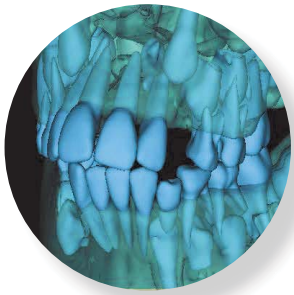
CDA JOURNAL, VOL 49, N°5



Applying the New ADA Quality Assurance Standard to Digital Intraoral Radiographic Systems

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ABSTRACT

This article is intended to describe the appropriate quality assurance (QA) methods for digital intraoral radiographic systems in accordance with ANSI/ADA Standard 1094. This article goes step by step through the digital imaging chain (the intraoral X-ray generator, the image receptor and acquisition software and the image display device), so the reader can achieve a complete understanding of what is required to successfully implement a comprehensive QA protocol within their own practice.

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The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense or its components.

Quality assurance (QA) is defined as the planned and systematic activities necessary to provide adequate confidence that a product or service will meet the given requirements.[1] The need for QA with digital intraoral radiography was identified as early as 2003 in the National Council on Radiation Protection and Measurements (NCRP) Report 145, which stated in section 3.4.3.3 Digital-Imaging Systems, "Procedures for evaluating the performance of digital-imaging systems are quite different from those used with film or screen-film image receptors. By using suitably designed phantoms and software, image quality aspects such as resolution, contrast, signal-to-noise ratio and contrast-to-noise ratio may be measured directly. However, the required standards, apparatus and software for dental systems do not currently exist. These limitations

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are important factors when considering the purchase of digital-imaging systems."[2] As a result, the updated NCRP Report 177, Radiation Protection in Dentistry and Oral & Maxillofacial Imaging, includes instruction on intraoral digital imaging and quality control.[2,3] Likewise, the American Dental Association (ADA) recognized the void in quality assurance for digital intraoral imaging and published Technical Report No. 1094 (TR 1094), Quality Assurance for Digital Intra-Oral Radiographic Systems, on May 31, 2017.[4] And, in keeping with this pursuit to improve digital imaging QA in dentistry, the ADA Standards Council on Dental Informatics (SCDI) updated Technical Report 1094 to Standard 1094 in February 2020.[5]

A standard is the legal duty of a professional to exercise the level of care, diligence and skill prescribed in the standard, which now applies to ANSI/ADA Standard 1094. This is different from guidelines, practice policies, recommendations and position statements in which strict adherence is not mandatory and, therefore, leaves room for professional discretion. Statutes are similar to standards in that they require compliance; yet, they differ in that they are not nationwide. Statutes apply only to the state in which they are passed. In cases where there may be conflict between an ADA standard and the state statute, the user would be mandated to comply with the stricter requirement.

A few states have implemented some aspects of QA requirements for digital intraoral radiographic systems by statute whereas most other states have only protocols for film-based intraoral imaging.[6–9] However, the methods to evaluate these are not clear and there are no acceptance or rejection criteria.[9] For example, one state uses a maximum entrance skin dose as a method of image quality and prevention of overexposure of the patient.[10] Other states rely on a mail-in QA program whereby one X-ray unit combination of an X-ray generator and image receptor is evaluated and assumed to be representative of all X-ray generator and image receptor combinations in the dental facility. Moreover, there are some states where the dental radiology statutes have not been updated since the 1980s prior to the widespread influx of digital intraoral radiography systems. Therefore, it was both necessary and prudent for the ADA to introduce a national quality assurance program for digital intraoral radiographic systems.

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The purpose of this article is twofold. First, it serves to familiarize the reader with the new ANSI/ADA standard 1094 (herein after referred to simply as Standard 1094). Second, it describes how to implement an effective QA program for digital intraoral radiographic systems in accordance with this new standard such that all X-ray generator and digital image receptors are evaluated. The methods described in this article will help clinicians generate and maintain image quality when using digital intraoral systems in their practices.

Introduction to Standard 1094: Quality Assurance for Digital Intraoral Radiographic Systems

Standard 1094 presents digital intraoral radiographic systems as a digital imaging chain consisting of interdependent components (the image display device, the intraoral X-ray generator and the image receptor and acquisition software) where a disruption in any one of the components may lead to a degradation in radiographic image quality. The components of the digital imaging chain often consist of equipment and software from different manufacturers, and each of these components affects the final displayed image. Therefore, it is necessary to implement a QA program to evaluate each component separately and then together as a single cohesive unit. With each of the three components in the imaging chain, there is a quality assurance acceptance test with specified requirements to ensure that the particular component performs as intended when delivered. Likewise, there are specified frequencies at which quality assurance tests are performed to ensure that the particular component continues to operate as intended.

The first component in the digital imaging chain is the image display device and should be evaluated by displaying a standard digital image test pattern on the display screen. An example of such a test pattern is shown in **FIGURE 1**. Details on how to use a standard digital image test pattern to calibrate the display device are provided in the section on implementation of the QA program.

The second part of the digital imaging chain is the radiographic unit (i.e., the X-ray generator). To evaluate the X-ray generator performance, the following should be measured: radiation output in milliroentgen (mR) or milliGray (mGy), the peak kilovoltage (kVp),

the exposure time in seconds and the half-value layer (HVL) in terms of thickness of aluminum. Additionally, tube head stability and collimation of the X-ray beam should be evaluated as part of the initial acceptance testing.

The third component in the digital imaging chain is the digital image receptor and acquisition software. Standard 1094 states that the image receptor must be evaluated for signs of physical damage and that image quality must be assessed using a suitable radiographic phantom. The suitability of the acquisition software and associated system drivers should also be assessed.

Implementing the QA Program for Digital Intraoral Radiographic Systems

The Image Display Device

Most modern commercial off-the-shelf monitors with 1920 x 1080 display format are acceptable for viewing intraoral radiographs.[11–13] There is no need to purchase expensive medical-grade monitors capable of displaying 12-bit grayscale images that meet DICOM Part 14 grayscale display function (GSDF) requirements. Because most dental radiographic systems display their radiographic images in 8 bits with 256 shades of gray, there is little to no benefit of using medical-grade monitors. Further, most publications suggesting that DICOM Part 14 GSDF calibration is required for dental viewing monitors have been from comparisons to the medical radiology viewing rooms where viewing conditions can be rigidly controlled and maintained, but this is not practical nor possible in a dental treatment room (DTR). DTRs require lighting conditions suitable for other dental tasks. The clinical viewing display in the DTR is used only for short bursts to visualize radiographs as part of a wider clinical assessment of oral health, therefore, it is not practical for a DTR display to match the ideal medical-grade radiology monitors, calibration and viewing environments.

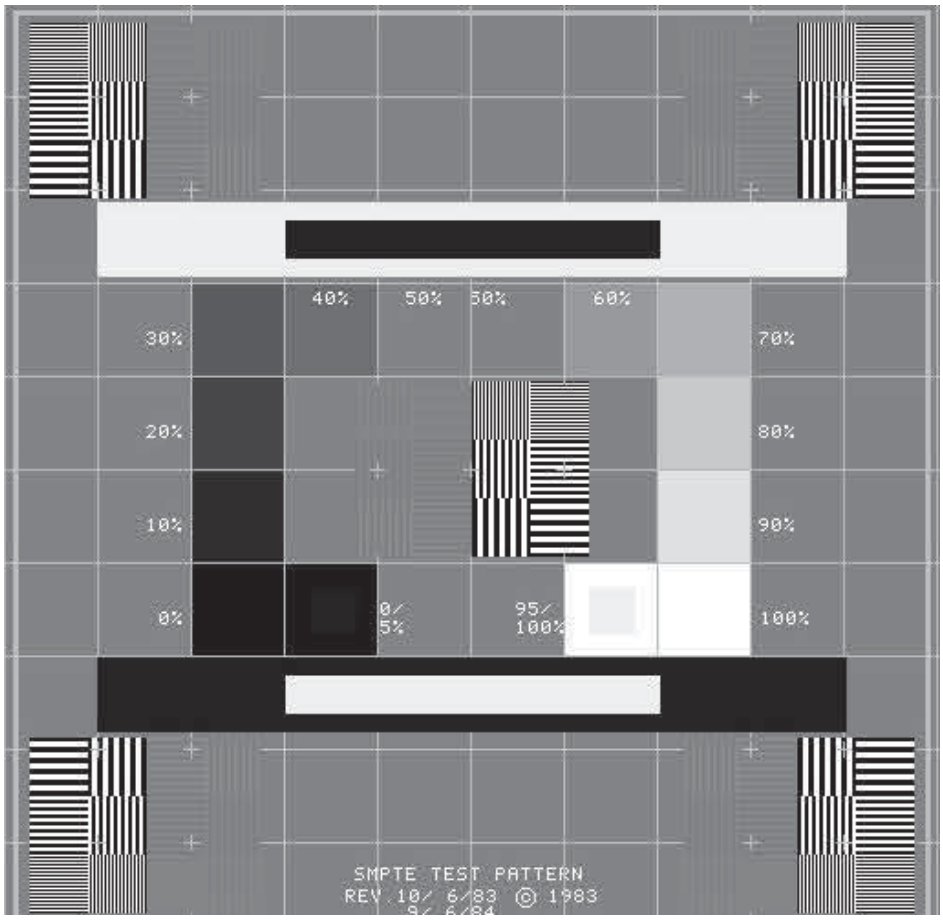

FIGURE 1. Society for Motion Picture and Television Engineers (SMPTE) Medical Diagnostic Imaging Test Pattern.

Instead, the image display device can be evaluated by displaying a standard digital image test pattern.[15] An example of such pattern is the Society for Motion Picture and Television Engineers (SMPTE) Medical Diagnostic Imaging Test Pattern and is available as freeware (**FIGURE 1**). Additionally, a vendor may provide a similar test pattern within the dental display software (**FIGURE 2**). This QA test protocol for the image display device shall be performed monthly and can be made in just a few minutes by the dentist, dental hygienist or dental auxiliary.[4,5] Proper adjustment of the image display device should be performed under proper viewing conditions (see below). The SMPTE test pattern image should be inspected for the absence of artifacts such as bleeding of bright display areas into dark areas or blurring of spatial resolution patterns.[14,15] Additionally, appropriate dynamic range can be confirmed by ensuring that both the 5% and 95% inner squares are distinct from their respective adjacent 0% and 100% outer squares.[4,5] The contrast and brightness settings of the monitor should be adjusted until all the gray levels are visible and delineation between the 5% and 0% and the 95% and 100% squares is achieved.[15]

The viewing environment, i.e., the level of ambient lighting, may affect the perceptibility of contrast differences in the digital radiograph.[12,16–18] In fact, the brighter the background lighting, the higher the screen luminance necessary for perception of grayscale changes.[18] Thus, the optimal viewing conditions are

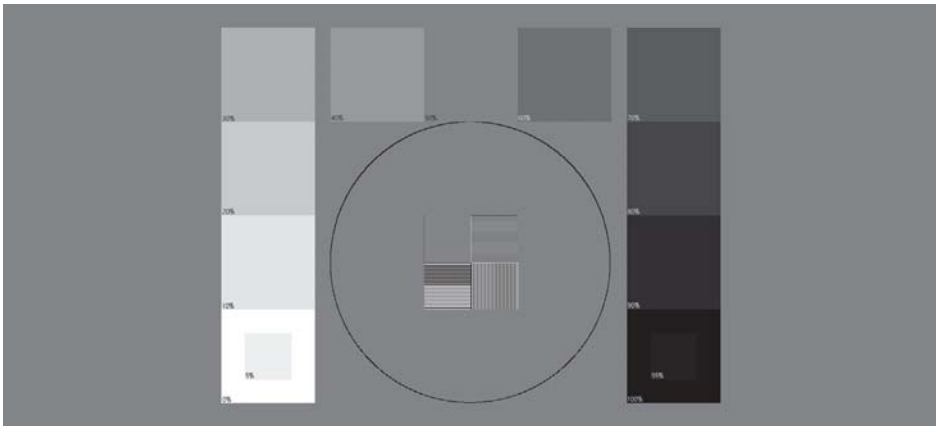

FIGURE 2. Software vendor monitor test pattern supplied with the dental display software.

FIGURE 3. Beam indicating device placed over sensor portion of a radiation meter to record intraoral X-ray generator performance.

a quiet, darkened room.[5] Additionally, the majority of the light from the display device should be from the digital image itself, therefore, use of a black background when viewing radiographs is appropriate.[4] Dimmed ambient lighting is the optimum environment for image interpretation; however, obscuring or hooding of the image display device can reduce the ambient lighting by an average of 70% and can be used if there is too much ambient lighting in the dental viewing environment.[12,19]

Most image display devices are very stable over time; however, optimizing the image display for tasks other than radiographic interpretation may affect diagnostic performance.[5] When LCD monitors are optimized for color display, the luminance of the display monitor decreases making it more difficult to discriminate grayscale differences.[20,21] Grayscale display monitors are operated at a higher luminance than color display monitors, and the loss in ability to visualize the grayscale is due to the decreased luminance that occurs.[21,22] Therefore, the use of personal color photos as screen savers is discouraged because this will cause automatic optimization of the monitor to display colors and therefore will reduce the ability of the monitor to properly display grayscale values from dental radiographs.

Intraoral X-Ray Generator

There can be confusion about the role of the state radiation inspector who inspects the radiographic equipment. These inspections are intended as safety checks to ensure that the radiographic equipment is functioning properly and, therefore, by itself does not constitute a QA program. In accordance with Standard 1094 and NCRP report 177, all X-ray generators shall be evaluated by a qualified expert prior to initial use.[3–5] This initial evaluation can be carried out by the equipment installer, a medical physicist or a state-approved radiation inspector and should be documented as part of the QA record for the device. Additionally, Standard 1094 recommends periodic constancy testing (i.e., measuring X-ray output) annually, unless there is a repair or other requirement to necessitate a shorter interval.[4,5]

Periodic constancy testing is a simple method to assess X-ray tube output and can be accomplished easily with the purchase of a modern electronic X-ray measuring device, sometimes referred to as a dosimeter, and additional training for the dental staff.[4,5] With the use of modern electronic X-ray measurement devices, the required QA tests may be completed in 10 to 15 minutes. The detector portion of the electronic X-ray meter is placed at the end of the beam indicating device (BID) and the exposure parameters utilized for the adult molar bitewing radiograph are used. These electronic X-ray meters are more than just dosimeters. With a single radiographic exposure, they provide radiation output in mR or mGy, the kVp, the exposure time in seconds, the HVL in terms of thickness of aluminum and the dose rate and number of pulses. **FIGURE 3** shows an example of an electronic radiation meter measuring intraoral X-ray generator performance. Alternatively, the dental facility may retain the services of an X-ray vendor, dental X-ray equipment repair service provider, state licensed dental X-ray inspection provider or medical physicist.

The periodic constancy testing performed by the dental facility is independent of the state-mandated tests that state inspectors may perform on the intraoral radiographic unit. The state-mandated inspections are an outside validation for the performance of the X-ray generating equipment, whereas periodic constancy testing of the X-ray output is part of the QA program included in Standard 1094. The required QA checks of the X-ray unit are specified in their respective state statutes for dental radiography. A quick reference to each of the state's applicable radiation regulations for dental imaging can be found at aaomr.org/radiation-regulations. Information for the state of California is also provided in the California Dental Association resource Radiation Safety in Dental Practice.[8] The state-mandated inspections usually consist of evaluating the X-ray generator only and, in some states, recording the entrance skin

exposure or air kerma value. Most states do not get involved with image quality.

Intraoral Image Receptor (Including Acquisition Software)

Intraoral digital image receptors should be evaluated initially (i.e., acceptance testing) and at periodic intervals. Two recent publications identified issues with new, unused intraoral image receptors.[1,23] These issues included artifacts, delamination (uncoupling of scintillator), nonuniformity (light and dark areas, dark banding) and latent images.[1,23] **FIGURES 4** and **5** provide examples of delamination and nonuniformity.

The first step in the evaluation of a digital image receptor should be a physical examination of the image receptor. Owing to differences in the construction and requirements for the physical inspection of direct capture and indirect capture receptors, these are divided into two sections.

Direct Capture Intraoral Image Receptor (CCD and CMOS) — Physical Inspection

The direct capture image receptor should be continually checked for integrity to make sure that the product is intact, not split or missing part of the protective plastic casing, the sensor wire is not frayed, broken, kinked or damaged and the computer connector is intact. Significant bitemarks on the active sensor side of the image receptor may be an indication of internal damage.

Indirect Capture Intraoral Image Receptor (PSP) — Physical Inspection

Photo-stimulable phosphor plate (PSP) inspection involves looking for obvious scratches, bitemarks and physical damage such as bent plates and separation or delamination of the phosphor layers from the base. Examples of damaged PSP plates are shown in **FIGURE 6**. Additionally, with PSP digital imaging systems, the scanner is another part of the imaging chain that must be inspected. NCRP Report 177 recommends regular cleaning of the PSP plate and scanner transport assembly as well as performing radiographic phantom tests on PSP plates every 40 exposures per plate.[3]

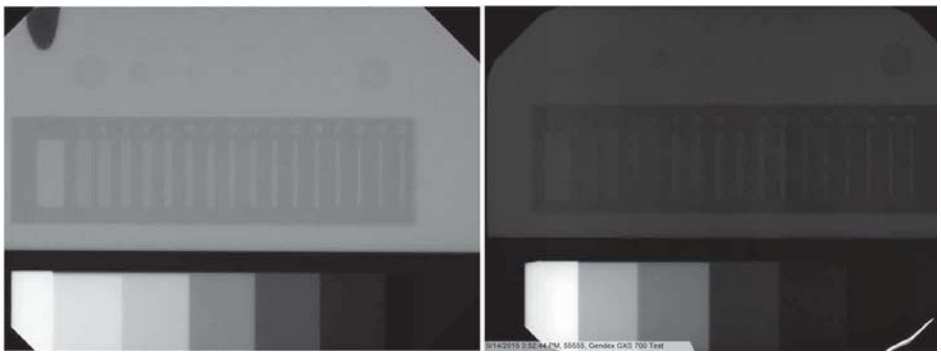

FIGURE 4. Examples of delamination with digital image receptors.

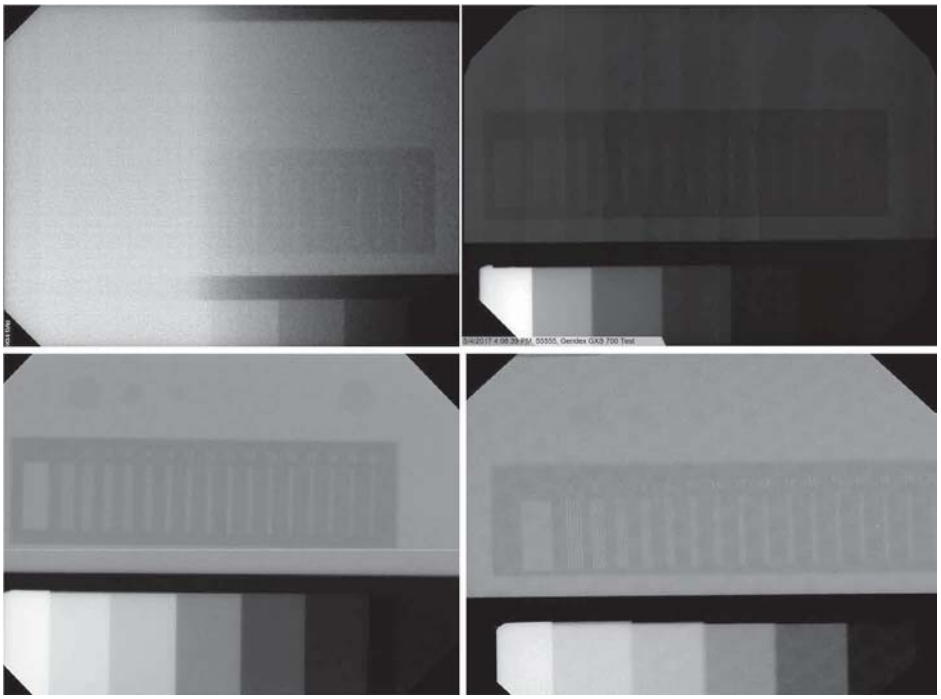

FIGURE 5. Examples of nonuniformity with digital image receptors.

Image Optimization and Radiation Dose Control

The maximum diagnostic yield of the image receptor is defined as the highest spatial and contrast resolutions achieved while maintaining visibility of the full dynamic range. The optimal exposure is defined as the exposure parameters that produce the maximum diagnostic yield for the image receptor at the lowest radiation exposure.[1,24–26] The radiographs produced at the lowest and highest radiation exposures while still maintaining the dynamic range represent the exposure range or latitude of the image receptor. The latitude of the image receptor may vary slightly depending upon the combination of components in the imaging chain such as the intraoral X-ray unit (i.e., generator), the image

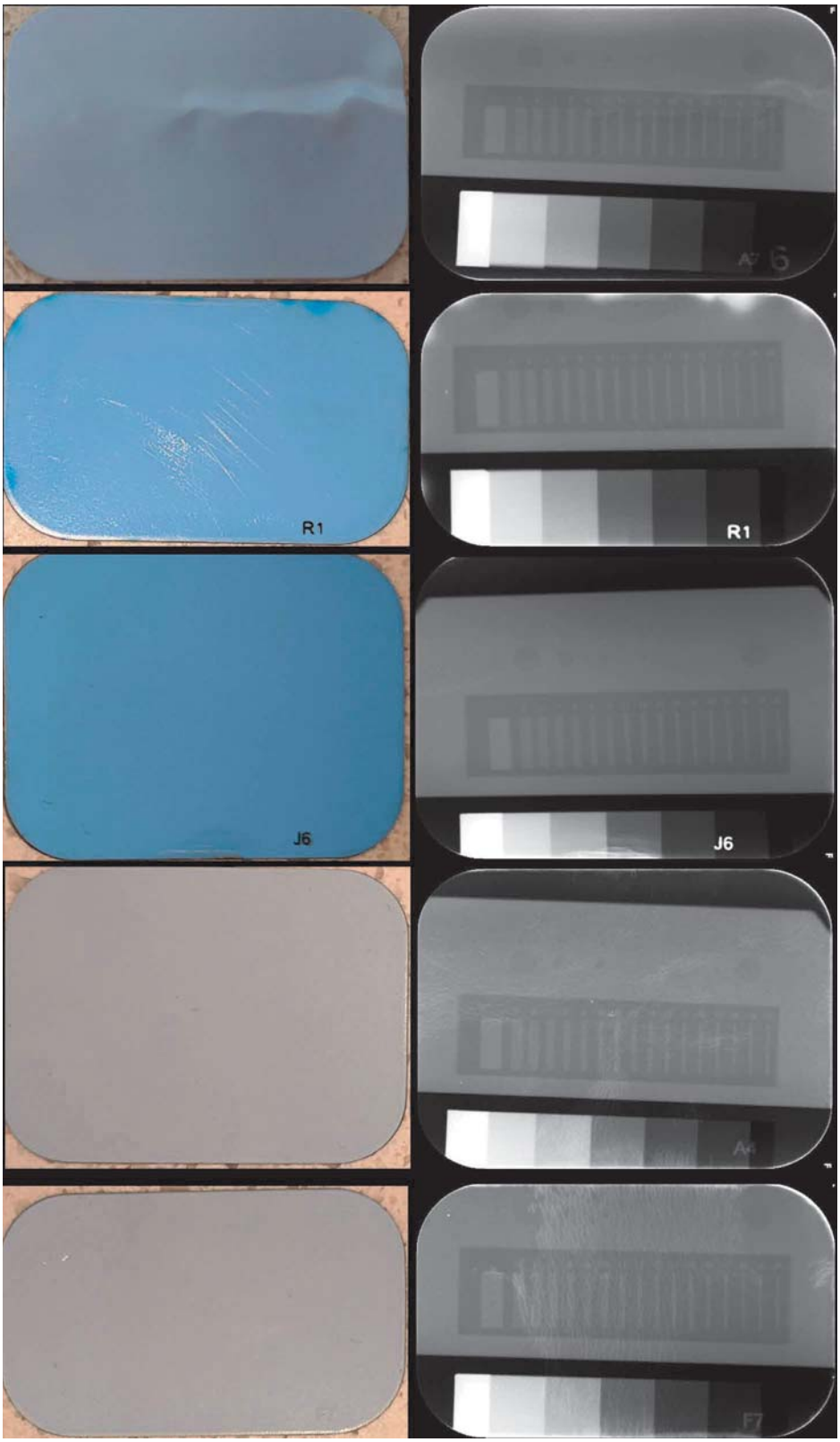

FIGURE 6. Examples of damaged PSP plates with a photograph of the PSP plate and resulting radiographic image.

acquisition software and the image display device. Even with the same brand, model and vintage of digital intraoral image receptor type, there are measurable differences in image quality using the same radiographic exposure parameters with the same X-ray generator.[25,27]

Quality Assurance Phantoms

The method to determine the optimal exposure with a radiographic phantom designed for digital intraoral radiographic systems is explained in Standard 1094, ADA TR 1094, Mah et al., Udupa et al., Walker et al., Reeves et al. and Buchanan et al.[1,4,5,24–26,28] This method works for all combinations of intraoral X-ray generators, short- and long-cone round and rectangular collimators (i.e., BIDs), image receptors (direct and indirect capture), viewing monitors and acquisition software. To determine the optimal exposure, the radiographic phantom should have repeatable projection geometry and the ability to measure the dynamic range across the entire range necessary for dental imaging (no attenuation to full attenuation of the X-ray beam), spatial resolution, contrast perceptibility and latitude.[1,3–5,14] Using a contrast detail phantom alone does not allow one to evaluate the spatial resolution, dynamic range or latitude of the intraoral radiographic system. Likewise, the use of a spatial resolution pattern alone does not allow the user to evaluate the contrast perceptibility, the dynamic range or the latitude of the intraoral radiographic system. It should also be noted that the use of an aluminum step wedge alone does not allow one to identify the optimal exposure for the image receptor (**FIGURE 7**). While gross under- and overexposure is apparent in **FIGURE 7**, there is no way to identify the optimum exposure due to the lack of measurement of spatial and contrast

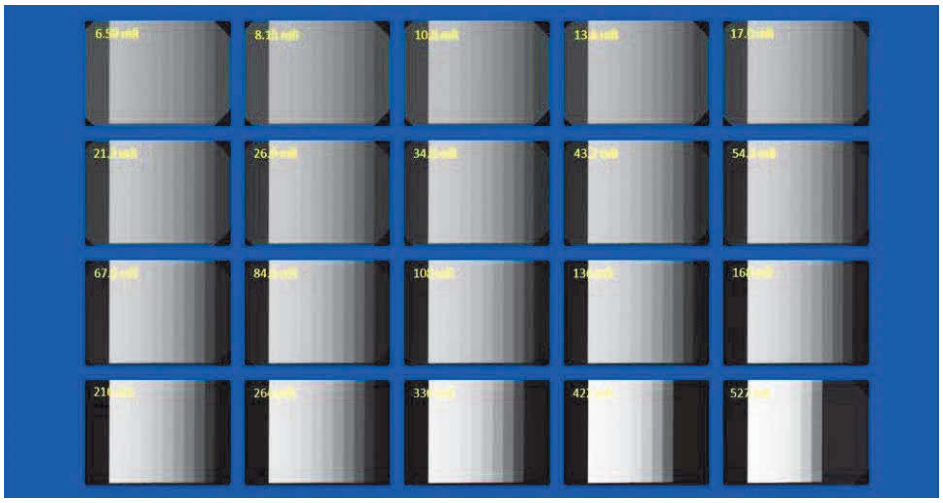

FIGURE 7. Aluminum step wedge over an incrementally increasing exposure from 6.59mR to 527mR.

resolutions and the inability to determine full dynamic range due to lack of air (no attenuation) and lead (full attenuation) steps. It is critical that the contrast perceptibility, spatial resolution and dynamic range of the intraoral radiographic system be evaluated simultaneously within the same radiographic image. Additionally, the projection geometry must simulate intraoral projection geometry to prevent erroneous errors owing to properties of the inverse square law.[3–5] The reader is cautioned to ensure that the QA phantom they acquire for their dental facility meets all the criteria mentioned above as specified in Standard 1094.

Software

It is important that there is minimal image processing from software when determining the optimal exposure for the image receptor.[1,26,29,30] One must turn off the enhancement options within the software to produce a "raw" image. In reality, this creates a minimally processed image rather than an actual raw image because some of the software enhancements are programmed by the manufacturer or installed by the digital system installer without the end-user having control over them.[30] Changes in software settings that can be made to produce a minimally processed image include setting the gamma value to 1 (a gamma value of 1 is equivalent to no gamma correction), turning off sharpening and smoothening filters and histogram adjustments.[1]

Once the optimal exposure has been determined, subsequent images can be acquired for comparison to ensure that any software filter that is applied does not result in loss of data. This allows one to assess the effects of software manipulation on diagnostic quality. A comprehensive QA program should include appropriate evaluation of the effects of software on the diagnostic quality of the image.[26] It should be stressed, however, that software changes, regardless of when in the imaging chain they are applied, should not be used in an attempt to compensate for an incorrectly exposed radiograph. Rather, one must start with a properly exposed radiograph (i.e., image optimization) in order to benefit from software adjustments.[29]

Discussion

As described in detail in this article, an effective QA program evaluates all portions of the imaging chain. The QA program should be implemented within the facility itself, as each component of the imaging chain (display device, X-ray generator and image receptor and software) can affect the ultimate image quality. Therefore, a request by the state to provide a radiographic image produced with one of the X-ray generator/image receptor combinations from the dental office is not an acceptable assessment of image quality. This one evaluation does not account for the different radiographic units (generators), different image receptors and accompanying software or the different display devices.

A review of recommendations by the state dental associations as well as the varied inspection requirements for digital intraoral radiography, illustrate the lack of consensus on effective QA protocols for digital intraoral radiographic systems.[6–10] A literature search on QA for digital intraoral radiographic systems seems just as varied with recommendations of measuring noise, signal to noise ratios, contrast to noise ratio, homogeneity, uniformity and other tests.[2,31,32]

It is clear from these practices and the lack of consensus on effective QA protocols in dentistry that there is a need for a universal QA standard for digital intraoral radiographic systems. With the introduction of Standard 1094, it is hoped that there will be a migration toward a practical and scientific approach to address this issue. "The American Dental Association (ADA) is an ANSI accredited standards developing organization. ADA standards have been approved as American National Standards by ANSI and thus they are designated as ANSI/ADA Standards. Further, ANSI is the U.S. member to ISO. The U.S. TAG for ISO/TC 106 determines the U.S. vote on all dental standards and provides this input to ANSI for ISO/TC 106."[33] As such, the ADA is the sole standards group for dentistry in the U.S. and failure to adhere to an ADA standard would be deemed as failing to meet equipment performance standard for intraoral X-ray systems. Standard 1094 will serve as the national standard for all dental facilities and should assist in consolidating an effective QA program nationwide.

Although the ADA is the dental standards organization in the U.S., not all publications from the ADA are standards and one must be able to differentiate and recognize the difference in compliance requirements of these ADA publications.[34] There are many special interest groups in addition to the ADA that propagate guidelines, practice policies, recommendations and position statements. However, strict adherence to these, unlike a standard, is not mandatory. Examples of agencies that publish guidelines, practice policies, recommendations and position statements are the National Council on Radiation Protection and Measurements (NCRP), the American Association of Physicists in Medicine (AAPM), the American Academy of Oral and Maxillofacial Radiology (AAOMR), state and local dental associations, Image Gently, Image Wisely and the ADA. Some states do adopt the guidelines issued by these special interest groups. An example of this is adoption of the radiation safety practices recommended by the NCRP by some states, and as such strict adherence would be required for those in that state.

Statutes are usually passed by an individual state to mandate those users of that technology, equipment or practice to comply with use terms as per state legislation. As mentioned previously, in cases where there is overlap or conflict between an ADA standard and the state statute, the stricter requirement prevails. State statutes are mandatory in that state only and failure to adhere to a state statute may result in warnings, fines, enforcement actions or a combination of these. As a standard is the legal duty to provide the level of care prescribed in the standard, the approval of Standard 1094 should help define QA for digital intraoral imaging on a national scale. Therefore, dental providers and personnel must understand QA in digital intraoral radiographic systems as well as accept responsibility for QA of the components used in the trusted care of their patients.

Conclusion

QA is critically important to maintaining high-quality diagnostic radiographs and in keeping with the radiation hygiene principle of ALARA. Throughout the paper, there are examples to help clinicians recognize many of the problems encountered in digital intraoral radiography. We have provided images wherever possible to help the reader visualize and appreciate the concerns. This paper presents and supports the need for a universal QA program for digital intraoral radiography given the varied and sometimes conflicting recommendations for digital intraoral radiography QA processes. ■

Note: No financial support was received from any external source or vendor for this project. This research did not receive any specific grant from funding agencies in the public, commercial or nonprofit sectors.

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