

American Dental Association
Specification No. 26

Dental X-Ray Equipment

ADA American
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Council on
Scientific Affairs

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REVISED AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 26 FOR DENTAL X-RAY EQUIPMENT

The Council on Scientific Affairs of the American Dental Association has reaffirmed American Dental Association Specification No. 26 for Dental X-Ray Equipment. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. Approval of Revised ADA Specification No. 26 as an American National Standard was granted by the American National Standards Institute on October 11, 1991 and subsequently reaffirmed on April 23, 1999. This document was withdrawn as an American National Standard and was reaffirmed as ADA Specification No. 26 in March 2009.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Charles Schoenfeld (Chairman), American Dental Association, Chicago, IL; Robert Avrutik, Philips Medical system, Inc., Shelton, CT; Robert Bloxom, U.S. Air Force, Brooks AFB, TX; Nicholas Braico, Gilberts, IL; W. Doss McDavid, University of Texas HSC, San Antonio, TX; Judy McVey, Rinn Corporation, Elgin, IL; B. Keith Moore, Indiana University, Indianapolis, IN; Ronald Newman, Morita Corporation, Culver City, CA; Alan Reiskin, University of Connecticut, Farmington, CT; Harry Schwill, Siemens Corporation, Iselin, NJ; and Stuart White, University of California, Los Angeles, CA.

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FOREWORD

(This Foreword does not form a part of ADA Specification No. 26 for Dental X-Ray Equipment)

The principal changes in this revision of Specification No. 26 are as follows:

1. Redundancies with the FDA Performance Standard have been removed. Requirements for timer accuracy, kilovoltage tolerance, and milliamperage tolerance have also been removed even though they do not explicitly appear as requirements in the FDA Performance Standards because these factors are encompassed within the radiation exposure reproducibility requirements of the FDA Performance Standard. On the other hand, the radiation exposure reproducibility requirement only provides for intra-unit reproducibility but not inter-unit reproducibility. Accordingly, a requirement to state the inter-unit radiation output tolerance has been retained.[5.1 (f)].
2. The designation of types and classes has been removed because none of the requirements were unique to specific types and classes.
3. The dependence of reach and range requirements upon minimum source to distal end of position indicating device distances has been eliminated because there appeared to be no rationale for the dependence.
4. In view of the fact that many x-ray units for intraoral radiography are constant potential or high frequency continuous discharge, the reference to American National Standard exposure time designation for times of dental x-ray machines has been eliminated because it is only applicable to 60 or 50 hertz half wave rectified units. A suggestion for providing suitable exposure time increments has been added to this specification (3.3.2).

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1. GENERAL CONSIDERATIONS

- 1.1 **Scope.** This specification applies to diagnostic x-ray equipment used for intraoral radiography.
- 1.2 **General design and construction.** Dental x-ray equipment shall include an x-ray source assembly, a means for supporting and for positioning the x-ray source assembly, and a means for controlling the x-ray exposure technique factors.

The system may be designed to incorporate one or more remotely located x-ray source assemblies.

2. APPLICABLE DOCUMENTS

- 2.1 **Reference documents.** The following specifications, standards, codes, or other publications, or the latest revisions thereof, should be consulted:
- (a) U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Performance Standard - Diagnostic X-ray Systems and Their Major Components. (Publication as Title 21, Code of Federal Regulations Chapter 1, Subchapter J, parts 1020.30, 1020.31, and 1020.32.) Copies may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.)
 - (b) American National Standard C33.67-1971, Safety Standard for X-ray equipment (UL 187-January 1971; Copies of American National Standard C33.67-1971 may be obtained from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036.)
 - (c) National Electrical Manufacturers Association, Standards Publication/No. XR5-1984, "Measurement of Dimensions of Focal Spots of Diagnostic X-Ray Tubes; (Copies may be obtained from the National Electrical Manufacturers Association, 2101 L Street, N.W., Suite 300, Washington, DC 20037).
 - (d) International Electrotechnical Commission, IEC Recommendation 336 (1982) Measurement of Dimension of Focal Spots of Diagnostic X-Ray Tubes Using a Pinhole Camera; (Copies may be obtained from the American National Standards Institute, 25 West 43rd Street, New York, NY 10036.)

3. DEFINITIONS

- 3.1 **Intraoral radiography.** Radiography whereby the image receptor is positioned intraorally.