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Recommended Standard Practices for Biological Evaluation of Dental Materials

American Dental Association
Council on Scientific Affairs 1979

AMERICAN NATIONAL STANDARDS /AMERICAN DENTAL ASSOCIATION DOCUMENT NO. 41 FOR RECOMMENDED STANDARD PRACTICES FOR BIOLOGICAL EVALUATION OF DENTAL MATERIALS

American Dental Association Document No. 41 for Recommended Standard Practices for Biological Evaluation of Dental Materials has been approved by the Council on Dental Materials, Instruments and Equipment of the American Dental Association. The formulation of this document and other specifications for dental materials and devices is being carried on through subcommittees of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council on Dental Materials, Instruments and Equipment acts as the administrative sponsor of the committee, which 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 Document No. 41 as an American National Standard was granted by the American National Standards Institute on June 11, 1979. This document became effective October, 1980 after publication in *The Journal of the American Dental Association* in October, 1979.

The Council acknowledges, with thanks, the work of the subcommittee members who formulated the standard: Harold R. Stanley (chairman), University of Florida, Gainesville, Florida; Ray L. Bowen, National Bureau of Standards, Washington, D.C.; John Autian, University of Tennessee, Memphis, Tennessee; C. T. Bonfield, Hazelton Laboratories, Falls Church, Virginia; Emery Dougherty, L. D. Caulk Company, Milford, Delaware; J. David Eick, Oral Roberts University, Tulsa, Oklahoma; John F. Glenn, Milford, Delaware; Derrick Griffiths, ICI United States, Inc., Wilmington, Delaware; R. S. Kennedy, Bureau of Medical Devices, Food and Drug Administration; Kaare Langeland, University of Connecticut, Farmington, Connecticut; Richard L. Myerson, Howmedica Dental Research, Groton, Massachusetts; Allen C. Rossi, Bureau of Medicine, Food and Drug Administration; Gunnar Ryge, University of the Pacific, San Francisco, California; R. J. Schlesinger, Bio-Technics Laboratories, Los Angeles, California; D. A. Wallace, Wilmette, Illinois; and H. A. Zander, Eastman Dental Dispensary, Rochester, New York.

method of testing dosages and physical characteristics play an important role. When a product does produce positive results and a "red flag", the recommendation is to contact one of those laboratories most experienced in carcinogenic testing for appropriate advice. Guidelines for carcinogenic bioassays in small rodents are periodically being updated by the National Cancer Institute at Bethesda, Maryland.

Several "usage preclinical tests" are listed in Table I. Comments have been made that the list is incomplete and this is very true. The examples presented are there because they have been used by many investigators. It would be useless to predict the proper usage test for all potential products. Each will require its own relevant and reasonable test design to be worked out between the producer and his biological consultants.

Use of this document in Certification and/or Acceptance Programs of the Council on Dental Materials, Instruments and Equipment of the American Dental Association: For purposes of evaluation of materials under the Council on Dental Materials, Instruments and Equipment programs, this document will replace the "Recommended Standards Practices for Biological Evaluation of Dental Materials" published in the February 1972 issue of *The Journal of the American Dental Association*. Products and materials that are already on the market and which are similar to products on the American Dental Association List of Certified Dental Materials, Instruments and Equipment or List of Classified Dental Materials, Instruments and Equipment, and have been used for years without problems or complaints will not require re-evaluation. Only if the ingredients are changed in an unknown direction or if one of the original ingredients is varied in concentration by more than 5% will there be a need for re-evaluation. (See section 4.1)

As stated in 1972, we do not want to discourage industrial development needed to provide new or improved materials for dentistry, but we do need biological test guidelines to follow. Any suggestions as to how the requirements and the costs of testing can be reduced will be appreciated.

AMERICAN NATIONAL STANDARDS /AMERICAN DENTAL ASSOCIATION DOCUMENT NO. 41 FOR RECOMMENDED STANDARD PRACTICES FOR BIOLOGICAL EVALUATION OF DENTAL MATERIALS

1. SCOPE AND CLASSIFICATION

1.1 *Scope.* This document covers recommended standard practices for biological evaluation of the safety of materials used in dentistry and is not intended for use in the evaluation of pharmacologically active medicaments.

1.2 *CLASSIFICATION*

1.2.1 *Types and Classes*

Type I. Restorative materials

- Class 1. Metallic materials
  - 1 a. Amalgam
  - 1 b. Alloys for inlays
- Class 2. Nonmetallic materials
  - 2 a. Resin materials
  - 2 b. Silicate materials
  - 2 c. Temporary materials
- Class 3. Cavity liners and bases
- Class 4. Cements
  - 4 a. Zinc phosphate
  - 4 b. ZOE and EBA
  - 4 c. Polycarboxylate
  - 4 d. Silico-phosphate
  - 4 e. Resin
- Class 5. Sealants (pit and fissure)
- Class 6. Reagents for pretreatment of enamel and/or dentin.
  - 6 a. Etchants
  - 6 b. Primers
  - 6 c. Cavity cleansers
  - 6 d. Desensitizers
- Class 7. Coatings for external surfaces of restorations.

Type II. Prosthetic materials*

- Class 1. Impression materials
  - 1 a. Hydrocolloids and alginates
  - 1 b. Rubber base

*Cements included in Type I, Class 4