

Radiological Health (HFZ-84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4766, ext. 156.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of guidance entitled "Recognition and Use of Consensus Standards." This notice described how FDA will implement its standard recognition program and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617); July 12, 1999 (64 FR 37546); November 15, 2000 (65 FR 69022); May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774), and October 2, 2002 (67 FR 61893), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA.

The agency maintains "html" and "pdf" versions of the list of "FDA Recognized Consensus Standards." Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information.

II. Modifications to the List of Recognized Standards, Recognition List Number: 008

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of "FDA Recognized Consensus

Standards" in the agency's searchable database. FDA will use the term "Recognition List Number: 008" to identify: (1) Supplementary information sheets for standards added to the list for the first time, (2) standards added to replace withdrawn standards, (3) recognized standards for which minor revisions are made to clarify the application of the standards, and (4) standards withdrawn with no replacement.

In the following charts, FDA describes: (1) Modifications that involve the withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the addition of certain recognized standards with revisions to the supplementary information sheets involving changes in significant applications of the standards.

In section III, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

A. Anesthesia

Old Item No.	Standard	Change	Replacement Item No.
12	ISO 5361:1999 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Withdrawn and replaced with newer version.	35
13	ISO 5361-2:1993 Tracheal Tubes—Part 2: Oro-tracheal and Naso-tracheal tubes of Magill Type (plain and cuffed).	Withdrawn and integrated into another standard.	(35)
14	ISO 5361-3:1984 Tracheal Tubes—Part 3: Murphy Type.	Withdrawn and integrated into another standard.	(35)
16	ISO 5361-5:1984 Tracheal Tubes—Part 5: Requirements and Methods of Test for Cuffs and Tubes.	Withdrawn and integrated into another standard.	(35)
17	ISO 5366-3:2001 Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 3: Paediatric tracheostomy tubes.	Withdrawn and replaced with newer version.	36
26	CGA C-9:1988 Edition: 3 Title: Standard Color Marking of Compressed Gas Containers Intended for Medical Use.	Withdrawn and replaced with newer version.	37
27	CGA V-1:2001 Edition: 9 Title: Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections.	Withdrawn and replaced with newer version.	38
28	CGA V-5:2000 Edition: 4 Title: Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications).	Withdrawn and replaced with newer version.	39
29	CGA V-7.1: 1997 Edition: 1 Title: Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases.	Withdrawn and replaced with newer version.	40
22	NFPA 99 Standard for Health Care Facilities CHAPTER 19—Hyperbaric Facilities.	Withdrawn and replaced with newer version.	41