Type of respondent	No. of respondents	No. of responses/ respondent	Avg. burden/ response (in hrs.)
Farmers (pretesting)	60	1	.5
Student (pretesting)	60	1	.5
Farmers	300	1	.333
Farmers	300	2	.333
Students	600	1	.5

Dated: November 8, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–29259 Filed 11–14–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–05–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

NIOSH Training Grants, 42 CFR Part 86, Application and Regulations (OMB No. 9020–0261)—Extension—National Institute for Occupational Safety and Health (NIOSH). Public law 91–596 requires CDC/NIOSH to provide an adequate supply of professionals to carry out the purposes of the Act to assure a safe and healthful work environment. NIOSH supports educational programs through training grant awards to academic institutions for the training of industrial hygienists, occupational physicians, occupational health nurses and safety professionals. Grants are provided to 15 Education and Research Centers (ERCs) which provide multi-disciplinary graduate academic and research training for professionals, continuing education for practicing professionals and outreach programs in the Region. There are also currently 41 Training Project Grants (TPGs) which provide single discipline academic and technical training throughout the country. 42 CFR Part 86, Grants for Education Programs in Occupational Safety and Health, Subpart B—Occupational Safety and Health Training, provides guidelines for implementing Public Law 91–596.

The training grant application form (CDC2.145.A) is used by the National Institute of Occupational Safety and Health to collect information from new grant applicants submitting competing applications, and from existing applicants for competing renewal grants. The information is used to determine the eligibility of applicants for grant review and by peer reviewers during the peer review process to evaluate the merit of the proposed training project. CDC Form 2.145B is used for non-competing awards to evaluate the annual progress of the applicant during the approved project period.

Extramural training grant awards are made annually following an extramural review process of the training grant applications, review by an internal Training Grants Council and an internal review of non-competing applicants. The estimated annualized burden is 6,161 hours.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response (in hrs)
Universities	61	1	101

Dated: November 8, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–29260 Filed 11–14–00; 8:45 am]

BILLING CODE 4163–18–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, Recognition List Number: 004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 004'' (Recognition List Number: 004) will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Written comments concerning this document may be submitted at any time. See section VI of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5′ diskette of ''Modifications to the List of Recognized Standards, Recognition List Number:

004,'' 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 contact person (address below). Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed on FDA's Internet site at http://www.fda.gov/cdrh/fedregin.html. See section V of this document for electronic access to the searchable data base for the current list of ''FDA Recognized Consensus Standards,'' including Recognition List Number: 004 modifications, and other standards related information.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 12725 Twinbrook Pkwy., Rockville, MD 20852, 301–827–4777.

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 a guidance entitled ''Recognition and Use of Consensus Standards.'' This notice described how FDA will implement its standards program recognizing the use of certain standards and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617) and July 12, 1999 (64 FR 37546), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. When these notices were published, the agency maintained ''html'' and ''pdf'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions were publicly accessible at the agency's Internet site. The agency maintains the current list in a searchable data base accessible to the public. See section V of this document for electronic access information.

II. Discussion of Modifications to the List of Recognized Standards, Recognition List Number: 004

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews for devices. FDA will incorporate these modifications in the list of ''FDA Recognized Consensus Standards'' in the agency's searchable data base. FDA will use the term ''Recognition List Number: 004'' to identify supplementary information sheets for standards added to the list for the first time, standards added to replace withdrawn standards, and still recognized standards for which minor revisions are made to clarify the application of the standards.

At the end of this notice, FDA lists modifications the agency is making that involve: (1) The initial addition of standards not previously recognized by FDA and (2) the addition of standards in conjunction with the withdrawal of other standards that are replaced by these later, or amended, or different standards.

Under headings ''A'' through ''L'' below, FDA describes modifications that involve: (1) The withdrawal of standards and their replacement by others (''replacement'' standards are included in the list at the end of this notice, but not ''withdrawn'' standards); (2) the correction of errors made in previously recognized standards, e.g., the name of the standard; (3) the withdrawal of standards not replaced; and (4) the minor revision of supplementary information sheets for standards that FDA still recognizes, e.g., to clarify the extent of recognition, or applicable devices.

Item numbers discussed below identify entries in the searchable data base list of ''FDA Recognized Consensus Standards.'' ''Previous item'' refers to entries in the list after modification on July 12, 1999 (64 FR 37546). ''Current item'' refers to entries in the list after Recognition List Number: 004 modifications are included. Within each category of standards, entries begin (or began) with item 1. Item numbers are not repeated if an entry is withdrawn, replaced, or added.

A. Biocompatibility

1. ASTM E1397–91 is withdrawn under previous item 5. ASTM E1397–91 (1998) is added under current item 37.
2. ASTM E1398–91 is withdrawn under previous item 6. ASTM E1398–91 (1998) is added under current item 38.
3. ASTM F763–87 (1993) is withdrawn under previous item 35. ASTM F763–99 is added under current item 40.
4. ASTM F981–93 is withdrawn under previous item 14. ASTM F981–99 is added under current item 41.
5. USP 23, ''Biological Reactivity Tests, In Vitro-Direct Contact Test (87),'' is withdrawn under previous item 23. The USP 24 version, Biological Tests <87>, is added under current item 46.
6. USP 23, ''Biological Reactivity Tests, In Vitro-Elution Test (87),'' is withdrawn under previous item 24. The USP 24 version, Biological Tests <87> is added under current item 47.
7. USP 23 (1988), ''Biological Reactivity Tests, In Vivo, Classification of Plastics Sample Preparation,'' is withdrawn under previous item 31. The USP 24 version, Biological Tests <88>, is added under current item 48.
8. USP 23, ''Biological Reactivity Test, In Vivo, Classification of Plastics-Intracutaneous Test (88),'' is withdrawn under previous item 25. The USP 24 version, Biological Tests <88>, is added under current item 49.
9. USP 23, ''Biological Reactivity Tests, In Vivo-Systemic Injection Test (88),'' is withdrawn under previous item 27. The USP 24 version, Biological Tests <88>, is added under current item 50.

B. Cardiovascular/Neurology

1. ASTM F1058–91 is withdrawn under previous item 13. ASTM F1058–97 is added under current item 28.
2. IEC 60601–2–30 (1995–03) is withdrawn, under previous item 19. IEC 60601–2–30: 1999–12 is added under current item 29.
3. IEC 60601–2–25 (1993–03) is withdrawn under previous item 17. IEC 60601–2–25 Amendment 1 (1999) is added under current item 30.

C. Dental/ENT

1. ANSI/ADA Specification No.15a (1992) is withdrawn under previous item 47. ANSI/ADA Specification No. 15: 1999 is added under current item 85.
2. ANSI/ADA Specification No. 38 (1991) is withdrawn under previous item 54. ANSI/ADA Specification No. 38: 2000 is added under current item 86.
3. ANSI/ADA Specification No. 69 (1991) is withdrawn under previous item 57. ANSI/ADA Specification No. 69: 1999 is added under current item 87.

4. ANSI/ADA Specification No. 78 (1994) is withdrawn under previous item 58. ANSI/ADA Specification No. 78: 2000 is added under current item 88.

D. General (General Applicability)

1. ANSI/AAMI/ISO 10993–1 (1997) is withdrawn under previous item 13. ANSI/AAMI/ISO 10993–1 (1997) is added back to the list as current item 51 under the Biocompatibility category of standards.

E. General Plastic Surgery/General Hospital

1. ASTM D6124–97 is withdrawn under previous item 45. ASTM D6124–00 is added under current item 51.

2. ASTM D5250 (1992) is withdrawn under previous item 35. ASTM D5250–00 is added under current item 52.

3. ASTM D5151 (1992) is withdrawn under previous item 34. ASTM D5151–99 is added under current item 53.

4. ASTM D3578 (1995) is withdrawn under previous item 31. ASTM D3578–00 is added under current item 54.

5. ASTM D3577 (1998) is withdrawn under previous item 30. ASTM D3577–00 is added under current item 55.

6. USP 23 <11>, ''Sterile Sodium Chloride for Injection,'' is withdrawn. The USP 24 <11> version of this standard is added under current item 56.

7. USP 23 <11>, ''Sterile Water for Injection,'' is withdrawn under previous item 28. The USP 24 <11> version of this standard is added under current item 57.

8. USP 23, ''Absorbable Surgical Sutures,'' is withdrawn under previous item 40. The USP 24 version of this standard is added under current item 58.

9. USP 23, ''Tensile Strength,'' is withdrawn under previous item 44. The USP 24 version of this standard is added under current item 59.

10. USP 23, ''Sutures-Diameter <861>,'' is withdrawn under previous item 42. The USP 24 <861> version of this standard is added under current item 60.

11. USP 23, ''Suture Needle Attachment <871>,'' is withdrawn under previous item 43. The USP 24 <871> version of this standard is added, under current item 61.

F. In Vitro Devices

1. NCCLS standard M11–A3 (1993) is withdrawn under previous item 9. FDA intended to replace this standard with NCCLS standard M11–A4 (1997), which it added to the list on July 12, 1999 (64 FR 37546) and which remains as current item 45.

G. OB GYN/Gastroenterology

1. In the supplementary information sheet(s) for IEC 60601–2–18: 1996, which was identified under previous item 5, minor revisions are made to the devices affected, related Code of Federal Regulations (CFR) citation(s) and procode(s), and relevant guidance. This standard remains recognized and identified under current item 5.

H. Ophthalmic

1. ISO 9394: 1994 is withdrawn under previous item 6, from the list of recognized consensus standards. ISO 9394: 1998 is added under current item 15.

I. Orthopaedics

1. ASTM F75–92 is withdrawn under previous item 2. ASTM F75–98 is added under current item 86.

2. ASTM F90–96 is withdrawn under previous item 4. ASTM F90–97 is added under current item 87.

3. ASTM F136–96 is withdrawn under previous item 5. ASTM F136–98 is added under current item 88.

4. ASTM F138–92 is withdrawn under previous item 6. ASTM F138–97 is added under current item 89.

5. ASTM F560–92 is withdrawn under previous item 9. ASTM F560–98 is added under current item 90.

6. ASTM F561–87 is withdrawn under previous item 10. ASTM F561–97 is added under current item 91.

7. ASTM F565–85 (R1996) is withdrawn under previous item 12. ASTM F565–85 (1996)(e1) is added under current item 92.

8. ASTM F601–86 (1992) is withdrawn under previous item 13. ASTM F601–98 is added under current item 93.

9. ASTM F603–83 is withdrawn under previous item 14. ASTM F603–83 (1995) is added under current item 94.

10. ASTM F620–96 is withdrawn under previous item 16. ASTM F620–97 is added under current item 96.

11. ASTM F621–92 is withdrawn under previous item 17. ASTM F621–97 is added under current item 97.

12. ASTM F629–86 is withdrawn under previous item 18. ASTM F629–97 is added under current item 98.

13. ASTM F648–84 is withdrawn under previous item 19. ASTM F648–98 is added under current item 99, with changes to the extent of recognition made in the supplementary information sheet(s).

14. ASTM F746–87 is withdrawn under previous item 22. ASTM F746–87 (1994) is added under current item 100.

15. ASTM F786–82 is withdrawn under previous item 23. It is not replaced.

16. ASTM F787–82, is withdrawn under previous item 24. It is not replaced.

17. ASTM F897–84 (R1993) is withdrawn under previous item 26. ASTM F897–84 (1997) is added under current item 101.

18. The title of ASTM F961–96, identified under previous item 28, is corrected to read ''Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (R30035).'' It remains identified as current item 28.

19. ASTM F983–86 is withdrawn under previous item 29. ASTM F983–86 (1996) is added under current item 102.

20. ASTM F1089–87 is withdrawn under previous item 32. ASTM F1089–87 (1994) is added, under current item 104.

21. ASTM F1091–91 (R1996) is withdrawn under previous item 33. ASTM F1091–91 (1996) E01 is added under current item 105.

22. ASTM F1147–95 is withdrawn under previous item 35. ASTM F1147–99 is added under current item 107.

23. ASTM F1160–91 is withdrawn under previous item 36. ASTM F1160–98 is added under current item 108.

24. ASTM F1185–88 (1993) is withdrawn under previous item 37. ASTM F1185–88 (1993) E01 is added under current item 109.

25. ASTM F1264–96a is withdrawn under previous item 38. ASTM F1264–99 is added under current item 110.

26. ASTM F1350–96 is withdrawn under previous item 42. ASTM F1350–91 (1996) E01 is added under current item 112.

27. ASTM F1377–92 is withdrawn under previous item 43. ASTM F1377–98a is added under current item 113.

28. In the supplementary information sheet(s) for ASTM F1672–95, identified under previous item 55, minor changes are made to the extent of recognition, devices affected, and related CFR citation(s) and procode(s). This standard remains recognized and identified under current item 55.

29. ASTM F1798 is withdrawn under previous item 59. ASTM F1798–97 is added under current item 114.

30. ASTM F1800 is withdrawn under previous item 60. ASTM F1800–97 is added under current item 115.

31. ASTM F1801 is withdrawn under previous item 61. ASTM F1801–97 is added under current item 116.

32. ISO 5832–2: 1993 is withdrawn under previous item 63. ISO 5832–2:1999 is added under current item 117.

33. ISO 5832–9: 1992 is withdrawn under previous item 68. ISO 5832–9:1995 is added under current item 118.

34. ISO 5832–10: 1996 is withdrawn under previous item 69. It is not replaced.

35. ISO 5834–2: 1985 is withdrawn under previous item 72. ISO 5834–2: 1998 is added under current item 119.

36. In the supplementary information sheets for ISO 7206–4: 1989 and ISO 7206–8: 1995, which were identified under previous items 78 and 79, respectively, minor changes are made to the devices affected, processes impacted, type of standards, and related CFR citations and procodes. They remain recognized and identified under current items 78 and 79.

J. Radiology

1. UL–122 is withdrawn under previous item 30. UL–122 (Fourth Edition) is added under current item 50.

2. UL–187 is withdrawn under previous item 31. UL–187 (Seventh Edition) is added under current item 51.

3. UL–544 (Third Edition) is withdrawn under previous item 32. UL–544 (Fourth Edition) is added under current item 52.

4. IEC 60601–2–8 (1987–04) is withdrawn under previous item 35. IEC 60601–2–8 (1999–04) is added under current item 54.

5. IEC 60601–2–29 (1993–04) is withdrawn under previous item 41. IEC 60601 2–9 (1999–01) is added under current item 55.

K. Software

1. In the supplementary information sheets for ISO/IEC 12207 and IEEE/EIA 12207.0–1996, which were identified under previous items 1 and 3, respectively, minor changes are made to the identities of organizations associated with the standards and the extent of recognition. These standards remain recognized and identified under current items 1 and 3.

L. Sterility

1. ANSI/AAMI ST24: 1992 is withdrawn under previous item 13. ANSI/AAMI ST24: 1999 is added under current item 38.

2. USP 23: 1995, is withdrawn under previous item 29. USP 24: 2000 is added under current item 39.

3. USP 23: 1995, ''Biological Indicator for Dry-Heat Sterilization, Paper Strip,'' is withdrawn under previous item 30. The USP 24: 2000 version of this standard is added under current item 40.

4. USP 23: 1995, ''Biological Indicator for Ethylene Oxide Sterilization, Paper Strip,'' is withdrawn under previous item 31. The USP 24: 2000 version of this standard is added under current item 41.

5. USP 23: 1995, ''Microbial Limits Test <61>,'' is withdrawn under previous item 32. The USP 24: 2000 <61> version of this standard is added under current item 42.

6. USP 23: 1995, ''Microbiological Tests, Sterility Tests <71>,'' is withdrawn under previous item 33. The USP 24: 2000 <71> version of this standard is added under current item 43.

7. USP 23: 1995, ''Biological Tests and Assays, Bacterial Endotoxin Test (LAL) <85>,'' is withdrawn under previous item 34. The USP 24: 2000 <85> version of this standard is added under current item 44.

8. USP 23: 1995, ''Pyrogen Test (USP Rabbit Test) <151>,'' is withdrawn under previous item 35. The USP 24: 2000 <151> version of this standard is added under current item 45.

9. USP 23: 1995, ''Sterilization and Sterility Assurance of Compendial Articles <1211>,'' is withdrawn under previous item 36. The USP 24: 2000 <1211> version of this standard is added under current item 46.

III. List of Recognized Standards

FDA maintains the agency's current list of ''FDA Recognized Consensus Standards'' in a searchable data base that may be accessed directly at FDA's Intranet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. The modifications and minor revisions described in this notice will be incorporated into the data base and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective.

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 ''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. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''Guidance on the Recognition and Use of Consensus Standards'' may also do so by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes this guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 004'' will be available on the CDRH home page.

The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable data base for ''FDA Recognized Consensus Standards,'' may be accessed through hyper links at http://www.fda.gov/cdrh/stdsprog.html. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, at http://www.fda.gov/cdrh/fedregin.html.

VI. Submission of Comments and Effective Date

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, Recognition list: 004.''

The recognition of standards announced in this notice of modifications will become effective on

[*insert date of publication in the* **Federal Register**].

VII. Listing of New Entries

The list of new entries and consensus standards added as ''Modifications to the List of Recognized Standards,'' under Recognition List Number: 004, is as follows:

Item Number	Title of Standard	Reference Number and Date
	Biocompatibility	
37	Standard Practice for the In Vitro Rat Hepatocyte DNA Repair Assay	ASTM E1397–91 (1998)
38	Standard Practice for the In Vivo Rat Hepatocyte DNA Repair Assay	ASTM E1398–91 (1998)
39	Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	ASTM F748–98
40	Standard Practice for Short-Term Screening of Implant Materials	ASTM F763–99
41	Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	ASTM F981–99
42	Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	ASTM F1984–99
43	Standard Practice for Testing for Biological Responses to Particles In Vitro	ASTM F1903–98
44	Standard Practice for Testing for Biological Responses to Particles In Vivo	ASTM F1904–98
45	Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications	ASTM F1983–99
46	Biological Reactivity Test, In Vitro—Direct Contact Test	USP 24 Biological Tests <87>
47	Biological Reactivity Test, In Vitro—Elution Test	USP 24 Biological Tests <87>
48	Biological Reactivity Test, In Vivo—Procedure—Preparation of Sample	USP 24 Biological Test <88>
49	Biological Reactivity Test, In Vivo—Intracutaneous Test	USP 24 Biological Tests <88>
50	Biological Reactivity Tests, In Vivo—Systemic Injection Test	USP 24 Biological Test <88>
51	Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing	ANSI/AAMI/ISO 10993–1 (1997)
	Cardiovascular/ Neurology	
25	Cardiac Defibrillators—Connector Assembly for Implantable Defibrillators-Dimensional and Test Requirements	ISO 11318–93/Amendment 1:1996 (E)
26	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Transcutaneous Partial Pressure Monitoring Equipment	IEC 60601–2–23: 1993
27	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Direct Blood Pressure Monitoring Equipment	IEC 60601–2–34 (1994–12)
28	Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloys for Surgical Implant Applications (UNS R30003 and UNS R30008)	ASTM F1058–97
29	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment	IEC 60601–2–30: 1999–12
30	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Electrocardiographs	IEC 60601–2–25 Amendment 1 (1999)
	Dental/ ENT	
85	Synthetic Resin Teeth	ANSI/ADA Specification No. 15: 1999
86	Metal-Ceramic Systems	ANSI/ADA Specification No. 38: 2000
87	Dental Ceramic	ANSI/ADA Specification No. 69: 1999
88	Endodontic Obturating Points	ANSI/ADA Specification No. 78: 2000
89	Polymer-Based Crown and Bridge Resins	ANSI/ADA Specification No. 53: 1999
90	Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	ANSI/ASA S3.39: 1996
	General (Generally Applicable)	
22	General Tolerances—Part 1: Tolerances for Linear and Angular Dimensions Without Individual Tolerance Indications	ISO 2768–1 (1989)
23	General Tolerances—Part 2: Geometrical Tolerances for Features Without Individual Tolerance Indications	ISO 2768–2 (1989)
24	Analysis Techniques for System Reliability—Procedure for Failure Modes and Effects Analysis (FMEA)	IEC 60812 (1985)

Item Number	Title of Standard	Reference Number and Date
	General Plastic Surgery/ General Hospital	
46	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment	IEC 60601–2–2: Third Edition 1998–09
47	Standard Test Method for Analysis of Protein in Natural Rubber and its Products Using the Modified Lowry Method	ASTM D5712–99
48	Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	ASTM D6499–00
49	Standard Test Method for Human Repeat Insult Patch Testing or Medical Gloves	ASTM D6355–98
50	Standard Specification for Nitrile Examination Gloves for Medical Application	ASTM D6319–00
51	Standard Test Method for Residual Powder on Medical Gloves	ASTM D6124–00
52	Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application	ASTM D5250–00
53	Standard Test Method for Detection of Holes in Medical Gloves	ASTM D5151–99
54	Standard Specification for Rubber Examination Gloves	ASTM D3578–00
55	Standard Specification for Rubber Surgical Gloves	ASTM D3577–00
56	Sterile Sodium Chloride For Irrigation	USP 24 <11>
57	Sterile Water for Injection	USP 24 <11>
58	Absorbable Surgical Sutures	USP 24
59	Tensile Strength	USP 24
60	Sutures—Diameters	USP 24 <861>
61	Sutures Needle Attachment	USP 24 <871>
	OB GYN/ Gastroenterology	
19	Optical and Optical Instruments—Medical Endoscopes and Endoscopic Accessories—Part 1: General Requirements	ISO 8600–1: 1997
20	Optical and Optical Instruments—Medical Endoscopes and Endoscopic Accessories—Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics	ISO 8600–3: 1997
21	Optical and Optical Instruments—Medical Endoscopes and Certain Accessories—Part 4: Determination of Maximum Width of Insertion Portion	ISO 8600–4: 1997
22	Standard Practice for Cleaning and Disinfecting of Flexible Fiberoptic and Video Endoscopes Used in the Examination of Hollow Viscera	ASTM F1518–94
	Ophthalmic	
15	Optics and Optical Instruments—Determination of Biological Compatibility of Contact Lens Material—Testing of the Contact Lens System by Ocular Study with Rabbit Eyes	ISO 9394–1998
16	Optics and Optical Instruments—Contact Lenses—Part 2: Determination of Oxygen Permeability and Transmissibility by the Coulometeric Method	ISO 9913–2: 2000
17	Optics and Optical Instruments—Ophthalmic Instruments—Slit-Lamp Microscopes	ISO 10939: 1998
18	Optics and Optical Instruments—Ophthalmic Instruments—Indirect Ophthalmoscopes	ISO 10943: 1999
19	Ophthalmic Optics—Contact Lenses—Classification of Contact Lenses and Contact Lens Materials	ISO 11539: 1999
20	Ophthalmic Implants—Intraocular Lenses—Part 1: Vocabulary	ISO 11979–1: 1999
21	Ophthalmic Implants—Intraocular Lenses—Part 2: Optical Properties and Tests Methods	ISO 11979–2: 2000
22	Ophthalmic Implants—Intraocular Lenses—Part 3: Mechanical Properties and Test Methods	ISO 11979–3: 1999
23	Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Determination of Physical Compatibility of Contact Lens Care Products with Contact Lenses	ISO 11981–1999
24	Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Guidelines for Determination of Preservative Uptake and Release	ISO 11986: 1999
25	Optics and Optical Instruments—Ophthalmic Instruments—Retinoscopes	ISO 12865: 1998
26	Ophthalmic Optics—Contact Lens Care Products—Guidelines for Determination of Shelf-Life	ISO 13212: 1999

Item Number	Title of Standard	Reference Number and Date
	Orthopaedics	
86	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)	ASTM F75–98
87	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	ASTM F90–97
88	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications	ASTM F136–98
89	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire For Surgical Implants (UNS S31673)	ASTM F138–97
90	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R 05200, UNS R05400)	ASTM F560–98
91	Recommended Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues	ASTM F561–97
92	Standard Practice for Care and Handling of Orthopedic Implants and Instruments	ASTM F 565–85 (1996) (e1)
93	Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	ASTM F601–98
94	Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application	ASTM F603–83 (1995)
95	Standard Test Method for Constant Amplitude Bending Fatigue Tests of Metallic Bone Staples	ASTM F1539–95
96	Standard Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)	ASTM F620–97
97	Standard Specification for Stainless Steel Forgings for Surgical Implants	ASTM F621–97
98	Standard Practice for Radiography of Cast Metallic Surgical Implants	ASTM F629–97
99	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	ASTM F648–98
100	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	ASTM F746–87 (1994)
101	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	ASTM F897–84 (1997)
102	Standard Practice for Permanent Marking of Orthopaedic Implant Components	ASTM F983–86 (1996)
103	Standard Test Method for Pull-Out Fixation Strength of Metallic Bone Staples	ASTM F1540–95
104	Standard Test Method for Corrosion of Surgical Instruments	ASTM F1089–87 (1994)
105	Standard Specification for Wrought Cobalt-Chromium Alloy Surgical Fixation Wire	ASTM F1091–91 (1996) E01
106	Standard Test Method for Determining Axial Pull-Out Strength of Medical Bone Screws	ASTM F1691–96
107	Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings	ASTM F1147–99
108	Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings	ASTM F1160–98
109	Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants	ASTM F1185–88 (1993) E01
110	Standard Specification and Test Methods for Intramedullary Fixation Devices	ASTM F1264–99
111	Standard Guide for Evaluating Modular Hip and Knee Joint Components	ASTM F1814–97a
112	Standard Specification for Stainless Steel Surgical Fixation Wire	ASTM F1350–91 (1996) E01
113	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	ASTM F1377–98a
114	Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	ASTM F1798–97
115	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	ASTM F1800–97
116	Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	ASTM F1801–97
117	Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	ISO 5832–2:1999

Item Number	Title of Standard	Reference Number and Date
118	Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel	ISO 5832–9: 1995
119	Implants for Surgery—Ultra-high-Molecular-Weight Polyethylene—Part 2: Moulded Forms	ISO 5834–2: 1998
120	Standard Specification and Test Method for Metallic Bone Plates	ASTM F0382–99
121	Implants for Surgery—Femoral and Tibial Components for Partial and Total Knee Joint Prosthesis—Part 1: Classification, Definitions and Designation of Dimensions—Second Edition	ISO 7207–1: 1994
122	Implants for Surgery—Components for Partial and Total Knee Joint Prosthesis—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastics Materials	ISO 7207–2: 1994
	Radiology	
50	Standard for Safety of Photographic Equipment—Fourth Edition	UL–122
51	Standard for Safety: X-ray Equipment—Seventh Edition	UL–187
52	Standard for Safety: Medical and Dental Equipment—Fourth Edition	UL–544
53	Radiation Protection—Sealed Radioactive Sources—General Requirements and Classification	ISO 2919 (1999)
54	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10kV to 1MV	IEC 60601–2–8 (1999–04)
55	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Radiotherapy Simulators	IEC 60601–2–29 (1999–01)
56	Medical Electrical Equipment—Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as used in X-ray Diagnostic Imaging	IEC 61674–1997
57	Medical Electrical Equipment—Dosimeters with Ionization Chambers as used in Radiotherapy	IEC 60731–1997
58	Classification of Sealed Radioactive Sources	ANSI/HPS N43.6–1997
59	Radiotherapy Simulators—Functional Performance Characteristics—First Edition	IEC 61168: 1993
60	Radiotherapy Equipment—Coordinates, Movements, and Scales	IEC 1217–1996
	Software	
4	Software in Programmable Components	ANSI/UL 1998
5	Standard for Developing Software Life Cycle Processes	IEEE 1074: 1997
6	Standard for Software Verification and Validation	IEEE 1012: 1998
	Sterility	
38	Automatic General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities, Third Edition	ANSI/AAMI ST 24: 1999
39	Biological Indicator for Dry-Heat Sterilization, Paper Strip	USP 24: 2000
40	Biological Indicator for Ethylene Oxide Sterilization, Paper Strip	USP 24: 2000
41	Biological Indicator for Steam Sterilization, Paper Strip	USP 24: 2000
42	Microbial Limits Test <61>	USP 24: 2000
43	Microbiological Tests, Sterility Tests <71>	USP 24: 2000
44	Biological Tests and Assays, Bacterial Endotoxin Test (LAL) <85>	USP 24: 2000
45	Pyrogen Test (USP Rabbit Test) <151>	USP 24: 2000
46	Sterilization and Sterility Assurance of Compendial Articles <1211>	USP 24: 2000
47	Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use	ANSI/AAMI ST37: 1996
48	Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Dental and Medical Facilities	ANSI/AAMI ST40: 1992/(R) 1998
49	Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness	ANSI/AAMI ST41: 1999
50	Steam Sterilization and Sterility Assurance Using Table-Top Sterilizers in Office-Based, Ambulatory-Care Medical, Surgical, and Dental Facilities	ANSI/AAMI ST42: 1998
51	Safe Use and Handling of Glutaraldehyde-Based Products in Health Care Facilities	ANSI/AAMI ST58: 1996
52	Biological Indicators Part 1: General Requirements Sterilization of Health Care Products	ANSI/AAMI ST59: 1999

Item Number	Title of Standard	Reference Number and Date
53	Sterilization of Health Care Products—Chemical Indicators—Part 2: Class 2 Indicators for Air Removal Test Sheets and Packs	ANSI/AAMI ST66: 1999
54	Sterilization of Medical Devices—Microbiological Methods—Part 2: Tests of Sterility Performed in the Validation of a Sterilization Process	ANSI/AAMI/ISO 11737–2: 1998
55	Sterilization of Single-Use Medical Devices Incorporating Materials of Animal Origin—Validation and Routine Control of Sterilization by Liquid Chemical Sterilants	ANSI/AAMI/ISO 14160: 1998
56	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	ASTM D3078: 1994
57	Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D4169: 1999
58	Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88: 1999
59	Standard Test Methods for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications	ASTM F1140: 1996
60	Standard Terminology Relating to Barrier Materials for Medical Packaging	ASTM F1327: 1998
61	Standard Guide for Integrity Testing of Porous Barrier Medical Packages	ASTM F1585: 1995
62	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	ASTM F1608: 1995
63	Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	ASTM F1886: 1998
64	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	ASTM F1929: 1998
65	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	ASTM F1980: 1999
66	Transfusion and Infusion Assemblies and Similar Medical Devices <161>	USP 24: 2000

Dated: October 31, 2000.

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[FR Doc. 00–29165 Filed 11–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Scholarship Program for Students of Exceptional Financial Need (EFN) and Program of Financial Assistance for Disadvantaged Health Professions Students (FADHPS): Regulatory Requirements (OMB No. 0915–0028)—Reinstatement, with change.

The EFN Scholarship Program, authorized by section 736 of the Public Health Service (PHS) Act, and the FADHPS Program, authorized by section 740(a)(2)(F) of the PHS Act, provides financial assistance to schools of allopathic and osteopathic medicine and dentistry for awarding tuition scholarships to health professions students who are of exceptional financial need. To be eligible for support under the FADHPS Program, a student must also be from a disadvantaged background. In return for this support, students of allopathic and osteopathic medicine must agree to complete residency training in primary care in 4 years, and practice in primary care for 5 years after completing residency training.

The program regulations contain recordkeeping requirements designed to ensure that schools maintain adequate records for the Government to monitor program activity and that funds are spent as intended.

The estimate of burden for the regulatory requirements of this clearance are as follows: