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June 30, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2017–N–1067; Request for Comments on Food and Drug Administration Accreditation Scheme for Conformity Assessment Pilot Program; Availability

Dear Sir or Madam:

The Advanced Medical Technology Association (hereinafter referred to as "AdvaMed") is pleased to provide these comments in response to the Food and Drug Administration ("FDA" or "Agency") Request for Comments: "Accreditation Scheme for Conformity Assessment ("ASCA") Pilot Program" (May 2017).

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems. AdvaMed member companies produce technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed's members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. AdvaMed members range from the smallest to the largest medical technology innovators.

We support the Agency's use of international voluntary consensus standards to meet regulatory requirements, which will further efforts to harmonize global medical technology regulations. Using international voluntary consensus standards to meet regulatory requirements has many benefits, including introducing efficiencies for both the regulators and the medical device industry. Such standards help minimize unnecessary costs and delays in patient access to innovative new devices. The open process encourages participation by a broad group of stakeholders in development of standards, resulting in consensus among users, practitioners, manufacturers, and government regulators on safety and effective use of devices. We agreed to the ASCA program as part of the MDUFA IV negotiations, and the commitment letter includes the pilot program.

Responses to Questions Posed in *Federal Register* Notice

1. ***For the ASCA Pilot Program to achieve success,***

    a. *What FDA-recognized consensus standards available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm need to be included to successfully get a sponsor/manufacturer to be willing to participate in the program?*

Please see Attachment A for a proposed list of testing standards. We have grouped the standards by the standards development organization ("SDO") that issued the standard to assist FDA's review. We would recommend that the pilot program limit itself to standards that have at least some defined pass / fail criteria and not involve standards that solely require risk management as a way to define a pass criterion.

In compiling this list, our focus was the pilot program. That being said, we did not limit ourselves to the number of standards mentioned in the commitment letter. We think it will be helpful to the Agency to provide broader input as to what standards are tested in laboratories that are accredited in accordance with ISO/IEC 17025 or ISO 15189. We believe this broader input will help FDA to assess where the Agency can obtain the greatest impact by gaining confidence in understanding how the laboratories are accredited and testing. While not limiting ourselves to the number in the commitment letter, we also did not attempt to generate an all-inclusive list of the ones that could be implicated in a full program.

We designated the higher-priority standards for inclusion in a pilot program under the heading "Priority Standards for Inclusion in the Pilot." We designated standards for further evaluation at a later point in the program under the heading "for Future Evaluation."

b. What impact/efficiencies would you like to see from the pilot program?

We would like to see reduced review times from FDA. We would like to see FDA accept the referenced standards that are part of the program entirely on the presentation of a Declaration of Conformity ("DoC"), with no additional data or review during a 510(k) evaluation. We seek very few, if any, additional information requests related to accredited reports/certifications and/or conformance to the cited standard. Specifically, we would request that FDA list, at the outset of the program with updates at least annually, documents and test facilities that it would accept in the manner described above when reviewing submissions.

c. What does success of the pilot program look like?

A successful pilot program would result in acceptance by FDA of the accredited report/certification without substantive review by FDA except as part of a periodic quality audit or if FDA becomes aware of new information materially relevant to safety and/or effectiveness.

We suggest that in the pilot at least 5 modality types of devices have recognized standards for which only a DoC is necessary for submission in a 510(k). For any long-term, full program, if such a program is authorized, we would hope that all Procodes have one or more standards for which only a DoC is needed for submission in a 510(k). We also would like FDA to consider whether standards with Risk Management criteria could eventually be added to the program after the pilot stage if the program continues beyond that point.

From a procedural prospective, a successful pilot program would include a *Federal Register* notice with an opportunity for public comments. It also would include consistent updates of the status of the program. Such updates would include disclosure of "results as measured by pre-published targets" and continuing dialogue with industry for further improvement of the program.

d. Outline any challenges in the use of recognized voluntary consensus standards (e.g., acceptance of test results from accredited test laboratories, standardized test reports, consistent test methods, well-defined standards) that FDA should focus on while developing the ASCA pilot.

In developing a successful pilot program, FDA will need to establish acceptable criteria for accrediting bodies. FDA also will have to establish criteria that the testing laboratory must meet to participate in the program, i.e., the ASCA-specific program requirements that the laboratory must fulfill. We provide additional input on these two topics below in response to Questions 2, 3 and 10.

We also recommend that FDA establish report/certification templates to facilitate the acceptance by FDA of the accredited report/certification without substantive review by FDA. We suggest that FDA list or show the format of documents and test results to provide transparency and clarity for all potential interested parties, including the manufacturer, FDA, and the testing laboratory. We also request clarity as to what documents, in addition to the already available IEC 60601 reports, could receive FDA acceptance without substantive FDA review, and would encourage FDA to include as many documents as possible.

We also request clarity from FDA as to the steps that an interested company would need to take to participate in the pilot program, e.g., the process that FDA intends to use.

If the pilot is successful and a full program is authorized, we believe that FDA may wish to consider incorporating standards that contain no clear acceptance criteria (e.g., acceptance criteria are determined solely by Risk Management). FDA should develop a strategy for considering inclusion of such standards into the full program if the pilot program is a success.

We recommend that FDA reiterate that the program is entirely voluntary. FDA should be clear that a company can choose to opt out of the program in part or in total and undergo the traditional review.

2. To help reduce duplicative efforts, overlap, or conflict with other conformity assessment schemes, what benefits/concerns of the ASCA work to align with other existing schemes that utilize the same consensus standards?

We would recommend that FDA solicit input from domestic and international standards bodies, align with product safety certification bodies such as UL and CSA in the certification of testing laboratories, and leverage existing assessment schemes. For instance, we would

suggest that FDA review the Certification Bodies Scheme already established by the International Electrotechnical Commission ("IEC"), the UL COMPASS Program, and the CSA Category Certification Program.

Moreover, we recommend that FDA consult with EU Notified Bodies through the auspices of the Notified Body Working Group, and Health Canada. Furthermore, we propose that FDA utilize industry-accepted test house certification standards (e.g., ISO 17025).

We also suggest that an organization's involvement with SDOs be considered in a positive manner with respect to an organization's acceptance into the ASCA program.

3. ***What are the benefits, weaknesses, incentives/disincentives associated with a model that uses one or more private sector accreditation bodies to accredit testing laboratories to the appropriate scope of accreditation for ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) or ISO 15189:2012—Medical laboratories—Requirements for quality and competence plus FDA ASCA program-specific requirements? FDA would still retain the authority to recognize, deny, amend, or revoke recognition of testing laboratories and maintain the official list of recognized testing laboratories.***

We believe that all interested parties could benefit from this proposed approach. In our view, such acceptance would align with existing industry activity, is consistent with a least-burdensome approach, reduces FDA and industry costs, utilizes harmonized requirements (and in some cases facilitates international use). We believe that this approach would result in more testing houses becoming certified and more manufacturers using certified test houses.

An organization seeking ASCA acceptance should be evaluated from a Quality Management perspective as well as a technical competency perspective, with respect to the standards within its ASCA scope of accreditation application. The "bar" should be set sufficiently high enough to weed out lesser quality testing facilities. We believe FDA will need to provide sufficient capabilities to ensure ASCA can be granted to an organization in a timely manner. If organizations that already perform these assessment capabilities elect to enter this program (which would be recommended) their relationship with a manufacturer with whom they have already established a relationship should be considered a benefit to the manufacture of the device if the manufacturer also chooses to enter the program.

4. ***Where no appropriate accreditation bodies step forward to serve the needs for the specific areas within the ASCA program, FDA is considering a model under which it will serve as the accreditation body. What are the benefits, weaknesses, incentives/ disincentives associated with this approach, and how do you compare this approach to the private sector approach?***

While there may be potential benefits such as increasing quality and testing levels, we believe that the potential issues raised by such an approach far outweigh the potential benefits. Such a role would be resource intensive for the Agency. Acting as an accrediting body is not a core capability for the FDA, and would require significant capital and skill

development investment. Also, the Agency would need to find a mechanism to ensure adequate separation between the accrediting function and its regulatory function. If such a model cannot be avoided because no appropriate accreditation bodies step forward to serve, FDA should rely upon the expertise of industry and supporting organizations such as the National Institute of Standards and Technology ("NIST") to help support FDA in these efforts.

5. ***Describe your familiarity with accreditation to ISO/IEC 17025 (General requirements for testing and calibration laboratories) or ISO 15189:2012—Medical laboratories—Requirements for quality and competence? If accredited, what is the scope of accreditation?***

   Multiple members have expressed familiarity with accreditation to those two standards, either because their internal laboratories are/have been accredited to those standards in the past or because they require such accreditation when selecting providers of outsourced activities (e.g., calibration vendors, validation testing).

6. ***Do you utilize another management system other than ISO/IEC 17025 or ISO 15189:2012—Medical laboratories—Requirements for quality and competence? If so, what management system has been implemented?***

   We believe that this question was primarily intended for testing laboratories. However, ISO 13485 and ISO 9001 may also be used for Quality Management purposes.

7. ***Are there specific FDA-recognized consensus standards available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm or testing capabilities related to the medical devices sector that you perform?***

   Our members have identified the ISO/IEC 60601 family of medical electrical standards as broadly applicable to the medical device industry. However, the answer to this question is very device-dependent. While the list of FDA-recognized standards covers very wide areas, some devices such as intravenous pumps and respirators must also operate in airlines and ambulances, and there are specific standards for these products. Also, some of our members' products must meet standards for integrated circuits.

8. ***For more complex standards, such as those that have normative references or include references to management systems (e.g., Risk Management, Quality Management, Cybersecurity, Infection Control), are there specific assessment techniques that should be included?***

   We believe FDA should further evaluate a firm's ability to conduct those additional assessments. Specific conformity assessment techniques should be developed in collaboration with SDO's for some of these areas. Several organizations either have standards or good practices documents in these areas that we believe FDA should include. Such standards and organizations include ISO 27001, NIST, the National Aeronautics and Space Administration, the Information Systems Audit and Control Association ("ISACA") and the International Society for Pharmaceutical Engineering.

9. ***Would you consider participating in the ASCA Pilot Program? If so, what scope of testing would you consider?***

   Some of our members have indicated interest in participating in the ASCA pilot program if the ASCA pilot program was designed in such a way as to maximize efficiencies and ensure success.

10. ***Generally, are there any other comments that you would like to provide regarding the development of the ASCA pilot program? Do you have recommendations for other alternatives to consider?***

    AdvaMed recommends that FDA look for similarities in other countries and in other industries, such as food or aerospace, as it develops the pilot program. Moreover, we suggest that FDA establish an informal committee with a broad range of members, including FDA, E.U. representatives, industry, AAMI/ASTM, and laboratory testing organizations, to help implement the program.

    We recommend that FDA accept ISO 17025/ISO 15189 accreditations already granted by existing accreditation organizations, and then find private sector organizations that can perform the competency evaluations. We propose that FDA accept or rely upon manufacturers' testing facility's technical competency to recognized standards based on privileges already granted by other similar programs, such as the Certification Body Scheme, UL COMPASS, and CSA Category Certification, especially if the firm granting these privileges is also entered into the ASCA program.

AdvaMed appreciates the opportunity to provide our comments on this important topic. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully submitted,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs

ASCA CANDIDATES	
PRIORITY STANDARDS FOR INCLUSION IN THE PILOT	
AAMI / ANSI ES60601-1	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance 2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) (FDA Recognition # 19-4)
AAMI ST67	Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled sterile (FDA Recognition # 14-314)
AAMI ST72	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing (FDA Recognition # 14-360)
AAMI/ANSI/IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests 2014 (FDA Recognition # 19-12)
AAMI/ANSI/IEC 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 2012 (FDA Recognition # 5-92)
AAMI/ANSI/ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices - Incorporates Amendment 1: 2013 (FDA Recognition # 14-428]
AAMI/ANSI/ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (FDA Recognition # 14-438)
AAMI/ANSI/ISO 11137-3	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects (FDA Recognition # 14-298)
AAMI/ANSI/ISO 11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (FDA Recognition # 14-296)
AAMI/ANSI/ISO 11737-1	Sterilization of health care products-Microbiological methods-Part 1: Determination of the population of microorganisms on product (FDA Recognition # 14-227)
AAMI/ANSI/ISO 11737-2	Sterilization of medical devices - Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (FDA Recognition # 14-287)
AAMI/ANSI/ISO 14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results (FDA Recognition # 14-285)
AAMI/ANSI/ISO 14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (FDA Recognition # 14-291)

ASCA CANDIDATES	
PRIORITY STANDARDS FOR INCLUSION IN THE PILOT	
AAMI/ANSI/ISO 17665-1	Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices (FDA Recognition # 14-261)
AAMI/ANSI/ISO 20857	Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (FDA Recognition # 14-339)
CLSI EP05-A3:2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition (FDA Recognition # 7-251)
CLSI EP09-A3:2013	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition (FDA Recognition # 7-245)
CLSI EP15-A3:2014	User Verification of Precision and Estimation of Bias; Approved Guideline—Third Edition (FDA Recognition # 7-253)
CLSI EP17-A2	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition; Vol 32; No 8 (FDA Recognition 7-233)
CLSI EP28-A3C:2010	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (FDA Recognition # 7-224)
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment 2009 (FDA Recognition # 9-91)
IEC 60601-2-63	Medical electrical equipment Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment - Edition 1.0 (FDA Recognition # 12-251)
IEC 60601-2-65	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment - Edition 1.1; Consolidated Reprint (FDA Recognition # 12-252)
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (FDA Recognition # 19-18)
ISO 11608-2	Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles - Second Edition (FDA Recognition # 6-275)
ISO 11608-3	Needle-based injection systems for medical use - Requirements and test methods - Part 3: Finished containers - Second Edition (FDA Recognition # 6-294)

ASCA CANDIDATES	
PRIORITY STANDARDS FOR INCLUSION IN THE PILOT	
ISO 11608-5	Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions - First Edition (FDA Recognition # 6-377)
ISO 11608-7	Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment - First Edition (FDA Recognition # 6-382)
ISO 80601-2-12	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators 2011 (FDA Recognition # 1-98)
ISO 80601-2-72	Medical electrical equipment -- Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients 2015 (FDA Recognition # 1-105)

ASCA CANDIDATES	
FOR FUTURE CONSIDERATION	
AAMI/ANSI/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA Recognition # 2-156)
AAMI/ANSI/ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (FDA Recognition # 2-173)
AAMI/ANSI/ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (FDA Recognition # 2-118)
AAMI/ANSI/ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (FDA Recognition # 2-198)
AAMI/ANSI/ISO 10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (FDA Recognition # 2-190)
AAMI/ANSI/ISO 10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (FDA Recognition 2-165)
AAMI/ANSI/ISO 10993-16	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (FDA Recognition # 2-180)
AAMI/ANSI/ISO 10993-17	Biological evaluation of medical devices - Part 17: Methods for the establishment of allowable limits for leachable substances (FDA Recognition # 2-236)
AAMI/ANSI/ISO 10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements (FDA Recognition # 2-221)
AAMI/ANSI/ISO 10993-3	Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity (FDA Recognition # 2-226)
AAMI/ANSI/ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood - Incorporates Amendment 1: 2006 (FDA Recognition # 2-234)
AAMI/ANSI/ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (FDA Recognition # 2-153)
AAMI/ANSI/ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (FDA Recognition # 2-120)
AAMI/ANSI/ISO 10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals (1FDA Recognition # 4-278)
AAMI/ANSI/ISO 10993-9	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (FDA Recognition # 14-278)

ASCA CANDIDATES	
FOR FUTURE CONSIDERATION	
AAMI / ANSI / ISO 11135	Sterilization of health care products - ethylene oxide - requirements for development, validation and routine control of a sterilization process for medical devices. . (Sterility) (FDA Recognition # 14-479)
AAMI / ANSI / ISO 11140-1	Sterilization of health care products - chemical indicators - part 1: general requirements. (Sterility) (FDA Recognition # 14-460)
IEC 60601-2-1	Medical Electrical equipment - Part 2-1: particular requirements for basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV 2009 and Amendment 1 2014 (FDA Recognition # 12-285)
IEC 62083	Safety of radiotherapy planning systems 2009 (FDA Recognition # 12-217)
IEC 62274	Safety of radiotherapy record and verify systems 2005 (FDA Recognition # 12-241)
AAMI ANSI IEC 62304	Medical device software -Software life cycle processes 2006 (FDA Recognition # 13-32)
AAMI/ANSI/IEC IEC 62366	Medical Devices - Application Of Usability Engineering To Medical Devices 2015 (FDA Recognition # 5-67)
ASTM D3078-02	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission (FDA Recognition # 14-257)
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems (FDA Recognition # 14-499)
ASTM D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing (FDA Recognition # 5-99)
ASTM D638-14	Standard Test Method for Tensile Properties of Plastics (FDA Recognition # 8-403)
ASTM D790-10	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials (FDA Recognition # 10-88)
ASTM D792-13	Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement (FDA Recognition # 8-378)
ASTM D882-12	Standard test methods for tensile properties of thin plastic sheeting. (Ophthalmic) (FDA Recognition # 10-87)
ASTM D903-98	Standard Test Method for Peel or Stripping Strength of Adhesive Bonds (FDA Recognition # 5-42)
ASTM F1140/F1140M	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages (FDA Recognition # 14-402)

ASCA CANDIDATES	
FOR FUTURE CONSIDERATION	
ASTM F1608-16	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method) (FDA Recognition # 14-496)
ASTM F1886/F1886M	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection (FDA Recognition # 14-288)
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (FDA Recognition # 14-484)
ASTM F2054/F2054M	Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates (FDA Recognition # 14-403)
ASTM F2095	Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates (FDA Recognition # 14-297)
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) (FDA Recognition # 14-359)
ASTM F2097	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products (FDA Recognition # 14-498)
ASTM F2228	Standard Test Method for Non-Destructive Detection of Leaks in Packaging Which Incorporates Porous Barrier Material by CO2 Tracer Gas Method (FDA Recognition # 14-434)
ASTM F2250	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials (FDA Recognition # 14-404)
ASTM F2251	Standard Test Method for Thickness Measurement of Flexible Packaging Material (FDA Recognition # 14-435)
ASTM F2338	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method FDA Recognition (# 14-238)
ASTM F2638	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier (FDA Recognition # 14-377)
ASTM F640	Standard Test Methods for Determining Radiopacity for Medical Use (FDA Recognition # 8-418)
ASTM F748	Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices (FDA Recognition # 2-244)
ASTM F88/F88M	Standard Test Method for Seal Strength of Flexible Barrier Materials (FDA Recognition # 14-482)
CEN 1618	Catheters Other than Intravascular Catheters - Test Methods for Common Properties (FDA Recognition # 9-113)

ASCA CANDIDATES	
FOR FUTURE CONSIDERATION	
ISO 80369-20	Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods (FDA Recognition # 597)
CLSI GP44-A4	Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition; Vol 30; No 10 (FDA Recognition # 7-213)
CLSI M07-A10	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard - See M07,M100 or M02,M07,M100 to order sold in packages only: Tenth Edition (FDA Recognition # 7-254)
CLSI M27-S4	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement - Vol 32; No 17 (FDA Recognition # 7-240)
CLSI MM01-A3	Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline - Third Edition; Vol. 32 No. 7 (FDA Recognition # 7-237)
ISO 23907	Sharps injury protection - Requirements and test methods - Sharps containers (FDA Recognition # 6-293)
ISO 23908	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (FDA Recognition # 6-273)
AAMI ANSI ISO 14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results - Second Edition (FDA Recognition # 14-285)
ISO 14644-3	Cleanrooms and associated controlled environments Part 3: Test methods - First Edition (FDA Recognition # 14-242)
ISO 14698-2 CORR 1	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data TECHNICAL CORRIGENDUM 1 - First Edition (FDA Recognition # 14-395)
AAMI ANSI ISO 18472	Sterilization of health care products Biological and chemical indicators Test equipment - First Edition (FDA Recognition # 14-222)
ISO 7864	Sterile hypodermic needles for single use - Requirements and test methods - Fourth Edition (FDA Recognition # 6-379)
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods - Second Edition (FDA Recognition # 6-380)