Proposed American National Standard/
American Dental Association

Standard No. 1099

Quality Assurance for Digital Panoramic and Cephalometric Systems

ADA American Dental Association®

2022

PROPOSED AMERICAN NATIONAL STANDARDS INSTITUTE/AMERICAN DENTAL ASSOCIATION STANDARD NO.1099 FOR QUALITY ASSURANCE FOR DIGITAL PANORAMIC AND CEPHALOMETRIC RADIOGRAPHIC SYSTEMS

FOREWORD

(This Foreword does not form a part of the Proposed ADA Standard No. 1099 for Digital Panoramic and Cephalometric Radiographic Systems).

In 1992, there was interest in the standardization of clinical information systems related to electronic technology in the dental environment. After evaluating current informatics activities, a Task Group of the ANSI Accredited Standards Committee MD156 (ASC MD156) was created by the ADA to initiate the development of technical reports, guidelines, and standards on electronic technologies used in dental practice. In 1999, the ADA established the ADA Standards Committee on Dental Informatics (SCDI). The ADA SCDI is currently the group that reviews and approves proposed American National Standards (ANSI approved) and technical reports developed by the standards committee's working groups. The ADA became an ANSI accredited standards organization in 2000.

The scope of the ADA SCDI is:

> *"The ADA SCDI shall develop informatics standards, specifications, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession."*

NOTE – The user's attention is called to the possibility that implementation of certain test methods contained in this technical report may require use of an invention that may be covered by patent rights. By publication of this technical report, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. Parties interested in seeking to obtain a license to use this invention may contact the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611 or email standards@ada.org for additional information.

The ADA Standards Committee on Dental Informatics thanks the voting members of ADA SCDI Working Group12.1 for Digital Imaging in Dentistry and the organizations with which they were affiliated at the time the standard was developed:

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RATIONALE

Quality assurance can be defined as the planned and systematic activities necessary to provide adequate confidence that a product or service will meet the given requirements. As this relates to digital panoramic and cephalometric radiography, quality assurance entails the consistent production of high quality radiographs in order to provide the maximum amount of diagnostic information with minimal radiation exposure to the patient.

The relationship between diagnostic information and patient radiation dose is critically important. Dose reduction practices that result in loss of diagnostic information are not recommended. Likewise, increasing the radiation dose to produce a more esthetically pleasing image with little or no significant increase in diagnostic information is also not a good practice. Safe and effective diagnostic imaging requires an optimal balance between image quality and radiation dose.

To facilitate optimization of radiation dose and image quality, the International Commission on Radiation Protection (ICRP) introduced the concept of Diagnostic Reference Levels (DRLs) (ICRP Publication 73, 1996[1]). DRLs provide a means for practices to compare their patient radiation dose data to benchmarks derived from aggregated dose data collected on a local, regional or national level. ICRP Publication 73 recommends that radiographic procedures within a practice that consistently exceeded the relevant diagnostic reference level should prompt a review of procedures and equipment and appropriate measures aimed at reduction of the doses should be taken. *DRLs are not the suggested or ideal dose for a particular procedure nor are they an absolute upper dose limit.* They should be used as part of a quality assurance program to ensure that radiation doses used in a dental practice are within an acceptable range.

Both the panoramic and cephalometric radiographic examinations use a collimated rectangular x-ray beam which moves over the imaged area and therefore an area of exposure is made during the examination unlike intraoral radiographic examinations where air kerma or entrance skin exposure values are measured. The National Council on Radiation Protection (NCRP) has established the diagnostic reference level for panoramic radiographic exam as a dose area product (DAP) of 100 $mGy•cm^2$. NCRP recommends a DRL for cephalometric radiography as a DAP of 26.4 and 32.6 $mGy•cm^2$ for children and adults, respectively. DRLs may change as technology for x-ray production and image capture advances and systems become more efficient in the production of radiographic images; therefore it is important to compare DRLs with similar x-ray sources and image receptors. Notably, the DRLs for panoramic and cephalometric radiography have not changed with the transition from film based imaging to digital imaging receptors.

Most states and regulatory bodies have guidelines that require that periodic quality assurance of all radiographic equipment be performed. However, these guidelines were primarily developed for x-ray film and not digital imaging technology. Currently, approximately 90 percent of dental practices in the United States use digital radiography. Therefore, the need for an effective quality assurance protocol for *digital* panoramic and cephalometric radiographic imaging is critical to the care of patients. The purpose of this standard is to establish clear and concise protocols to ensure adequate quality assurance for digital panoramic and cephalometric radiographic imaging systems.

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1 SCOPE

Components involved with a panoramic and cephalometric digital imaging system include:

- The x-ray source
- The image receptor system: Either a solid-state sensor with associated acquisition and display software; or a photostimulable phosphor (PSP) imaging plate, its associated scanner and p acquisition-display software
- The image display device (computer, monitor, and display-software)
- The image viewing environment.

Each of these components will be addressed in this standard.

2 NORMATIVE REFERENCES

Society of Motion Picture and Television Engineers (SMPTE) RP133 *Specification for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-copy Recording Cameras.*1991
(SMPTE standards are available from the Society of Motion Picture and Television Engineers, White Plains Plaza, 445 Hamilton Ave., Ste. 601, White Plains NY 10601-1827, or www.SMPTE.org)

Acceptance Testing and Quality Control of Dental Imaging Equipment. The report of AAPM Task Group 175. ISBN: 978-1-936366-56-9; ISSN: 0271-7344

3 TERMS AND DEFINITIONS

AAPM-American Association of Physicists in Medicine

CCD-Charged Coupled Device

CMOS- Complementary Metal Oxide Semiconductor

DAP – Dose Area Product

DICOM- Digital Imaging and Communications in Medicine

ICRP- International Commission on Radiological Protection

NCRP- National Council on Radiation Protection and Measurements

PSP- Photostimulable Phosphor

Qualified Expert: A medical physicist or manufacturer representative with advanced training in the mechanics and operation of a panoramic and cephalometric x-ray units to locate and measure the x-ray photon beam, i.e. an individual with skills beyond image acquisition and interpretation of panoramic and cephalometric radiographs

SMPTE: Society of Motion Picture and Television Engineers

Absorbed Dose: Measure of the energy deposited in a medium by ionizing radiation. It is equal to the energy deposited per unit mass of medium, and so has the unit J/kg or gray (Gy) where 1 Gy = 1 J kg-1

Air Kerma: The total amount of radiation dose absorbed by air at a specific point in space relative to the X-ray source, measured free-in-air, during an imaging procedure.

Diagnostic Reference Level (DRL): Dose levels for typical clinical examinations for groups of standard-sized patients or standard phantoms. These are based on the third quartile values for the distributions of doses found in national or regional surveys, that is, 75% of practices are using a dose below the DRL for a specific examination.

Dose Area Product (DAP): Absorbed dose multiplied by the area irradiated, expressed in gray-centimeters squared (Gy•cm2).

Entrance Skin Exposure (ESE): The measure of the radiation dose that is absorbed (measured in milligray) by the skin as it reaches the patient.

Half Value Layer (HVL): The thickness of a material (usually aluminum) required to reduce the air kerma of an **x-ray** beam to half its original value and thus the measure of the quality or intensity of the beam.

Lux: A standardized unit of measurement of light level intensity equal to the direct illumination on a surface that is everywhere one meter from a uniform point source of one candle intensity or equal to one lumen per square meter.

Quality Assurance: Planned and systematic activities necessary to provide adequate confidence that a product or service will meet the given requirements.

4 REQUIREMENTS

This standard may serve as the basis for a written quality assurance program to be maintained by each dental practice. The program should specify periodic testing and documentation, specific activities, the personnel responsible for performing each activity, procedures to be followed for each activity, acceptable ranges of results, and actions to be taken when results are outside acceptable limits.

4.1 Image Viewing Environment

Optimal viewing conditions including a quiet, darkened room with proper digital background masking of the screen so that the majority of the light from the display is from the digital image. Ambient light can impact perception of a digital image viewed on a display device. Ambient light levels should be as low as possible but not completely dark, with a recommended range of 25-75 lux. Ambient light reflects off the front surface of the display increasing luminance in dark areas of the image reducing the contrast resolution. A display pixel with luminance lower than ambient light will not be observed—it is effectively “washed out” by the ambient light. Thus, the minimum luminance setting of the display should be adjusted to match the ambient light settings. The AAPM Report No. 270 recommends that the minimum display luminance be at least four times the measured ambient luminance.

Where possible, bias lighting should be used as the ambient light source. For bias lighting, the light source is placed behind the image display device such that it raises the ambient light levels in the viewing area without directly shining light toward the viewer or the screen. Because the light originates outside of

the sightline of the viewer and is not in a direct path to reflect onto the screen, the viewer benefits from increased ambient luminance without the problems of glare or direct light.

The viewing environment should be continually monitored by the dentist, dental hygienist or dental auxiliary with appropriate training.

4.2 Image Display Device

Digital radiographic images are viewed on an image display device. Radiologic images may contain up to 256 shades of gray that should be distinguishable to the average human eye. If the display is too dim, then contrast between adjacent shades of gray scales is decreased, lowering the number of perceptible shades of gray.

The quality of the display device influences the quality of the digital image and thus, the image display is a key component of the digital imaging chain. Image display devices should be able to display at least 8-bit or 256 discrete gray levels provided by in-plane-switching (IPS) or vertical alignment (VA) flat panels, and a minimal display matrix of 1280 x 1024 or 1920 x 1080. Notably, twisted nematic (TN) displays do not provide for 8-bit or 256 discrete gray levels and are not recommended. Display monitors whether of the cathode ray type or modern curved wide screen display monitors are not appropriate for viewing panoramic or cephalometric radiographs as the curvature of the viewing screen may introduce geometric distortions or shadows on the displayed image with potential for diagnostic errors. Further, display monitors should provide for adjustment of brightness and contrast. Some all-in-one computer systems with an integrated computer and display monitor do not allow for independent adjustment of brightness and contrast. An all-in-one unit which combines the computer with the monitor together as a single unit should not be used for viewing radiographic images unless it can be verified that brightness and contrast can be independently adjusted to properly display the full contrast spectrum on the Society for Motion Picture and Television Engineers (SMPTE) Medical Diagnostic Imaging Test Pattern.

A static contrast ratio (difference between brightest and darkest luminance) of at least 800:1 is recommended, although a ratio of 1000:1 is preferred. Dynamic contrast ratio describes the rate of change in brightness (which differs from static contrast ratio) and does not affect diagnostic performance.

4.2.1 Initial acceptance testing of the image display device

The image display device can be evaluated by displaying a standard digital image such as the SMPTE Medical Diagnostic Imaging Test Pattern (Figure 1). The contrast and brightness should be adjusted using the monitor controls to optimize contrast at the lowest and highest luminance of the image. The overall SMPTE image appearance should be inspected to assure the absence of gross artifacts such as blurring or bleeding of bright display areas into dark areas or aliasing of spatial resolution patterns, geometric distortion, field uniformity and dynamic range. As a dynamic range test, both the 5% and 95% areas should be seen as distinct from the respective adjacent 0% and 100% areas. While most display devices are very stable over time, any adjustment by the user to optimize the image display for other than radiographic interpretation may dramatically affect diagnostic performance.

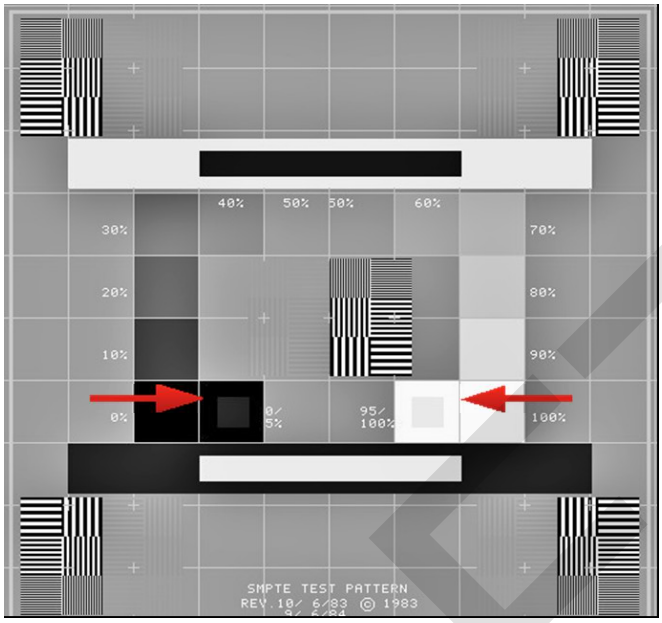

Figure 1. Society of Motion Picture and Television Engineers (SMPTE) Medical Diagnostic Imaging Test Pattern.

Key: Left arrow indicates 5% intensity on a 0% intensity background; right arrow indicates 95% intensity on a 100% background. Also displayed are intensities ranging from 0% to 100% intensities in 10% intervals. Geometric lines are displayed to assess any distortion at the corners and in the center.

4.2.2 Periodic constancy testing of the image display device

All display devices should be assessed monthly by displaying a standard digital image such as the SMPTE Medical Diagnostic Imaging Test Pattern (Figure 1) and evaluated as described above. The assessments require less than 5 minutes and can be performed by the dentist, dental hygienist or dental assistants with appropriate equipment and training.

4.3 The X-ray Source

4.3.1 Initial Acceptance Testing of the X-ray Source

Initial acceptance testing should be performed by a qualified expert or the original equipment installer, recognized by the state, at the time of installation. At minimum, the testing should include:

- Assessment of leakage radiation: Visual inspection to detect damage to exterior of housing, and assess leakage radiation, when damage detected.
- Beam-collimator-receptor alignment: The x-ray beam should not extend beyond the edge of the image receptor in either the vertical dimension or horizontal dimensions, for both, panoramic and cephalometric operating modes.
- Beam quality: Determined from half-value layer
- Accuracy of kVp: Measure output kVp and compare with tube settings
- Exposure timer accuracy (for cephalometric devices only): Assess reproducibility of x-ray output and confirm linear relationship between exposure time and radiation dose

The American Association of Physicists in Medicine (AAPM) Report No. 175 describes the details of procedures for the initial acceptance testing of panoramic and cephalometric x-ray devices. A written report of installation and acceptance testing must be provided by the qualified expert or original equipment installer.

4.3.2 Periodic constancy testing of the x-ray source

The AAPM Report No. 175 recommends that assessments of the x-ray source made at initial acceptance be repeated annually. The assessments should include leakage radiation, beam-collimator-receptor alignment, beam quality, accuracy of kVp and exposure reproducibility, as applicable.

Periodic verification of all operating parameters should be evaluated by a qualified expert or the original equipment installer recognized by the state at least every four years.

4.4 Patient Positioning Assembly

Panoramic and cephalometric x-ray devices are equipped with accessories to facilitate appropriate patient positioning, a key step to making diagnostic quality images. Confirming appropriate alignment of components in this assembly should be part of the initial and periodic assessments. These assessments must be done after assessments of the image display device and the x-ray source output.

4.4.1 Panoramic Positioning Assembly

When making a panoramic radiograph, the patient is positioned into the image layer or focal trough—the zone where images are cast with least amount of distortion. Patient positioning is facilitated by laser beams that allow the radiographer to position the patient's head in all three orthogonal planes, thereby placing the jaws into the focal trough. The design and construction of head-stabilizing components are unique to each panoramic device model. The components should be checked for integrity and mechanical loosening according to the manufacturer's instructions. Some newer panoramic devices have an autofocus feature which allows the panoramic machine to select the sharpest image layer without user selection and the patient's head is simply placed within a defined region.

Generally, the position and shape of the image layer is determined by the relative speeds of x-ray beam rotation and the receptor movement past the collimator. There are some digital panoramic acquisition devices that provide a digital tomosynthesis feature and allows selecting different image layers after the image has been acquired. With the traditional digital panoramic devices, changes in the mechanical controls of these movements could potentially alter the location of the image layer manifesting as distortion or artifacts on the panoramic image. A radiographic test phantom provided by the manufacturer should be used to objectively evaluate critical parameters including the image layer position (focal trough) and symmetry of x-ray beam rotation. The radiographic test phantom should provide for the same projection geometry as that used clinically, i.e., the same x-ray source to object distance and x-ray source to image receptor distance. The phantom should be positioned such that the beam rotation on the right and left sides are equidistant. Assessment of image quality should be performed in a region of the focal trough that does not include the overlapped area of the left and right arcs of rotation around the patient's head and is preferably on one side of the panoramic image where the test phantom is nearest the image receptor to reduce penumbra. A written report should be provided by the original equipment installer or expert.

4.4.1 Cephalometric Positioning Assembly

When making a cephalometric radiograph, the patient's head is positioned in a cephalostat—a head-stabilizing device with ear rods that assists to position the patient's midsagittal plane parallel to the receptor and at specified distances from the source and receptor. The central beam is directed through the center of both ear rods such that the beam passes through the external auditory canals, bilaterally. In many units, the manufacturer incorporates radiopaque objects into each ear-rod to easily identify mispositioning of the ear rods.
The cephalostat also incorporates a nasion pointer—a midline device positioned to indicate the location of the nasal bridge, and often with a scale or markers for calibration of linear measurements.
All components should be checked for integrity and mechanical loosening.

4.5 Digital Image Receptor System

Solid state CCD-CMOS image sensors and photostimulable phosphor (PSP) imaging systems are two technologies used to make digital panoramic and cephalometric radiographic images. Both systems provide substantive advantages relative to film-based imaging, including ease of image storage, retrieval and display through a computer network, digital image processing, and the potential for reduction in radiation exposure to the patient. Quality assessments of the digital receptor system should be done after quality assurance assessments of the image display device and x-ray source are completed, and rectified to be within acceptable performance indicators.

Panoramic Imaging

Initial acceptance testing

In order to assess the image quality, the x-ray sensor must be calibrated to a uniform response. The x-ray beam should be assessed to ensure that the x-ray beam is centrally located within a narrow slit and does not extend beyond the image receptor in both the height or length of the x-ray field and width. Further, the radiographic image should be verified for the proper alignment of the rows of image detectors in the case of solid state image receptors.

The plate scanner for PSP imaging systems panoramic systems should also be evaluated. Visual inspection of the PSP scanner should be made to ensure that the unit is intact and free of any debris that may lodge in the PSP scanner, rollers, belts or obscure the infrared light. A square or rectangular grid pattern of known dimensions with incremental markings should be placed overtop the PSP plate. This square grid pattern should be imaged with PSP plate and then scanned in the PSP scanner to check for image distortion due to roller discrepancies or slipping belts. On some large PSP scanners, this process should then be repeated by imaging the square grid pattern again and by turning scanning the PSP plate 90 degrees and placing it into the PSP scanner to check for possible image distortion in the other perpendicular direction. Some PSP scanners are unidirectional and will not the PSP plate to be turned 90 degrees and scanned. Further, the scanned image should be inspected for presence of contamination on the rollers in the PSP scanner.

Periodic constancy testing

Radiographic test phantoms provided by the manufacturer should be used to objectively evaluate the image layer position and accuracy, asymmetrical path of rotation and gross artifact detection annually. This measurement can be made by the dentist, dental hygienist or dental auxiliary with appropriate training.

Periodic verification of all operating parameters should be evaluated by a qualified expert or the equipment installer, recognized by the state, every four years.

The PSP scanner should be evaluated at intervals commensurate with work load and working conditions for proper functionality. Visual inspection of the PSP scanner should be made to ensure that the unit is intact and free of debris that may lodge in the rollers or belts. A square or rectangular grid pattern of known dimensions and incremental markings should be imaged with PSP plate in one direction and then scanned in the PSP scanner to check for image distortion due to roller discrepancies. On some large PSP scanners, this process should then be repeated by imaging the square grid pattern again and by turning scanning the PSP plate 90 degrees and placing it into the PSP scanner to check for possible image distortion in the other direction. Some PSP scanners will not the PSP plate to be turned 90 degrees and scanned. Further, the scanned image should be inspected for presence of contamination on the rollers in the PSP scanner.

Cephalometric Imaging Initial acceptance testing
In order to assess image quality, the x-ray sensor should be calibrated to a uniform response. An image should be acquired with no object in the field to detect any gross artifacts, field uniformity and alignment of cephalometric ear positioning pins. A written report should be provided by the expert or original equipment installer.

The plate scanner for PSP imaging systems cephalometric systems should also be evaluated. Visual inspection of the PSP scanner should be made to ensure that the unit is intact and free of debris that may lodge in the rollers or belts. A square grid pattern of known dimensions and incremental markings should be imaged with PSP plate in one direction and then scanned in the PSP scanner to check for image distortion due to roller discrepancies. On some large PSP scanners, this process should then be repeated by imaging the square grid pattern again and by turning scanning the PSP plate 90 degrees and placing it into the PSP scanner to check for possible image distortion in the other direction. Some PSP scanners will not allow the PSP plate to be turned 90 degrees and scanned. Further, the scanned image should be inspected for presence of contamination on the rollers in the PSP scanner.

Periodic constancy testing
In order to assess image quality, the x-ray sensor should be calibrated to a uniform response. An image should be acquired with no object in the field to detect any gross artifacts, field uniformity and alignment of cephalometric ear positioning pins annually. This measurement can be made by the dentist, dental hygienist or dental auxiliary with appropriate training.

Periodic verification of all operating parameters should be evaluated by a qualified expert or the equipment installer, recognized by the state, every four years.

The PSP scanner should be evaluated at intervals commensurate with work load and working conditions for proper functionality. Visual inspection of the PSP scanner should be made to ensure that the unit is intact and free of debris that may lodge in the rollers or belts. For this periodic constancy test, a square grid pattern of known dimensions and incremental markings should be imaged with PSP plate in one direction and then scanned in the PSP scanner to check for image distortion due to roller discrepancies. On some large PSP scanners, this process should then be repeated by imaging the square grid pattern again and by turning scanning the PSP plate 90 degrees and placing it into the PSP scanner to check for

possible image distortion in the other direction. Some PSP scanners will not the PSP plate to be turned 90 degrees and scanned. Further, the scanned image should be inspected for presence of contamination on the rollers in the PSP scanner.

Schedule for Quality Assurance Assessments

Assessment Type	Diagnostic Display	Radiography X-ray Source	Radiography Sensor/Receptor
Initial Acceptance Testing	Performed by trained dental staff at time of installation	Performed by qualified expert or equipment installer recognized by state at time of installation	Performed by trained dental staff at time of installation
Periodic Constancy Testing	Performed by trained dental staff on a monthly	Performed by trained dental staff on an annual schedule	Performed by trained dental staff on an annual schedule
Periodic Verification Testing	No verification of constancy testing required	Verification performed by qualified expert recognized by state every 4 years	No verification of constancy testing required

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