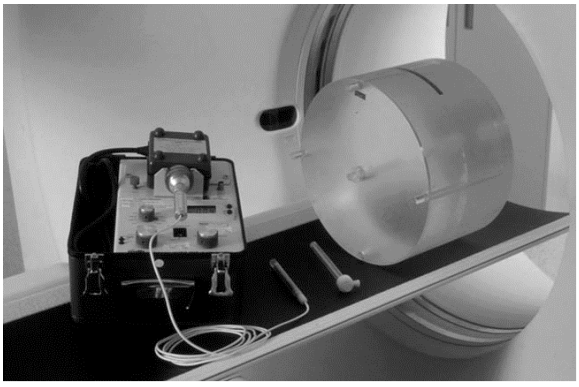


Figure 5-5.

(5) Dose calculation Excel spreadsheet, is available at www.acr.org under the CT Accreditation page.

d. Procedure:

(1) Position the phantom appropriately at the isocenter of the scanner. Ensure that the phantom is correctly aligned in all three planes (sagittal, axial and coronal).

(a) For the adult position the 16 cm phantom in the head holder or as heads are scanned clinically.

(b) For the adult abdomen scans, position the 32 cm phantom on the table top.

(c) For the pediatric head scans, position the 16 cm phantom on the table top.

(d) For the pediatric abdomen scans, position the 16 cm phantom on the table top.

NOTE: For pediatric (40-50 pounds) abdomen protocols, some CT scanners report $CTDI_{vol}$ using the 16 cm phantom, while others use the 32 cm phantom. The physicist should select the phantom (16- or 32-cm) that is used by the scanner to report $CTDI_{vol}$.

(2) Connect the pencil chamber to the electrometer and insert the pencil chamber into the central hole in the phantom. Ensure that all other holes (those at 3, 6, 9, and 12 o'clock positions) are filled with acrylic rods.

(3) Using the appropriate protocol as entered in the phantom data form, acquire a single axial slice at the center of the phantom, with no table increment. If the protocol is normally scanned helically, change to an axial scan, keeping the remaining technical parameters unchanged. **All CTDI dose information must be acquired using axial scans.**

(a) In multislice CT, CTDI is a function of detector configuration. It is **imperative** that the detector configuration and total beam width used matches the site's clinical protocol (N x T) as closely as possible.

(b) If N x T used for dosimetry does not exactly match the clinical value, be sure to modify the table increment used in the calculation to yield the same pitch value as used clinically.

(4) Measurements and Data Collection:

(a) Record the $CTDI_{vol}$ reported by the scanner.

(b) Position the phantom as described above.

(c) Place the dosimeter probe in the central position.

(d) Make one exposure in axial mode using the clinical N × T configuration. If this configuration is not accessible in axial mode, use the N × T configuration most closely matching the clinical value.

(e) Record the exposure value reported by electrometer (usually in units of mR).

(f) Repeat the scan two more times and record the exposure.

NOTE: If the repeated measurements differ by more than 5%, check your equipment and rescan the data until the three measurements agree within 5%.

(g) Repeat steps d–f above with the probe positioned at the 12 o'clock location.

(h) Repeat steps a–g above for each clinical protocol to be tested.

(5) The ACR's dose calculation spreadsheet will calculate the following:

(a) Average of the three measurements in each position in mR.

(b) $CTDI_{100}$ at each position in mGy.

(c) $CTDI_{w}$ in mGy.

(d) $CTDI_{vol}$ in mGy.

(e) DLP in mGy-cm.

(f) Effective Dose in mSv.

e. Interpretation of Results.

(1) Compare the measured $CTDI_{vol}$ values with the scanner reported values, the previous year measured values, and the ACR recommended reference levels.

(2) If the measured $CTDI_{vol}$ values exceed the recommended criteria, consult with the lead interpreting radiologist and senior CT technologist to adjust scanning protocols to acceptable dose levels.

11. Scatter Radiation

a. Purpose. To establish and maintain control of the scatter pattern created by the CT scanner.

b. Criteria. Refer to manufacturer's isodose area plot for interior room measurements. Exterior room measurements should be less than 100 mrem per year for the general public.

c. Equipment. CTDI body phantom and electrometer with large (180 sq. cm) probe.

d. Procedure:

(1) Center the CTDI phantom in the gantry opening and width of table.

(2) Place the probe at the first position to be evaluated.

(3) Scan under highest technique clinically used (1 slice) for body mode with the largest slice thickness. Record the electrometer reading.

(4) Move the probe to the next location and repeat the Procedure:

e. Interpretation of Results.

(1) Exterior walls should not exceed the general public dose limit of 100 mrem per year.

(2) If doses within the room are significantly greater than the expected isodose values provided by the manufacturer a service engineer should be consulted.

12. CT Scanner Display Calibration

a. Purpose. To ensure that images on the CT scanner monitors display the entire range of gray shades produced by the CT scanner.

b. Equipment.

(1) SMPTE Test Pattern or equivalent.

(2) Calibrated photometer with adequate precision, accuracy, and calibration to effectively measure to 0.1 cd/m2 significance.

c. Procedure:

(1) Display the test pattern on the imaging console. Set the display window width/level to the manufacturer-specified values for the pattern. Do not set the window width/level by eye; doing so invalidates this Procedure:

(2) Examine the pattern to confirm that the gray level display on the imaging console is subjectively correct.

(a) Review the line pair patterns in the center and at each of the corners.

(b) Review each black-white transition.

(c) Look for any evidence of “scalloping” (loss of bit depth) or geometric distortion.

(3) Use the photometer to measure the maximum and minimum monitor brightness (0% and 100% steps).

(4) Measure additional steps within the pattern to establish a response curve.

(5) Measure the brightness near the center of the monitor and near all four corners (or all four sides, depending on the test pattern used).

(6) In the scan room, displays used for interventional/biopsy procedures must provide good low-contrast visualization in typically bright room conditions. Consider repeating the above on all CT image acquisition displays.

d. Interpretation of Results.

(1) Visual Analysis:

(a) The visual impression should be an even progression of gray levels around the ring of gray level patches. All gray level steps in the ring of gray levels must be visibly distinct from adjacent steps.

(b) The 5% patch must be visible in the 0/5% patch; the 95% patch must be visible in the 95/100% patch.

(c) If these conditions are not met, do not adjust the display window width/level in an effort to correct the problem. Corrective action for the monitor is needed.

(d) Ensure that the finest line pair pattern can be visualized in the center and at each of the four corners.

(e) There must not be visible bleed-through in either direction of all black-white transitions. All high-contrast borders must be straight, not jagged.

(f) There must not be scalloping of the gray scale. There must not be geometric distortion in the image.

(2) Photometric Analysis:

(a) The maximum brightness should be greater than or equal to 100 cd/m^2.

(b) Calculate the luminance ratio (LR') using the equation:

$$LR' = \frac{L_{max}}{L_{min}},$$

where: L_{max} and L_{min} are the maximum and minimum measured luminance values of the five measurements made in step 16.d(5) above, respectively. The luminance ratio should be ≥100.

(c) The measured response curve data should be compared visually to the prior year's result, verifying no significant change to the curve.

(d) Calculate the nonuniformity of the display brightness using the equation:

$$\%\ difference = 200 \times \frac{(L_{max} - L_{min})}{(L_{max} + L_{min})},$$

(e) The non-uniformity should be within ±15% for flat-panel displays.

13. ***CT Technologist Quality Control (QC) Program Review***

a. Purpose. To ensure CT equipment conforms to ACR and/or manufacturer's performance standards.

b. Equipment. None.

c. Procedure: Review the facility's existing quality control program to ensure that the following elements are included:

(1) Water CT number and standard deviation.

(2) Artifact evaluation.

(3) Visual checklist.

(4) Gray level performance of acquisition display monitors.

(5) Film QC (if used for primary interpretation).

(6) Additional manufacturer's tests (if applicable).

d. Interpretation of Results. Technologists should perform these tests at the frequency prescribed by the manufacturer or the ACR (if ACR accredited). A properly functioning program should contain these elements; ideally performed as prescribed by the ACR. ACR accredited facilities must follow ACR guidelines. Review QC results and advise CT staff on how to establish baselines define pass/fail criteria (acceptance), evaluate results, and respond to test failures.

Computed Tomography Requirements

Table 5-2.—Computed Tomography Unit Survey Requirements.

	Tests	Frequency	Measurements	Tolerance
1.	**Review of Clinical Protocols**	A/P	Review the facility's existing CT protocols.	Protocols adhere to current standards of practice, account for changes in CT imaging equipment and are designed to optimize dose and image quality.
2.	**Alignment Light Accuracy**	A/P	Image position in which all markers are seen.	± 2 mm from zero location.
3.	**Scout Prescription Accuracy**	A/P	Image position in which all markers are seen.	± 2 mm from prescribed location.
4.	**Table Travel Accuracy**	A/P	Table travel distance and return position.	± 2 mm.
5.	**Radiation Beam Width**	A/P	Actual radiation beam width.	Greater of + 3 mm or 30% of the total nominal collimated beam width (N × T).
6.	**Low-Contrast Performance**	A/P	ACR Phantom Module 2 ROI HU mean in target; mean & SD out of target.	CNR > 1.0 for adult head & body; > 0.7 for peds head; > 0.4 for peds body.
7.	**Spatial Resolution**	A/P	ACR Phantom Module 4 Evaluate limiting resolution (lp/cm).	6 lp/cm for adult abdomen protocol; 8 lp/cm for high resolution adult chest protocol.
8.	**CT Number Accuracy**	A/P	ACR Phantom Module 1 ROI HU mean.	Water: -7 to +7 HU Air: -1005 to -970 HU See ACR standards.
9.	**Artifact Evaluation**	A/P	ACR Phantom Module 3 or manufacturer's phantom.	Rings or streaking artifacts.
10.	**CT Number Uniformity**	A/P	ACR Phantom Module 3 ROI measurements at edge & center of image.	Difference between edge ROI and center ROI < 5 HU.

Abbreviations: A: acceptance, P: periodic, N: number of detector channels, T: z-axis detector channel width, ROI: region of interest, HU: Hounsfield units, SD: standard deviation, lp/cm: line pairs per centimeter, CTDI: Computed tomography dose index, mGy: milligray = 1/1000 gray

Table 5-2.—Computed Tomography Unit Survey Requirements (con't).

	Test	Frequency	Measurements	Tolerance
11.	**Geometric or Distance Accuracy**	A/P	ACR Phantom Module 3 Measure distance between 2 BBs.	Measured distance < 10% of nominal distance (100 mm).
12.	**Radiation Dosimetry ($CTDI_{vol}$)**	A/P	CTDI of adult head & abdomen protocol, and pediatric head & abdomen protocol.	Adult Head < 80 mGy Adult Abd < 30 mGy Ped Head < 40 mGy Ped Abd < 20 mGy
13.	**Scatter Radiation**	A/P	CTDI Body Phantom simulating patient, Largest slice thickness Body FOV, std body algorithm Measure @ occupied locations.	< 100 mR/yr to the public in occupied spaces.
14.	**CT Scanner Display Calibration**	A/P	SMPTE pattern luminance response, resolution, and spatial accuracy; maximum luminance, luminance ratio, and luminance uniformity.	Even progression of gray levels, 5% & 95% squares visible, fine line pairs visible, no scalloping, distortion, or bleedthrough; max lum > 100 cd/m^2; lum ratio > 100; nonuniformity ±15%.
15.	**CT Technologist Quality Control Program Review**	P	Review the facility's existing quality control program.	QC tests performed within periodicity and results meet pass criteria; failing results properly evaluated.

Abbreviations: A: acceptance, P: periodic, FOV: field of view, CTDI: Computed tomography dose index, mR: milliroentgen = 1/1000 roentgen, SMPTE: Society of Motion Picture and Television Engineers, cd/m^2: candela per sq. meter

Computed Tomography Unit Survey

Facility:	Room Number/Location:
Date:	ECN:
Manufacturer:	Model Number:
Tube Serial Number:	Manufactured Date:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Review of Clinical Protocol				
Alignment Light Accuracy				
Scout Prescription Accuracy				
Table Travel Accuracy				
Radiation Beam Width				
Low-Contrast Performance				
Spatial Resolution				
CT Number accuracy				
Geometric or Distance Accuracy				
Radiation Dosimetry ($CTDI_{vol}$)				
Scatter Radiation				
CT Scanner Display Calibration				
Quality-Control Program Review				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 6. Mammographic Units

A. *Introduction*

The Mammography Quality Standards Act (MQSA); Correction; Final Rule, 21 CFR 16 and 900, November 10, 1997, requires any facility that produces, processes or interprets mammograms to be certified by the FDA. To be certified, facilities must meet the federal regulations and must be accredited by a FDA approved private or state accrediting body.

B. *Minimum Required Personnel Qualifications*

As specified by the MQSA, American College of Radiology (ACR), and manufacturer's quality control manual, as applicable.

C. *Testing Periodicity*

As specified by the MQSA, ACR, and manufacturer's quality control manual, as applicable.

D. *Equipment*

As specified by the MQSA, ACR, and manufacturer's quality control manual, as applicable.

E. *References*

1. Code of Federal Regulations, Title 21, Chapter 1, Parts 1020.30, 1020.31, 1020.32.

2. Mammography Quality Standards Act (MQSA) of 1992.

3. *Mammography Quality Assurance Manual*. American College of Radiology (ACR), 1999.

4. *Digital Mammography Quality Assurance Manual*. American College of Radiology (ACR), 2018.

5. *Stereotactic Breast Biopsy Quality Assurance Manual*. American College of Radiology (ACR), 1999.

Chapter 7. Performance Tests for Ultrasound Scanners

A. *Introduction*

There currently exist only recommendations for Quality Control (QC) programs for ultrasound. However, such programs are important for ensuring the accuracy of patient examinations as well as for controlling repair and maintenance costs of the units themselves.

The tests listed in Table 7-1 should be performed using the most clinically used transducers with Time Gain Compensation (TGC) and depth settings as described in ref.4. For acceptance testing, all transducers need to be tested.

This chapter only applies to real-time B-mode operation ultrasound systems. Doppler and any other flow imaging modes quality control test procedures are not cover under this chapter.

B. *Minimum Required Personnel Qualifications*

Advanced Diagnostic Imaging Equipment Ultrasound (US).

C. *Testing Periodicity*

See Table 7-1 for the periodicity of each test.

D. *Equipment*

1. Tissue equivalent phantom with average velocity of sound of 1540 m/s ± 10 m/s and an attenuation coefficient of 0.5 to 0.7 dB/MHz·cm

2. Ultrasound Scanner System Survey

E. *References*

1. Hendrick, W.R., and Hykes, D.L., *Journal of Diagnostic Medical Sonography*, 1997.

2. AAPM Report No 8, *Pulse Echo Ultrasound Imaging Systems Performance Tests and Criteria*, American Institute of Physics, 1981.

3. NCRP Report No. 99, *Quality Assurance for Diagnostic Imaging*; National Council on Radiation Protection and Measurements, 1988.

4. Goodsitt M.M and Carson P.L., *Real-time B-mode Ultrasound Quality Control Test Procedures, Report of AAPM Ultrasound Task Group No. 1*, 1998.

F. *Performance Tests for Ultrasound (US) Scanners*

1. Vertical Distance Accuracy

a. Purpose. To determine the accuracy of distances measured along the beam axis.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. Tissue-Mimicking (TM) phantom.

d. Procedure:

(1) Rest ultrasound transducer on scanning surface of the phantom.

(2) Adjust the focal zone and depth controls until the vertical pin targets are clearly visualized and freeze the image.

(3) Measure the distance between two of the vertical pin targets and compare this measurement with the actual vertical pin distance specified by the phantom. Always measure the distance on the between the same two targets that were used during the baseline tests. Record the measured distance and compared with known distance.

2. Horizontal Distance Accuracy

a. Purpose. To determine the accuracy of distances measured perpendicular to the beam axis.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Repeat step 1.d. (1) thru d. (2).

(2) Measure the distance between two of the horizontal pin targets and compare this measurement with the actual horizontal pin distance specified by the phantom. Always measure the distance between the same two targets that were used during the baseline tests. Record the measured distance and compared with known distance.

e. Interpretation of Results. If vertical and or horizontal distance accuracy exceeds tolerance levels specified in Table 7-1 consult a qualified service engineer.

3. Transducer Sensitivity / Depth of Penetration

a. Purpose. To determine the sensitivity of an ultrasound instrument's weakest echo signal level that can be detected and clearly displayed.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Rest ultrasound transducer on scanning surface of the phantom.

(2) Adjust focal zone to maximum depth, gain and output power to maximum.

(3) Scan phantom and freeze image. Measure and record the maximum depth of visualization of background echoes from the phantom. This is the distance from the top of the scan window to the deepest cylindrical or spherical object that is barely visible. Record the depth of penetration.

e. Interpretation of Results. The maximum depth of penetration is the point at which usable tissue echoes disappear from the image, i.e. how far one can "see" into the patient. The maximum depth of penetration should remain the constant over time; variations indicated performance degradation. If changes in depth exceed tolerance levels specified in Table 7-1 consult a qualified service engineer.

4. Dead Zone (Ring Down)

a. Purpose. To determine the zone were useful data is missing (dead zone).

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Adjust focal zone and depth controls to contain a set of filaments targets located very close to the scanning window (dead zone target group) and freeze the image.

(2) Determine the closest pin which can be imaged and record its depth.

e. Interpretation of Results: The dead zone is the result of reverberations in the transducer, adjacent tissue, and the scanner's attempts to compensate for these problems. Damage to the transducer or poor acoustic coupling may accentuate this defect. If dead zone exceeds specifications listed in Table 7-1 consult a qualified service engineer or if there is any consistent measurable change from baseline.

5. Physical and Mechanical Inspection

a. Purpose. To evaluate the integrity of the scanner's mechanical components.

b. Regulations. Visual determination of satisfactory or unsatisfactory per Table 7-1.

c. Equipment. None

d. Procedure:

(1) Check unit and transducer cables, housing, and transmitter surfaces for cracks, separations, and discolorations.

(2) Transducer(s) plug-ins should be marked if they can be plugged into one of several outlets and check for bent or loose prongs.

(3) Verify that transducer(s) within the scan head move(s) smoothly without excessive noise or vibration, and the absence of air bubbles in the scan heads.

(4) Check for dirty or broken switches, knobs, and burnt out lights.

(5) The video monitor should be clean and free of scratches.

(6) Check that all wheels rotate freely and that the unit is easy to maneuver, and that wheels are seated securely and lock properly.

(7) Inspect that the dust filters are clean and free of lint and clumps of dirt, as overheating may result and shorten the life of electronic components.

e. Interpretation of Results. Take damaged systems or components out of service and repair them before using the system to image patients.

6. Image Uniformity

a. Purpose. To ensure the absence of image artifacts and non-uniformities.

b. Regulations. Visual determination of satisfactory or unsatisfactory per Table 7-1.

c. Equipment. TM phantom.

d. Procedure:

(1) Adjust the focal zone and depth controls to scan the region of the phantom with the fewest targets (most commonly the area opposite the phantom cysts) and freeze the image. Record the settings for future use.

(2) Print a hard copy, visualize results, and grade the image.

e. Interpretation of Results. The hard copy of the image should be inspected for the absence of non-uniformities. A service engineer should be contacted if noticeable and/or serious non-uniformities are present.

7. Lateral Resolution

a. Purpose. To determine the instrument's ability to distinguish small, adjacent structures perpendicular to the beam's major axis.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Adjust the control settings to obtain a clear image that shows as many of the vertical pin targets as possible and freeze the image.

(2) Measure and record the width of the three vertical pin targets in the near, middle, and far field zones, always measuring the pin width from edge-to-edge.

NOTE: Lateral resolution is highly dependent upon machine the settings used to generate an image; therefore be sure to record the baseline settings and use the same settings for all follow up procedures.

e. Interpretation of Results. Lateral resolution is approximately equal to beam width and varies with depth, transducer focusing characteristics, and the system's gain and sensitivity settings. Objects smaller than the ultrasound beam are displayed with a

width equal to the width of the ultrasound beam at that depth. The lateral resolution of transducers with a fixed focus will vary noticeably with depth. Lateral resolution is typically affected by the loss of transducer elements or by problems in the system's beam-forming circuits. Although minor variations are normal, the pin width should remain relatively constant over time. A service engineer should be contacted if beam width changes by more than 1 mm from baseline values.

8. Axial Resolution

a. Purpose. To determine the instrument's ability to detect and clearly display closely spaced objects that lie on the beam's axis.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) For each axial resolution target group (near, middle, and far), adjust the focal zone and depth controls to scan the target group and freeze the image.

(2) Determine the axial resolution by finding the two pin targets with the smallest vertical spacing that are visible as distinct objects and have no vertical overlap and record the resolution level.

(3) Record machine baseline settings and use the same settings for all follow up procedures.

NOTE: Pin targets larger than 0.15mm in diameter may produce a doubling artifact for transducer frequencies greater or equal to 5 MHz.

e. Interpretation of Results. Axial resolution depends on the transducer's spatial pulse length or pulse duration, which depend on the center frequency and damping factor. Axial resolution should remain stable over time. A service engineer should be contacted if any consistent measurable change from baseline values.

9. Cyst Imaging (Anechoic Imaging)

a. Purpose. To evaluate the system's ability to display a round, negative contrast object.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Adjust the focal zone and depth controls until the target cyst is clearly visualized, the edges of the cyst are sharply defined, and the cyst interior is echo free. Freeze the image.

NOTE: Bright spots at the top and bottom of cysts are specular reflections and are considered normal for some systems.

(2) Measure and record the height and width of each cyst.

(3) Rate the cyst for no distortion, minor distortion, and/or major distortion.

(4) If using a phantom that has cysts of different sizes, determine the smallest cyst at near, middle, and far field zones.

(5) Repeat steps 1-3 for each phantom cyst. Record settings for future use.

e. Interpretation of Results. Cyst imaging combines aspects of contrast resolution and image uniformity into a single test. Cyst image quality can be affected by electrical noise, side lobes in the transducer beam and problems in the image processing hardware. Flattened cyst indicates geometric distortion. Echoes inside the cyst may be the result of system noise or side lobe contamination. A service engineer should be contacted if you observe any major distortions e.g. height differs from width by 20% or more; are detected or any measureable change from baseline.

10. Display Monitor and Hardcopy Fidelity

a. Purpose. To independently evaluate the monitor and printer capabilities.

b. Regulations. Refer to manufacturer's specifications.

c. Equipment. TM phantom.

d. Procedure:

(1) Display grayscale test pattern (or step-wedge) and count number of grayscale steps.

(2) Make a hard copy and count number of grayscale steps. Record machine settings for future use and save printed image.

NOTE: The number of grayscale steps displayed on the monitor and hardcopy should be the same. The baseline hardcopy can be used as a reference to verify the monitor in all post-baseline tests.

e. Interpretation of Results. If the number of grayscale steps for monitor and /or hardcopy exceeds tolerance levels specified in Table 7-1 consult a qualified service engineer.

Ultrasound Imagining System Requirements

Table 7-1.—Ultrasound Imaging System Survey Requirements.

	Test	Frequency	Measurements	Tolerance
1	**Display Monitor Fidelity**	A/S	Display and count number of grayscale steps visible on monitor Contrast and brightness controls are at baseline positions	#gray bars displayed < control value -2, fuzzy or blooming annotation
2	**Hardcopy Fidelity**	A/S	Print grayscale pattern and count number of grayscale steps Contrast and brightness controls are at baseline positions	#gray bars displayed < control value -2, fuzzy or blooming annotation
3	**Image Uniformity**	A/S	Examine image for nonuniformities and artifacts	Nonuniformity> 4dB or, any consistent measurable change from baseline values.
4	**Depth Visualization/ Penetration**	A/S	Scan phantom and freeze the image. Measure and record the deepest cylindrical or spherical object barely visible.	Change > 0.6 cm from baseline
5	**Vertical Distance Accuracy**	A/S	Scan phantom and freeze image. Measure distance between most widely separated filament target in vertical column.	Error >1.5 mm or 1.5%
6	**Horizontal Distance Accuracy**	A/S	Scan phantom and freeze image. Measure distance between most widely separated filament target in horizontal column.	Error >2 mm or 2%, whichever is greater
7	**Anechoic Object Imaging**	A/Y	Scan phantom and freeze image. Record smallest anechoic object visualized at different depths. Record height and width and ratio for anechoic object larger than smallest perceived. Record cyst image quality.	Major distortion or any consistent measurable change from baseline.

Abbreviations: A= acceptance; S= semiannually; Y= yearly.

Table 7-1.—Ultrasound Imaging System Survey Requirements (con't).

	Test	Frequency	Measurements	Tolerance
8	**Axial Resolution**	A/Y	Scan phantom and freeze image. Zoom at each axial target group. Record smallest separation between targets perceived at various depth.	1 mm or 2mm if frequency <4 MHz, or any consistent measurable change from baseline.
9	**Lateral Resolution**	A/Y	Scan phantom and freeze image. Measure width of the pin targets in the near, mid and far fields of the image.	Change>1 mm from baseline value
10	**Dead Zone**	A/Y	Scan the region in the phantom containing the dead zone and freeze image. Record the depth of the shallowest visible filament.	7 mm for f<3 MHz 5 mm for 3 MHz< f<7MHz 3 mm for f≥7 MHz
11	**Physical and Mechanical Inspection**	A/S	Check cables and transducer for cracks, damage, filter cleanliness, housing dents and any other visible damage.	Report findings to staff and/or service personnel as applicable.

Abbreviations: A= acceptance; S= semiannually; Y= yearly.

Ultrasound Scanner System Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	Model Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Display Monitor Fidelity				
Hardcopy Fidelity				
Image Uniformity				
Vertical Distance Accuracy				
Horizontal Distance Accuracy				
Anechoic Object Imaging				
Axial Resolution				
Lateral Resolution				
Dead Zone				
Physical and Mechanical Inspection				

Additional Comments:

Transducer Model Number:	Serial Number:
Phantom Model Number:	Serial Number:

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 8. Magnetic Resonance Imaging (MRI) Units

A. *Introduction*

This section is designed to assist Navy medical physicists and qualified surveyors at medical treatment facilities in testing and maintaining whole body MRI equipment in accordance with the Joint Commission (JC) standards, which follow the procedures delineated in the 2015 ACR MRI Quality Control Manual and ACR Phantom Test Procedures. This section does not cover extremity MRI equipment. The recommended tests, performance criteria, and operating procedures are for general guidance, and are subject to change based on subsequent revisions to TJC and/or ACR performance test standards. The user should refer to the ACR MRI QC Manual for detailed discussions on theory and concepts used for each test protocol, and to the ACR Small Phantom Test procedures for evaluating dedicated extremity MRI equipment.

Due to the potential complexity of the MRI scanner operation, a qualified MRI technologist should be present during physics testing of the equipment.

B. *Minimum Required Personnel Qualifications*

Board Certified Diagnostic Physicist by the American Board of Radiology (DABR), or equivalent, or Qualified Navy Surveyor in MRI, as approved by the Medical Physics Advisory Board (MPAB).

C. *Testing Periodicity*

Upon acceptance, annually, and after major repairs, per BUMEDINST 6470.22B.

D. *Equipment*

1. Large ACR MRI Test Phantom
2. Calibrated Photometer (Luminance Light Meter)
3. Calibrated Gauss Meter
4. MRI Unit Survey (found in Appendix F)

E. *Minimum Evaluation for MRI Units*

1. Magnetic Field Homogeneity

a. Purpose. To ensure the magnetic field is uniform across the entire imaging FOV.

b. Regulations. None.

c. Equipment. Large (at least 30 cm diameter) uniform spherical phantom. Generic Digital Imaging and Communications in Medicine (DICOM) capable reading software.

d. Procedure - (Method 1 – Spectral Peak):

(1) Obtain a spectrum from the phantom. This can be done by going into manual tuning or pre-scan mode. Ensure that the frequency resolution is much less than the expected peak width.

(2) Measure Full Width at Half Maximum (FWHM) of the spectral peak. Convert the FWHM from Hz to ppm of the B_0 field strength by using the following equation:

$$\text{FWHM (ppm)} = \text{FWHM (Hz)} / (42.576\ (\text{Hz/T})\ B_0\ (\text{T}))$$

(3) Some manufacturers do not allow analysis of pre-scan or manual shimming. In these cases, you may have to use manufacturer software to provide a line width. Contact your field engineer to find out details.

e. Procedure - (Method 2 – Phase Diff Map):

NOTE: Requires the availability to display phase images, which may not be available on all MRIs.

(1) Position the phantom in the center of the large volume (body) Radiofrequency (RF) coil. Scan the phantom using a simple field echo (spoiled gradient echo) sequence. Do not use a RF spin echo to avoid rephrasing field inhomogeneity caused of phase differences.

(2) Acquire an image using an Echo Time (TE) of approximately 10 – 20 ms (TE_1). Display the image as a phase map. Acquire a second image using a slightly longer TE (TE_2).

(3) Subtract the second image from the first to obtain a phase difference image.

(4) Calculate the difference between the B_0 field at a given voxel and the reference value at the center of the field of view:

$$\Delta B_0 = \frac{\delta\varphi}{\gamma}\left(\frac{1}{TE_1} - \frac{1}{TE_2}\right)$$

Where:

ΔB_0 is in mT;
$\delta\varphi$ = phase difference in radians
γ = gyromagnetic ratio (42,576 $HZ \cdot mT^{-1}$ = 267,513 $radians \cdot mT^{-1}$ for protons)
TE values are in sec

(5) Repeat the procedure for to obtain data from the other two planes.

(6) Determine the greatest differences in any plane between the values of ΔB_0 within circular regions of interest having specific Diameter of Spherical Volumes (DSOVs). This difference divided by the B_0 field strength will provide the homogeneity in ppm for the specified DSOV.

f. Procedure - (Method 3 – Bandwidth Diff):

(1) Position the phantom in the center of the large volume (body) RF coil.

(2) Scan the phantom twice using a Gradient Echo (GRE) sequence appropriate for the scanner (e.g. flip angle = 25, TR = 52 ms, TE = 8.5 ms, thickness = 6 mm, scan time 1:06, 256 x 256 matrix, 400 mm FOV) and alternately with small and large Bandwidths (BW). The low BW should be near minimum (e.g. < 20 Hz pixel^{-1}); the high BW should be near the system's available maximum (e.g. ~ 500 Hz pixel^{-1}).

(3) Measure and record the displayed phantom diameters for each band width (For axial image, measure in the left to right direction; in coronal and sagittal images, measure in the anterior to posterior direction).

(4) Calculate the difference between the B_0 field at a given voxel and the reference value at the center of the field of view:

$$H_B(\text{ppm}) = \frac{BW_1 \cdot BW_2 \cdot (x_1' - x_2')}{\left(\frac{\gamma}{2\pi}\right) \cdot B_0 \cdot FOV_x(BW_2 - BW_1)}$$

Where:

H_B = inhomogeneity (*ppm*)
BW_1 = low bandwidth (*Hz*)
BW_2 = high bandwidth (*Hz*)
x_1' = measured sphere diameter for low BW (*mm*)
x_2' = measured sphere diameter for high BW (*mm*)
γ = gyromagnetic ratio (42,576 $Hz \cdot mT^{-1}$ = 267,513 $radians \cdot mT^{-1}$ for protons)
B_0 = center frequency (*Hz*)

FOV = field of view (*mm*)

(5) Repeat the procedure for to obtain data from the other two planes.

(6) Calculate the total field inhomogeneity as the mean of the inhomogeneities in the three planes.

g. Interpretation of Results. Homogeneity is specified by the system manufacturer. The values obtained should be compared to those specified. Typical values are approximately 2 ppm for a 30 to 40 cm diameter sphere.

2. ACR Phantom Image Acquisition

a. Purpose. To acquire appropriate cross sectional images of the ACR MRI Phantom to allow for effective image quality testing.

b. Equipment. ACR MRI Phantom.

c. Procedure:

(1) Place the large ACR MRI phantom in the head coil and align to phantom crosshairs. Advance the table to the magnet isocenter.

(2) Acquire a sagittal localizer (scout) image using the following parameters: 1 slice, sagittal spin echo, TR = 200 ms, TE = 20 ms, slice thickness = 20 mm, FOV = 25 cm, matrix = 256 x 256, NEX = 1, scan time = 0:56 sec.

(3) Display the resulting sagittal slice. Inspect the image to ensure the entire phantom is visible. Acquire axial slices of the relevant phantom sections using 11 slices, starting at the vertex of the crossed 45 degree wedges at the inferior end of the ACR phantom and ending at the vertex of the crossed 45 degree wedges at the superior end. The ACR T1 series: (11 slices, spin echo, TR = 500 ms, TE = 20 ms, FOV = 25 cm, slice thickness = 5 mm, slice gap = 5 mm, matrix= 256 x 256, NEX = 1). See Figure 1 below:

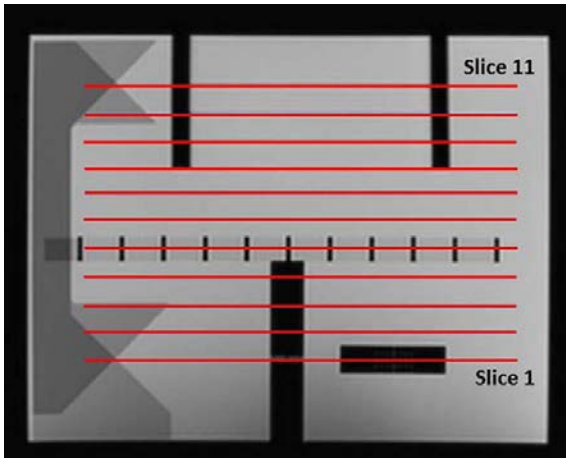


Figure 1. Sagittal image of ACR large phantom w/ positions of the 11 axial slices of the T1-weighted series superimposed.

(4) Repeat scans using the ACR T2 series: (11 slices, double echo spin echo, TR = 2000 ms, TE / TE_2 = 20/80 ms, FOV = 25 cm, slice thickness = 5 mm, slice gap = 5 mm, matrix= 256 x 256, NEX = 1)

(5) As necessary, determine and record the facility's Axial Head T1 and T2 weighted sequences.

3. Center Frequency Evaluation

a. Purpose. To ensure resonance frequency and transmitter attenuation or gain are within manufacturer specification and/or do not exceed established action limits.

b. Equipment. ACR MRI Phantom.

c. Procedure: During pre-scan, the system will automatically check the center frequency and set the transmitter attenuation or gain. Record this information.

d. Interpretation of Results: If the center frequency and/or transmitter attenuation or gain exceed established action limits, repeat the pre-scan and record the measurements. If action limit is still exceeded, notify the service engineer of this results. Recommended action limits can be found in the ACR MRI QC Manual.

4. Alignment Light Accuracy

a. Purpose. To determine that the MRI scanner is performing patient setup, data entry, and pre-scan tasks properly.

b. Equipment. ACR MRI Phantom.

c. Procedure:

(1) Place the ACR large phantom in the head coil as described in paragraph 2 above.

(2) Position the phantom so that the axial alignment light is on the superior (head direction) edge of the grid structure. By ensuring that the thickness of the line is uniform along the edge, you will prevent any "yaw" in the phantom, assuming the axial light is square. See Figure 2 on the following page:

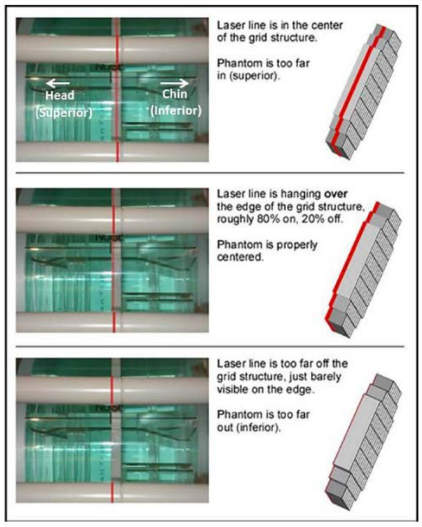
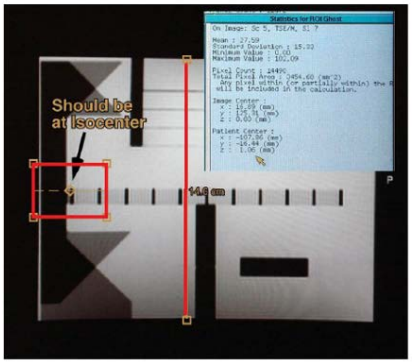


Figure 2. Illustration of the use of the central grid structure for alignment of the large phantom when the head coil has a central bar that block visualization of the small cross-line positioning marker.

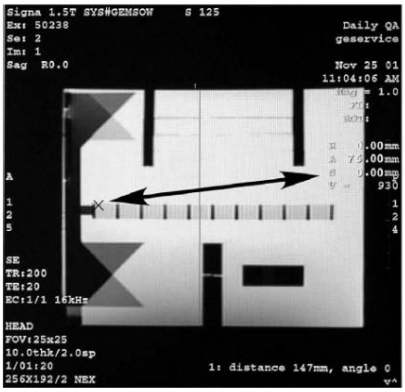
(3) It is recommend that a three-plane localizer be used initially to ensure the phantom is properly positioned.

(4) Use the ACR sagittal localizer ACR T-1 sequence as described in paragraph 2 above.

d. Interpretation of Results. If the positioning laser is properly calibrated and the table positioning system functions properly, the superior edge of the grid structure should be at magnetic isocenter. Every vendor provides a method to determine the S/I or z-coordinate of a location in the image. It usually entails placing a cursor or a region of interest (ROI) on the image and then reading the z coordinate or S/I value. See Figure 3 on the following page. If the location of the superior edge of the grid structure should be within ±5 mm of the magnetic isocenter. If not, contact the MRI service organization following the QC Procedure:



a.



b.

Figure 3. a) An example taken from a scanner where a square ROI has been placed with its center on the anterior/superior edge of the grid – exactly where the laser was positioned. In this example the z-coordinate is +1.06. b) An example taken from a scanner and showing the cursor on the superior edge of the grid is exactly at isocenter, S0.00 mm; the S indicates distance from isocenter in the superior z-direction.

5. Slice Position Accuracy

a. Purpose. To determine whether locations of acquired axial slices differ excessively from their prescribed locations for a properly operating scanner.

b. Equipment. ACR MRI Phantom.

c. Procedure:

(1) Display the T1-weighted series. Differences between the prescribed and actual positions of slices #1 and #11 are measured.

(2) Display the slice magnified on the monitor by a factor of 2 to 4. Keep the vertical bars of the crossed wedges with the displayed portion of the image.

(3) Adjust the display window so that the ends of the vertical bars are clear using a narrow display window. The display level should be set to a level one half that of the signal of the bright portions of the phantom.

(4) Use the viewer's measurement tool to measure the difference in length between the left and right bars. If the left bar is longer, then assign a negative value to the number; if the right bar is longer, assign a positive value. See Figures 4 and 5 below:

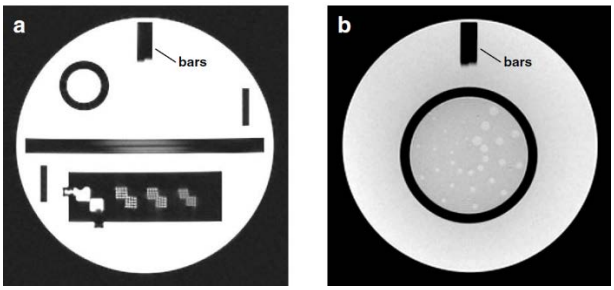


Figure 4. Images of slice 1 (a) and slice 11 (b) with the pairs of vertical bars from the 45° crossed wedges indicated. On these images the length difference between the right and left bars is small and typical of well-positioned slices.

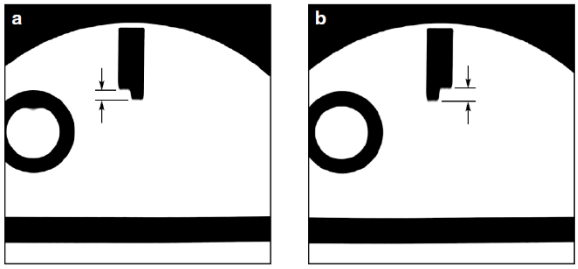


Figure 5. Images of slice 1 illustrating measurement of slice position error. The arrows indicate the bar length difference measurement that is to be made.

d. Interpretation of Results. The crossed wedges have a 45 degree slope. Therefore the bar length difference is twice the actual slice displacement error. The magnitude of the bar length difference should be less than or equal to 5 mm.

6. Slice Thickness Accuracy

a. Purpose. To determine accuracy of specified slice thickness.

b. Equipment. ACR MRI Phantom.

c. Procedure:

(1) Display slice #1 with a magnification of two to four while keeping the slice thickness insert fully visible (The slice thickness inserts are the two opposed horizontal thick bright lines). See Figure 6 below:

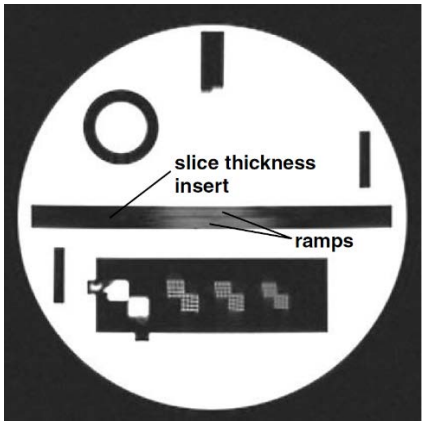


Figure 6. Slice 1 with the slice thickness insert and signal ramps indicated.

(2) Adjust the display level so that the signal ramps are well visualized. Place a rectangular ROI at the middle of each signal ramp. Note the mean signal values for each of the two ROI's and determine a joint ramp man signal value. If the two ROI mean values differ more than 20%, the ROI's may include some of the area surrounding the ramps. Adjust the ROI sizes to only include the ramps and note the new mean values and joint mean value. See Figure 7:

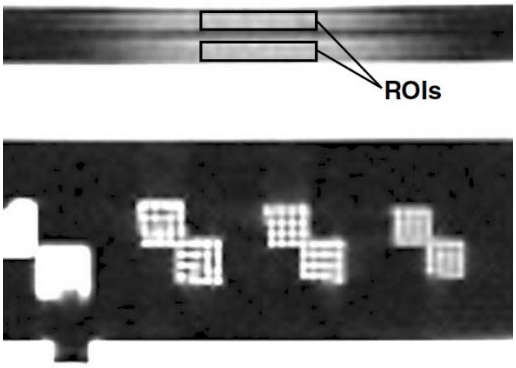


Figure 7. Magnified region of slice 1 showing slice thickness signal ramps with ROIs placed for measuring average signal in the ramps.

(3) Lower the display level to one half of the average ramp signal. Leave the display window set to minimum.

(4) Use the display station length measurement tool to measure the lengths of the top and bottom ramps. Record these measurements.

d. Interpretation of Results. The slice thickness is calculated using the following formula:

Slice Thickness = 0.2 x (top x bottom) / (top x bottom)

where "top" and "bottom" refer to measured lengths of the top and bottom ramps respectively. This measurement is best for slice thicknesses between 3 mm and 7 mm. For the ACR T1-weighted axial imaging series, the measured slice thickness should be 5.0 mm ± 0.7 mm.

7. Geometric Accuracy

a. Purpose. To ensure that the geometric relationships are accurate and concentrates on deciphering the tissue contrast relationships for a variety of pulse sequences to make an accurate diagnosis. The objective of the following tests is to verify that the image is scaled in a manner reflecting the true dimensions of the body part under investigation.

b. Procedure:

(1) Display the sagittal localizer image of the ACR phantom. Set the window width to a very narrow value (0 - 1). Adjust the window level until about one half of the phantom is white and the other half is black.

(2) Change the window width value to one half of the window level noted above. Change the window level value to one-half of the window width value.

(3) Use the measuring tool to measure vertically from one end of the phantom to the other. Record the value as "z direction". The actual phantom length in this direction is 148 mm. See Figure 8:

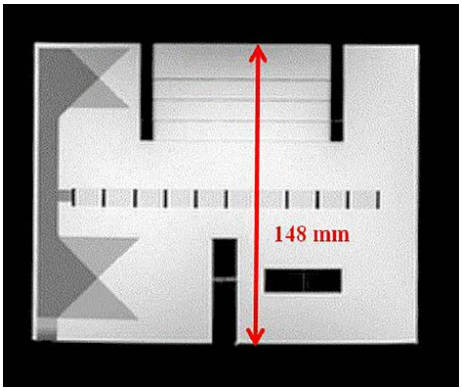


Figure 8. Positioning of length measurement on ACR MRI phantom.

(4) Display slice #5 using the same window and level routine as for the sagittal localizer view.

(5) Determine the diameter of the signal producing circular phantom volume measured vertically and horizontally. Record these values as “y direction” and “x direction,” respectively. The actual phantom diameter in both directions is 190 mm. See Figure 9 below:

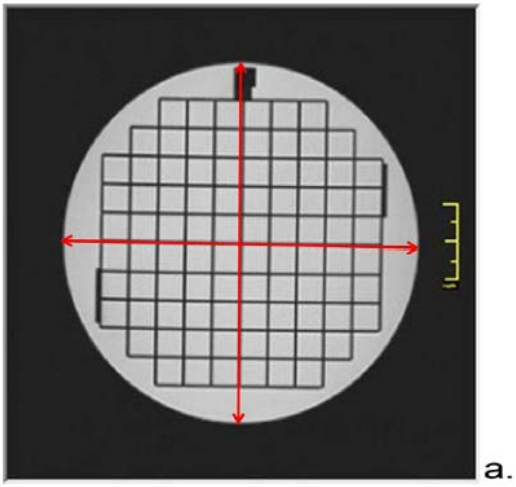


Figure 9. Position for x- and y-direction diameter measurements on ACR MRI phantom.

(6) Repeat with sagittal and coronal slices if desired.

c. Interpretation of Results. The length measurements obtained from a 25 cm FOV should vary less than ± 2 mm from their true values.

8. High Contrast Spatial Resolution

a. Purpose. To assess the scanner’s ability to resolve small objects. A failure of this test means that for a given field of view and acquisition matrix size the scanner is not resolving small details as well as normal for a properly functioning scanner.

b. Equipment. ACR MRI Phantom.

c. Procedure:

(1) Display slice #1 of the ACR T1 weighted axial image series.

[There are three pairs of not-quite-square hole arrays. They consist of Upper Left (UL) and Lower Right (LR) hole arrays. The UL array is used to assess resolution in the right-left direction. The LR array is used to assess resolution in the top-bottom (anterior-posterior if the phantom were a patient head). The hole diameters differ between the array pairs (left = 1.1 mm, center = 1.0 mm, right= 0.9 mm)]. See Figure 10 on the following page:

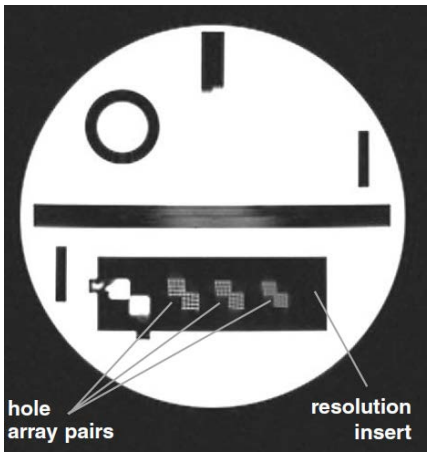


Figure 10. Slice 1 with resolution insert and hole array pairs indicated.

(2) Magnify the image by a factor of 2 to 4, keeping the resolution arrays visible in the display. Reduce window width to a small value. Adjust window level until the holes in the arrays are distinguishable.

(3) For each of the arrays, adjust the window and level to best show the holes as distinct from one another. If all four holes in any single row or column (row for UL arrays, column for LR Arrays) are distinguishable from one another, the image is considered resolved.

(4) Determine the smallest hole size (1.1 mm, 1.0 mm, 0.9 mm) that can be resolved in the UL (rows resolved) and LR (column resolved) arrays. See Figure 11 below.

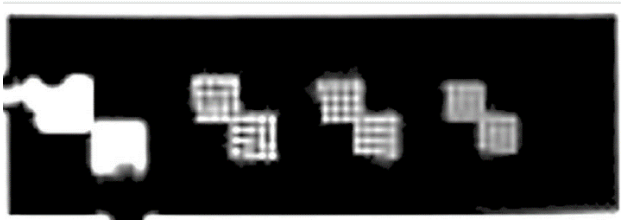


Figure 11. Phantom high-contrast resolution insert from slice 1 of an axial series shows three sets of two array holes. Hole sizes and spacing: from left, 1.1 mm, 1.0 mm, and 0.9 mm.

(5) Repeat for ACR T2 weighted series.

d. Interpretation of Results. Resolution in both directions should be 1.0 mm or better.

9. Low Contrast Detectability (LCD)

a. Purpose. To assess the extent to which low contrast objects are discernible in the images.

b. Regulations. None.

c. Equipment. ACR MRI Phantom.

d. Procedure:

(1) Using images 8, 9, 10 and 11 of the T1 weighted axial series, display each one at a time and adjust the display window and width and level settings for best visibility of the low contrast spokes.

(2) Each slice has 10 low contrast disk spokes. Each spoke is made of 3 disks. All of the spokes of a given slice have the same contrast level (Contrast is 1.4%, 2.5%, 3.6%, and 5.1% for slices #8 to #11, respectively). Count the number of complete spokes in each slice. The number of complete spokes counted is the score for this slice. The ACR recommends choosing a single slice in which all of the spokes are not normally observable as the slice to score. However, for an annual check it is easy to score all the slices and add them together. See Figure 12.

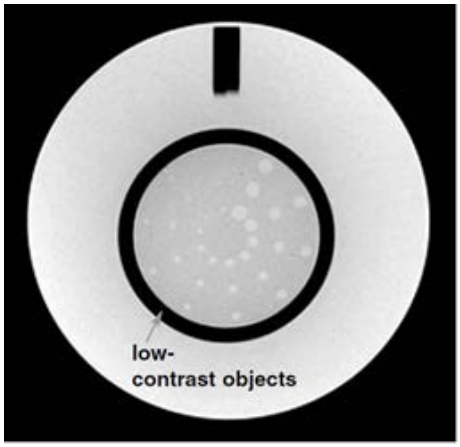


Figure 12. Image of slice 11 showing the circle of low-contrast objects for the low-contrast object detectability test.

(3) Repeat for T2 weighted series, but evaluate the slice images from the second echo (T = 80 ms).

e. Interpretation of Results. Low contrast detectability should be equal to or greater than or equal to 9 spokes (total) for 1.5 T systems and equal to or greater than 37 spokes (total) for 3 T units.

10. Artifact Evaluation

a. Purpose. To ensure that overall MRI system performance is remaining stable.

b. Equipment. ACR MRI phantom.

c. Procedure:

(1) Adjust the display window and level to show the full range of pixel values for each slice of the T1 weighted ACR axial series.

(2) Check to make sure that the phantom appears circular, there are no ghost images in the background or overlying the phantom, there are no streaks or artifact bright or dark spots visible and there are no unusual or new features in the image.

(3) Repeat for T2 weighted series, if desired.

d. Interpretation of Results. There should be no artifacts visible in any of the images.

11. RF Coil Checks (Signal to Noise Ratio [SNR], Percent Image Uniformity [PIU], Percent Signal Ghosting [PSG])

a. Purpose. To ensure that the radio frequency coils are functioning properly.

b. Regulations. None.

c. Equipment. ACR MRI phantom or a phantom that simulates the geometry body part of interest for the coil being tested.

d. Procedure:

(1) Volume Coils

(a) Display slice #7.

(b) Select an ROI that covers approximately 80% of the phantom cross section (approximately 200 cm^2). Record the ROI mean signal and standard deviation values.

(c) Select a second ROI that covers approximately 0.15% of the FOV (for a 256 x 256 matrix, the ROI should be about 100 pixels). Move this ROI to the area of maximum intensity within the “mean signal ROI”. This area can be found by narrowing the window and adjusting the level value to find the brightest area. Determine the ROI mean signal in this area. Record as “high”. Repeat this measurement for the location of lowest signal intensity. This value is “low”. See Figure 13 on the following page:

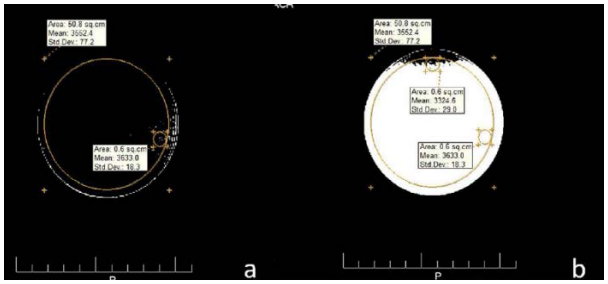


Figure 13. Evaluation of percent uniformity in the knee coil and phantom shown. a) Appropriate windowing and ROI placement on few bright pixels for determination of maximum signal within the larger ROI. b) Appropriate windowing and ROI placement on few dark pixels for determination of minimum signal within the larger ROI.

(d) Select a third oval ROI (Approximately 120 cm^2). Using the ROI, measure the mean signal values above, below, and to the left and right of the phantom. Calculate "ghost signal" as (top +bottom) and "background signal" as (left + right). Record all results. See Figure 14.

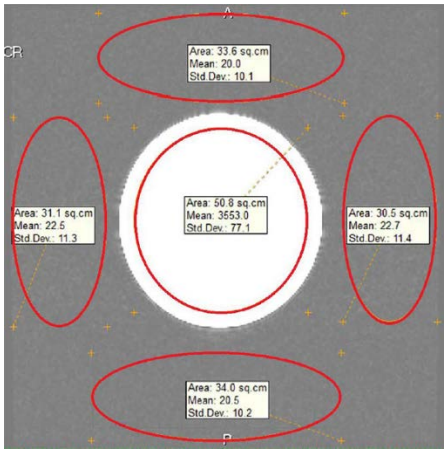


Figure 14. Placement of ROIs inside and outside the phantom to determine percent signal ghosting.

(e) Calculate SNR:

SNR = Mean Signal / Noise Standard Deviation

(2) Calculate PIU.

PIU = 100 x [1 - (High – Low) / (High + Low)]

(a) Calculate PSG:

PSG = 100 x | (Ghost Signal – Background Signal) / (2 x Mean Signal) |

(b) Perform these tests for at least one volume coil using the ACR T1 and T2 sequences during annual inspections and all volume coils during acceptance.

(3) Surface Coils

(a) Set up the coil of interest with its appropriate phantom in its normal clinical orientation with the phantom centered in the coil. Run a pulse sequence with a slice positioned near the center of the RF coil and in the imaging plane most often used in clinical practice. Scan the phantom using a T1weighted series (the T1-weighted series used by the ACR MRI Accreditation program is a good standard- single spin echo, TR = 500 ms, TE = 20 ms).

(b) Place a large ROI that covers as much of the cross-sectional area of the phantom as possible. Record the mean signal.

(c) Place a ROI of as large a size as possible in a position in the background area outside the phantom volume in the frequency encoding direction. This is the background air ROI. Image noise is defined to be the standard deviation in the background air ROI. See Figure 15.

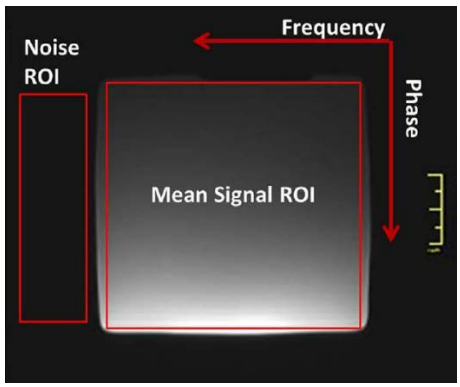


Figure 15. Image illustrating ROI placement when estimating the mean SNR.

(d) Calculate SNR:

SNR = Mean Signal / Noise Standard Deviation

(e) Observe signal intensity distribution and note whether it generally appears the same as when previous measurements were performed on the coil. During acceptance, save a hard or softcopy image with window settings for future reference.

(f) Perform this test for at least one volume coil using coil T1 and T2 sequences during annual inspections and all volume coils during acceptance.

e. Interpretation of Results. Volume and surface RF coil SNRs should match manufacturer's specifications and be consistent from one annual inspection to the

next. Volume coil PIU should be equal to or greater than 87.5% for 1.5 T systems and equal to or greater than 82%. Volume coil PSGs should be less than or equal to 2.5%.

12. Soft Copy Display Evaluation

a. Purpose. To determine if the system monitors are operating within manufacturer's specifications. Soft copy display device quality control is defined in accordance with DICOM Part 14.

b. Equipment. Precision luminance meter.

c. Procedure:

(1) Maximum and Minimum Luminance:

(a) Measurements are performed on the acquisition workstation monitors. Set the window width and window level to their minimum values so that the monitor is uniformly at its brightest

(b) Measure the luminance in the center and at each of the four corners of the image display area. Record these maximum luminance values.

(c) Measurements are also performed in the same manner on the monitor screen when the image display is at its darkest level. Set the window width to its minimum values and window level so that the monitor is uniformly at its darkest value. Record these values.

(d) Take the average maximum luminance and average minimum luminance.

(2) Luminance Uniformity:

(a) Calculate the percent difference of the brightest luminance values measured in the image display area using the following equation:

$$\% \text{ diff} = 200\% \times | (L_{max} - L_{min}) / (L_{max} + L_{min}) |$$

(3) Resolution. Linearity, Contrast & Distortion. View the SMPTE pattern on the monitor while positioned directly in front of the image display and at least 50 cm from the monitor surface. The SMPTE pattern should be evaluated as follows:

(a) The 0-5% contrast pattern should be visible.

(b) The 95-100% contrast pattern should be visible.

(c) Each gray-level step from 0% to 100% should be distinct from adjacent steps.

(d) The borders and lines of the SMPTE pattern should be straight.

(e) There should be no distortion or misalignment using the grids across the screen (linearity).

(f) The alphanumeric characters should be sharp and in focus.

(g) The high contrast line-pair images in the squares at the center and in the corners should be distinct without magnification.

(h) There should be no streaking in and around the white rectangles and the black rectangles.

(4) Spatial Accuracy. A SMPTE test pattern that displays a rectangular grid is typically displayed with a magnification factor that allows it to fill the entire screen. Display a similar grid pattern over the screen. Compare the displayed SMPTE pattern to the overlaid grid.

d. Interpretation of Results:

(1) Maximum and minimum luminance: The maximum brightness of the monitors should exceed 90 Cd/m^2.

(2) Luminance uniformity: The calculated % difference in the maximum luminance values should be $\leq$ 30%.

(3) The resolution, linearity, contrast, and distortion criteria described above should be met.

13. Magnetic Field Room Survey

a. Purpose. To map out the magnetic field inside the magnet room and in adjacent areas to ensure patient and staff safety. This should be done during acceptance testing of the MRI equipment, after structural modifications or, after any major upgrades/changes are made to the MRI equipment. Room survey is repeated as required.

b. Equipment. Gauss meter.

c. Procedure:

(1) Using a calibrated Gauss meter perform a survey inside the magnet room. Record these measurements using a room diagram.

(2) Take additional readings in areas directly adjacent to the magnet room and record these values as well.

e. Interpretation of Results. Any measurements of 5 Gauss or more outside the MRI scan room should be marked by signs to warn people (e.g. patients, staff and visitors) with pacemakers and other restrictive devices to avoid being in the area. In most modern MRI suites, the 5 Gauss line is contained within the scanner room.

14. Physical and Mechanical Inspection

a. Purpose. To assess the physical and mechanical integrity of the MRI unit and associated equipment.

b. Equipment. None.

c. Procedure:

(1) Visually inspect the MRI magnet for obvious defects, damage or other safety hazards. Visually inspect the cryogen venting system to ensure there are no obvious impediments to its proper function.

(2) Visually inspect the magnet equipment room for general and missile effect safety hazards. Inspect ancillary equipment and supplies in the magnet room and adjacent spaces for MR compatibility (items should be appropriately labeled as MRI safe or MRI conditional at the relevant magnetic field strength).

(3) Visually inspect the magnet equipment room for electrical, trip and falling object hazards.

d. Interpretation of Results. MRI equipment should be physically and mechanically stable, showing no obvious mechanical or electrical conditions that suggest patient or operator safety concerns. All ancillary equipment (e.g. surface coils, phantoms, power injectors, anesthesia machines, etc.) should be in good working order and compatible for the unit strength being used. Report violations to staff for corrective action (some items may require immediate removal from the magnet room to prevent missile hazards).

15. MRI Safety Program Assessment

a. Purpose. To evaluate facility's compliance with ACR MRI safety zone and procedure recommendations in accordance with the ACR Guidance Document on MR Safe Practices: 2013, Journal of MRI 37:501-530 (2013).

b. Equipment. Gauss meter.

c. Procedure:

(1) Walk about the MRI spaces to determine whether the layout meets the ACR's most recent safety zone scheme. Does the arrangement make sense and are its instructions and intent obvious to an untrained member of the general public? Are the various zones posted correctly? Are the facility's MRI Medical Director and MRI Safety Officer identified designated in writing?

(2) Review the facility's MRI policy and procedures manual to determine if it is operating in conformance with the ACR's safety guidelines with respect to: safety zones, patient screening, public access, contrast administration, patient consent, fire and code blue safety.

(3) Review MRI staff and non-staff MRI safety training records.

d. Interpretation of Results. The facility's design should conform to the ACR's four zone configuration to maximize patient safety. All personnel expected to enter the MRI spaces should have current magnet specific safety training on file. The MRI Policy and procedures manual should be current and contain necessary elements. Advise the facility on what steps it can take to meet the ACR's current safety criteria if elements are missing or inadequate.

16. MRI Technologist Quality Control (QC) Program Review

a. Purpose. To ensure MRI equipment conforms to ACR and/or manufacturer's performance standards.

b. Equipment. None.

c. Procedure: Review the facility's existing quality control program to ensure that the following elements are included:

(1) Setup/positioning accuracy

(2) Center frequency

(3) Transmit gain/attenuation

(4) Geometric accuracy

(5) Spatial resolution

(6) Low contrast detectability

(7) Artifact analysis

(8) Visual Checklist

(9) Film QC (if used for primary interpretation)

d. Interpretation of Results. Technologist should perform these tests on a weekly basis. A proper functioning program should contain these elements; ideally performed as prescribed by the ACR. ACR accredited facilities must follow ACR guidelines. Review QC results and advise MRI staff on how to establish baselines define pass/fail criteria (acceptance), evaluate results and respond to test failures.

Magnetic Resonance Imaging Unit Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	Model:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Magnetic Field Homogeneity				
ACR Phantom Acquisition				
Center Frequency				
Alignment Light Accuracy				
Slice Position Accuracy				
Slice Thickness Accuracy				
Geometric Accuracy				
High-Contrast Spatial Resolution				
Low-Contrast Detectability (LCD)				
Artifact Evaluation				
RF Coil checks (SNR, Ghosting, Uniformity)				
Soft Copy Display Evaluation				
Magnetic Field Room Survey				
Physical and Mechanical Inspection				
MRI Safety Program Assessment				
MRI Technologist QC Program Review				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 9. Nuclear Medicine Imaging

A. *Introduction*

The modern gamma camera is a highly sophisticated imaging system but its underlying principle of operation is still the same as the original Anger camera. The evolution of the gamma camera has led to improved performance by optimizing the various sub systems as new technology was implemented. Today the most of the imaging degrading problems associated with the original camera have been either engineered out or sophisticated methods have been devised to correct data prior to generating the image.

As the gamma camera evolved so did the methods of collecting and displaying images. Today the gamma camera can provide cross sectional images of patient anatomy as well as general planar images. The cross sectional imaging places far greater demands on the camera performance then does planar imaging and subsequently increase demands on quality control of the systems.

To ensure the best possible imaging, all gamma camera systems should be tested when first purchased to establish that the system meets its claimed performance and to collect data to be used to verify continued system performance over the life of the system. The tests provided in this document are based on several reports prepared by the AAPM. Although the documents are somewhat dated, the fact that the gamma camera's underlying principle of operation and its general design have not changed much over time, makes these reports still relevant. The performance gains have been achieved by improved engineering of components, implementation of computer chips, and a better understanding of the underlying problems and the procedures in the reports still test the end result of these improvements.

The testing required of a system will be dependent on how the system will be used -planar imaging, Single Photon Emission Computed Tomography (SPECT) imaging or both -and whether it is a single head system or a multi-head system. Multi-headed system used for both planar and SPECT imaging will require substantially more testing and more time than a single headed planar system.

B. *Minimum Required Personnel Qualifications*

Advanced Diagnostic Imaging Equipment (NMI).

C. *Testing Periodicity*

Upon acceptance, annually, and after major repairs, per BUMEDINST 6470.22B.

D. *References*

1. AAPM Report No. 6, *Scintillation Camera Acceptance Testing and Performance Evaluation*, 1980.

2. AAPM Report No.9, *Computer-Aided Scintillation Camera Acceptance Testing*, 1982.

3. AAPM Report No. 22, *Rotating Scintillation Camera SPECT Acceptance Testing and Quality Control*, 1987.

4. AAPM Report No.52, *Quantitation of SPECT Performance*, 1995.

5. National Electrical Manufacturers Association Standard NU 1, *Performance Measurement of Scintillation Cameras*, 1994.

E. *Planar Gamma Camera*

The planar gamma camera only generates planar emission images. These systems do not have the capability to collect data while rotating around the patient and therefore cannot produce cross sectional images. Only the following tests are required to be performed to evaluate the performance of these systems. If more than one imaging head all must be tested.

1. Installation Check

Prior to performing any of these tests evaluate the installation of the system by observing the following:

a. Check the integrity of the system looking for any loose fitting or inappropriately aligned components.

b. Look at all the cables and ensure they are properly supported and will not interfere with any of the systems motion or patient movement. Ensure the cables and cable connections are all secure.

c. Move the camera in all its directions to ensure that it moves smoothly. The system should start and stops smoothly and without any significant time delay. This is particularly important on stopping since a patient could be injured if the camera is being lowered on to the patient.

d. Verify the alignment of the system as appropriate. If the system has indicator noting when it is horizontal or perpendicular check these with a level. If the system indicates angles of the head check this using a level and protractor.

e. The gamma camera head should be appropriately shielded to prevent interference from extraneous radiation. This should be checked using the most common radioisotope used in the area of the gamma camera. The source (5 to 10 millicuries for 99mTc) should be slowly moved around the back and sides of the head at about one to two feet and the count rate noted. Excessive background will reduce the contrast of the images acquired with the camera. If the manufacturer quotes a shielding performance, ensure the system meets the standard. Repeat using a high

energy source (67Ga or 131 1) if such sources are used in the clinic. These should be approximately 200 µCi.

f. Check all collimators for any sign of physical damage.

g. Check the scan table for stability and ensure there are no sharp edges that could injure the patient or technologist. If the table is designed to be locked into place then check that the locking is secure and snug. Check the alignment of the table in the vertical and horizontal direction.

2. Temporal Resolution

The performance of the gamma camera is highly dependent on the timing characteristics (system dead time) of the system. The maximum count rate will define the activity that can be administered to a patient. Excessive count rate (excessive activity) will degrade the image quality and at the same time increase the unnecessary dose to the patient. The timing characteristics for the intrinsic (bare crystal-no collimator) and the extrinsic (collimated crystal) should be measured.

a. Intrinsic Temporal Resolution.

(1) Remove any collimator from the camera head.

(2) Select a 20% energy window width (or use the manufacturers recommended window width for measuring 99mTc.

(3) Ensure that the background radiation level is less than 500 counts per second.

(4) Make two 99mTc sources (#1 and #2) each with between 2 and 7 mCi activity. Place the sources in container with at least 6 mm lead shielding on sides and bottom. Place at least 6 mm of Cu on top of the container to absorb scatter from the container.

(5) Place the source at a distance that gives a count rate of approximately 30,000 cps or if the dead time is quoted by the manufacturer use the following equation to calculate the count rate:

$$Count\ Rate\ = \frac{0.1}{\tau} + 1.2$$

Ensure that the entire crystal is being irradiated by the source.

(6) Using a preset time of 100 sec and a fixed time between each measurement measure the sources in the following order.

(a) Measure source #1 and record counts.

(b) Place source #2 next to source #1 and record counts.

(c) Remove source #1 and measure source #2 alone and record counts.

(d) As a control the sources can be re-counted in the reverse order.

NOTE: If the count is displayed at the camera head and on the computer console record both.

(7) Calculate the dead time using the following equation:

$$\tau = \left[\frac{2 \times R_{12}}{(R_1 + R_2)^2}\right] in \left[\frac{R_1 + R_2}{R_{12}}\right]$$

If the counts recorded at the camera head and the computer console are different; calculate the dead time for each. A larger τ at the computer console indicates additional count losses at the computer interface. This is rare but if it does occur the difference should be small.

(8) Calculate the count rate at which the count loss is 20% due to the dead time (τ).

$$R_{20\%\, loss} = \frac{1}{\tau} \times in\ \frac{10}{8} = \frac{0.23311}{\tau}$$

Compare this value with the manufacturer's specification. Note that this method of measure dead time eliminates scatter and the NEMA method does not. Therefore the NEMA method gives a larger τ (~1.3x).

b. Maximum Intrinsic Count Rate. This measurement is dependent on the dead time of the system and is the maximum count rate the system will record. At this level the count rate will not increase with increasing activity and may in fact decline.

(1) With the collimator removed and using the energy window as the dead time test, place approximately 4 mCi of 99mTc in container shielded on the bottom and sides by 6mm of lead and with 6mm Cu on top at a distance of 1.5 meters. Move the source and or camera head until a maximum count rate is observed. See Figure 9-1.

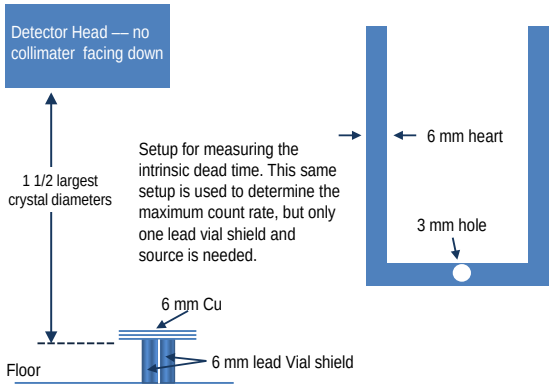


Figure 9-1.

(2) Record the maximum count rate and compare to any published manufacturers specification.

c. Extrinsic Temporal Resolution. The above measured is for the non-clinical situation where no collimator is installed on the camera head. This test measures the dead time in a more clinical situation and requires the use of a scatter phantom. If such a phantom is not available then skip this test.

(1) Select the most common collimator used clinically (usually a general purpose or high sensitivity collimator).

(2) Adjust the energy window to 20% or to the value indicated by the manufacturer in their collimator performance specifications.

(3) Prepare two sources (#1 and #2) that give a count rate of approximately 20,000 cps or if the extrinsic dead time is known a count rate determined by:

$$Count\ Rate = 1.2 \times \frac{100{,}000}{\tau_{extrinsic}}$$

where the source is in the scatter phantom. The expected range of activity is 1 to 7 mCi and the source volume should be around 5 mL.

(4) Orient the gamma camera head so it point horizontally and place the scatter phantom against the collimator face with the sources closest to the collimator and centered.

(5) Using a count time of 100 sec record the counts from the sources as follows:

(a) Count source #1 alone.

(b) Count source #1 and source #2.

(c) Count source # 2 alone.

(6) Calculate the intrinsic dead time.

$$\tau_{extrinsic} = \left[\frac{2 \times R_{12}}{(R_1 + R_2)^2}\right] in \left[\frac{R_1 + R_2}{R_{12}}\right]$$

(7) Calculate the observed counting rate that will generate a 25% count loss.

$$R_{extrinsic-25\%\ loss} = \frac{1}{\tau_{ext}}\left(In\ \frac{4}{3}\right) = \frac{0.216}{\tau_{ext}}$$

During imaging, the recommended upper limit for count loss due to dead time is 25%. Use of activities in patients in excess of that which gives this count rate merely increases the dose to the patient with no gain in image quality of imaging time. See Figure 9-2.

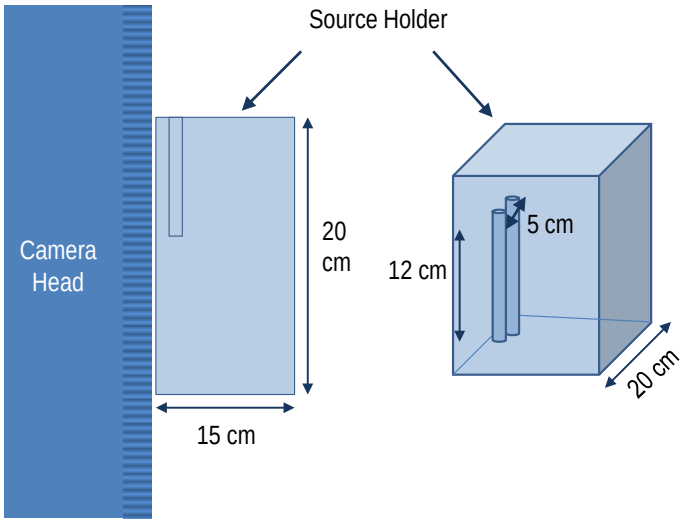


Figure 9-2.

3. Uniformity Testing

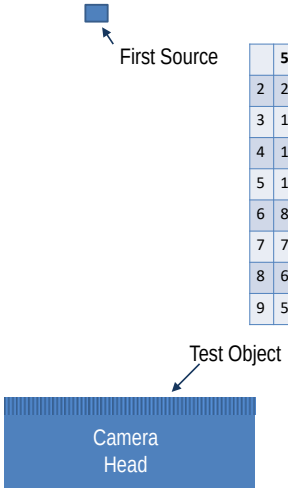
Uniformity is one of the most important performance parameters of the modern gamma camera and can be influenced by many factors such as energy window, count rate, correction circuitry, etc.

a. Intrinsic Uniformity (no collimator).

(1) Install the 3 mm lead mask if available on the gamma camera head to limit the FOV to the Useful Field Of View (UFOV) as defined by the manufacturer. Disable the uniformity correction circuitry if possible.

(2) Obtain a 99mTc point source (l cc or less) with an activity that will give a count rate (~30,000 cps) that generates more than a 10% count loss for the energy window used clinically (15% or 20%) at a distance of five times the UFOV diameter. Use the intrinsic dead time value previously calculated to verify that the count loss does not exceed 10% (see chart below). Record the activity and time it was measured.

(3) Place the source centered over the crystal at a distance of 5 UFOV diameters. Be extremely careful not to drop the source on the detector as this could damage the crystal (a thin sheet of Styrofoam placed on the crystal face is good protection). Record the count rate indicated on the console and/or camera gantry. See Figure 9-3 on the following page:



	5%	10%	15%	20%	25%	30%
2	25647	52680	81259	111572	143841	178337
3	17098	35120	54173	74381	95894	118892
4	12823	26340	40630	55786	71921	89169
5	10259	21072	32504	44629	57536	71335
6	8549	17560	27086	37191	47947	59446
7	7328	15052	23217	31878	41097	50954
8	6412	13170	20315	27893	35960	44584
9	5699	11707	18058	24794	31965	39631

Figure 9-3.

(4) Acquire an image with in a 64x64 (or smallest matrix size available) matrix and a bit depth of 16 bits.

(5) Collect a minimum of 10,000 counts in the center pixel to generate a 1% standard deviation. Record the time.

(6) Using a window of 200 counts observe the image for any lines of pixels in the horizontal or vertical direction. If seen they should be corrected before further analysis of the image uniformity is done.

(7) Compare the recorded count rate from (3) above to the calculated count rate based on the total counts recorded divided by the time in (5). These should agree to within 1%.

(8) Average the counts in the center 100 pixels and draw a ROI to include all pixels with counts greater than Y:z of this average.

(9) If able smooth the image using a 9 point filter function:

121

242

121

or if not available then use the standard smoothing function provided by the manufacturer.

(10) Calculate the "integral uniformity" (maximum deviation of the counts in the pixels as a percent) using:

$$Int\ Uniformity\ =\ \pm 100 \times \left[\frac{Max - Min}{Max\ + Min}\right]$$

where Max and Min are the minimum and maximum counts in pixel.

(11) Calculate the "differential uniformity" (max rate of change over a specified number of pixels) using:

$$Diff\ Uniformity\ =\ \pm 100 \times \left[\frac{Hi - Low}{Hi\ + Low}\right]$$

where Hi and Low are the highest and lowest counts in a five pixel series.

(12) Calculate the integral and differential uniformity for the Central Field Of View (CFOV) using the same formulae but with the periphery of the previously defined ROI moved in 4 pixels per size.

NOTE: Many modern gamma camera systems have QC functions that calculate these uniformity parameters automatically and can be used for testing if desired.

(13) Repeat the above measurement using a count rate of 75,000 cps and evaluate the effect of the high count rate on the uniformity of the image.

(14) Repeat the uniformity measurements after adjusting the energy window up and down by an amount that reduces the observed count rate by 10°/t). This should not make the flood images unacceptable.

(15) Repeat the uniformity measurements using a low energy radioisotope (70-80 keV) and a high energy radioisotope (300-400 keV) if these are used in the clinic.

(16) If the uniformity correction circuitry was disable, re-enable it and repeat the intrinsic uniformity correction measurements.

b. Extrinsic Uniformity.

(1) For all commonly used collimators, repeat the uniformity measurements using each collimator and a flood source that does not give a count rate in excess of 30,000 cps.

4. Systems Sensitivity and Relative Collimator Efficiency

The sensitivity of a system defines how efficiently it uses the radiation emitted from the patient. Since nuclear medicine imaging is geometrically inefficient due to general geometry of the imaging process, it is desirable to maximize the use of any photons that intersect the face of the gamma camera imaging head.

a. System Sensitivity.

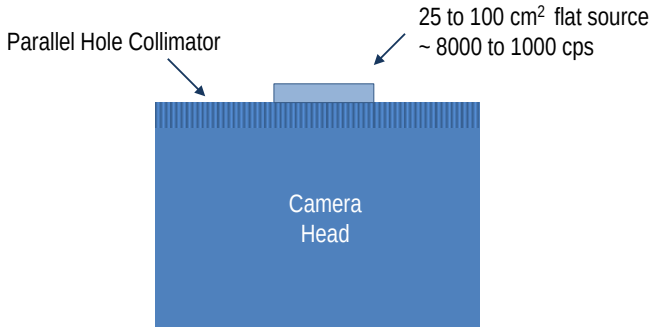
(1) Install a general purpose parallel hole collimator on the camera. Record the identity of the collimator.

(2) Prepare a flat disc source of 99mTc with a surface area of around 25 to 100 cm. Use an activity that will generate a count rate of 8,000 to 10,000 cps with a 20% energy window. Record the activity in the source and the time it was assayed.

(3) Place the source at the center of the collimator and collect 100,000 counts. Record the time and the indicated count rate. Verify the calculated count rate and the indicated count rate are the same.

(4) Remove the source and record the indicated background count rate.

(5) Determine the system sensitivity in cps per microcurie (SI units of cps per becequrel). See Figure 9-4.



$$System\ Sensitivity\ = \frac{R_{source}(cps) - R_{background}\ (cps)}{Act\ (\mu Ci)}$$

Figure 9-4.

b. Relative Collimator Sensitivity.

(1) For each clinically used collimator, determine the decay corrected count rate (cps) using the technique above.

(2) Record the background count rate for each collimator.

(3) Calculate the relative sensitivity of the collimators using the general purpose collimator (or the one specified by the manufacturer) as the reference. Relative sensitivity is the ratio given by:

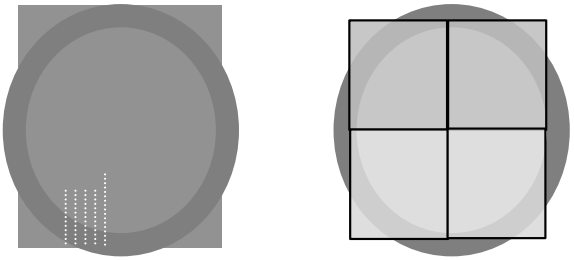
$$Sens_{rel} = \frac{R_{col}}{R_{reference\ col}}$$

Compare to the manufacturer's specification.

5. Spatial Linearity

Modern gamma cameras have elaborate correction circuitry to correct the incorrect positioning of point of photon interaction which led to non-linearity. Although elaborate methods are available to determine linearity, a simple visual check is considered adequate with today's systems.

a. Remove the collimator from the gamma camera and place a linearity bar phantom (or an orthogonal hole phantom) on the crystal face. Be very careful not to drop or bump the exposed crystal as this can lead to damage to the crystal. See Figure 9-5.



Orthogonal Hole Phantom Quadrant Bar Phantom

Figure 9-5.

b. Prepare a point source of about 100 to 200 /-lei and place it six or so away from the camera head. If the count rate exceeds 30,000 cps move the source further away to reduce the count rate.

c. Start the camera and collect approximately 1 million counts.

d. Review the image with attention to the linearity of the bars or of the holes. There should be little if any wavy or curved distortion of the lines in the center or the periphery of the image. If the computer console has a line tool, draw a straight from one end of the bar to the other or from the centroids of the first and last hole of the

orthogonal hole phantom. The deviation of bar image or the centroids of the hole images from this straight line should be minimal.

e. If the system has an automated linearity calculation tool then this tool can be used to evaluate the system but a visual check should also be done. If the image shows significant deviations on observation and the program does not then further analysis should be done to determine the reason for the discrepancy.

6. Point Source Sensitivity

This test is performed to determine the uniformity of the sensitivity of the crystal at various locations. Ideally, the crystal should have the same sensitivity at all points.

a. Disable the uniformity correction circuitry of the system if allowed.

b. A lead container at least 6 mm in thickness with a 3 mm hole in the bottom will be required. This can be made from a lead vial holder that is no longer needed or can be purchased from a nuclear medicine supply source. See Figure 9-6.

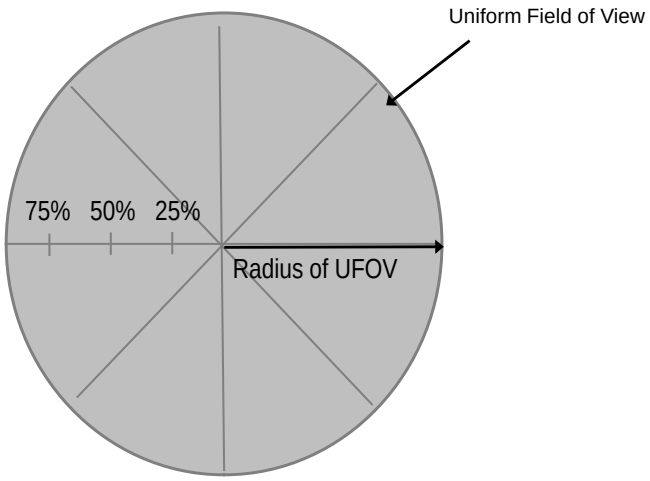


Figure 9-6.

c. Remove the collimator from the gamma camera head and rotate the head so the face of the detector is facing up. Be very careful not drop or bump the unprotected detector as severe damage can occur.

d. Place a 20% energy window (or whatever the manufacturer recommends for ^{99m}Tc) centered on the ^{99m}Tc peak energy of 140 keV.

e. Place a vial containing ^{99m}Tc in the vial shield. Adjust the source activity to give no more than 10,000 cps when place on the face of the uncollimated gamma camera head.

f. Adjust the system to collect a 128 x 128 by 16 bit image and place the vial at the center of the detector. Collect an image for about 5 sec. Note the time since all subsequent images will have to be collected for the same period of time for the results to be valid. Observe the image to ensure there is no pixel overflow. If so then reduce the time for image collection until no overflow is seen. Record the counts in the image.

g. Using the time determined above repeat the measurement with the vial located at 25%, 50% and 75% of the radius in both the plus and minus direction of the X axis. Repeat the measurement in the Y axis and then along the 45° angle between the X and Y axes for a total of 25 measurements. At each measurement record the time and counts collected.

h. Determine the average and standard deviation of the measurements and the maximum deviation from the mean. The coefficient of variation (avg/sd) should not exceed 2%.

i. Review the data and note any local deviations (between two points) of more than 1%.

7. Spatial Resolution

To accurately measure intrinsic resolution requires a slit mask made of 3 mm lead with a 1 mm wide slit extending for a distance equal to the UFOV of the camera being tested. If such a slit mask is not available, a more straight forward but less accurate method is to use a line bar phantom that has a set of bars just below and just above the intrinsic resolution. Extrinsic resolution can be measured by imaging a simple line source or a bar phantom.

a. Intrinsic Resolution (slit mask method):

(1) Remove the collimator for the camera head and orient the crystal facing up. Select a 20% energy window center on the 140 keV peak of ^{99m}Tc and use the maximum matrix size available (at least 512 by 512 by 16 bits.

(2) Place the slit mask along the X axis flush against the detector and suspend a point source approximately five crystal diameters away from the mask.

(3) Collect an image with at least 10,000 counts in the central pixel of the image of the slit.

(4) Determine the FWHM from the image of the slit by direct measurement using linear interpolation. This is most accurate if the pixel is approximately 1/10th the FWHM. If this is the case then also estimate FWTM. See Figure 9-7 below.

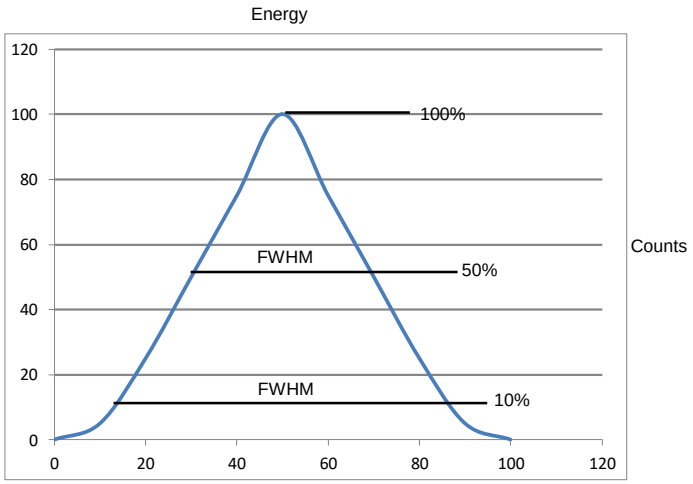


Figure 9-7.

(5) Repeat this measurement along the X and Y axes at points 25%, 50%, and 75% of the distance from the edge of the UFOV to the center point for a total of 13 measurements.

(6) Optionally repeat this measurement using radioisotopes of interest (I, Tl, etc.).

b. Intrinsic Resolution (bar pattern method):

NOTE: For this test to be useful at least one of the bar patterns must be smaller than the intrinsic resolution of the system (~3-4 mm).

(1) Remove the collimator for the camera head and orient the crystal facing up. Select a 20% energy window center on the 140 keV peak of ^{99m}Tc and use the maximum matrix size available (at least 512 by 512 by 16 bits).

(2) Mask the outer edge of the crystal physically or electronically to limit the image to the UFOV of the system.

(3) Place a ^{99m}Tc point source at a distance of 5 UFOV distances from the crystal face.

(4) Place the bar phantom flush against the crystal face aligned carefully in the X and Y directions.

(5) Acquire an image of 3 million counts.

(6) Repeat the above rotating the bar phantom 90° each time until each quadrant has been tested with the highest frequency (smallest bar size).

(7) Observe the images to assess the uniformity of resolution across all quadrants.

c. Extrinsic Resolution:

(1) Install a general purpose or the most frequently used collimator to the camera head and orient the crystal facing up. Select a 20% energy window center on the 140 keV peak of ^{99m}Tc and use the maximum matrix size available (at least 512 by 512 by 16 bits).

(2) Fill two capillary tubes (inner diameter less than 1mm and at least 5 cm long) with high concentration ^{99m}Tc to give no more than 10,000 cps.

(3) Place the capillary tube along the X axis at a distance of 5 cm from the face of the collimator.

(4) Acquire an image with at least 10,000 counts in the central pixel of the Line Spread Function (LSF) image.

(5) Place the second capillary tube 5 cm away from the first and parallel to it and collect a second image. Calculate the pixel size by dividing 5 cm by the number of pixels between the peaks of the two LSF images.

(6) Repeat with the tubes aligned along the Y axis.

(7) Calculate the FWHM and FWTM for both the X and Y directions.

(8) Optionally, repeat using other collimators and higher count rates.

8. Energy Registration

For maximum image quality when imaging radioisotopes that emit several photons of different energy, the positioning of the point at which the radiation interacts with the crystal cannot be dependent on the energy of the photon.

a. The collimator will be removed from the camera and the camera oriented facing up.

b. The source to be used is ^{67}Ga (93 keV, 184 keV and 296 keV energy peaks). The source will be placed in a vial shield (at least 6 mm lead) with a 3 mm hole in the bottom. The activity will be adjusted to give no more than 10,000 cps for all energy windows being tested.

c. The vial containing the source will be placed on the-X axis at 75% of the UFOV radius.

d. Use a zoom that will ensure that at least 10 pixels are included in the FWHM of the image. An image for each of the energy windows will be acquired (minimum of 1000 counts in the central pixel).

e. Move the source a known distance along the X axis and repeat the measurement.

f. Determine the pixel size by measuring the number of pixels between the two peaks and dividing this in to the known distance.

g. For each of the images (one at each image) determine the location of the center of the peak.

h. Calculate the difference between the position of the 93keV peak and each of the other peaks:

$$diff_{x\ direction} = \left[Centrepixel_{93keV\ xazis} = Centerpixel_{otherenergy\ xaxis}\right] \times pixelsize_{x\ axis}$$

$$diff_{y\ direction} = \left[Centrepixel_{93keV\ xazis} = Centerpixel_{otherenergy\ xaxis}\right] \times pixelsize_{y\ axis}$$

$$diff = \sqrt{diff_x^2 + diff_y^2}$$

i. Repeat in the Y axis direction.

j. Record both the X and Y deviation ($diff_x$ and $diff_y$) and the mixed deviation (diff).

F. *SPECT Gamma Camera*

The test procedure in this section is based on key system performance parameters which most strongly influence image quality. These tests are designed to measure the clinical acceptability of the system and not necessarily to verify the stated performance by the vendor.

1. Rotational Uniformity and Sensitivity

This will test the system's sensitivity to stray magnetic fields and to the thermal changes in the detector heads.

a. Prepare a flood source with 99mTc ensuring the activity is uniformly disbursed throughout the phantom. Alternatively and preferably use a solid 57Co flood source with a uniformity of at least +/-5% or better.

b. Secure the flood source to the face of the collimator (a low energy general purpose collimator) so that it does not move during motion of the imaging head.

c. Center a 20% energy window on the photopeak energy of the radioisotope being used and collect a 5 million count flood in a 64x64 matrix with the detector at 0 degree position. Record the time necessary to acquire the 5 million counts.

d. Repeat the flood image at 90, 180, 270 and 360 degrees, using the time recorded for the first flood image.

e. Calculate the maximum sensitivity variation:

$$Max\ Sens\ Var(\%) = \frac{Counts_{max} - Counts_{min}}{Counts_{max} + Counts_{min}} \times 100$$

In the absence of vendor performance criteria, the sensitivity variation should not exceed 1%.

f. Using the system's computer, subtract the 90 degree flood image from the 270 degree image. Review each of the subtracted images for indications of structure noise and other non-random noise. Save the images for reference.

2. Spatial Resolution

This test will use a line source which is at least 30 cm in length and no more than 2 mm inside diameter. These can be made from catheters.

a. Fill the line source with ^{99m}Tc with a concentration of 1 mCi/cm^3. If the line source is not rigid, then attach it to a rigid support which will not generate scatter (tape the catheter to a piece of cardboard or Styrofoam).

b. Suspend the line source over the end of the imaging table so that it is over the detector without any interfering objects.

c. Adjust the table so that the line source is at the center of rotation and then set the radius of rotation to 20 cm or the smallest that is achievable. Make sure the line source and the collimator face are parallel to the axis of rotation and level.

d. Peak the system on the photopeak energy using a 20% window, select a 128 x 128 matrix and 128 views over 360 degrees.

e. A pixel size in the range of 3-3.5 mm is desirable (a 16 inch crystal with a 128 matrix will give a pixel size of 3.2 mm). If necessary, select a magnification mode that will deliver this pixel size or smaller.

f. Acquire the tomographic study using a time that will deliver at least 100k counts in the first projection image.

g. Reconstruct the data using a ramp filter into 10 mm transverse sections, starting at the top of the line. Uniformity and attenuation correction do not need to be applied. Consult the vendor to determine the appropriate filter to use if in doubt.

h. Using the first section, draw a one pixel wide profile in the X direction through the hottest pixel in the reconstructed image of the line source. From the profile, calculate the FWHM by linear interpolation.

i. Repeat the above for the Y direction and then for a slice at the bottom of the stack and in the middle.

j. Acquire a planar image of the line source containing 500k counts with the collimator 20 cm from the line source.

k. At approximately the same positions as the three tomographic resolution results were determined, use a ~10 mm (3 pixel) wide count profile through the planar image of the line source to calculate FWHM.

l. Record the ratio of the SPECT/Planar FWHM to the three locations. These should not exceed 1.1. If so, then the Center of Rotation (COR) may be incorrect. Collect a new COR and repeat the test. Large errors can be due to the X or Y axis' being out of alignment with reference to the line source.

k. In the absence of vendor performance criteria, the ratio should not exceed 10% and must not exceed 15%.

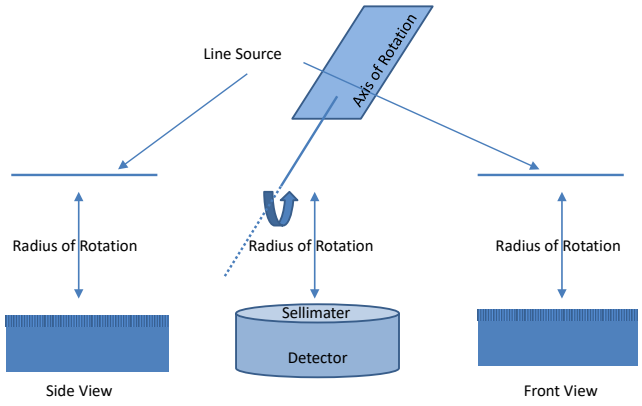


Figure 9-8.

3. System Performance

To evaluate the system performance a Jaszczak SPECT phantom is used. Other phantoms that include sections with just water and sections with other test objects to measure contrast can also be used by modifying this Procedure:

a. Tomographic Data Collection.

(1) Install a low energy general purpose collimator or the one used most often clinically.

(2) Fill the SPECT phantom with 8 to 10 mCi if a high resolution collimator is being used and mix the solution to ensure uniform distribution of the activity.

(3) Position the phantom on the end of the imaging table with the long axis parallel to and aligned with the axis of rotation. Fasten the phantom in place using tape or Velcro strips.

(4) Peak the system on the photopeak energy using a symmetrical 20% window, set the radius of rotation to 20 cm or the smallest radius attainable and select a 64x64 matrix with 64 projection views over 360 degrees.

(5) Use a magnification factor that will give a pixel size in the range of 6 to 7 mm if needed.

(6) Acquire the tomographic study using a time sufficient to give at least 500k counts in the first projection image.

(7) Reconstruct the data without system flood correction applied if possible, using a Hann filter and a one Nyquist cutoff. If the filter is not readily available ask the vendor to provide the name of the filter that most closely matches it.

(8) Repeat the above, but apply linear attenuation correction using 0.11/cm attenuation coefficient or the system default value.

(9) Repeat 1 thru 8 with flood correction turned on.

b. Attenuation Correction Analysis.

(1) Using the uniformity corrected tomographic data set, select a transverse slice through the uniform part of the phantom image and draw 5 pixel wide horizontal count profile through the center of the section. Look at the plot for flatness.

(2) Repeat for the vertical direction.

(3) Any over or under correction for attenuation can be due to miscalibration of the pixel size, inappropriate attenuation coefficient selected, incorrect selection of the boundary for attenuation correction or there is a software error.

c. Uniformity and Root Mean Square Noise Analysis.

(1) Display the entire set of tomographic images generated from the data not corrected for uniformity. Look for artifacts such as profound ring artifacts.

(2) Select one uniform slice close to the center of the uniform slices and draw a 15 x 15 pixel ROI at the center and record this information from the region:

(a) Mean Counts per pixel.

(b) Maximum count.

(c) Minimum count.

(d) Standard Deviation.

(3) Manually determine the maximum and minimum counts in pixel if this information is not provided automatically.

$$Int\ Uniformity = \frac{\max count - \min count}{\max count + \min count} \times 100$$

$$rms\ noise(\%) = \frac{Standard\ Deviation}{mean\ counts} \times 100$$

(4) Calculate the integral uniformity and the root mean square (rms) noise.

(5) Repeat the above using the data set corrected for uniformity.

(6) In the absence of vendor provided performance criteria, the following values are considered acceptable:

(a) Without uniformity correction:

Integral uniformity:	9.9–18.3%
rms noise:	4.5–5.7%

(b) With uniformity correction:

Integral uniformity:	10.7–18.8%
rms noise:	3.6–7.2%

d. Contrast Analysis.

(1) Using the tomographic slice image set generated from the data set not corrected for uniformity, select the image that most clearly displays the cold spheres and record the number of spheres visible.

(2) For each of the spheres, record the counts from the “coldest” pixel and determine the contrast.

(3) Repeat (2) using the tomographic image set generated from the data corrected for uniformity.

(4) If there are not vendor provided performance criteria then use the following values as a guide. The data in Table 9-1 is from a Jaszczak phantom.

Table 9-1. Data from Jaszczak Phantom.

Sphere Size (mm)	Min. Contrast	Max. Contrast
31.8	0.53	0.73
25.4	0.35	0.56
19.1	0.21	0.38
15.4	0.11	0.27

Nuclear Medicine Camera Unit Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	Model Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Uniformity				
System Resolution				
Multi-Energy Registration				
Pixel Size				
Count Rate				
System Sensitivity				
System Linearity				
Center of Rotation (SPECT only)				
Slice Uniformity (SPECT only)				
Slice Thickness (SPECT only)				
In Place Resolution (SPECT only)				
Image Contract (SPECT only)				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 10. Linear Accelerators (LINACs) and Diagnostic Imaging Equipment Used in Radiotherapy

A. *Minimum Required Personnel Qualifications*

Each Navy radiation oncology department should establish local qualification standards for personnel performing performance and safety evaluations of Linear Accelerators (LINACs) and diagnostic imaging equipment used in radiotherapy. These personnel should be either Medical Physicists with board-certification in radiation therapy physics (such as certification by the ABR or ABMP as a Therapeutic Radiologic Physicist), a board-eligible Medical Physicist as determined by the certification board, or an individual under the direct supervision of one of the above.

B. *Policies and Procedures*

1. It is highly recommended that performance and safety evaluation procedures provided by the equipment manufacturer and/or by nationally-recognized protocols are followed when applicable, such as Task Group (TG) reports published by the AAPM, as well as reports published by the National Council on Radiation Protection and Measurements (NCRP), International Council on Radiation Protection (ICRP), and other nationally-recognized organizations.

2. Local policies and procedures should specify facility-specific requirements and periodicities, or at a minimum, indicate the use of specific nationally-recognized protocols.

3. A Medical Physicist specialized in Radiation Therapy should determine which acceptance tests and periodic quality assurance tests should be performed for therapeutic x-ray units (e.g., superficial x-ray and orthovoltage units) and radiotherapy LINACs.

4. A Medical Physicist specialized in Radiation Therapy should determine which acceptance tests and periodic quality assurance tests should be performed on diagnostic imaging equipment associated with radiation therapy. These tests should be determined in consultation with a Diagnostic Medical Physicist. Diagnostic imaging equipment includes but is not limited to the following:

    a. Rad/Fluoro radiotherapy simulators;

    b. CT, Photon Emission Tomography (PET), CT/PET, and MRI units utilized as radiotherapy simulators;

    c. X-ray film portal imaging;

d. Electronic portal imaging (EPI);

e. Cone beam CT (i.e., Kilovoltage Computed Tomography [KVCT] and Megavoltage Computed Tomography [MVCT]); and,

f. Other Onboard Imaging (OBI) devices.

5. Policies and procedures in other chapters in this manual should be followed as applicable regarding acceptance and periodic testing of diagnostic imaging equipment used within the practice of Radiation Therapy. A Medical Physicist specialized in Radiation Therapy should determine which of the policies and procedures are applicable.

C. *Testing Periodicity*

LINACs and Tomotherapy: Annually, monthly, daily Quality Assurance (QA) test per AAPM TG-40, TG-51, and TG-142, upon acceptance and after major repairs per TG-45.

Additional QA tests (if applicable) for LINACs and Tomotherapy: Intensity-Modulated Radiation Therapy (IMRT) QA prior to patient treatment and Stereotactic Radiosurgery/ Stereotactic Beam Radiation Therapy QA according to TG-142.

CT-simulator: Annually, monthly, and daily QA tests per TG-40 and TG-66, upon acceptance and after major repairs per TG-66.

D. *Equipment*

LINACs: Phantom (solid for monthly or distilled water for annual/monthly QA tests), MapCheck (if applicable), ionization chamber, electrometer, QA mechanical device (if applicable), other equipment as specified by the physicist per TG-142.

CT simulator: Laser alignment tool, head/body water phantom, radiographic/radiochromic film (when available), laser QA device, other equipment as specified by the physicist per TG-66.

Tomotherapy: Phantoms (solid/liquid water) for weekly or monthly quality assurance (QA), radiochromic film (if available) or MapCheck for dose Delivery Quality Assurance (DQA) – i.e. IMRT QA prior to treatment, specified by the physicist per TG-148.

E. *References*

1. AAPM TG-21, *A Protocol for Absorbed Dose From High-Energy Beams,* Med. Phys. 10(6), 1983.

2. AAPM TG-40, *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40*, Med. Phys. 21(4), 1994.

3. AAPM TG-45, *AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group No. 45*, Med. Phys. 21(7), 1994.

4. AAPM TG-51, *Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams: Report of AAPM Radiation Therapy Committee Task Group 51*, Med. Phys. 26(9), 1999.

5. AAPM TG-66, *Quality Assurance for Computed-Tomography Simulators and the Computed-Tomography-Simulation Process: Report of the AAPM Radiation Therapy Committee Task Group No. 66*, Med. Phys. 30(10), 2003.

6. AAPM TG-142, *Quality Assurance of Medical Accelerators*, Med. Phys. 36(9), 2009.

7. AAPM TG-148, *QA for helical Tomotherapy: Report of the AAPM Task Group 148*, Med. Phys. 37(9), 2010.

8. NCRP Report No. 151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities*, National Commission on Radiation Protection and Measurements, 2006.

Chapter 11. High Dose Rate (HDR) Brachytherapy

A. *Minimum Required Personnel Qualifications*

Each Navy radiation oncology department should establish local qualification standards for personnel performing performance and safety evaluations of High Dose Rate (HDR) brachytherapy used in radiotherapy. These personnel should be either Medical Physicists with board-certification in radiation therapy physics (such as certification by the ABR or ABMP as a Therapeutic Radiologic Physicist), a board-eligible Medical Physicist as determined by the certification board, or an individual under the direct supervision of one of the above.

B. *Policies and Procedures*

1. It is highly recommendation that performance and safety evaluation procedures provided by the equipment manufacturer and/or by nationally-recognized protocols (e.g. Nuclear Regulatory Commission) are followed when applicable, such as TG) reports published by the AAPM) as well as reports published by the NCRP, ICRP, and other nationally-recognized organizations.

2. Local policies (e.g. the applicable Navy Radioactive Materials Permit) and procedures should specify facility-specific requirements and periodicities, or at a minimum, indicate the use of specific nationally-recognized protocols.

3. A Medical Physicist specialized in Radiation Therapy should determine which acceptance and periodic quality assurance tests should be performed for the specific HDR unit.

4. Policies and procedures in other chapters in this technical manual should be followed as applicable regarding acceptance and periodic testing of HDR equipment utilized within the practice of Radiation Therapy. A Medical Physicist specialized in Radiation Therapy should determine which of the tests are applicable, and which additional tests should be performed.

C. *Testing Periodicity*

Remote afterloader: Upon acceptance and after major repairs, annual QA, quarterly QA, and daily QA per AAPM TG-59.

D. *Equipment*

Radiochromic (Gafchromic) film, applicators, source guide tubes, and radioactive source.

E. *References*

1. AAPM TG-41, *Remote Afterloading Technology: A Report of AAPM Task Group No. 41*, 1993.

2. AAPM TG-59, *High Dose-Rate Brachytherapy Treatment Delivery: Report of AAPM Radiation Therapy Committee Task Group No. 59,* Med. Phys. 25(4), 1998.

3. NCRP Report No. 151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities*, National Commission on Radiation Protection and Measurements, 2006.

Chapter 12. Radiation Shielding Design and Evaluation for Medical and Dental X-Ray Facilities

A. *Introduction*

Shielding design for medical facilities must protect workers and members of the public from excessive exposure to ionizing radiation from radiographic and nuclear imaging, and radiation therapy. In Title 10, Code of Federal Regulations Part 20, the United States Nuclear Regulatory Commission requires that the effective dose does not exceed 1mSv (100 mrem) per year for a member of the general public and 50 mSv (5 rem) per year for radiation workers from radioactive materials.

The National Council on Radiation Protection and Measurements has established similar recommendations for ionizing radiation exposure from other sources of ionizing radiation including x-rays. The concept of ALARA mandates that the exposure be kept below these limits. Thus when designing shielding, the target limit should be lower to ensure that the regulatory limits are not likely to be exceeded.

The current recommended design criteria is 0.02 mSv (2 mrem) per week for members of the general public and 0.1 mSv (10 mrem) per week for radiation workers. It is the responsibility of the shielding designer to keep abreast of changes in these limits. Magnetic Resonance Imaging facilities will also require shielding designs that reduce magnetic and radiofrequency interference. The design of these shields are typically beyond the capabilities of site personnel and will generally be included as part of the purchase contract for such units.

B. *Minimum Required Personnel Qualifications*

Board certification from ABR in the appropriate subspecialty or American Board of Health Physics (ABHP) is the normal pathway for obtaining the Advanced Radiological Systems Shielding Design qualification. This is in line with the NCRP 147 and NCRP 151 recommendation that only “Qualified Experts” should perform shielding designs.

On a case by case basis, NMCPHC may evaluate individual shielding design experience as an exemption to board certification. The Shielding Design Qualification experience should include a minimum of 2 designs each of the following applicable type(s):

Basic Shielding Design Qualification: Dental, Fluoroscopy, and Radiographic units.

Advanced Shielding Design Qualification: Linear Accelerators, High Dose Radiation therapy units, Nuclear Medicine, Positron Emission Tomography, Magnetic Resonance Imaging, and Computed Tomography.

Designs used to demonstrate competency may be example shielding problems approved and reviewed by any individual who has been granted the appropriate qualification level in shielding

design qualification from the MPAB. Shielding designs for construction projects must be reviewed and countersigned during training by a qualified expert based on the categories listed above.

Navy Shielding Design Qualified individuals will verify and review proposed shielding plans provided by manufacturers (which are normally contracted) for acquisition projects. Navy physicists are discouraged from approving or designing initial shielding designs if at all possible as it puts the government fiscally at risk for design mistakes.

C. ***Design and Evaluation Periodicity***

Shielding design is required for all new radiographic, nuclear medicine, therapy installations, and after major renovations to existing facilities. Replacement or modification of CT, PET or NM systems requires a refresh of the shielding design and confirmation or verification of the shielding design prior to clinical use of the room per Joint Commission requirements. As recommended in NCRP Report No. 147, sites designed using the previous NCRP Report No. 49 standard do not need to be upgraded as long as the room has not changed in functionality.

D. ***Equipment***

Large volume ion chamber (≥ 180 cm^3 nominal volume) to check radiation levels.

E. ***References***

1. Code of Federal Regulations, Title 10, Part 20, 2007.

2. NCRP Report No. 147, *Structural Shielding Design for Medical X-Ray Imaging Facilities*, Bethesda, MD, 2004.

3. AAPM, *Task Group Report 108: Shielding for PET/CT Facilities*, 2006.

4. NCRP Report No. 151, *Structural Shielding Design for Megavoltage Radiotherapy Facilities*, Bethesda, MD, 2005.

5. NCRP Report No. 145, *Radiation Protection in Dentistry*, Bethesda, MD, 2003.

6. AAPM, *Task Group Report 100: Acceptance Testing and Quality Assurance Procedures for Magnetic Resonance Imaging Facilities*, 2010.

7. American College of Radiology, *ACR Guidance Document for Safe MR Practices*, June 2007.

8. NCRP Report No. 116, *Limitations of Exposure To Ionizing Radiations*, Bethesda, MD, 1993.

9. Dixon, RL and Simpkin, DJ, *Application of New Concepts for Radiation Shielding of Medical Diagnostic X-Ray Facilities*, RSNA, 1998.

10. Simpkin, DJ, *Evaluation of NCRP Report 49 Assumptions and Use Factors in Diagnostic Radiology Facilities*, Med Physics 23:577-584, 1996.

11. Simpkin, DJ, *Transmission Data for Shielding Diagnostic X-Ray Facilities*, Health Phys. 68:704-709, 1995.

12. Suleiman, OH, Conway, BJ, Fewell, TR, Slayton, RJ, Rueter, FG, and Gray, J, *Radiation Protection Requirements for Medical X-Ray Film*, Med. Physics 22:1691-1693, 1995.

13. Dixon, RL: *On the Primary Barrier in Diagnostic X-ray Shielding*, Med Physics 21:1785-1794, 1994.

14. Archer, BR, Fewell, TR, Conway, BJ, and Quinn, PW, *Attenuation Properties of Diagnostic X-ray Shielding Materials*, Med Physics 21:1499-1507, 1994.

15. Simpkin, DJ, *Shielding Requirements for Mammography*, Health Phys. 53:267-179; 1987.

16. NCRP Report No. 49, *Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up To 10 Mev*, Bethesda, MD, 1976.

Chapter 13. Performance Tests for Monitors in Picture Archiving and Communication System (PAC)

A. *Introduction*

Display testing in the form of acceptance testing or frequent QC provides a means by which the user can be assured that the display quality is adequate and is maintained throughout the useful life of the device. It will also determine when a display device should be decommissioned before diagnosis is adversely affected. Furthermore, a comprehensives display.

QC program ensures the consistency and integrity of image presentations throughout the clinic, reducing possible inconsistencies in clinical decisions based on images displayed on different devices.

The purpose of this section is to provide guidance for visually testing display systems. For more comprehensive quantitative or advanced testing, refer to the primary reference, AAPM TG 18.

This section does not cover performance testing for mammography monitors. Refer to the manufacturer's manual for specific testing requirements for these monitors.

B. *Testing Periodicity*

Acceptance, annually, and after major repairs

C. *Reference*

AAPM Online Report No. 3, Imaging Informatics Subcommittee Task Group #18, Assessment of Display Performance for Medical Imaging Systems, 2005.

D. *General Performance Tests for Picture Archiving and Communication System (PACS) Monitor Equipment*

Prior to acceptance of the monitor, the ambient lighting level should be measured and documented and a DICOM luminance calibration should be performed. The calibration of the DICOM luminance should be done by the manufacturer of the monitor or software used to perform quality control tests. Prior to the annual evaluation of the monitor the ambient lighting level should be measured and documented and a verification of the DICOM luminance calibration should be done (to include verifying the L_{max} and L_{min}). Most monitors have software installed to perform the verification of the DICOM luminance calibration.

1. Geometric Distortion

a. Purpose. To ensure the display of the monitor is free from geometric distortions.

b. Equipment. AAPM TG18-QC test pattern.

c. Procedure:

(1) The pattern should be maximized to fill the entire display area. For displays with rectangular display areas, the patterns should cover at least one orientation of the display area and be placed at the center of the area used for image viewing.

(2) The linearity of the pattern should be checked visually at a viewing distance of 30 cm across the display area and at the edges.

d. Interpretation of Results. The patterns should appear straight without significant geometrical distortions. The pattern should be properly scaled to the aspect ratio of the video source pixel format so that grid lines represent squares. The lines should appear straight without any curvature or waviness, indicative of proper linearity. Some small barrel and pincushion distortions are normal for Cathode Ray Tube (CRT) devices but should not be excessive.

2. Display Reflection

a. Purpose. Assess and minimize display reflection.

b. Description. Reflections can have two general forms, specular and diffuse. Specular reflection is said to occur when the angle of the incident light rays equals that of the emerging rays as dictated by geometrical optics. Such a reflection produces a virtual image of the source as would a mirror. In diffuse reflection, the light is randomly scattered out of the specular direction and no virtual image of the source is produced. There are two types of diffuse reflection. One is where the scattering angles of the emergent light are broadly distributed and poorly correlated with the angle of the incident light such as with a Lambertian reflector where the direction of the incident light has little effect on the observed reflected luminance. The other type of diffuse reflection is where light is randomly scattered into a narrow distribution of angles in the vicinity of the specular direction.

c. Equipment. AAPM TG18-AD test pattern.

d. Procedure:

(1) Turn the display device off or put in power save mode. Ensure the ambient lighting in the room is the same as when the radiologist is interpreting images.

(2) Examine the display's faceplate at a distance of 30-60 cm with an angular view of +/-15 degrees for secularly reflected light sources or illuminated objects.

(3) Load the TG18-AD test pattern and view the low contrast patterns with normal ambient lighting.

(4) Turn off all lights and view the test pattern in total darkness.

e. Interpretation of Results. In examining the display's faceplate under normal ambient light condition, no specularly reflected patterns of high contrast objects should be seen. If light sources such as that from a film illuminator or window are seen, the position of the display device in the room is not appropriate. If high contrast patterns are seen such as an identification badge on a white shirt or a picture frame on a light wall, then the ambient illumination in the room should be reduced. The threshold of visibility for low-contrast patterns in the TG18-AD test pattern should not be different when viewed in total darkness and when viewed in ambient lighting condition. If the ambient lighting renders the "dark-threshold" not observable, the ambient illuminance on the display surface is causing excess contrast reduction and the room ambient lighting needs to be reduced.

3. Luminance Response

a. Purpose. To ensure the luminance of the display device is consistent and uniform.

b. Equipment. AAPM TG18-CT and TG18-MP test patterns.

c. Procedure:

(1) The TG18-CT pattern should be evaluated for visibility of the central half-moon targets and the four low-contrast objects at the corners of each of the 16 difference luminance regions at a viewing distance of 30 cm.

(2) The TG18-MP test pattern should be viewed to evaluate the bit-depth resolution of the display. The evaluation includes ascertaining the horizontal contouring bands, their relative locations, and grayscale reversals at a viewing distance of 30 cm.

e. Interpretation of Results.

(1) The appearance of the TG18-CT test pattern should clearly demonstrate the low contrast target in each of the 16 regions. Since this pattern is viewed in one state of visual adaptation, it is expected that the contrast transfer will be better at the brightness for which the visual system is adapted as opposed to the darkest or the brightest regions. A common failure is not to be able to see the targets in one or two of the dark regions.

(2) In the evaluation of the TG18-MP pattern, the relative location of contouring bands and any luminance levels should not be farther than the distance between the 8 bit markers (long markers). No contrast reversal should be visible.

4. Luminance Uniformity

a. Purpose. To ensure the luminance across the display area is uniform.

b. Equipment. AAPM TG18-UN10 and TG18-UN80 test patterns.

c. Procedure: Display each of the test patterns and assess the uniformity of the image visually.

d. Interpretation of Results. The patterns should be free of gross non-uniformities from center to the edges. Typical CRTs show symmetrical non-uniformities and LCD displays are associated with non-symmetrical ones. No luminance variations with dimensions on the order of 1 cm or more should be observed.

5. Display Resolution

a. Purpose. To ensure the display system is capable of producing separable images of different points of an object with high fidelity.

b. Equipment. AAPM TG18-QC test pattern and magnifying glass.

c. Procedure:

(1) Display the test pattern ensuring one display pixel per image pixel is displayed.

(2) Using the test pattern and magnifier, inspect the displayed "Cx" patterns at the center and four corners of the display area and score the appearance using the provided scoring scale (from 1, the sharpest reference pattern to 12, the blurriest reference pattern).

(3) Evaluate the line pair patterns at the Nyquist and half-Nyquist frequencies in the horizontal and vertical directions in terms of visibility of lines.

d. Interpretation of Results.

(1) The visual evaluation should render all the targets except the smallest one visible. It should be pointed out that failure of a device in this test can also be an indication of improper luminance response. That can be ruled out by first verifying the proper luminance response of the device. However, the results are independent of the absolute luminance value of the pattern's background; since the mean value and the standard deviation of the background are linearly dependent on the luminance, their ratio, i.e., signal to noise, remains independent of luminance.

(2) The Cx elements should be scored between 0 and 4 at all locations. The horizontal and vertical line pair patterns at Nyquist frequency should be discernable at all locations and for all directions.

(3) In CRTs, it is normal for the performance at the center to be better than any corner due to normal deflection distortions. Also, the horizontal line pair patterns at Nyquist frequency usually appear overall slightly brighter than the vertical patterns because the vertical patterns contain a higher percentage of rise/fall time per pixel, delivering less beam energy to the phosphor screen. At the Nyquist frequency, the difference in the average luminance should be less than 30%. A difference more than 50% indicates a slow video amplifier not well suited for the matrix size. The line pair pattern at half-Nyquist frequency should show less luminance difference since the vertical patterns contain two pixels/line providing more dwell time for the electronic beam. A significant difference between the thicknesses of the black and white lines is also indicative of a poorly shaped pixel with excessive spread of the pixel, which diminishes the black content.

6. Display Noise

a. Purpose. To visually quantify the spatial noise of the display system.

b. Equipment. AAPM TG18-AFC test pattern.

c. Procedure:

(1) Each quadrant of the test pattern contains a large number of regions with varying target position. In each quadrant the contrast and size of the target is constant. The contrast-size values for the four quadrants are 20-2, 30-3, 40-4, and 60-6. The observer views the patterns from a distance of 30 cm.

(2) Evaluate each of the quadrants and establish the contrast-size for which the observer can confidently place the position of all targets.

d. Interpretation of Results. The visual evaluation should render al the targets except the smallest one visible for primary monitors and the second largest targets should be visible for secondary monitors.

7. Veiling Glare

a. Purpose. To assess the veiling glare of the display system.

b. Equipment. AAPM TG18-GV and TG18-GVN test patterns.

c. Procedure:

(1) Display the test patterns such that the white region is 20 cm in diameter.

(2) Observe the visibility of the low contrast objects in each of the test patterns with the bright region masked from view. Because the human visual system will change adaptation if it views the bright field, it is imperative that the bright field

is fully blocked from view and that no reflected light from the bright field be observable.

d. Interpretation of Results. No significant reduction in the contrast of the target object should be observed between the two patterns with and without the bright field. This test is sensitive to the perceived contrast of the target with a black surrounding region. If this is exactly at the just noticeable threshold, then any reduction in contrast will render the pattern not visible. The third object should be visible in either pattern for primary monitors and at least one target for secondary monitors.

8. Display Chromaticity

a. Purpose. To verify the color of the display system is uniform.

b. Equipment. AAPM TG18-UN80 test pattern.

c. Procedure:

(1) Display the test pattern on all monitors associated with the workstation.

(2) Look for color uniformity of the test pattern across the display area of each monitor.

d. Interpretation of Results. No significant perceivable color difference should be present among the monitors. With monochrome phosphor-based displays such as CRTs, any perceivable differences can be attributed to the use of different phosphors, different batches of phosphor materials in the manufacturing process, aging of multiple component phosphors, or differences in faceplate's anti-reflection/glare treatments.

Chapter 14. Guidance for the Use, Care, Evaluation, and Disposal of Lead Aprons

A. *Background*

The Environment of Care standards set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) require performance inspections on medical equipment. Lead aprons are considered medical equipment. In addition, all state radiation control programs require evaluations of lead aprons. In recent years, references (a) and (b) have addressed the topic of the proper care, evaluation and disposal of lead aprons.

B. *Guidance*

The Bureau of Medicine and Surgery (BUMED) guidance for the use, care, evaluation and disposal of lead aprons (including thyroid and gonadal shields) utilized in medical facilities is as follows:

C. *References*

1. *Implementation of an X-ray Radiation Protective Equipment Inspection Program*, Operational Radiation Safety, 82(2): S51-S53, 2002.

2. *Inspection of Lead Aprons: A Practical Rejection Model*, Operational Radiation Safety, 95(Supplement 2): S133-S136, 2008.

D. *Use, Care, Evaluation, and Disposal*

1. Use of Lead Aprons

Based on NCRP recommendations, lead aprons of a minimum of 0.5 mm lead-equivalency should be used for fluoroscopic applications and for shielding direct gonadal exposures. Lead aprons of a minimum of 0.25 mm lead-equivalency should be sufficient for all other radiographic applications.

Newer technology has led to the development of lead equivalent aprons that utilize lighter weight materials to accomplish lead shielding. Careful consideration by the Radiation Safety Officer of these aprons should be considered prior to their purchase and implementation of their use.

2. Care of Lead Aprons

Properly cared for lead aprons have a life expectancy of approximately 10 years. They should be properly hung on hooks/racks when not in use. They should never be folded, creased or draped across another piece of equipment. They should be kept clean of dirt, grease and other contaminants.

3. Evaluation of Lead Aprons

Pursuant to references (a) and (b), lead aprons should be evaluated at least annually. This evaluation should consist of a visual inspection and physical evaluation. If a suspicious area is found, i.e. tears, perforations, or thinning creases at the time of the annual check or on any other occasion, an x-ray evaluation should be performed. Depending on the availability of the facility, the x-ray evaluation may be done with either fluoroscopy or x-rays. A record of the date of the check, the type of check (visual, tactile, and/or x-ray), the results, and who performed the check, should be kept for three years. It is expected that an inspector will be able to verify that the evaluations have been done by either looking at the aprons and/or the documentation system.

4. Rejection Criteria

Whole body lead aprons should be rejected and replaced if the tear length exceeds 2 in for the single layered material or 10 in for the double layered material. If the defect(s) occur in an area that would cover the reproductive organs, and the area exceeds 1.5 in, the apron should be replaced. If the defect(s) occurs on a thyroid shield and the area exceeds a ½ in, the lead thyroid shield should be replaced. See Table 14-1 below**.**

Table 14-1.—Apron Rejection Criteria.

Type of Apron	**Definition Area**	**Length of Defect**	
		Lead Equivalency (mm)	
		0.25	**0.50**
Double Layered	Whole Body	13.5 cm	27 cm
	Gonads	4.4 cm	8.7 cm
Single Layered	Whole Body	5.9 cm	5.4 cm
	Gonads	1.9 cm	1.7 cm
	Thyroid	1.9 cm	1.8 cm

5. Disposal of Lead Aprons

Lead aprons contain hazardous materials, and it is illegal to dispose of lead aprons in a landfill. For the disposal of lead aprons that remain in a condition to warrant their re-use, it is recommend that commands contact their nearest Defense Reutilization & Marketing Office (DRMO) through their host or activity Environmental Department. For lead aprons damaged beyond their safe use as defined in the paragraphs above, it is recommended that commands process the aprons for disposal through their Hazardous Materials (HAZMAT) office. Alternately, some manufacturers of lead aprons may take them back for recycling or disposal.

Chapter 15. Direct Digital Radiography Systems

A. *Introduction*

Digital Radiography (DR) consists of specialized equipment using Photoconductors (Direct DR or DDR) to replace the cassette and cassette tray altogether with a specialized digital detector system. The photoconductor material – Selenium – is placed on top of a Thin Film Transistor (TFT) array. The detector captures ionizations and measures the charge deposited directly. The data from the detector are directly digitized and sent out as a picture to the PACS.

If available from the manufacturer of the X-ray unit automated Quality Control (QC) programs exist for evaluating the DR detector performance. The QC program shall be evaluated as part of the annual inspection for the DR unit. Technologists shall perform QC automated programs on periodicities set by the manufacturer.

This document describes a series of tests to assess digital detector performance. The following tests are intended as a recommendation to detect advanced artifacts and test image quality and sensitivity. All images should be acquired with a minimal amount of pre-processing and a linear Look Up Table (LUT) applied, unless otherwise stated. Some of the images should be assessed on either a reporting quality monitor or printer. These devices should be monitored as part of a QA program. Ambient lighting conditions should be consistent and appropriate.

B. *Minimum Required Personnel Qualifications*

Basic Diagnostic Imaging Equipment.

C. *Testing Periodicity*

Acceptance and troubleshooting advanced problems.

D. *Equipment*

1. Tape measure
2. Adhesive tape
3. 10 mm copper filtration (> 10 x 10 cm)
4. TO20 threshold contrast test object
5. Resolution test object (e.g. Huttner 18)
6. M1 geometry test object
7. Contact mesh

8. Ionization chamber

9. Small lead or copper block (~ 5 x 5 cm)

10. Direct Digital Radiography System Survey (found in Appendix H)

E. *References*

1. KCARE, *DDR Commissioning and Annual QA Protocol Manual*, January 2005.

2. Bushberg, J.T., Seibert, J.A., Leidholdt Jr., E.M., Boone, J.M., *The Essential Physics of Medical Imaging*, Lippincott, Williams & Wilkins, Philadelphia, 2002.

F. *General Requirements for Radiographic Equipment*

1. Dosimetry

a. Purpose. To measure entrance detector exposures.

b. Regulations. Measures dose required for later tests 3, 4, 5, 6, 10.

c. Equipment. Ionization chamber, 1.0 mm Cu filter.

d. Procedure:

(1) Set a Source to Image Distance (SID) of at least 150 cm (see Figure 15-1). Record this distance.

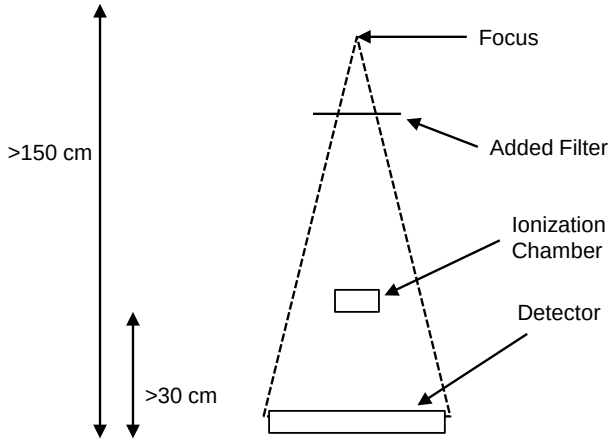


Figure 15-1.

(2) Position a chamber at least 30 cm in front of the detector (away from backscatter). If possible either point the tube away from the detector or shield the detector with a lead apron.

(3) Collimate to the chamber.

(4) Expose the chamber such that the inverse square law corrected receptor entrance air KERMA is approximately 10 µGy, using 70 kVp and 1.0 mm Cu filtration.

(3) Record the measured dose and repeat twice. Under the same beam conditions determine the mAs required to deliver 1 µGy, 4 µGy, 12 µGy, and 50 µGy.

e. Interpretation of Results. Data collected here are used in tests 3, 4, 5, 6, 10.

2. Dark Noise

a. Purpose. To assess the level of noise inherent in the system.

b. Regulations. Test is used to set a baseline for future QA tests. On future annual tests, the tolerance should be +/- 50% exposure equivalent.

c. Equipment. None.

d. Procedure:

(1) If possible, remove the grid from the system. Close the collimators and cover the detector with a lead apron.

(2) Set a low exposure (e.g. 50 kVp and 0.5 mAs). This will give an effectively zero dose, or 'dark noise' image.

(3) Record the detector dose indicator value, and pixel value.

e. Interpretation of Results. Used to establish a baseline for future QA tests. If tolerance outside of +/- 50% of baseline is observed, consult with qualified service engineer.

3. Linearity and System Transfer Properties

a. Purpose. To establish relationship between receptor dose and pixel value, and establish exposure index varies linearly with the increasing exposure.

b. Regulations. The trend-line plotted in Excel should have an R^2 fit value > 0.95. There is no tolerance for the system transfer properties (STP) equation; however the pixel value to dose relationship should be a simple relationship (e.g. log, linear, or square root). There is also no tolerance for the dark noise image; however the data may be useful as a baseline when rechecking the dark noise in the event of other image quality problems.

c. Equipment. 1.0 mm Cu filter.

d. Procedure:

(1) If possible, remove the grid from the system. Open the collimators and expose the entire area of the detector at 10 kVp with 1.0 mm Cu filter at the tube head.

(2) Set a mAs and SID to deliver a dose of order 1 µGy (as determined in test 1 – Dosimetry). Record the detector dose indicator value.

(3) Repeat for doses of order 4 µGy, 12 µGy, and 50 µGy. Record a pixel value from the center of each image from the acquisition workstation. If ROI analysis is not available at the acquisition workstation the images should be transferred to the reporting workstation to perform this task.

(4) Plot a graph of pixel value versus receptor dose using a graph plotting package (e.g. Microsoft Excel). A zero dose point can be obtained using the result of test 2 – Dark Noise.

(5) Obtain the equation of the trend line for this graph. This equation is the STP equation and is used for making corrections in tests 4 and 6. An equation of the form "dose = f(pixel value)" where f is some arbitrary function, is required.

e. Interpretation of Results. Establishes relationship between receptor dose and pixel value, and establish exposure index varies linearly with the increasing exposure. Consult with qualified service engineer for relationships outside of tolerance.

4. Image Retention

a. Purpose. To test that any detectable residual signal (ghosting) that remains in subsequent images is minimal.

b. Regulations. If no evidence of ghosting is found from visual inspection of the images then the test is satisfactory and there is no need to perform ROI analysis. There should be <5% (remedial) difference between the STP corrected pixel values in the ghosted region and the surrounding areas.

c. Equipment. Attenuating material – either copper or lead 5 x 5 cm.

d. Procedure:

(1) Ensure the grid is removed from the system, if possible, and there is no attenuation in the beam. Set the SID to be approximately 180 cm.

(2) Close the collimators and cover the detector with a lead apron.

(3) Set a low exposure (e.g. 50 kVp and 0.5 mAs).

(4) Open the collimators and place the attenuating material (Cu or Pb 5 x 5 cm) on the detector such that it covers part of the field.

(5) Make an exposure at 70 kVp and mAs to deliver a receptor dose of order 4 µGy.

(6) Obtain another blank image as described above. This exposure should be made 1 minute after the previous one.

(7) Set a very narrow window and adjust the level. Visually inspect the image for any remnant of the previous image. If a remnant is visible, use ROI analysis to quantify the difference in pixel value between the ghosted and unghosted areas. See Figure 15-2. If ROI analysis is not available the image should be transferred to a reporting workstation. The ROI values should be used to calculate the indicated receptor doses using the STP equation established in test 3 – Linearity, STP, and Dark Noise.

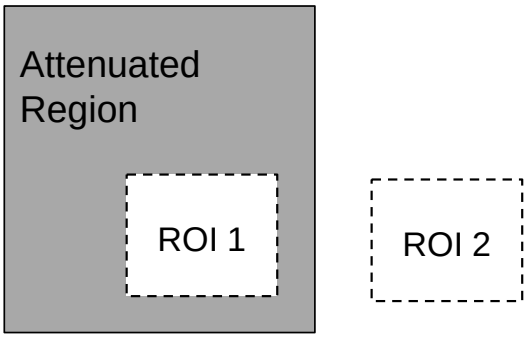


Figure 15-2.

e. Interpretation of Results. If evidence of ghosting present, consult with qualified service engineer.

5. Detector Dose Indicator Consistency

NOTE: This test can only be performed if the unit has a form of detector dose indicator.

a. Purpose. To assess the variation of sensitivity between exposures, and set a baseline for monitoring system sensitivity for future QA testing.

b. Regulations. The measurements should be used to set a baseline for future QA tests. The indicated sensitivity indices should not differ by greater than 20% of equivalent exposure, between exposures.

c. Equipment. 1.0 mm Cu filter.

d. Procedure:

(1) If possible, remove the grid from the system. Set a field size to cover the entire detector and a SID as for Test 1 – Dosimetry.

(2) Expose the detector to a known dose of 10 µGy at 70 kVp with 1.0 mm Cu at the tube head. Set a mAs as established from Test 1 – Dosimetry.

(3) Record the organ program, LUT name and detector dose indicator, without changing the window and leveling.

(4) Repeat at least 3 times. Also repeat for 1 µGy and 12 µGy (1 image for each).

e. Interpretation of Results. If indices differ by greater than 20% of baseline, consult with qualified service engineer.

6. Uniformity

a. Purpose. To assess the uniformity of the recorded signal from a uniformly exposed detector. A non-uniform response could affect clinical image quality.

b. Regulations. The images should not have obvious artifacts. The ratio of the standard deviation of the 5 STP corrected ROI values to their mean (the coefficient of variation) should be less than 10%.

c. Equipment. None.

d. Procedure:

(1) Visually inspect all images obtained in Test 5 – Detector Dose Indicator Consistency for uniformity and artifacts.

(2) The uniformity of one of the images should be assessed using ROI analysis, if available; to measure the mean and standard deviation of the pixel values in positions a-e, as indicated in Figure 15-3 (i.e. the center of the image and the center of the four quadrants).

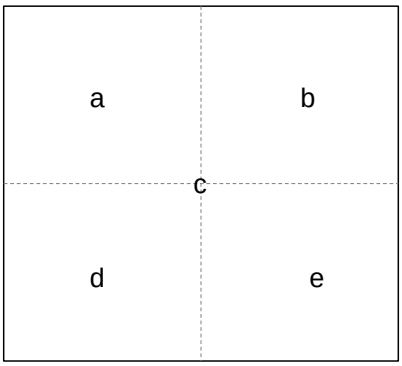


Figure 15-3.

(3) For detectors that are tiled detectors an ROI should be drawn at the center of all tiles. The ROIs should be on the order of 10000 pixels. If ROI analysis is not available at the acquisition workstation then the images should be transferred to a reporting workstation.

(4) If uniformity is poor in the direction of the anode-cathode axis, this is likely to be a result of the anode heel affect. To confirm this, the test should be repeated with the tube rotated 90 degrees. The five values obtained from ROI analysis should be used to calculate five indicated receptor dose values using the STP equation obtained in Test 4 – Image Retention.

e. Interpretation of Results. If the ratio of corrected values to mean is greater than 10%, consult with qualified service engineer.

7. Scaling Errors

a. Purpose. To assess the accuracy of software distance indicators and check for distortion.

b. Regulations. See in Figure 15-4 that measured distances x and y should agree within 3% of the actual distances at the center or 5% at the corners. All calculated aspect ratios should be within 1.00 +/- 0.03 at the center or 5% at the corners.

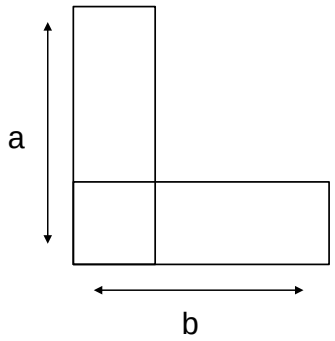


Figure 15-4.

c. Equipment. M1 test object.

d. Procedure:

(1) Ensure the grid is removed from the system, if possible. Position the M1 test object directly onto the detector with an SID of 150 cm.

(2) Expose the detector at 50-60 kV with no attenuation in the beam and 10 mAs.

(3) Using the distance measuring software tools measure the dimensions (x and y) of the five central squares in both the horizontal and vertical directions.

(4) Calculate the aspect ratio x/y.

(5) Select any corner of the image and measure the horizontal (a) and vertical (b) sizes of two squares as indicated in Figure 16-4 above and calculate the aspect ratio a/b. Repeat this for one other corner.

(6) If possible download the image as a DICOM file and open the image using a DICOM viewer such as Santeviewer.

(7) Hold the cursor over a corner of a square in the grid and record the position within the image (i.e. the x and y coordinates).

(8) Move the cursor to the corner of the square of the grid 10 cm from the first corner in the x direction and record the coordinates again.

(9) Calculate the pixel pitch, p(mm) = 100/n, where n=number of pixels covering 10 cm of the grid.

(10) Repeat for the y direction. This test is only necessary for commissioning. Compare the pixel pitch to that stated by the manufacturer. The difference should be no greater than the estimated measurement error.

e. Interpretation of Results. If distances measure outside of tolerances, consult with qualified service engineer.

8. Blurring and Stitching Artifacts

a. Purpose. To test for any localized distortion or blurring and to highlight any stitching artifacts if the system is formed from more than one detector element.

b. Regulations. No blurring should be present. If stitching artifacts are present there should be no loss of information.

c. Equipment. Contact mesh MS4 or MS5 test object.

d. Procedure:

(1) The test should be made with the grid both in and out of the detector. Ensure there is no attenuation in the beam and that the SID is set as large as possible.

(2) With a contact mesh on the detector, make an exposure at 50-60 kVp and 10 mAs using fine focus. An MS4 or MS5 test object is appropriate.

(3) Visually inspect the image for blurring and stitching artifacts. Repeat with a finer mesh if available.

e. Interpretation of Results. If blurring or stitching artifacts with loss of information are present consult with qualified service engineer.

9. Limiting Spatial Resolution

a. Purpose. To test the high contrast limit of the system's ability to resolve details.

b. Regulations. These measurements should be used to set a baseline for future QA tests. Print or save the images for future reference, if possible. Future annual QA testing should be +/- 20% of baseline.

c. Equipment. Resolution test object.

d. Procedure:

(1) Ensure the grid is removed from the system, there is no attenuation in the beam and the SID is set as large as possible. Place the resolution test object onto the detector aligned at 45^{o} to its edges.

(2) Set 50-60 kV and expose the cassette using 10 mAs on fine focus.

(3) Adjust the window level and magnification to optimize the resolution. Score the number of resolvable groups of lines from the screen. The image should be scored at a magnification of order x5. If this facility is not available on the review workstation then images should be transferred to the reporting workstation for scoring. Look up the corresponding resolution.

(4) Repeat the measurement twice with the resolution test object placed at a slight angle to the lateral or longitudinal axis. If the system has more than one detector element, measurements at 45° should be made for each element.

e. Interpretation of Results. Compare acceptance test to future QA test results. Significant divergences in limiting spatial resolution (outside of 20% of baseline) require consultation with qualified service engineer.

10. Threshold Contrast Detail Detectability

a. Purpose. To monitor image quality by assessing the visibility of low contrast details.

b. Regulations. The results of this test are used to set a baseline for future QA tests. Results could be compared to those form other similar systems if available. Print or save the images for future reference, if possible. Future annual QA testing should be performed only at 4 µGy and be +/- 30% of baseline.

c. Equipment. 1.0 mm Cu filtration.

d. Procedure:

(1) Ensure the grid is removed from the system, if possible. With the tube, detector, and 1.0 mm Cu filtration in the same positions as for Test 5 – Detector Dose Indicator Consistency.

(2) Place the TO20 (or equivalent) test object on the detector and collimate down to the size of the test object.

(3) Set 70 kVp and the appropriate mAs to deliver ~4 μGy.

(4) Ascertain whether clinical images are most commonly viewed soft or hard copy. If images are viewed soft copy, score them on a reporting workstation optimizing window and level settings for each detail size. If they view hard copy, adjust the window to optimize the visibility of the details, ensuring that background noise is perceptible, and print the image out on the largest film size.

(5) View the image on a masked light box and calculate an image quality factor, IQF, as follows:

$$IQF = \frac{1}{n}\sum_{i=1}^{n}\frac{H_T(A_i)}{H_T^{ref}(A_i)}\left[\frac{D_{ref}}{D}\right]^{0.5}$$

where:

$H_T(A)$ = threshold contrast detail index values calculated from the image

$H_T^{ref}(A)$ = threshold contrast detail index values calculated from a reference image of a system known to be in good adjustment

D = the dose to the image plate

D_{ref} = the dose to the image plate for the reference image

n = the number of details in the test object

(6) Repeat this test for exposures of ~1 μGy and ~12 μGy.

e. Interpretation of Results. Compare acceptance test to future QA test results. Significant divergences (outside of 30% baseline) in image quality require consultation with qualified service engineer.

Direct Digital Radiography System Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	
Model Number:	Detector Serial Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Mechanical Checks				
Dosimetry				
Dark Noise				
Linearity and System Transfer Properties				
Image Retention				
Detector Dose Indicator Consistency				
Uniformity				
Scaling Errors				
Blurring and Stitching Artifacts				
Limiting Spatial Resolution				
Threshold Contrast Detail Detectability				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Chapter 16. Computed Radiography (CR) Systems

A. *Introduction*

CR is a marketing term for photo-stimulable phosphor detector systems. CR utilizes a phosphor plate based vice screen/film combination to retain and ultimately generate a diagnostic image. The technology uses conventional radiographic acquisition geometry to deposit x-ray energy in a photo-stimulable phosphor screen with delayed luminescence properties. Stored x-ray energy is released via photo-stimulable emission of the imaging plate as it is scanned by a laser beam located within the reading unit. Phosphorescent light with intensity proportional to the absorbed x-ray energy is emitted as the trapped electrons transition back to the valence band. The emitted light is captured, amplified within a Photomultiplier Tube (PMT), and then converted into a digital format for manipulation. The digital data may be converted into analog format for viewing on a CRT laser/thermal film or flat panel monitor.

It is highly recommended upon acceptance, that the field service engineer for the given product be on site for administrative access and training on use of the system.

The testing protocols covered in this manual may not be the only way to test the equipment and may require adjustment from time to time. Three vendors (Kodak, Fuji, and Agfa) are covered in this chapter. Other manufacturers may have more or fewer requirements for testing their systems.

The imaging chain consists of both the CR device (and plates) and the radiographic system used. The radiographic room used for the testing must have passed all of its physics testing sometime within the prior twelve months.

For acceptance testing use all guidelines of Reference 1 listed below, or the most up to date report from the AAPM.

B. *Minimum Required Personnel Qualifications*

Basic Diagnostic Imaging Equipment.

C. *Testing Periodicity*

All reading units and each plate used in clinical applications: Annually, upon acceptance and applicable portions after major repairs (i.e. replacement of laser).

D. *Equipment*

1. X-ray system which passed all testing within last 12 months

2. Calibrated ion chamber with a test stand

3. 0.1 – 0.01 mm Pb line pair phantom

4. Low contrast digital phantom, 14 x 17 inch screen-film contact test tool
5. Metal ruler (straight metal edge)
6. Copper/aluminum filters per manufacturer's recommendation
7. Variable thickness Lucite step wedge
8. Lead block or sheet
9. Measuring tape
10. Stopwatch
11. Computed Radiography System Survey

E. *Reference*

1. AAPM TG Report 93, *Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems*, October 2006.

F. *General Requirements for Computed Radiographic Equipment*

1. Phosphor Plate Throughput

a. Purpose. To verify the manufacturer's plate throughput.

b. Regulations. The throughput should be within 10% of the manufacturer's stated rate.

c. Equipment. Watch with a second sweep hand (stopwatch).

d. Procedure:

(1) If needed, pre-identify the plates. Choose a processing type appropriate for the plate size/type. Start the time when the first plate is placed either in the buffer (multi-plate system) or into the single reader slot.

(2) Run at least ten plates (maximum available if this is not possible) or four plates each exposed to ~ 2 mR.

(3) Stop the time when the image is displayed on the vendor processing station and extrapolate to an hourly rate.

(4) Repeat this for all plate sizes and types.

e. Interpretation of Results. If the measured rate does not meet the vendor's specifications, consult with a qualified service engineer and the local networking staff. Some vendors' specifications are network dependent.

2. Phosphor Plate Uniformity (Reproducibility)

a. Purpose. To verify that the plates respond in a uniform manner and that all respond in a similar manner as a group. To verify that artifacts will not obscure the clinical image.

b. Regulations. The pixel values should be within 10% of the average pixel value for all of the plates. The standard deviation of each average pixel value amongst all plates should be less than 25 for Agfa, less than 20 for Fuji and Kodak. The standard deviation of the exposure indicator values (lgM-Agfa, Sensitivity-Fuji, EI-Kodak) should be less than 0.02 for Agfa, less than 5% for Fuji (standard deviation / mean sensitivity) and less than 20 for Kodak. The images should also be artifact free.

c. Equipment. 180 cc ion chamber, 1.5 mm Copper filter (Agfa).

d. Procedure:

(1) Pre-expose the ion chamber free in air to approximately 5 - 10 mR at 72" SID using 80 kVp with 0.5 mm Cu and 1.0 mm Al filtration.

(2) Expose the full plate in the same fashion. If unable to obtain 72" SID, expose the plate to half the value necessary for the exposure and rotate the plate in between exposures. All plates / cassettes should be tested.

(3) Process the plate with the vendor recommended algorithm (system diagnosis/flat field/200 speed-Agfa, Test/sensitivity, Semi EDR- Fuji, Pattern-Kodak). Take global ROIs of each image and record the average pixel values and standard deviation.

(4) Record the proprietary exposure indicator values for each image.

e. Interpretation of Results. If artifacts appear on the image, clean the plate with the appropriate cleaner. If the artifact is still visible after re-exposure, consider taking the plate out of service (the technologists should also be making this decision between annual evaluations). If the pixel values are not appropriate, consider taking the "guilty plate / plates" out of service. Plates should be replaceable to the activity at no cost.

3. Exposure Indicator

a. Purpose. To verify that system is calibrated in the manner intended by the manufacturer.

b. Regulations. The values should be within 2% of the manufacturer's programmed value. The values must be within 10% of manufacturer's programmed value (Agfa lgM = 2.2 < ± 0.045; Fuji S = 200 < ± 20; Kodak EI = 2000 < ± 45).

c. Equipment. Same as for previous test.

d. Procedure:

(1) Expose three plates of each size to approximately 1 mR at 72" SID with the appropriate vendor energy, filter as per vendor requirements.

(2) Process the plate with the appropriate vendor algorithm (Fuji test/sens (L = 1) semi-EDR; Agfa-previous; Kodak-pattern).

e. Interpretation of Results. If values are outside of the 2% range, pay closer attention to this throughout the year. If they fall outside of 10%, consult the vendor for proper calibration. This value is crucial in daily use by the technologist in monitoring dose and determining the need for repeat images.

4. Linearity

a. Purpose. To verify that the calibration is linear.

b. Regulations. Noise should decrease with increased exposure. Proprietary values and average pixel values versus Log (exposure) should have linearity coefficients greater than 95%.

c. Equipment. Same as in previous test.

d. Procedure:

(1) Pre-expose the ion chamber free in air to 0.1, 1 and 5 or 10 mR at 72" SID to a beam with 80 kVp in the same fashion as in the previous test.

(2) Expose the same plate nine times (three using each exposure level) in the same fashion. Process per previous test - Agfa (Fuji- Test/ave 4.0 Semi-EDR).

(3) Place ROIs on the images to get pixel values; technologists should also be making this decision in between annual evaluations.

(4) Plot the average pixel value of the three, and the proprietary indicators versus Log of the exposure in Roentgens.

e. Interpretation of Results. Consult the field service engineer if values vary greater than expected.

5. Laser Beam Evaluation

a. Purpose. To ensure that the CR reader unit laser is sampling all plate data points and is not skipping data lines.

b. Regulations. There should be no signal drop out and no more than occasional jitters.

c. Equipment. Metal coated or steel straight edged ruler and 180 cc ion chamber.

d. Procedures:

(1) Pre-expose an ion chamber free in air at 72" SID to a beam with 80 kVp, no added filtration and enough mAs to deliver 5 mR.

(2) Expose a single cassette in the same fashion with the ruler centered perpendicularly to the scan lines (scan lines are in direction of plate opening) at a slight angle.

(3) Process with vendor specific algorithm as in previous test-Agfa (Fuji-test/sens semi-EDR).

(4) View the image using the magnifying glass tool.

e. Interpretation of Results: If significant jitter is seen, consult with the qualified service engineer.

6. Spatial Resolution

a. Purpose. To ensure that the system meets the manufacturer's stated sampling rate (expected resolution of Nyquist limit).

b. Regulations. The resolution must be within 10% of the manufacturer's expected resolution.

c. Equipment. Line pair resolution pattern (0.01 - 0.1 mm Pb) and 180 cc ion chamber.

d. Procedure:

(1) Pre-expose an ion chamber free in air at 72" SID to a beam using 60 kVp, no added filtration and enough mAs for 5 mR.

(2) Expose a cassette of each size in the same fashion. If multiple test patterns are available, you may expose each size once. If not, the pattern must be exposed two times each (center x (y-acceptance), periphery x). Collimation is necessary to avoid wash out, but too much collimation may cause the software to misjudge auto collimation. It may also misjudge if multiple patterns are on a small cassette.

(3) Process the plates with an appropriate algorithm for the plate size (as in the throughput test).

(4) View the image with the magnification tool (10 X on narrow window) on a 2 K workstation (if not available at the site, consider printing on film, or viewing on a 1 K workstation).

e. Interpretation of Results. If the resolution is below the expected value, first ensure that the resolution for the radiographic tube is adequate and then consult with a qualified service engineer. The laser may need to be replaced.

7. Low Contrast Resolution

a. Purpose. To ensure that contrast detail is satisfactory.

b. Regulations. The low contrast sensitivity should be comparable to that of film / screen systems. The low contrast sensitivity should also be similar to that seen in the previous annual evaluation.

c. Equipment. Low contrast test pattern and 180 cc ion chamber.

d. Procedure:

(1) Pre-expose an ion chamber in a tabletop 40" SID free in air mode using 75 kVp, 1.5 mm added copper filtration, and enough mAs for 0.1, 1 and 5 (Agfa), and 10 (Fuji) mR, respectively.

(2) Expose three cassettes in the same manner with the test tool on top of each cassette.

(3) Process the image using a general low contrast algorithm (Agfa-flat field, 200 speed Fuji-test/sensitivity, semi-EDR, Kodak-pattern).

(4) View using window and level as appropriate on a 2K/printer/1K workstation (depending on availability).

e. Interpretation of Results. Consult with the qualified service engineer if low contrast resolution is noticeably degraded. Consider using a DSA step wedge phantom to compensate for anode-heel effect.

8. Erasure Thoroughness

a. Purpose. To ensure that vestiges of previous images do not appear in the current image.

b. Regulations. Ghost images of prior exposures should not appear in a current image.

c. Equipment. High contrast tool (Pb or line pair phantom)

d. Procedure:

(1) Expose a plate at 72" SID to an 80 kVp beam with a high incident exposure and the test tool in the image center (i.e. apply collimation).

(2) Process the plate with an appropriate algorithm for the plate size.

(3) Re-expose at a very low exposure without the test tool and using slightly smaller collimation.

(4) View on the image processing station.

e. Interpretation of Results. Consult a qualified service engineer if a residual image is seen.

9. Phosphor Plate Dark Noise

a. Purpose. To ensure that electronic artifacts do not exist.

b. Regulations. There should be no visible artifacts. (Agfa- lgM < 0.28 / SAL < 130, average pixel value < 350 and stand dev < 5, Fuji- Average pixel value < 280, stand dev < 4, Kodak EI < 80, stand dev < 4).

c. Equipment. None.

d. Procedure:

(1) Process three newly erased plates per the manufacturer's specified algorithms (Agfa-system diagnosis / flat field / speed 200, Fuji-Test / sensitivity (L = 1), fixed EDR (S = 10,000).

(2) Perform ROIs on the resulting images. Record average pixel values, standard deviation and proprietary values.

e. Interpretation of Results. Consult with the qualified service engineer if values are not below the specified limit or artifacts are seen.

Computed Radiography Systems Survey

Facility:	Date:
Room Number/Location:	ECN:
Manufacturer:	
Model Number:	Serial Number:

Test Performed	**Pass**	**Fail**	**N/A**	**Comments** (failure comments must annotate minor or significant finding)
Phosphor Plate Throughput				
Phosphor Plate Uniformity (Reproducibility)				
Exposure Indicator				
Linearity				
Laser Beam Evaluation				
Spatial Resolution				
Low Contrast Resolution				
Erasure Thoroughness				
Phosphor Plate Dark Noise				
Additional Comments:				

Purpose:	Results:
Surveyor Name:	
Surveyor Signature:	

Basic Diagnostic Imaging Equipment Surveyor
Personal Qualification Standard

Name	**Rank**	**Command**

Practical Factors:
Perform a minimum of three (3) Under Instruction evaluations of each modality:
Each evaluation must include all parameters performed during acceptance testing.

General Radiographic Unit:

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Dental Radiographic Unit:

Intraoral		Intraoral		Pano/Ceph	
Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Pano/Ceph		CBCT		CBCT	
Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Computed Radiographic Systems:

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Digital Radiographic Systems:

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

The applicant adequately demonstrated all applicable knowledge factors, in accordance with AAPM Report 90, and the ability to perform evaluations independently. I recommend the applicant for qualification at the level of Basic Diagnostic Imaging Equipment Surveyor.

Regional Medical Physicist	**Date**

The applicant is qualified to perform all modalities listed as Basic Diagnostic Imaging Equipment

BUMED Representative	**Date**

Advanced Diagnostic Imaging Equipment Surveyor
Personal Qualification Standard

Name	**Rank**	**Command**

Practical Factors:
Perform a minimum of three (3) Under Instruction evaluations of each modality:
Each evaluation must include all parameters performed during acceptance testing.

General Fluoroscopic Imaging (GFI):

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Interventional Radiology Imaging (IRI):

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Ultra Sound (US):

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Magnetic Resonance Imaging (MRI):

Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Nuclear Medicine (NM):

SPECT		SPECT		SPECT	
Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

PET		PET		PET	
Qualified Surveyor	**Date**	**Qualified Surveyor**	**Date**	**Qualified Surveyor**	**Date**

Advanced Diagnostic Imaging Equipment Surveyor
Personal Qualification Standard

Name	**Rank**	**Command**

Shielding Design (SD):

Qualified Surveyor Date	**Qualified Surveyor Date**	**Qualified Surveyor Date**

Computed Tomography (CT) (Assistant):*

Qualified Surveyor Date	**Qualified Surveyor Date**	**Qualified Surveyor Date**

*Assistant CT surveyor must perform three CT surveys under supervision of a qualified medical physicist (QMP). Under special circumstances (following major repairs/upgrades) when a qualified medical physicist is not locally available, the CT assistant surveyor is qualified to acquire CT survey data of the equipment. The CT data must be reviewed and approved by a QMP prior to clinical use of the CT scanner. This does not obviate the requirement for the annual CT performance survey of the equipment by a QMP.
*QMP for CT as defined by Joint Commission requirements for Diagnostic Imaging Services, Jan 2015

The applicant is qualified as a Basic Diagnostic Imaging Equipment Surveyor, adequately demonstrated all applicable knowledge factors (in accordance with AAPM Report 90), and the ability to perform evaluations independently. I recommend the applicant for qualification at the level of Advanced Diagnostic Imaging Equipment Surveyor in the following modalities: (circle all that apply)

General Fluoroscopic Imaging (GFI)
Interventional Radiology Imaging (IRI)
Ultrasound (US)
Magnetic Resonance Imaging (MRI)
Nuclear Medicine (NM) (SPECT) (PET)
Shielding Design (SD)
Computed Tomography (CT)
Computed Tomography Assistant (CT-A)

Regional Medical Physicist	**Date**

The applicant is qualified to perform diagnostic performance surveys of the above modalities.

BUMED Representative	**Date**

Minimum Half Value Layer Requirements (HVL)
(From Code of Federal Regulations, 21 CFR Part 1020.30)[1]

X-ray Tube Voltage (kVp)	**Minimum HVL (millimeters of Al)**			
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[2]	I – Other X-Ray Systems[3]	II – Other X-Ray Systems[4]
Below 51…	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1]Future revisions to 21 CFR 1020.30 that change the minimum HVL requirements will supersede this table.

[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[3]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[4]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.