ANSI/ADA Specification No. 69
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American National Standard/
American Dental Association
Specification No. 69

Dental Ceramic

Modified adoption of ISO 6872:1995, Dental ceramic

American Dental Association
Council on Scientific Affairs 1999

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 69 FOR DENTAL CERAMIC

American Dental Association Specification No. 69 for Dental Ceramic has been approved by the Council on Scientific Affairs of the American Dental Association. 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 ADA Specification No. 69 as an American National Standard was granted by the American National Standards Institute on December 29, 1999. This standard becomes effective December 29, 2000.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: J. Robert Kelly (Chairman), NIST, Gaithersburg, MD; Ramon Baez, University of Texas Health Science Center at San Antonio, TX; Michael Bagby, West Virginia University, Morgantown; Tom Cameron, Ney Dental, Inc., Bloomingfield, CT; Ronald Dudek, Austenal, Inc., Chicago, IL; Lawrence Gettleman, University of Louisville, KY; Steven Hondrum, Martinez, GA; Clyde Ingersoll, Tonawanda, NY; Abdul Khan, CMP Industries, Albany, NY; J. Rodway Mackert Jr., Medical College of Georgia, Augusta; Carl Panzera, American Thermocraft Corp., Somerset, NJ; Arun Prasad, Jeneric Pentron, Inc., Wallingford, CT; Carolyn Primus, Ceramco, Inc., Burlington, NJ; Monty Reiger, University of Texas Health Science Center at Houston; TX; and Nikhil Sarkar, Louisiana State University, New Orleans.

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FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification 69 for Dental Ceramic)

This specification is essentially an adoption of the ISO 6872:1995 as modified by amendment and corrigendum. Both the amendment and related corrigendum deal with radioactivity assessment and limits. The U.S. delegation to ISO TC106 was instrumental in developing the corrigendum, in response to data from and concerns expressed by U.S. ceramics manufacturers.

Revisions to ISO 6872:1995 resulting from the combined amendment and corrigendum are detailed below:

Clause 5.2.2 is deleted and replaced by the following:

5.2.2 Dental ceramic materials shall not have an activity concentration of more than 1.0 Bq/g of uranium 238. Test according to clause 8.2.2.

Clause 8.2.2 is deleted and replaced by the following:

8.2.2 Counting procedure

Use a sample volume of 60 ml bulk powder and determine the activity concentration of uranium 238 by neutron activation.

INTRODUCTION

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this specification but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1:1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests, or to ISO/TR 7405:1984 Biological Evaluation of Dental Materials, or any more recent edition.

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1. SCOPE

This standard specifies the requirements and corresponding test methods for dental ceramic materials for all fixed ceramic restorations.

2. NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of the ISO maintain registers of currently valid International Standards.

ISO 3696:1987 Water for Analytical Laboratory Use—Specification and Test Methods

ISO 4799:1978 Laboratory Glassware—Condensers

3. DEFINITIONS

For the purposes of this standard, the following definitions apply:

3.1 Air-Fired Dental Ceramic

Dental ceramic fired under ambient atmospheric pressure.

3.2 Batch Lot

Defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

3.3 Castable Dental Ceramic

Dental ceramic specially prepared to be cast using a lost wax process.

3.4 Class of Dental Ceramic

Classification of a dental ceramic according to its intended use.

3.5 Condensation of Dental Ceramic

Any process by which dental ceramic is compacted before firing.

3.6 Core Dental Ceramic

Dental ceramic that provides a supporting structure for building up a ceramic restoration.

3.7 Dental Ceramic

Material specifically prepared for the fabrication of ceramic prostheses and restorations.

3.8 Dental Ceramic Stain

Highly pigmented dental ceramic used for a ceramic restoration or prosthesis to simulate the details of color and/or appearance of a natural tooth.