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American Dental Association

Technical Report No. 1094

Quality Assurance for Digital Intra-Oral Radiographic Systems

ADA American Dental Association®

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AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT. NO. 1094 FOR QUALITY ASSURANCE FOR DIGITAL INTRA-ORAL RADIOGRAPHIC SYSTEMS

The ADA Standards Committee on Dental Informatics (SCDI) has approved American Dental Association Technical Report No. 1094 for Quality Assurance for Digital Intra-Oral Radiographic Systems. Working Groups of the ADA SCDI formulate this and other specifications and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information technology and other electronic technologies used in dental practice. The ADA SCDI confirmed approval of ADA Technical Report No. 1094 on May 31, 2017.

ADA Technical Report No. 1094 was prepared by ADA SCDI Working Group 12.1 on Digital Imaging at the request of Jonathan Knapp, chairman, ADA SCDI Subcommittee on Information Exchange. The ADA SCDI thanks the members of Working Group 12.1 and the organizations with which they were affiliated at the time the specification was developed:

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FOREWORD

(This Foreword does not form a part of ADA Technical Report No. 1094 for Quality Assurance for Digital Intra-Oral 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, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession.*

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 intra-oral radiography, quality assurance entails the consistent production of x-ray images of high quality in order to provide the maximum amount of diagnostic information with minimal radiation exposure to the patient. The relationship between diagnostic information and radiation to the patient is critically important. Decreasing the radiation dose to the patient, resulting in the loss of diagnostic information is not a good practice. Inversely, increasing the radiation dose to produce a more aesthetically pleasing image, with little or no significant increase in diagnostic information, also is not a good practice. A balance must be made between these two factors.

The concept of Diagnostic Reference Level (DRL) was first introduced in 1996 by the International Commission on Radiological Protection (ICRP Publication 73, 1996). DRLs provide a means for practices to compare their radiation dose data to benchmarks derived from aggregated dose data collected on a local, regional or national level. Their recommendation was that if any radiographic procedure within a practice consistently exceeded the relevant diagnostic reference level, a review of procedures and equipment should be undertaken to determine whether the procedure has been adequately optimized. If not, measures aimed at reduction of the doses should be taken. Diagnostic Reference Levels are not the suggested or ideal dose for a particular procedure or an absolute upper limit for dose. They should be used as part of a quality assurance program to ensure that radiation doses used in a dental practice are consistent with other dental practices for the same radiographic procedures. The National Council on Radiation Protection has established the diagnostic reference level for intra-oral periapical and bitewing radiography as 1.6 mGy (183 mR) entrance skin dose.

While most states and regulatory bodies have guidelines which state that quality assurance of all radiographic equipment be performed, these guidelines were primarily developed for x-ray film and not digital imaging technology. Today, a growing percentage of practicing dentists use some form of digital intra-oral radiographic system for aiding their clinical diagnosis. Therefore, the need for an effective quality assurance protocol for digital intra- oral radiographic imaging is critical to the care of patients. The purpose of this technical report is to establish clear and concise protocols to ensure adequate quality assurance for digital intra-oral radiography.

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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.

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1 SCOPE

There are essentially three components involved with any intra-oral digital imaging system: the intra-oral x-ray source, the image display device (computer/monitor and display- software), and the digital image acquisition device (solid-state sensor or PSP imaging plate and scanner, and associated acquisition-software). Each of these components will be addressed in this technical report.

2 REFERENCES

National Council on Radiation Protection and Measurements. NCRP Report No. 145 Radiation Protection in Dentistry. 2003

National Council on Radiation Protection and Measurements. NCRP Report No. 172 Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States. 2012

International Commission on Radiological Protection. ICRP Report No. 73 Radiological Protection and Safety in Medicine. 1996

American Association of Physicists in Medicine. AAPM Task Group 175 Report Acceptance Testing and Quality Control of Dental Imaging Equipment. 2016

3 TERMS AND DEFINITIONS

CCD - Charged Coupled Device

CMOS - Complementary Metal Oxide Semiconductor PSP - PhotoStimulable Phosphor

Contrast Resolution - the ability of an imaging system to distinguish between differences in x- ray intensity in an image.

Contrast Detail Detectability - the ability to detect small changes in radiographic densities of objects with varying size.

Diagnostic Reference Level - 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.

Dynamic Range - the range of x-ray intensities that an image receptor can capture simultaneously.

ICRP - International Commission on Radiological Protection

NCRP - National Council on Radiation Protection

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

SMPTE - Society of Motion Picture and Television Engineers

Spatial Resolution - the ability of an imaging system to discriminate between two adjacent high- contrast objects, generally measured in line pairs per mm (lp/mm)

4 TEST METHODS

Intra-oral X-Ray Source

The tube potential, exposure time accuracy and reproducibility, x-ray filtration, half-value layer, tube output and reproducibility, x-ray beam collimation/alignment and beam stability should be evaluated by a qualified expert or the original equipment installer as part of the initial equipment acceptance testing. All parameters should be within the manufacturer's allowed variance from the nominal specification. A written report should be provided by the expert or original equipment installer.

Periodic testing and calibration should be performed thereafter. The simplest and most effective quality assurance