will continue to provide services to the families to ensure the children's safety and work towards successful reunification.

The State plans to operate this demonstration project in rural counties including Boone, Cabell, Clay, Jackson, Roane, Kanawha, Lincoln, Mason, Mingo, Putnam, and Wayne. The target population includes all youth ages 0–18 who would likely enter formal foster care if their parents do not receive substance abuse treatment, according to formal risk assessments.

The State is requesting a waiver of the placement standards and eligibility requirements. West Virginia plans to assess the impact of the five year demonstration using a random assignment evaluation design.

Contact Person: Ann Burds, Director, Bureau for Children & Families/Office of Social Services, Department of Health and Human Resources, State Capital Complex, Building 6, room 850, Charleston, West Virginia 25305, Phone: (304) 558–7980, Fax: (304) 558–8800.

Dated: July 7, 1999.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 99–17655 Filed 7–9–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the publication of modifications to the list of standards that will be recognized for use in the premarket review process. This will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: This recognition of standards is effective on July 12, 1999; however, written comments concerning this document may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of ''Modifications to the List of Recognized Standards'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the listed contact person. Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed via the Internet at FDA's web site ''http://www.fda.gov/cdrh/fedregin.html''. See the **SUPPLEMENTARY INFORMATION** section for electronic access to ''Guidance on the Recognition and Use of Consensus Standards,'' the current list of ''FDA Recognized Consensus Standards Appendix A,'' and other standards related information.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: James J. McCue, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 101.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d) to allow the agency to recognize consensus standards established by international and national standards development 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 a guidance document entitled ''Recognition and Use of Consensus Standards,'' which describes how FDA will implement that part of FDAMA. The February 1998 notice also provided the initial list of recognized standards.

In a notice published in the **Federal Register** of October 16, 1998 (63 FR 55617), FDA made modifications to the initial list of recognized standards. This October 1998 notice described the changes made in the initial list and also provided a listing of the ''Modifications to the List of Recognized Standards.''

II. Discussion of Modifications to the List of Recognized Standards

Modifications to the list of consensus standards to be recognized for use in premarket review and to meet other requirements are presented in a listing at the end of this notice.

Modifications identified in the listing include: (1) The initial addition of certain recognized standards not previously identified by FDA; (2) the addition of certain recognized standards in conjunction with the withdrawal of other previously recognized standards and their replacement by later, amended, or different standards; and (3) the addition of certain recognized standards with revisions to the supplementary information sheets for the standards, involving changes in significant applications of the standards, e.g., changes in the extent of recognition.

The listing of modifications presented at the end of this document does not include minor revisions which the agency is making in certain previously recognized standards. These revisions are made for editorial, corrective, or technical purposes, such as adding a previously omitted date, or changing the contact person(s) in the supplementary information sheet for a recognized standard. Particular minor revisions in the specific recognition of standards are described in the following paragraphs.

As noted previously, FDA is making modifications to the list of recognized standards that represent the initial addition of certain standards not previously recognized by the agency. These additions are identified in the listing presented at the end of this document and are not otherwise described.

Modifications that FDA is making, which represent the addition of certain recognized standards in conjunction with the withdrawal of other standards, or with changes in significant applications of the standards, are also identified in the listing at the end of this document. However, the agency is further describing the actions it is taking in making these additions, and in sections II.A through H of this document it is identifying the minor revisions it is making in certain recognized standards.

A. Generally Applicable Standards

1. ANSI/AAMI/ISO 10993–1 and ISO 10993–1 are withdrawn, under previous items 1 and 3,[1] respectively, from the list of recognized consensus standards. The latest version of the standard ISO 10993–1 (1997) is added, under current

[1] Item numbers identify entries in the ''FDA Recognized Consensus Standards Appendix A.'' Within each grouping, entries begin with item 1. Item numbers are not repeated if an entry is withdrawn, replaced, or added.

item 13, to the list of recognized standards.

2. EN 1441 (1997) is withdrawn, under previous item 9, from the list of recognized consensus standards. EN 1441 (1997) is added back, under current item 21, to the list of recognized standards, with changes to the extent of recognition and relevant guidances made in the supplementary information sheet(s) for the recognized standard.

B. Anesthesia

1. IEC 60601–2–13 (1998–05) is withdrawn, under previous item 10, from the list of recognized consensus standards. This 1998 version of the standard is not yet finalized. The latest version of the standard IEC 60601–2–13 (1989) is added, under current item 30, to the list of recognized standards.

C. Biocompatibility

1. ANSI/AAMI/ISO 10993–12 (1996) is withdrawn, under previous item 22, from the list of recognized consensus standards. ANSI/AAMI/ISO 10993–12 (1996) is added back, under current item 28, with changes to the extent of recognition made in the supplementary information sheet(s) for the recognized standard.

2. ANSI/AAMI/ISO 10993–5 (1993) is withdrawn, under previous item 17, from the list of recognized consensus standards. ANSI/AAMI/ISO 10993–5 (1998) is added, under current item 29, to the list of recognized standards.

3. ASTM F720–81 (r1996) is withdrawn, under previous item 8, from the list of recognized consensus standards. ASTM F720–81 (r1996) is added, under current item 30, to the list of recognized standards, with changes to the extent of recognition made in the supplementary information sheet(s) for the recognized standard.

4. USP 23, ''Biological Reactivity Tests, In Vivo, Classification of Plastics, Sample Preparation (88),'' is withdrawn, under previous item 26, from the list of recognized consensus standards. USP 23, ''Biological Reactivity Tests, In Vivo, Classification of Plastics, Sample Preparation (1988),'' is added back, under current item 31, to the list of recognized standards, with changes to the extent of recognition made in the supplementary information sheet(s) for the recognized standard.

5. ASTM F750 is withdrawn, under previous item 10, from the list of recognized consensus standards. The latest version of the standard ASTM F750–96 is added, under current item 32, to the list of recognized standards.

6. ASTM E1372–90 is withdrawn, under previous item 4, from the list of recognized consensus standards. ASTM E1372–95 is added, under current item 33, to the list of recognized standards.

7. ASTM F749–87 (r1996) is withdrawn, under previous item 9, from the list of recognized consensus standards. The latest version of the standard ASTM F749–98 is added, under current item 34, to the list of recognized standards.

8. ASTM F763–87 is withdrawn, under previous item 11, from the list of recognized consensus standards. ASTM F763–87 (1993) is added, under current item 35, to the list of recognized standards.

9. ASTM F1408–92 is withdrawn, under previous item 15, from the list of recognized consensus standards. ASTM F1408–97 is added, under current item 36, to the list of recognized standards.

D. Cardiovascular/Neurology

1. ASTM F75–92 is withdrawn, under previous item 6, from the list of recognized consensus standards. ASTM F75–98 is added, under current item 21, to the list of recognized standards.

2. ASTM F90–96 is withdrawn, under previous item 7, from the list of recognized consensus standards. ASTM F90–97 is added, under current item 22, to the list of recognized standards.

3. ASTM F136–96 is withdrawn, under previous item 8, from the list of recognized consensus standards. ASTM F136–98 is added, under current item 23, to the list of recognized standards.

4. ASTM F560–92 is withdrawn, under previous item 10, from the list of recognized consensus standards. ASTM F560–98 is added, under current item 24, to the list of recognized standards.

E. General Plastic Surgery/General Hospital

1. IEC 60601–2–19 (1990–12) is withdrawn, under previous item 7, from the list of recognized consensus standards. IEC 60601–2–19 (1996) is added, under current item 29, to the list of recognized standards.

2. IEC 60601–2–20 (1990–12) is withdrawn, under previous item 8, from the list of recognized consensus standards. IEC 60601–2–20 (1996) is added, under current item 32, to the list of recognized standards.

3. USP 21, ''Absorbable Surgical Sutures,'' is withdrawn, under previous item 22, from the list of recognized consensus standards. The latest version of USP 23, ''Absorbable Surgical Sutures,'' is added, under current item 40, to the list of recognized standards.

4. USP 21, ''Nonabsorbable Surgical Sutures,'' is withdrawn, under previous item 23, from the list of recognized consensus standards. The latest version of USP 23, ''Nonabsorbable Surgical Sutures,'' is added, under current item 41, to the list of recognized standards.

5. USP 21, ''Sutures—Diameter <861>,'' is withdrawn, under previous item 24, from the list of recommended consensus standards. USP 23, ''Sutures— Diameter <861>,'' is added, under current item 42, to the list of recognized standards.

6. USP 21, ''Sutures Needle Attachment <871>,'' is withdrawn, under previous item 25, from the list of recognized consensus standards. USP 23, ''Sutures Needle Attachment <871>,'' is added, under current item 43, to the list of recognized standards.

7. USP 21, ''Tensile Strength <881>,'' is withdrawn, under previous item 26, from the list of recognized consensus standards. USP 23, ''Tensile Strength <881>,'' is added, under current item 44, to the list of recognized standards.

F. Ob-Gyn/Gastroenterology

1. ASTM D3492–96 was inadvertently listed twice and is withdrawn, under previous items 2 and 15, from the list of recognized consensus standards. The latest version of the standard ASTM 3492–97 is added, under current item 17, to the list of recognized standards, with changes to the extent of recognition made in the supplementary sheet(s) for the recognized standard.

2. For ISO Standards for ''Rubber Condoms,'' Parts 1 through 9, specifically: ISO 4074–1:1996(E), ISO 4074–2:1994(E), ISO 4074–3:1994(E), ISO 4074–5:1996(E), ISO 4074–6:1996(E), ISO 4074–7:1996(E), and ISO 4074–9:1996(E), which were identified under previous items 8 through 14, respectively, on the list of recognized consensus standards, the FDA technical contact person has been changed on the supplementary information sheets for the recognized standards. These standards remain identified under current items 8 through 14 on the list of recognized standards.

G. Ophthalmic

1. For ISO 10942 listed, under previous item 13, on the list of recognized consensus standards, the previously omitted publication date of 1988 has been added. ISO 10942:1998 remains identified, under current item 13, on the list of recognized standards.[2]

H. Sterility

1. ANSI/AAMI/ISO 10993–7:1995 is withdrawn, under previous item 23, from the list of recognized consensus

[2] These minor revisions are not identified in the listing of ''Modifications to the List of Recognized Standards,'' but are to be included in the current list in the ''FDA Recognized Consensus Standards Appendix A.''

standards. ANSI/AAMI/ISO 10993–7:1995 is added, under current item 37, to the list of recognized standards, with changes to the extent of recognition made in the supplementary information sheet(s) for the recognized standard.

III. List of Recognized Standards

The complete list of consensus standards to be recognized for use in premarket review and to meet other requirements is contained in the document, ''FDA Recognized Consensus Standards Appendix A.'' The modifications and minor revisions to the list of recognized standards set forth in this document are to be incorporated in that document, which is maintained on the FDA World Wide Web (WWW) site, ''http://www.fda.gov/cdrh/modact/recstand.html''. Also posted on the WWW site are supplementary information sheets for each recognized standard. These information sheets list the address(es) where the standard can be obtained, information on any limitations on the application of the standard in medical device review or in satisfying other regulatory requirements, and a list of devices for which declarations of conformity with the recognized standard will be routinely accepted by agency reviewers. In addition to these documents, the WWW site contains answers to frequently asked questions regarding the use of recognized standards.

Additional modifications and minor revisions, as needed, to the list of recognized consensus standards will be announced in the **Federal Register** once a year, or more often if necessary.

IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (address above). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

In order to receive the guidance entitled ''Guidance on the Recognition and Use of Consensus Standards,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 321, followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of the guidance may also do so by using the WWW. CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the ''Guidance on the Recognition and Use of Consensus Standards,'' as well as the current list in the ''FDA Recognized Consensus Standards Appendix A,'' ''Supplementary Information'' sheets for each recognized standard, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Guidance on the Recognition and Use of Consensus Standards'' is available at ''http://www.fda.gov/cdrh/ modact/k982.html''. The ''FDA Recognized Consensus Standards Appendix A'' may be accessed at ''http://fda.gov/cdrh/modact/recstand.html'' and provides hyperlinks to the ''Supplementary Information'' sheets for listed recognized standards.

VI. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be considered in determining whether to amend the current listing of ''Modifications to the List of Recognized Standards.''

The listing of ''Modifications to the List of Recognized Standards'' is set forth below:

Item Number	Title of Standard	Reference Number and Date
	Generally Acceptable Standards	
10	Medical Devices—Risk Management—Part 1: Application of Risk Analysis	AAMI/ISO 14971–1 (1998)
11	Sampling Procedures and Tables for Inspection by Attributes	ISO 2859 (1995)
12	Quality Assurance Requirements for Measuring Equipment Part 1: Metrological Confirmation System for Measuring Equipment	ISO 10012 (1993)
13	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	ISO 10993–1 (1997)
14	Inspection by Attributes	ANSI/ASQC Z1.4 (1993)
15	Inspection by Variables	ANSI/ASQC Z1.9 (1993)
16	Test Methods for Peel or Stripping Strength of Adhesive Bonds	ASTM D–903 (1993)
17	Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D–4169 (1993)
18	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	ASTM D–4332 (1991)
19	Standard Practice for Use of Statistics in the Evaluation of Spectrometric Data	ASTM E–876 (1995)
20	Standard Test Method for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications	ASTM F–1140 (1988)
21	Medical Devices—Risk Management	EN 1441 (1997)

Item Number	Title of Standard	Reference Number and Date
	Anesthesia	
23	Conical Fittings of 15 millimeters (mm) and 22 mm Sizes	ASTM F 1054 (1987)
24	Standard Specification for Capnometers	ASTM F 1456 (1992)
25	Specification for Oxygen Analyzers	ASTM F 1462 (1993)
26	Standard Color Marking of Compressed Gas Containers Intended for Medical Use	CGA C–9 (1988)
27	Standard for Compressed Gas Cylinder Valve Outlets and Inlet Connection	CGA V–1 (1994)
28	Diameter-Index Safety System	CGA V–5 (1989)
29	Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases	CGA V–7 (1997)
30	Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Anesthetic Machines	IEC 60601–2–13 (1989)
31	Anesthetic and Respiratory Equipment—Conical Connectors	ISO 5356–1 (1996)
32	Oxygen Monitors for Monitoring Patient Breathing Mixtures—Safety Requirements	ISO 7767 (1997)
33	Capnometers for Use With Humans—Requirements	ISO 9918 (1993)
	Biocompatibility	
28	Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials	ANSI/AAMI/ISO 10993–12 (1996)
29	Biological Evaluation of Medical Devices—Part 5: Tests for Cytotoxicity: In Vitro Methods	ISO 10993–5 (1998)
30	Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	ASTM F720–81 (r1996)
31	Biological Reactivity Tests, In Vivo, Classification of Plastics-Sample Preparation	USP 23 (1988)
32	Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	ASTM F750 (1996)
33	Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	ASTM E1372–95
34	Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	ASTM F749–98
35	Standard Practice for Short Term Screening for Implant Material	ASTM F763–87 (1993)
36	Standard Practice for Subcutaneous Screening Test for Implant Materials	ASTM F1408–97
	Cardiovascular/Neurology	
21	Specification for Cobalt-28 Chromium-6 Molyb- denum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)	ASTM F75–98
22	Specification for Wrought Cobalt–20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	ASTM F90–97
23	Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications	ASTM F136–98
24	Specification for Unalloyed Tantalum for Surgical Implant Applications	ASTM F560–98
	Dental/ENT	
40	Specification for Audiometers	ANSI S3.6 (1996)
41	Specification of Hearing Aid Characteristics	ANSI S3.22 (1996)
42	Dental Impression Compound	ANSI/ADA Specification No. 3 (1994)
43	Dental Casting Alloys	ANSI/ADA Specification No. 5 (1988)
44	Agar Impression Material	ANSI/ADA Specification No. 11 (1968)
45	Denture Cold-Curing Repair Resin	ANSI/ADA Specification No. 13 (1981)
46	Dental Base Metal Casting Alloys	ANSI/ADA Specification No. 14 (1982)
47	Synthetic Resin Teeth	ANSI/ADA Specification No. 15a (1992)
48	Dental Impression Paste Zinc Oxide-Eugenol Type	ANSI/ADA Specification No. 16 (1989)
49	Denture Base Temporary Reclining Resin	ANSI/ADA Specification No. 17 (1983)
50	Alginate Impression Materials	ANSI/ADA Specification No. 18 (1992)
51	Dental Duplicating Material	ANSI/ADA Specification No. 20 (1968)
52	Resin-Based Filling Materials	ANSI/ADA Specification No. 27 (1993)
53	Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements	ANSI/ADA Specification No. 30 (1990)
54	Metal-Ceramic Systems	ANSI/ADA Specification No. 38 (1991)
55	Ultraviolet Activator and Disclosing Lights	ANSI/ADA Specification No. 48 (1983)

Item Number	Title of Standard	Reference Number and Date
56	Endodontic Sealing Materials	ANSI/ADA Specification No. 57 (1993)
57	Dental Ceramic	ANSI/ADA Specification No. 69 (1991)
58	Endodontic Obturating Points	ANSI/ADA Specification No. 78 (1994)
59	Color Stability Test Procedure	ANSI/ADA Specification No. 80 (1997)
60	Dental Water-Based Cements	ANSI/ADA Specification No.96 (1994)
61	Dental Casting Gold Alloys	ISO 1562 (1993)
62	Dental Alginate Impression Material	ISO 1563 (1990)
63	Dental Aqueous Impression Materials Based on Agar	ISO 1564 (1995)
64	Dental Zinc Oxide/Eugenol Cements and Zinc Oxide Non-Eugenol Cements	ISO 3107 (1988)
65	Dentistry—Synthetic Polymer Teeth	ISO 3336 (1993)
66	Dentistry—Resin-Based Filling Materials	ISO 4049 (1988)
67	Dental Base Metal Casting Alloys—Part 1: Cobalt-Based Alloys	ISO 6871–1 (1994)
68	Dental Base Metal Casting Alloys—Part 2: Nickel-Based Alloys	ISO 6871–2 (1994)
69	Dental Ceramic	ISO 6872 (1995) Amendment 1 (1997)
70	Dental Resin-Based Pit and Fissure Sealants	ISO 6874 (1988)
71	Dental Root Canal Sealing Materials	ISO 6876 (1986)
72	Dental Root-Canal Obturating Points	ISO 6877 (1995)
73	Dentistry—Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry—Test Methods for Dental Materials	ISO 7405 (1997)
74	Dental Units	ISO 7494 (1996)
75	Part 1: High-Speed Air Turbine Handpieces	ISO 7785–1 (1997)
76	Part 2: Straight and Geared Angle Handpieces	ISO 7785–2 (1995)
77	Dental Casting Alloys With Noble Metal Content of 25% Up to but Not Including 75%	ISO 8891(1993)
78	Dental Handpieces—Hose Connectors	ISO 9168 (1991)
79	Dental Ceramic Fused to Metal Restorative Material	ISO 9693 (1991)
80	Dental Water-Based Cements	ISO 9917 (1991)
81	Dentistry—Resilient Lining Materials for Removable Dentures—Part 1: Short Term Materials	ISO 10139–1 (1991)
82	Dentistry—Polymer-Based Crown and Bridge Materials	ISO 10477 (1998)
83	Dental Handpieces: Dental Low Voltage Electrical Motors	ISO 11498 (1997)
84	Dental Handpieces—Dental Air-Motors	ISO 13294 (1997)
	General Plastic Surgery/General Hospital	
29	Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Baby Incubators	IEC 60601–2–19 (1996)
30	Standard Specification for Rubber Surgical Gloves	ASTM D3577 (1998)
31	Standard Specification for Rubber Examination Gloves	ASTM D3578 (1995)
32	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Transport Incubators	IEC 60601–2–20 (1996)
33	Standard Specification for Rubber Finger Cots	ASTM D3772 (1997)
34	Standard Test Method for Detection of Holes in Medical Gloves	ASTM D5151 (1992)
35	Standard Specification for Poly (vinyl chloride) Gloves for Medical Application	ASTM D5250 (1992)
36	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	ASTM F862 (1998)
37	Standard Specification for Conical Fittings of 15-mm and 22-mm Sizes	ASTM F1054 (1987)
38	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacterio-phage Penetration as Test System	ASTM F1671 (1997b)
39	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	ASTM F1670 (1997)
40	Absorbable Surgical Sutures	USP 23
41	Nonabsorbable Surgical Sutures	USP 23
42	Sutures—Diameters <861>	USP 23
43	Sutures Needle Attachment <871>	USP 23
44	Tensile Strength <881>	USP 23
45	Standard Test Method for Residual Powder on Medical Gloves	ASTM D6124–97
	In Vitro Devices	
49	Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard	NCCLS H26–A (1996)
50	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents, and Reference Materials—Second Edition; Approved Guideline	NCCLS D11–A2

Item Number	Title of Standard	Reference Number and Date
51	Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline	NCCLS GP27–A
52	Terminology and Definition for Use in NCCLS Documents; Approved Standard	NRSCL 8–A
53	Continuous Quality Improvement: Essential Management Approaches; Approved Guideline	NCCLS GP22–A
	OB–GYN/Gastroenterology	
16	Enteral Feeding Set Connectors and Adapters	ANSI/AAMI ID54 (1996)
17	Standard Specifications for Rubber Contraceptives (Male Condoms)	ASTM D3492–97
18	Electrosurgical Device	ANSI/AAMI HF–18 (1993)
	Ophthalmic	
14	Ophthalmics—Contact Lenses—Standard Terminology, Tolerances, Measurements, and Physicochemical Properties	ANSI Z80.20–1998
	Radiology	
44	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	AIUM (1998)
45	Standard for Real-Time Display of Thermal andMechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. Revision 1.	AIUM RTD (1998)
46	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data	AIUM AOL (1998)
47	Medical Electrical Equipment: Radionuclide Calibrators *B* Particular Methods for Describing Performance	IEC 61303 (1994–10)
48	Calibration and Usage of ''Dose Calibrator'' Ionization Chambers for the Assay of Radionuclides	ANSI N42.13 (1986)
49	Calibration and Usage of Ionization Chamber Systems for Assay of Radionuclides	IEC 61145 (1992–05)
	Software	
2	Standard for Developing Software Life Cycle Processes	IEEE 1074 (1997)
3	Industry Implementation of International Standard ISO/IEC 12207: 1995 (ISO/IEC 12207) Standard for Information Technology—Software Life Cycle Processes	IEEE/EIA 12207.0 (1996)
	Sterility	
37	Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	ANSI/AAMI/ISO 10993–7 (1995)

Dated: June 30, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy.

[FR Doc. 99–17429 Filed 7–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–289]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to