

## **AAMI Standards Program (active projects only) – 5 August 2010**

This list will be updated monthly to help members and other interested parties determine what activities they wish to participate in. In addition to active projects, the list includes final documents that are due (or overdue) for periodic review in the next 12 months and therefore likely to become active in the coming year.

If an AAMI committee is not listed as the ballot committee (national) or TAG (international) for a project you are interested in, contact the AAMI Standards Department at 703-525-4890 ext 1250, or [standards@aami.org](mailto:standards@aami.org) to determine the status of the activity and how to participate. Otherwise, you can obtain a committee membership application form from [http://www.aami.org/standards/tc\\_join.html](http://www.aami.org/standards/tc_join.html).

Additional information about participating in AAMI standards activities, submitting a new work item proposal to AAMI, etc., is available at <http://www.aami.org/standards/about.html>.

### **KEY to draft codes**

-#— Indicates the number of times the document has been distributed at a particular stage, for example, "CD-2" means this is the second Committee Draft

CD—Committee Draft (circulated to ballot committee for comment, only)

CDV—Committee Draft for Vote (circulated to ballot committee for comment and vote)

CD-V—Same as CDV (used only for ISO documents; in ISO, a "CD" can be with or without vote—AAMI uses this code to differentiate between the two; it is not an official ISO designation)

DIS—draft International Standard (international draft standard circulated to Member Bodies for comment and vote; used in ISO, only)

DS—Proposed Draft (national draft circulated by AAMI for public review, or international standard circulated by AAMI for U.S. public review)

DTR—draft Technical Report (international draft technical report circulated to Member Bodies for comment)

DTS—draft Technical Specification (same as DTR)

FDIS—Final draft International Standard (international draft circulated to ISO or IEC member bodies for final comment and vote. At this stage, comments can only be submitted with a negative vote)

FDS—Final draft American Standard (AAMI standard circulated to ballot committee and any public reviewers for final review prior to final submission)

FDT—Final draft Technical Information Report (AAMI TIR circulated to ballot committee for final review prior to final submission)

FDSB—Standards Board Ballot Draft (national standard or technical information report submitted to AAMI Standards Board for final AAMI approval)

TS—International Technical Specification

WD—Working Draft (any draft that has not been subjected to formal comment or vote)

## ***AAMI National Standards Activity Report -Active and soon to be active projects, only***

<i><b>Project</b></i>	<i><b>Title</b></i>	<i><b>Item</b></i>	<i><b>AAMIActivity</b></i>
<i><b>BallotCommittee:</b></i>			
	Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	NWIP	
	Active implantable medical devices - Requirements for Universal Radio Frequency Identification (RFID) of implantable cardiac pacemakers and implantable cardioverter defibrillators (ICD)	NWIP	
	Cochlear implants - Output characteristics and performance requirements	NWIP	
	Medical Demagnetization	NWIP	
	Processing of flexible and semi-rigid scopes	NWIP	
<i><b>BallotCommittee:</b>    AAMI/AT, Autologous Transfusion Committee</i>			
AAMI AT6/Ed.3	Autologous transfusion devices, 31-May-06	Final (Due for review 12/6/2009)	Development and Adoption
AAMI AT6/Ed.3-Reaff	Periodic review of AAMI AT6:2005, Autologous transfusion devices, 18-Dec-09	Periodic Review Ballot (AAMI/CDV-1)	Periodic Review
<i><b>BallotCommittee:</b>    AAMI/BE/WG 01, Systematic approach to biological evaluation and terminology</i>			
AAMI/ISO TIR15499/Ed.1	Guidance on the conduct of biological evaluation within a risk management process, 08-Mar-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<i><b>BallotCommittee:</b>    AAMI/BE/WG 02, Degradation aspects related to biological testing</i>			
AAMI/ISO 10993-13/Ed.2	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices, 04-Mar-10	Draft (AAMI/FDS-1)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/BE/WG 03, Animal protection aspects</i></b>			
AAMI/ISO 10993-02/Ed.2	Biological evaluation of medical devices - Part 2: Animal welfare requirements, 20-Oct-06	Final (Due for review 7/26/2010)	US Consensus/Parallel Adoption
AAMI/ISO 10993-02/Ed.2-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 10993-2:2006, Biological evaluation of medical devices - Part 2: Animal welfare requirements, 01-Jan-06	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
<b><i>BallotCommittee: AAMI/BE/WG 04, Clinical investigations of medical devices in humans</i></b>			
AAMI/ISO 14155/Ed.3	Clinical investigation of medical devices for human subjects, 27-Oct-09	Draft (AAMI/CDV-3)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/BE/WG 06, Mutagenicity, carcinogenicity and reproductive toxicity</i></b>			
AAMI/ISO 10993-03/Ed.3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, 19-Mar-10	Draft (AAMI/CDV-3)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/BE/WG 07, Systemic toxicity</i></b>			
AAMI/ISO 10993-11/Ed.2	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, 08-Dec-06	Final (Due for review 10/19/2010)	US Consensus/Parallel Adoption
AAMI/ISO 10993-11/Ed.2-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, 17-Feb-10	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
<b><i>BallotCommittee: AAMI/BE/WG 08, Irritation and sensitization</i></b>			
AAMI/ISO 10993-10/Ed.3	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 22-Apr-10	Draft (AAMI/FDS-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/BE/WG 10, Implantation</i></b>			
AAMI/ISO 10993-06/Ed.2	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation, 27-Sep-07	Final (Due for review 4/11/2011)	US Consensus/Parallel Adoption
AAMI/ISO 10993-06/Ed.2-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 10993-6:2007, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation, 01-Jan-07	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee:</i></b> <i>AAMI/BE/WG 11, Allowable limits for leachable substances</i>			
AAMI/ISO TIR29741/Ed.1	Development of Tolerable Intake Values for Di(2-ethylhexyl)phthalate (DEHP)	Project	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BE/WG 12, Sample preparation and reference materials WG</i>			
AAMI/ISO 10993-04/Ed.3	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	NWIP	US Consensus/Parallel Adoption
AAMI/ISO 10993-12/Ed.4	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials, 06-May-10	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BE/WG 14, Material characterization</i>			
AAMI BE83/Ed.1	Biological evaluation of medical devices - Part 18: Chemical characterization of materials, 09-Jun-06	Final (Due for review 5/4/2011)	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BE/WG 16, Pyrogenicity</i>			
AAMI/ISO TIR(194)2/Ed.1	Biological evaluation of medical devices - Principles and methods for pyrogen testing of medical devices	Project	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BF, Blood Filter Committee</i>			
AAMI BF64/Ed.1	Leukocyte reduction filters, 01-Jul-03	Final (Due for review 8/24/2011)	Development and Adoption
AAMI BF7/Ed.2	Blood transfusion micro-filters, 01-Dec-89	Final (Due for review 8/24/2011)	Development and Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BG, Blood/Gas Exchange Device Committee</i>			
AAMI/ISO 11658/Ed.1	Cardiovascular implants and extracorporeal systems - Blood-contact coatings for extracorporeal perfusion systems, 26-Apr-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO TIR23810/Ed.1	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup	Project	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/BP, Blood Pressure Monitoring Committee</i>			
AAMI BP22/Ed.2	Blood pressure transducers, 01-Nov-94	Final (Due for review 11/2/2010)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/CV, Cardiac Valve Prosthesis Committee</i></b>			
AAMI/ISO 5840/Ed.5	Cardiovascular implants - Cardiac valve prostheses	Project	US Consensus/Parallel Adoption
AAMI/ISO 5840-03/Ed.1	Heart valve substitutes implanted by minimally invasive techniques, 29-Mar-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/DF, Defibrillator Committee</i></b>			
AAMI/IEC 60601-2-04/Ed.5	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators, 30-Jan-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/DP, Medical Device Particulates Committee</i></b>			
AAMI TIR(DP)01/Ed.1	Particulates associated with vascular medical devices, 22-Mar-10	Draft (AAMI/CDV-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/EC/WG 01, Ambulatory electrocardiograph WG</i></b>			
AAMI/IEC 60601-2-47/Ed.2	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems, 09-Apr-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/EC/WG 02, Arrhythmia monitoring WG</i></b>			
AAMI EC57/Ed.3	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms, 21-Jan-10	Draft (AAMI/CD-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/EC/WG 03, Cables and leads WG</i></b>			
AAMI EC53/Ed.2	ECG cables and leadwires, 21-Jan-10	Draft (AAMI/CD-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/EC/WG 04, Cardiac monitor and diagnostic ECG WG</i></b>			
AAMI/IEC 60601-2-25/Ed.3	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs, 20-Feb-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/IEC 60601-2-27/Ed.4	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment, 16-Jan-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/EC/WG 06, ECG Electrode WG</i></b>			
AAMI EC12/Ed.3	Disposable ECG electrodes, 27-Oct-00	Final (Due for review 1/6/2009)	Development and Adoption
AAMI EC12/Ed.3-Reaff2	Proposed reaffirmation of ANSI/AAMI EC12:2000/(R)2005, Disposable ECG electrodes, 18-Jun-10	Proposed Reaffirmation (AAMI/FDSB-1)	Reaffirmation
<b><i>BallotCommittee: AAMI/EM, Electromagnetic Compatibility Committee</i></b>			
AAMI/IEC 60601-1-02/Ed.3	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Project	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ES, Electrical Safety Committee</i></b>			
AAMI ES60601-1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, 09-Mar-06	Final (Due for review 2/9/2011)	Intl Secretariat/Parallel Adoption
AAMI ES60601-1:2005/A1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment A1, 29-Jan-10	Draft (AAMI/CD-1)	Intl Secretariat/Parallel Adoption
AAMI ES60601-1:2005/A2/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment A2, 20-Jul-10	Final (Due for review 2/9/2011)	Development and Adoption
AAMI ES60601-1:2005/C1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment C1, 12-Jan-10	Final (Due for review 2/9/2011)	Adoption Only
<b><i>BallotCommittee: AAMI/HA, Medical Devices and Systems in Home Care Applications</i></b>			
AAMI/IEC 60601-1-11/Ed.1	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in home care applications, 08-Jul-10	Draft (AAMI/CDV-1)	US Consensus/Adoption
<b><i>BallotCommittee: AAMI/HE, Human Factors Engineering Committee</i></b>			
AAMI TIR38/Ed.1	Usability objectives - Illustrative examples for home parenteral infusion pumps, 07-Aug-09	Draft (AAMI/CDV-2)	Development and Adoption
AAMI/IEC 62366/Ed.2	Medical devices - Application of usability engineering to medical devices, 31-Aug-09	Draft (AAMI/CDV-2)	Intl Secretariat/Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/ID, Infusion Device Committee</i></b>			
AAMI/IEC 60601-2-24/Ed.4	Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers, 17-Jul-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ID/WG 01, Enteral administration sets connector WG</i></b>			
AAMI ID54/Ed.1	Enteral feeding set adapters and connectors, 21-Oct-96	Final (Due for review 11/29/2010)	Development and Adoption
<b><i>BallotCommittee: AAMI/IT, Information Technology Networks Incorporating Medical Devices</i></b>			
AAMI/IEC 80001-01/Ed.1	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities, 31-Jul-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/MC, Mechanical Circulatory Support Systems Committee</i></b>			
AAMI MC84/Ed.1	Mechanical circulatory support device evaluation - Preclinical testing	NWIP	Development and Adoption
<b><i>BallotCommittee: AAMI/MP, Multi-parameter Patient Monitoring Equipment Committee</i></b>			
AAMI/IEC 60601-2-49/Ed.1	Medical electrical equipment - Part 2-49: Particular requirements for basic safety and essential performance of multifunction patient monitoring equipment, 01-Jul-09	Draft (AAMI/DS-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/NS/WG 01, ICP device WG</i></b>			
AAMI NS28/Ed.1	Intracranial pressure monitoring devices, 01-Dec-88	Final (Due for review 7/26/2010)	Development and Adoption
AAMI NS28/Ed.1-Reaff4	Periodic review of ANSI/AAMI NS28:1988 (R)2006, Intracranial pressure monitoring devices, 18-Jun-10	Proposed Reaffirmation (AAMI/CDV-1)	Periodic Review
<b><i>BallotCommittee: AAMI/NS/WG 03, Transcutaneous electrical stimulator WG</i></b>			
AAMI NS4/Ed.2	Transcutaneous electrical stimulators, 01-Feb-96	Draft (AAMI/WD-1)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/PB, Protective Barriers Committee</i></b>			
AAMI PB70/Ed.2	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, 16-Oct-09	Draft (AAMI/WD-1)	Development and Adoption
AAMI TIR11/Ed.2	Selection and use of protective apparel and surgical drapes in health care facilities, 05-Feb-06	Final (Due for review 10/17/2008)	Development and Adoption
<b><i>BallotCommittee: AAMI/PC, Cardiac Rhythm Management Device Committee</i></b>			
AAMI PC85/Ed.1	Active implantable medical devices - Test protocols for transvenous leads for implantable cardiac pacemakers and implantable cardioverter defibrillators (ICD)	NWIP	Development and Adoption
AAMI TIR21/Ed.2	Systems used to forecast remaining pacemaker battery service life, 14-Dec-09	Draft (AAMI/CDV-1)	Development and Adoption
AAMI TIR41/Ed.1	Guideline for interface between device connector cavity and lead connector for implantable cardiovascular applications, 05-Nov-09	Draft (AAMI/CDV-1)	Development and Adoption
AAMI/ISO 12962/Ed.1	Implants for surgery - Active implantable medical devices - Pacemaker magnet mode response, 20-Oct-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO 14708-06/Ed.1	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators), 10-Dec-09	Draft (AAMI/FDS-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/QM/WG 01, Application of quality systems to medical devices</i></b>			
AAMI/ISO 13485:2003/C1/Ed.1	ANSI/AAMI/ISO 13485:2003, Corrigendum 1, 01-Aug-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO TIR14969/Ed.2	Quality management systems - Medical devices - Guidance on the application of ISO 13485:2003, 06-Jan-05	Final (Due for review 2/28/2011)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/QM/WG 03, Symbols and nomenclature for medical devices</i></b>			
AAMI/ISO 15223-01/Ed.4	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements, 04-Jun-09	Draft (AAMI/CDV-3)	US Consensus/Parallel Adoption
AAMI/ISO TIR19218-01/Ed.2	Medical devices - Hierarchal coding structure for adverse events - Part 1: Event type codes, 10-Jun-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee:</i></b> <i>AAMI/QM/WG 04, Application of risk management to medical devices</i>			
AAMI/ISO 14971/Ed.3-Reaff	Proposed reaffirmation of ANSI/AAAMI/ISO 14971:2007, Medical devices - Application of risk management to medical devices, 01-Jan-07	Proposed Reaffirmation (AAMI/FDS-1)	Reaffirmation
<b><i>BallotCommittee:</i></b> <i>AAMI/QM/WG 05, Small bore connectors for liquids and gases in healthcare applications</i>			
AAMI/ISO 80369-01/Ed.1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements, 18-Jun-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO 80369-02/Ed.1	Small bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases applications, 21-Jul-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO 80369-06/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications, 20-May-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/RD, Renal Disease and Detoxification Committee</i>			
AAMI RD61/Ed.2	Concentrates for hemodialysis, 04-May-07	Final (Due for review 9/29/2010)	Development and Adoption
AAMI RD62/Ed.2	Water treatment equipment for hemodialysis applications, 16-Jan-07	Final (Due for review 12/5/2010)	Development and Adoption
AAMI RD62:2006/A1/Ed.1	Water treatment equipment for hemodialysis applications, Amendment 1 - 4.2.6, Deionization, 08-May-09	Final (Due for review 12/5/2010)	Development and Adoption
AAMI TIR(RD01)/Ed.1	Ultrapure fluids for hemodialysis and related therapies, 04-Mar-10	Draft (AAMI/CDV-1)	Development and Adoption
AAMI TIR(RD02)/Ed.1	Test methodologies used to detect contaminant levels in water used for hemodialysis	NWIP	Development and Adoption
AAMI/IEC 60601-2-16/Ed.4	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, 21-Jan-10	Draft (AAMI/CDV-1)	US Consensus/Adoption
AAMI/ISO 11663/Ed.1	Quality of dialysis fluid for haemodialysis and related therapies, 15-Apr-09	Draft (AAMI/CDV-1)	Adoption Only
AAMI/ISO 23500/Ed.1	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies, 28-Jan-10	Draft (AAMI/CDV-1)	Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/ST/WG 01, Industrial EO sterilization WG</i></b>			
AAMI/ISO 11135-01/Ed.4	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 25-Jul-07	Final (Due for review 7/23/2011)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 02, Radiation sterilization WG</i></b>			
AAMI TIR(ST02)1/Ed.1	Guide for Establishing Process Equivalency in Cobalt 60 Radiation Sterilization Facilities	NWIP	Development and Adoption
AAMI TIR29/Ed.2	Guide for process control in radiation sterilization	Project	Development and Adoption
AAMI TIR37/Ed.1	Sterilization of health care products - Radiation - Guidance on sterilization of human tissue-based products, 20-Nov-07	Final (Due for review 10/15/2010)	Development and Adoption
AAMI/ISO 11137-02/Ed.2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, 02-Jul-10	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
AAMI/ISO 13004/Ed.1	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method Vdmax	NWIP	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 03, Industrial moist heat sterilization WG</i></b>			
AAMI/ISO 17665-01/Ed.3	Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices, 05-Oct-06	Final (Due for review 12/23/2010)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 04, Biological indicators WG</i></b>			
AAMI/ISO 11138-06/Ed.1	Sterilization of health care products - Biological indicators - Part 6: Biological indicators for hydrogen peroxide vapour sterilization processes	Project	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b>BallotCommittee:</b> <i>AAMI/ST/WG 06, Chemical indicators WG</i>			
AAMI/ISO 11140-03/Ed.1	Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test, 17-Jul-07	Final (Due for review 4/12/2011)	US Consensus/Parallel Adoption
AAMI/ISO 11140-04/Ed.1	Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration, 17-Jul-07	Final (Due for review 4/12/2011)	US Consensus/Parallel Adoption
AAMI/ISO 11140-05/Ed.2	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests, 17-Jul-07	Final (Due for review 4/12/2011)	US Consensus/Parallel Adoption
AAMI/ISO 11140-06/Ed.1	Sterilization of health care products - Chemical indicators - Part 6: Class 2 indicators and process challenge devices for use in performance testing for steam sterilizers	Project	US Consensus/Parallel Adoption
<b>BallotCommittee:</b> <i>AAMI/ST/WG 07, Packaging</i>			
AAMI TIR22/Ed.2	Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices - Part 1 and Part 2:2006, 12-Apr-07	Final (Due for review 3/20/2010)	Development and Adoption
AAMI TIR22:2007/A1/Ed.2	Amendment 1 to AAMI TIR22:2007, Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices - Part 1 and Part 2:2006, 12-Jan-09	Final (Due for review 3/20/2010)	Development and Adoption
AAMI/ISO 11607-01/Ed.3	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging, 01-May-06	Final (Due for review 12/23/2010)	US Consensus/Parallel Adoption
AAMI/ISO 11607-01/Ed.3-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging, 28-Jul-09	Proposed Reaffirmation (AAMI/CDV-1)	Reaffirmation
AAMI/ISO 11607-02/Ed.1	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 01-May-06	Final (Due for review 12/23/2010)	US Consensus/Parallel Adoption
AAMI/ISO 11607-02/Ed.1-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 11607-2:2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 28-Jul-09	Proposed Reaffirmation (AAMI/CDV-1)	Reaffirmation
AAMI/ISO 11607-03/Ed.1	Packaging for terminally sterilized medical devices - Part 3: Guidance on the application of ISO 11607-1 and ISO 11607-2	Project	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/ST/WG 08, Microbiological methods WG</i></b>			
AAMI ST72/Ed.2	Bacterial endotoxin -Test methods, routine monitoring and alternatives to batch testing, 09-Jul-10	Draft (AAMI/CDV-4)	Development and Adoption
AAMI/ISO 11737-01/Ed.2	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products, 28-Apr-06	Final (Due for review 1/18/2011)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 09, Aseptic processing WG</i></b>			
AAMI/ISO 13408-07/Ed.1	Aseptic processing of health care products - Part 7: Aseptic qualification of solid medical devices and combination medical devices, 25-Mar-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 10, Liquid chemical sterilization WG</i></b>			
AAMI/ISO 14160/Ed.2	Sterilization of HC products-Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives-Requirements for characterization, devel, valid, and routine control of a sterilization process for med devices, 09-Apr-09	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 12, Instructions for reusable device reprocessing</i></b>			
AAMI TIR12/Ed.3	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 04-Aug-10	Draft (AAMI/FDS-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 13, Washer-disinfectors</i></b>			
AAMI ST15883-02/Ed.1	Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc, 28-Jan-10	Draft (AAMI/CDV-1)	Development and Adoption
AAMI ST15883-03/Ed.1	Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers, 28-Jan-10	Draft (AAMI/CDV-1)	Development and Adoption
AAMI ST15883-04/Ed.1	Washer-disinfectors, Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for themolabile endoscopes	Project	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/ST/WG 40, Steam sterilization hospital practices WG</i></b>			
AAMI ST79:201X/A1/Ed.1	Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Amendment 1, 07-Jun-10	Draft (AAMI/FDS-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 42, Dry heat sterilization WG</i></b>			
AAMI/ISO 20857/Ed.1	Sterilization of health care products - Dry heat: Requirements for the development, validation and routine control of an industrial sterilization process for medical devices, 29-Apr-09	Draft (AAMI/CDV-3)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/ST/WG 43, Hospital steam sterilizer WG</i></b>			
AAMI ST55/Ed.3	Table-top steam sterilizers, 03-Feb-10	Draft (AAMI/CDV-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 61, Chemical sterilants hospital practices WG</i></b>			
AAMI ST58/Ed.3	Chemical sterilization and high-level disinfection in health care facilities, 17-Feb-10	Draft (AAMI/WD-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 90, Sterility Assurance Level (SAL) WG</i></b>			
AAMI ST67/Ed.2	Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled 'sterile', 31-Mar-10	Draft (AAMI/CDV-1)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 91, Resistometer WG</i></b>			
AAMI/ISO 18472/Ed.4	Sterilization of health care products - Biological and chemical indicators - Test equipment, 15-May-06	Final (Due for review 12/23/2010)	US Consensus/Parallel Adoption
AAMI/ISO 18472/Ed.4-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 18472:2006, Sterilization of health care products - Biological and chemical indicators - Test equipment, 28-Jul-09	Proposed Reaffirmation (AAMI/CDV-1)	Reaffirmation
<b><i>BallotCommittee: AAMI/ST/WG 93, Cleaning of reusable medical devices</i></b>			
AAMI TIR30/Ed.2	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, 04-Mar-10	Draft (AAMI/CDV-1)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee: AAMI/ST/WG 94, Rigid sterilization container systems WG</i></b>			
AAMI ST77/Ed.1	Containment devices for reusable medical device sterilization, 16-Jan-07	Final (Due for review 11/2/2010)	Development and Adoption
AAMI ST77/Ed.1-Reaff	Periodic review of ANSI/AAMI ST77:2006, Containment devices for reusable medical device sterilization, 17-Feb-10	Periodic Review Ballot (AAMI/CDV-1)	Periodic Review
<b><i>BallotCommittee: AAMI/ST/WG 95, Water quality for reprocessing medical devices</i></b>			
AAMI TIR34/Ed.1	Water for the reprocessing of medical devices, 15-Jan-08	Final (Due for review 10/15/2010)	Development and Adoption
<b><i>BallotCommittee: AAMI/ST/WG 96, Compatibility of materials subject to sterilization</i></b>			
AAMI TIR17/Ed.2	Compatibility of materials subject to sterilization, 20-Nov-08	Final (Due for review 8/26/2011)	Development and Adoption
<b><i>BallotCommittee: AAMI/SW, Medical Device Software Committee</i></b>			
AAMI TIR32/Ed.1	Medical device software risk management, 15-Feb-05	Final (Due for review 3/21/2011)	Development and Adoption
AAMI TIR36/Ed.1	Validation of software for regulated processes, 17-Mar-08	Final (Due for review 12/13/2010)	Development and Adoption
AAMI/IEC 62304/Ed.1	Medical device software - Software life cycle processes, 19-Jul-06	Final (Due for review 7/17/2011)	Intl Secretariat/Parallel Adoption
<b><i>BallotCommittee: AAMI/TS, Tissue Product Safety Committee</i></b>			
AAMI/ISO 13022/Ed.1	Application of risk management to medical products containing viable human cells, 19-Jan-10	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
<b><i>BallotCommittee: AAMI/TS/WG 04, TSE elimination</i></b>			
AAMI/ISO TIR22442-04/Ed.1	Medical devices utilizing animal tissues and their derivatives- Part 4: Guidance on inactivation or removal of TSE agents / prions potentially contaminating bovine tissue-derived devices and similar or related devices, 16-Feb-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<b><i>BallotCommittee:</i></b> <i>AAMI/VP, Vascular Prostheses Committee</i>			
AAMI/ISO 25539-01/Ed.2	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses	Project	US Consensus/Parallel Adoption
AAMI/ISO 25539-03/Ed.1	Cardiovascular implants - Endovascular devices - Part 3: Vena Cava Filters, 01-Apr-10	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
AAMI/ISO 7198/Ed.2	Cardiovascular implants - Tubular vascular prostheses	Project	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>AAMI/VP/WG 01, Vascular device/Drug combination products</i>			
AAMI/ISO TIR12417/Ed.1	Vascular device-drug combination products, 15-Dec-09	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<b><i>BallotCommittee:</i></b> <i>ISO/TC 150/SC 6, Active Implants</i>			
AAMI/ISO 14117/Ed.1	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices, 26-Jul-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

Endnote: This list includes new work items for which a project record has not yet been set up in the AAMI database, either because the NWIP is still under consideration or for some other reason (staff can supply more information about why an item is on this list on request). Also on this list are any AAMI monographs that are not assigned to a specific committee.

## ***AAMI International Standards Activity Report (listed by U.S. TAG) - Active and soon to be active projects, only***

**TAG:** *AAMI/AD, Aids for Ostomy and Incontinence*

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 12505/Ed.1	Skin barrier - Test methods, 21-Dec-09	Draft (CD-1)	US Consensus
ISO 15621/Ed.2	Urine-absorbing aids - General guidance on evaluation, 14-Sep-09	Draft (DS/DIS-1)	US Consensus
ISO 16021/Ed.1	Urine-absorbing aids - Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers, 29-Dec-00	Final (Due for review 12/29/2005)	US Consensus
ISO 16391/Ed.1	Aids for ostomy and incontinence - Irrigation sets - Requirements and test methods, 17-Oct-02	Final (Due for review 10/17/2007)	US Consensus
ISO 17190-01/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 1: Determination of pH, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-02/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 2: Determination of amount of residual monomers, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-03/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 3: Determination of particle size distribution by sieve fractionation, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-04/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 4: Determination of moisture content by mass loss upon heating, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-05/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 5: Gravimetric determination of free swell capacity in saline solution, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-06/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 6: Gravimetric determination of fluid retention capacity in saline solution after centrifugation, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus

ISO 17190-07/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 7: Gravimetric determination of absorption under pressure, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-08/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 8: Gravimetric determination of flowrate, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-09/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 9: Gravimetric determination of density, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-10/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 10: Determination of extractable polymer content by potentiometric titration, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17190-11/Ed.1	Urine-absorbing aids for incontinence - Test methods for characterizing polymer-based absorbent materials - Part 11: Determination of content of respirable particles, 06-Dec-01	Final (Due for review 12/6/2006)	US Consensus
ISO 17191/Ed.1	Urine-absorbing aids for incontinence - Measurement of airborne respirable polyacrylate superabsorbent materials - Determination of dust in collection cassettes by sodium atomic absorption spectrometry, 01-Feb-04	Final (Due for review 2/1/2009)	US Consensus
ISO 8669-01/Ed.1	Urine collection bags - Part 1: Vocabulary, 01-Jan-88	Final (Due for review 6/24/2004)	US Consensus
ISO 8669-02/Ed.2	Urine collection bags - Part 2: Test methods and requirements, 01-Dec-96	Final (Due for review 12/20/2006)	US Consensus
ISO 8670-02/Ed.2	Ostomy collection bags - Part 2: Test methods and requirements, 01-Dec-96	Final (Due for review 12/20/2006)	US Consensus
ISO 8670-03/Ed.1	Ostomy collection bags - Part 3: Determination of escape of odor, 01-Mar-00	Final (Due for review 3/1/2005)	US Consensus
ISO 9949-01/Ed.1	Urine absorbing aids - Vocabulary - Part 1: Conditions of urinary incontinence, 01-Jan-93	Final (Due for review 10/28/2003)	US Consensus
ISO 9949-02/Ed.1	Urine absorbing aids - Vocabulary - Part 2: Products, 01-Jan-93	Final (Due for review 10/28/2003)	US Consensus
ISO 9949-03/Ed.1	Urine absorbing aids - Vocabulary - Part 3: Identification of product types, 01-Jan-93	Final (Due for review 10/28/2003)	US Consensus

**TAG: AAMI/BE/WG 01, Systematic approach to biological evaluation and terminology**

<b>BallotCommittee:</b>	<i>ISO/TC 194</i>	<b>Secretariat:</b>	<i>DIN</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO TS 20993/Ed.1	Biological evaluation of medical devices - Guidance on a risk management process, 26-Jul-06	Final (Due for review 7/26/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 02, Degradation aspects related to biological testing**

<b>BallotCommittee:</b>	<i>ISO/TC 194</i>	<b>Secretariat:</b>	<i>DIN</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 10993-14/Ed.1	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics, 15-Nov-01	Final (Due for review 7/4/2011)	US Consensus/Parallel Adoption
ISO 10993-15/Ed.1	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys, 01-Feb-01	Final (Due for review 7/4/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 03, Animal protection aspects**

<b>BallotCommittee:</b>	<i>ISO/TC 194</i>	<b>Secretariat:</b>	<i>DIN</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 10993-02/Ed.2	Biological evaluation of medical devices, Part 2: Animal welfare requirements, 06-Jul-06	Final (Due for review 7/6/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 04, Clinical investigations of medical devices in humans**

<b>BallotCommittee:</b>	<i>ISO/TC 194</i>	<b>Secretariat:</b>	<i>DIN</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 14155/Ed.3	Clinical investigation of medical devices for human subjects, 27-Oct-09	Draft (DS/DIS-2)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 06, Mutagenicity, carcinogenicity and reproductive toxicity**

<b>BallotCommittee:</b>	<i>ISO/TC 194</i>	<b>Secretariat:</b>	<i>DIN</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 10993-03/Ed.3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, 19-Mar-10	Draft (CDV/CD-3)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 07, Systemic toxicity**

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-11/Ed.2	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, 15-Aug-06	Final (Due for review 8/15/2011)	US Consensus/Parallel Adoption
ISO TS 10993-20/Ed.1	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices, 03-Aug-06	Final (Due for review 8/3/2009)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 08, Irritation and sensitization**

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-10/Ed.3	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 22-Apr-10	Draft (FDS/FDIS-1)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 11, Allowable limits for leachable substances**

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-17/Ed.1	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances, 27-Nov-02	Final (Due for review 11/27/2007)	US Consensus/Parallel Adoption
ISO TS 29741/Ed.1	Development of Tolerable Intake Values for Di(2-ethylhexyl)phthalate (DEHP), 25-Aug-06	NWIP	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 12, Sample preparation and reference materials WG**

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-04/Ed.3	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood, 25-Aug-06	NWIP	US Consensus/Parallel Adoption
ISO 10993-12/Ed.4	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials, 06-May-10	Draft (DS/DIS-1)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 14, Material characterization**

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-18/Ed.1	Biological evaluation of medical devices - Part 18: Chemical characterization of materials, 30-Jun-05	Final (Due for review 6/30/2010)	US Consensus/Parallel Adoption

ISO TS 10993-19/Ed.1	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials, 19-May-06	Final (Due for review 5/19/2011)	US Consensus/Parallel Adoption
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**TAG: AAMI/BE/WG 15, Strategic approach to biological assessment**

<b>BallotCommittee:</b> ISO/TC 194		<b>Secretariat:</b> DIN	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO TR 15499/Ed.1	Guidance on the conduct of biological evaluation within a risk management process, 08-Mar-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/BE/WG 16, Pyrogenicity**

<b>BallotCommittee:</b> ISO/TC 194		<b>Secretariat:</b> DIN	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO TS (194)2/Ed.1	Biological evaluation of medical devices - Principles and methods for pyrogen testing of medical devices, 02-Feb-07	NWIP	US Consensus/Parallel Adoption

**TAG: AAMI/BG, Blood/Gas Exchange Device Committee**

<b>BallotCommittee:</b> ISO/TC 150/SC 2		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 11658/Ed.1	Cardiovascular implants and extracorporeal systems - Blood-contact coatings for extracorporeal perfusion systems, 26-Apr-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/BP, Blood Pressure Monitoring Committee**

<b>BallotCommittee:</b> IEC/SC 62D		<b>Secretariat:</b> AAMI (USNC)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-34/Ed.3	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment, 20-Feb-09	Draft (CDV/CD-1)	US Consensus

**TAG: AAMI/CV, Cardiac Valve Prostheses Committee**

<b>BallotCommittee:</b> ISO/TC 150/SC 2		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 5840-03/Ed.1	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by minimally invasive techniques, 29-Mar-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/DF, Defibrillator Committee**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b>	<i>AAMI (USNC)</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-04/Ed.3	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators, 05-Nov-08	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/DI, Medical Devices for Injections Committee**

<b>BallotCommittee:</b>	<i>ISO/TC 84</i>	<b>Secretariat:</b>	<i>DS</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 10555-01/Ed.2	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements, 03-Mar-10	Draft (CDV/CD-1)	US Consensus
ISO 11608-01/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods - Part 1: Needle-based injection systems, 17-Feb-10	Draft (CDV/CD-2)	US Consensus
ISO 11608-02/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles, 17-Feb-10	Draft (CDV/CD-2)	US Consensus
ISO 11608-03/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Container closures, 17-Feb-10	Draft (CDV/CD-2)	US Consensus
ISO 11608-04/Ed.1	Pen-injectors for medical use - Part 4: Requirements and test methods for electronic and electromechanical pen-injectors, 17-Mar-06	Final (Due for review 3/17/2011)	US Consensus
ISO 11608-05/Ed.1	Needle-based injection systems for medical use -- Requirements and test methods -- Part 5: Automated functions, 17-Feb-10	Draft (CDV/CD-2)	US Consensus
ISO 23907/Ed.1	Sharps injury protection -- Requirements and test methods -- Sharps containers for potentially infectious medical waste, 27-Aug-09	Draft (CDV/CD-1)	US Consensus
ISO 23908-01/Ed.1	Sharps injury protection -- Requirements and test methods -- Part 1: Sharps protection features for single-used hypodermic needles, catheters, introducers for catheters and needles used for blood sampling, 27-Oct-09	Draft (DS/DIS-1)	US Consensus
ISO 23908-02/Ed.1	Sharps injury protection - Requirements and test methods - Part 2: Accessories for handling hypodermic needles after use	NWIP	US Consensus
ISO 594-02/Ed.2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings - Revision of ISO 594-2:1991, 03-Sep-98	Final (Due for review 10/20/2008)	US Consensus
ISO 595-02/Ed.1	Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests, 01-Jan-87	Final (Due for review 5/30/2010)	US Consensus

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10555-01:1995/A1/Ed.1	Amendment No 1 to ISO 10555-1 - Sterile, single use intravascular catheters Part 1: 1995 - General requirements, 22-Jul-99	Final (Due for review 7/25/2010)	US Consensus
ISO 10555-01:1999/A2/Ed.1	Amendment 2 to ISO 10555-1, Sterile, single-use intravascular catheters - Part 1: General requirements, 13-May-04	Final (Due for review 7/25/2010)	US Consensus
ISO 10555-02/Ed.1	Sterile single use intravascular catheters - Part 2: Angiographic catheters, 15-Jun-96	Final (Due for review 7/10/2011)	US Consensus
ISO 10555-03/Ed.1	Sterile single use intravascular catheters - Part 3: Central venous catheters, 15-Jun-96	Final (Due for review 7/10/2011)	US Consensus
ISO 10555-04/Ed.1	Sterile single use intravascular catheters - Part 4: Balloon dilation catheters, 15-Jun-96	Final (Due for review 7/10/2011)	US Consensus
ISO 10555-05/Ed.1	Sterile single use intravascular catheters - Part 5: Over-the-needle peripheral intravascular catheters, 15-Jun-96	Final (Due for review 7/10/2011)	US Consensus
ISO 10555-05:1996/A1/Ed.1	Amendment No 1 to ISO 10555-5 - Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters, 06-Jun-02	Final (Due for review 6/6/2007)	US Consensus
ISO 11070/Ed.1	Sterile single-use intravascular catheter introducers, 01-Jun-98	Final (Due for review 2/7/2010)	US Consensus
ISO 14972/Ed.1	Sterile obturators for single use with over-needle peripheral intravascular catheters, 01-Dec-98	Final (Due for review 2/7/2010)	US Consensus
ISO 7864/Ed.3	Sterile hypodermic needles for single use, 01-Jan-93	Final (Due for review 2/7/2010)	US Consensus
ISO 7886-01/Ed.1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use, 01-Jan-93	Final (Due for review 2/7/2010)	US Consensus
ISO 7886-02/Ed.1	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps, 15-Jun-96	Final (Due for review 7/10/2011)	US Consensus
ISO 7886-03/Ed.1	Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed dose immunisation, 09-Mar-05	Final (Due for review 3/9/2010)	US Consensus
ISO 9626/Ed.1	Stainless steel needle tubing for the manufacture of medical devices, 01-Jan-91	Final (Due for review 7/25/2010)	US Consensus
ISO 9626:1991/A1/Ed.1	Stainless steel needle tubing for the manufacture of medical devices, Amendment 1, 28-Jun-01	Final (Due for review 7/25/2010)	US Consensus

**TAG: AAMI/DI/WG 01, Needle-free injections working group**

<b>BallotCommittee:</b>	<i>ISO/TC 84</i>	<b>Secretariat:</b>	<i>DS</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 21649/Ed.1	Needle-free injectors for medical use - Requirements and test methods, 19-May-06	Final (Due for review 5/19/2011)	US Consensus

**TAG: AAMI/EC/WG 01, Ambulatory electrocardiograph WG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b>	<i>AAMI (USNC)</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-47/Ed.2	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems, 09-Apr-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/EC/WG 04, Cardiac monitor and diagnostic ECG WG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b>	<i>AAMI (USNC)</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-25/Ed.2	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs, 20-Feb-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption
IEC 62D/60601-2-27/Ed.3	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment, 16-Jan-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption
IEC 62D/60601-2-51/Ed.1	Medical electrical equipment, Part 2-51: Particular requirements for the safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs, 03-Feb-03	Final (Due for review 1/1/2009)	US Consensus

**TAG: AAMI/EV/WG 01, Anesthesia equipment sub-TAG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b>	<i>AAMI (USNC)</i>
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 80601-2-13/Ed.4	Medical electrical equipment - Part 2-13: Particular requirements for the basic safety and essential performance of an anaesthetic workstation, 03-Oct-09	Draft (CDV/CD-1)	AAMI Comments

<b>BallotCommittee:</b>	<i>See Endnote</i>	<b>Secretariat:</b>		
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 8835-01/Ed.1	Inhalational anaesthesia systems - Part 1: Anaesthetic workstations and their requirements - Particular requirements, 01-May-98	Final (Due for review 5/1/2003)	AAMI Comments	

**TAG: AAMI/EV/WG 02, EEG/Electroconvulsive equipment sub-TAG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b> <i>AAMI (USNC)</i>		
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
IEC 62D/60601-2-26/Ed.3	Medical electrical equipment - Part 2-26: Particular requirements for basic safety and essential performance of electroencephalographs, 24-Apr-09	Draft (CDV/CD-1)	US Consensus	

**TAG: AAMI/EV/WG 03, EMG and evoked response equipment sub-TAG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b> <i>AAMI (USNC)</i>		
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
IEC 62D/60601-2-40/Ed.1	Medical electrical equipment, Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment, 01-Feb-98	Final (Due for review 1/1/2009)	US Consensus	

**TAG: AAMI/EV/WG 04, Electro-optical equipment sub-TAG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b> <i>AAMI (USNC)</i>		
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
IEC 62D/60601-2-18/Ed.3	Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment, 12-Aug-09	Final (Due for review 8/12/2011)	US Consensus	

**TAG: AAMI/EV/WG 05, Hospital beds sub-TAG**

<b>BallotCommittee:</b>	<i>IEC/SC 62D</i>	<b>Secretariat:</b> <i>AAMI (USNC)</i>		
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
IEC 62D/60601-2-46/Ed.2	Medical electrical equipment - Part 2-46: Particular requirements for basic safety and essential performance of operating tables, 16-Jan-09	Draft (CDV/CD-1)	US Consensus	

**TAG: AAMI/EV/WG 06, Misc. electromedical equipment sub-TAG**

<i>BallotCommittee: IEC/SC 62D</i>		<i>Secretariat: AAMI (USNC)</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-03/Ed.3	Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment, 02-Oct-09	Draft (CD-1)	US Consensus	
IEC 62D/60601-2-06/Ed.2	Medical electrical equipment - Part 2-6: Particular requirements for basic safety and essential performance of microwave therapy equipment, 02-Oct-09	Draft (CD-1)	US Consensus	

**TAG: AAMI/EV/WG 07, Transc. partial pressure monit. equip. sub-TAG**

<i>BallotCommittee: IEC/SC 62D</i>		<i>Secretariat: AAMI (USNC)</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-23/Ed.3	Medical electrical equipment - Part 2-23: Particular requirements for basic safety and essential performance of transcutaneous partial pressure monitoring equipment, 20-Feb-09	Draft (CDV/CD-1)	US Consensus	
IEC 62D/60601-3-01/Ed.1	Medical electrical equipment, Part 3: Particular requirements for the performance of transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment, 01-Jul-96	Final (Due for review 1/1/2009)	US Consensus	

**TAG: AAMI/EV/WG 08, Ultrasound sub-TAG**

<i>BallotCommittee: IEC/SC 62D</i>		<i>Secretariat: AAMI (USNC)</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-62/Ed.1	Medical electrical equipment - Part 2-62: Particular requirements for basic safety and essential performance of high intensity therapeutic ultrasound (HITU) system, 16-Apr-10	Draft (CD-1)	US Consensus	
IEC 62D/60601-2-62/Ed.1	Medical electrical equipment - Part 2-62: Particular requirements for basic safety and essential performance of high intensity therapeutic ultrasound (HITU) system, 13-Jun-08	NWIP	US Consensus	
IEC 87/61689/Ed.2	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz, 09-Aug-07	Final (Due for review 8/9/2011)	AAMI Comments	

**TAG: AAMI/EV/WG 09, Lung ventilators sub-TAG**

<i>BallotCommittee:</i> IEC/SC 62D		<i>Secretariat:</i> AAMI (USNC)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO 27427/Ed.1	Anaesthetic and respiratory equipment - Nebulizer systems and components, 31-Aug-07	Draft (CDV/CD-1)	AAMI Comments	
ISO 80601-2-12/Ed.1	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators, 31-Jul-09	Draft (CDV/CD-1)	AAMI Comments	
ISO 80601-2-55/Ed.2	Medical electrical equipment - Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors, 09-Oct-09	Draft (CDV/CD-1)	AAMI Comments	

<i>BallotCommittee:</i> See Endnote		<i>Secretariat:</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO 10651-01/Ed.2	Medical electrical equipment, Part 2: Particular requirements for the safety of lung ventilators, 01-Oct-01	Final (Due for review 10/1/2006)	AAMI Comments	

**TAG: AAMI/ID, Infusion Device Committee**

<i>BallotCommittee:</i> IEC/SC 62D		<i>Secretariat:</i> AAMI (USNC)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-24/Ed.2	Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential performance of infusion pumps and controllers, 17-Jul-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	

**TAG: AAMI/II, Infant Incubator Committee**

<i>BallotCommittee:</i> IEC/SC 62D		<i>Secretariat:</i> AAMI (USNC)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-50/Ed.2	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment, 24-Mar-09	Final (Due for review 3/24/2011)	US Consensus/Parallel Adoption	

**TAG: AAMI/MP, Multi-parameter Patient Monitoring Equipment Committee**

<i>BallotCommittee:</i> IEC/SC 62D		<i>Secretariat:</i> AAMI (USNC)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 62D/60601-2-49/Ed.2	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment, 20-Feb-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	

**TAG: AAMI/NS/WG 03, Transcutaneous electrical stimulator WG**

<b>BallotCommittee:</b> IEC/SC 62D		<b>Secretariat:</b> AAMI (USNC)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-10/Ed.2	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators, 02-Oct-09	Draft (CD-1)	US Consensus

**TAG: AAMI/PC, Cardiac Rhythm Management Device Committee**

<b>BallotCommittee:</b> IEC/SC 62D		<b>Secretariat:</b> AAMI (USNC)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
IEC 62D/60601-2-31/Ed.2	Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source, 26-Mar-08	Final (Due for review 3/1/2010)	US Consensus
IEC 62D/60601-2-31:2008/A1/Ed. 1	Medical electrical equipment - Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source, Amendment 1, 26-Mar-10	Draft (CDV/CD-1)	US Consensus

<b>BallotCommittee:</b> ISO/TC 150/SC 6		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 12962/Ed.1	Implants for surgery - Active implantable medical devices - Pacemaker magnet mode response, 21-Oct-09	Draft (CD-1)	US Consensus/Parallel Adoption
ISO 14117/Ed.1	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators, 26-Jul-10	Draft (DS/DIS-1)	US Consensus/Parallel Adoption
ISO 14708-02/Ed.2	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers, 16-Feb-10	Draft (CD-1)	US Consensus
ISO 27185/Ed.1	Active implantable medical devices - Symbols to be used with cardiac device labels, labeling and information to be supplied by the manufacturer, 05-Sep-08	Draft (CDV/CD-1)	US Consensus
ISO 5841-02/Ed.2	Implants for surgery - Cardiac pacemakers - Part 2: Reporting of the clinical performance of populations of pulse generators or leads, 15-Oct-00	Final (Due for review 12/9/2010)	US Consensus
ISO 5841-03/Ed.2	Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers, 29-Dec-00	Final (Due for review 12/9/2010)	US Consensus

**TAG: AAMI/QM, Quality Management and Corresponding General Aspects for Medical Devices**

<b>BallotCommittee:</b>	<i>ISO/TC 210</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO TS 19218-01/Ed.2	Medical devices - Hierarchal coding structure for adverse events - Part 1: Event type codes, 10-Jun-10	Draft (CDV/CD-2)	US Consensus/Parallel Adoption	

**TAG: AAMI/QM/WG 01, Application of quality systems to medical devices**

<b>BallotCommittee:</b>	<i>ISO/TC 210</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 13485:2003/C1/Ed.1	ISO 13485:2003, Corrigendum 1	NWIP	US Consensus/Parallel Adoption	
ISO TR 14969/Ed.2	Quality management systems - Medical devices - Guidance on the application of ISO 13485:2003, 15-Oct-04	Final (Due for review 11/1/2010)	US Consensus/Parallel Adoption	

**TAG: AAMI/QM/WG 02, General aspects stemming from the application of quality principles to medical devices**

<b>BallotCommittee:</b>	<i>ISO/TC 210</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO TR 16142/Ed.2	Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices, 13-Jan-06	Final (Due for review 1/13/2011)	US Consensus/Parallel Adoption	

**TAG: AAMI/QM/WG 03, Symbols and nomenclature for medical devices**

<b>BallotCommittee:</b>	<i>ISO/TC 210</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 15223-01/Ed.4	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements, 04-Jun-09	Draft (DS/DIS-1)	US Consensus/Parallel Adoption	

**TAG: AAMI/QM/WG 04, Application of risk management to medical devices**

<b>BallotCommittee:</b>	<i>ISO/TC 210</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO/IEC Guide 63/Ed.2	Guide to the development and inclusion of safety aspects in International Standards for medical devices, 01-Jul-09	Draft (CD-1)	US Consensus	

**TAG: AAMI/QM/WG 05, Small bore connectors for liquids and gases in healthcare applications**

<i>BallotCommittee:</i>	<i>ISO/TC 210</i>	<i>Secretariat:</i>	<i>AAMI (ANSI)</i>
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 80369-01/Ed.1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements, 18-Jun-09	Draft (DS/DIS-1)	US Consensus/Parallel Adoption
ISO 80369-01/Ed.1	Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements, 18-Jun-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption
ISO 80369-02/Ed.1	Small bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases applications, 21-Jul-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption
ISO 80369-03/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications, 10-Feb-10	NWIP	US Consensus/Parallel Adoption
ISO 80369-03/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications, 10-Mar-10	NWIP	US Consensus/Parallel Adoption
ISO 80369-05/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications, 10-Mar-10	NWIP	US Consensus/Parallel Adoption
ISO 80369-05/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications, 19-Mar-10	NWIP	US Consensus/Parallel Adoption
ISO 80369-06/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications, 11-Jun-10	Draft (CD-1)	US Consensus/Parallel Adoption
ISO 80369-06/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications, 20-May-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/RD, Renal Disease and Detoxification Committee**

<i>BallotCommittee:</i>	<i>IEC/SC 62D</i>	<i>Secretariat:</i>	<i>AAMI (USNC)</i>
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62D/60601-2-16/Ed.3	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, 25-Apr-08	Final (Due for review 4/25/2011)	US Consensus/Adoption
IEC 62D/TR 62653/Ed.1	Guideline for the safe use of medical products in dialysis treatment (proposed technical report), 28-Apr-10	NWIP	US Consensus
IEC 62D/TR 62653/Ed.1	Guideline for the safe use of medical products in dialysis treatment (proposed technical report), 05-Jun-09	NWIP	US Consensus

**BallotCommittee:** ISO/TC 150/SC 2 **Secretariat:** AAMI (ANSI)

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 23500/Ed.1	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies, 28-Jan-10	Draft (DS/DIS-2)	US Consensus

**TAG: AAMI/SP, Sphygmomanometer Committee**

**BallotCommittee:** IEC/SC 62D **Secretariat:** AAMI (USNC)

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62D/80601-2-30/Ed.1	Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers, 28-Jan-09	Final (Due for review 1/28/2011)	US Consensus/Parallel Adoption
IEC 62D/80601-2-30:2009/A1/Ed.2	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, 07-May-10	NWIP	US Consensus/Parallel Adoption
ISO 81060-2:2009/A1/Ed.2	Non-invasive sphygmomanometers - Clinical validation of automated measurement type, Amendment 1, 07-May-10	NWIP	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 01, Industrial EO sterilization WG**

**BallotCommittee:** ISO/TC 198 **Secretariat:** AAMI (ANSI)

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO TS 11135-02/Ed.2	Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1, 17-Jul-08	Final (Due for review 7/17/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 02, Radiation sterilization WG**

**BallotCommittee:** ISO/TC 198 **Secretariat:** AAMI (ANSI)

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 11137-02/Ed.2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, 02-Jul-10	Draft (DS/DIS-2)	US Consensus/Parallel Adoption
ISO TS 13004/Ed.1	Expansion of Vdmax substantiation doses in ISO 11137-2, 25-Apr-08	NWIP	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 03, Industrial moist heat sterilization WG**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 17665-01/Ed.2	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, 17-Aug-06	Final (Due for review 8/17/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 04, Biological indicators WG**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 11138-06/Ed.1	Sterilization of health care products - Biological indicators - Part 6: Biological indicators for hydrogen peroxide vapour sterilization processes, 01-Jun-09	Draft (WD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 05, Sterilization Terminology WG**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO TS 11139/Ed.2	Sterilization of health care products - Vocabulary, 13-Jan-06	Final (Due for review 1/13/2011)	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 06, Chemical indicators WG**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 11140-06/Ed.1	Sterilization of health care products - Chemical indicators - Part 6: Class 2 indicators and process challenge devices for use in performance testing for steam sterilizers, 15-May-08	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 07, Packaging**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 11607-03/Ed.1	Packaging for terminally sterilized medical devices - Part 3: Guidance on the application of ISO 11607-1 and ISO 11607-2, 22-May-08	NWIP	US Consensus/Parallel Adoption

**TAG: AAMI/ST/WG 08, Microbiological methods WG**

<b>BallotCommittee:</b>	<i>ISO/TC 198</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 11737-01/Ed.2	Sterilization of medical devices - Microbiological methods - Part 1: Estimation of the population of microorganisms on product, 20-Mar-06	Final (Due for review 3/20/2011)	US Consensus/Parallel Adoption	

**TAG: AAMI/ST/WG 09, Aseptic processing WG**

<b>BallotCommittee:</b>	<i>ISO/TC 198</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 13408-02/Ed.1	Aseptic processing of health care products - Part 2: Filtration, 26-Mar-03	Final (Due for review 3/26/2008)	US Consensus	
ISO 13408-03/Ed.1	Aseptic processing of health care products - Part 3: Lyophilization, 01-Sep-06	Final (Due for review 9/1/2011)	US Consensus	
ISO 13408-04/Ed.1	Aseptic processing of health care products - Part 4: Clean-in-place technologies, 28-Oct-05	Final (Due for review 10/28/2010)	US Consensus	
ISO 13408-06/Ed.1	Aseptic processing of health care products - Part 6: Isolator systems, 20-Jun-05	Final (Due for review 6/20/2010)	US Consensus	
ISO 13408-07/Ed.1	Aseptic processing of health care products -- Part 7: Aseptic qualification of solid medical devices and combination medical devices, 23-Mar-10	Draft (CD-1)	US Consensus	
ISO 13408-08/Ed.1	Aseptic processing of health care products - Part 8: Cell based health care products, 25-Apr-08	NWIP	US Consensus/Parallel Adoption	

**TAG: AAMI/ST/WG 10, Liquid chemical sterilization WG**

<b>BallotCommittee:</b>	<i>ISO/TC 198</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 14160/Ed.2	Sterilization of HC products-Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives-Requirements for characterization, devel, valid, and routine control of a sterilization process for med devices, 09-Apr-09	Draft (DS/DIS-1)	US Consensus/Parallel Adoption	

**TAG: AAMI/ST/WG 13, Washer-disinfectors**

<b>BallotCommittee:</b>	<i>ISO/TC 198</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO 15883-01/Ed.1	Washer-disinfectors, Part 1: General requirements, terms and definitions and tests, 06-Apr-06	Final (Due for review 4/6/2011)	US Consensus	

ISO 15883-02/Ed.1	Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc, 06-Apr-06	Final (Due for review 4/6/2011)	US Consensus
ISO 15883-03/Ed.1	Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers, 06-Apr-06	Final (Due for review 4/6/2011)	US Consensus
ISO 15883-06/Ed.1	Washer-disinfectors, Part 6: Requirements and tests for general purpose washer-disinfectors employing thermal disinfection for non-invasive medical devices, washbowls, utensils, transit containers, etc, 20-May-09	Draft (DS/DIS-1)	US Consensus
ISO TS 15883-05/Ed.1	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy of washer-disinfectors, 23-Nov-05	Final (Due for review 11/23/2010)	US Consensus

**TAG: AAMI/ST/WG 42, Dry heat sterilization WG**

<b>BallotCommittee:</b> ISO/TC 198		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 20857/Ed.1	Sterilization of health care products - Dry heat: Requirements for the development, validation and routine control of an industrial sterilization process for medical devices, 18-Dec-09	Draft (FDS/FDIS-1)	US Consensus/Parallel Adoption

**TAG: AAMI/TS, Tissue Product Safety Committee**

<b>BallotCommittee:</b> ISO/TC 194/SC 1		<b>Secretariat:</b> DIN	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 13022/Ed.1	Tissue product safety - Application of risk management to viable materials of human origin used for the production of medical products, 19-Jan-10	Draft (CDV/CD-2)	US Consensus/Parallel Adoption
ISO TR 22442-04/Ed.1	Medical devices utilizing animal tissues and their derivatives: Part 4: Guidance on inactivation or removal of TSE agents / prions potentially contaminating bovine tissue-derived devices and similar or related devices, 16-Feb-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

**TAG: AAMI/VP, Vascular Prostheses Committee**

<b>BallotCommittee:</b> ISO/TC 150/SC 2		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 25539-03/Ed.1	Cardiovascular implants - Endovascular devices - Part 3: Vena Cava Filters, 01-Apr-10	Draft (DS/DIS-1)	US Consensus/Parallel Adoption
ISO TS 15539/Ed.1	Cardiovascular implants - Endovascular prostheses, 26-Oct-00	Final (Due for review 10/26/2009)	US Consensus

**TAG: AAMI/VP/WG 01, Vascular device/Drug combination products**

<b>BallotCommittee:</b>	<i>ISO/TC 150/SC 2</i>	<b>Secretariat:</b>	<i>AAMI (ANSI)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
ISO TS 12417/Ed.1	Vascular device-drug combination products, 15-Dec-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	

**TAG: Advamed**

<b>BallotCommittee:</b>	<i>IEC/SC 62A</i>	<b>Secretariat:</b>	<i>AAMI (USNC)</i>	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>	
IEC 62/60601-1-04/Ed.1	Medical electrical equipment, Part 1: General requirements for safety. 4. Collateral standard: Programmable electrical medical systems, 01-May-96	Final (Due for review 12/1/2010)	AAMI Comments	
IEC 62/60601-1-04:1996/A1/Ed.1	Amendment to IEC 60601-1-4:1996, Medical electrical equipment, Part 1: General requirements for safety - 4: Collateral standard: Programmable electrical medical systems, 01-Dec-99	Final (Due for review 12/1/2010)	AAMI Comments	
IEC 62A/1288-01/Ed.1	Cardiac defibrillators - Cardiac defibrillators-monitors, Part 1: Operation, 01-Oct-93	Final (Due for review 11/15/2009)	AAMI Comments	
IEC 62A/1288-02/Ed.1	Cardiac defibrillators - Cardiac defibrillators-monitors, Part 2: Maintenance, 01-Oct-93	Final (Due for review 11/15/2009)	AAMI Comments	
IEC 62A/1289-01/Ed.1	High frequency surgical equipment, Part 1: Operation, 01-Jul-94	Final (Due for review 11/15/2009)	AAMI Comments	
IEC 62A/1289-02/Ed.1	High frequency surgical equipment, Part 2: Maintenance, 01-Aug-94	Final (Due for review 11/15/2009)	AAMI Comments	
IEC 62A/60601-1:2005/A1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment 1, 29-Jan-10	Draft (CD-1)	Intl Secretariat/Parallel Adoption	
IEC 62A/60601-1-01/Ed.2	Medical electrical equipment, Part 1: General requirements for safety- 1. Collateral standard: Safety requirements for medical electrical systems, 15-Dec-00	Final (Due for review 12/1/2010)	Intl Secretariat Only	
IEC 62A/60601-1-02/Ed.4	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, 28-Aug-09	Draft (CD-1)	Parallel Adoption	
IEC 62A/60601-1-08:2006/A1/Ed.1	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, 03-Jul-09	NWIP	Intl Secretariat/AAMI Comments	
IEC 62A/62304/Ed.1	Medical device software - Software life cycle processes, 09-May-06	Final (Due for review 5/9/2011)	US Consensus/Parallel Adoption	

IEC 62A/80001-01/Ed.1	Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities, 31-Jul-09	Draft (CDV/CD-1)	US Consensus/Parallel Adoption
IEC 62A/TR 60513/Ed.3	Fundamental aspects of safety, 01-May-09	Draft (CD-1)	Intl Secretariat/AAMI Comments
IEC 62A/TR 60878/Ed.2	Graphical symbols for electrical equipment in medical practice, 01-Jul-03	Final (Due for review 7/1/2009)	Intl Secretariat/AAMI Comments
IEC 62A/TR 62348/Ed.1	Mapping between the clauses of the third edition of IEC 60601-1 and the 1988 edition as amended, 22-May-06	Final (Due for review 5/22/2011)	Intl Secretariat/Parallel Adoption

**BallotCommittee:** *IEC/TC 62* **Secretariat:** *DKE*

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62/60788/Ed.2	Medical electrical equipment - Glossary of defined terms, 17-Feb-04	Final (Due for review 9/1/2005)	Tracking Only

**TAG:** *See Endnote*

**BallotCommittee:** *IEC/SC 3C* **Secretariat:** *NNI*

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62A/60417 f45 Ed.1	Graphical symbol for radiological radiation filter, 31-Aug-99	Final (Due for review 8/31/2004)	Intl Secretariat Only
IEC 62A/60417/f57/Ed.1	Amendment to IEC 60417, Ed.1: Graphical symbol for baby, 31-Jul-00	Final (Due for review 7/31/2005)	Intl Secretariat Only
IEC 62A/60878/F3/Ed.2	Amendment to IEC 60878, Ed. 2: Graphical symbols for use on medical equipment - Part 4: Ultrasonic diagnostic (5687 Pr through 5724 Pr and 5754 Pr through 5756 Pr), 31-Jul-00	Final (Due for review 7/31/2005)	Intl Secretariat Only

**BallotCommittee:** *IEC/SC 62D* **Secretariat:** *AAMI (USNC)*

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62D/60601-2-36/Ed.1	Medical electrical equipment, Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy, 01-Mar-97	Final (Due for review 1/1/2009)	Intl Secretariat Only

**BallotCommittee:** *See Endnote* **Secretariat:**

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO/TC 150/SC 2 N561	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators), Amendment 1: Clarifications for test methodologies, labelling, and sampling schedule, 15-Jan-10	NWIP	
ISO/TC 173/SC 3 N472	Urine-absorbing aids for incontinence -- Measurement of airborne respirable polyacrylate superabsorbent materials -- Determination of dust in collection cassettes by sodium atomic absorption spectrometry, 30-Jun-09	NWIP	

ISO/TC 84 N636	Sterile, single-use intravascular catheters -- Part 3: Central venous catheters, 16-Dec-09	NWIP
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**TAG: US TAG for IEC/SC 62D, Electromedical Equipment**

<b>BallotCommittee:</b> IEC/SC 62D		<b>Secretariat:</b> AAMI (USNC)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 80601-2-60/Ed.1	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment, 30-Apr-10	Draft (CDV/CD-1)	US Consensus
ISO 80601-2-61/Ed.1	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeters, 22-May-09	Draft (CDV/CD-1)	US Consensus

**TAG: US TAG for ISO/TC 150/SC 6, Active Implants**

<b>BallotCommittee:</b> ISO/TC 150/SC 6		<b>Secretariat:</b> AAMI (ANSI)	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 10310/Ed.1	Neurosurgical implants - Marking and packaging of implantable neural stimulators, 01-Jan-95	Final (Due for review 8/1/2011)	US Consensus
ISO 14708-01/Ed.2	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer, 20-Jul-10	Draft (CD-1)	US Consensus
ISO TS 10974/Ed.1	Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device, 16-Feb-07	NWIP	US Consensus

**TAG: US TAG for ISO/TC 76, Transfusion, Infusion and Injection Equipment for Medical or Pharmaceutical Use**

<b>BallotCommittee:</b> ISO/TC 76		<b>Secretariat:</b> DIN	
<b>Project</b>	<b>Title</b>	<b>Item</b>	<b>AAMIActivity</b>
ISO 11040-02/Ed.1	Prefilled syringes -- Part 2: Plungers and discs for dental local anaesthetic cartridges, 22-Dec-94	Final (Due for review 12/22/1999)	US Consensus
ISO 11040-02/Ed.2	Prefilled syringes -- Part 2: Plunger stoppers for dental local anaesthetic cartridges, 23-Feb-10	Draft (DS/DIS-1)	US Consensus
ISO 11040-03/Ed.2	Prefilled syringes -- Part 3: Seals for dental local anaesthetic cartridges, 03-May-10	Draft (DS/DIS-1)	US Consensus
ISO 11040-05/Ed.2	Prefilled syringes -- Part 5: Plungers for injectables, 20-Dec-01	Final (Due for review 12/20/2006)	US Consensus
ISO 11040-05/Ed.3	Prefilled syringes -- Part 5: Plunger stoppers for injectables, 23-Feb-10	Draft (DS/DIS-1)	US Consensus
ISO 11040-06/Ed.1	Prefilled syringes -- Part 6: Plastics barrels for injectables, 15-Mar-10	Draft (CDV/CD-1)	US Consensus

ISO 1135-03/Ed.1	Transfusion equipment for medical use -- Part 3: Blood-taking set, 06-Nov-86	Final (Due for review 11/6/1991)	US Consensus
ISO 11418-05/Ed.1	Containers and accessories for pharmaceutical preparations -- Part 5: Dropper assemblies, 25-Dec-97	Final (Due for review 12/25/2002)	US Consensus
ISO 11418-07/Ed.1	Containers and accessories for pharmaceutical preparations -- Part 7: Screw-neck vials made of glass tubing for liquid dosage forms, 24-Sep-98	Final (Due for review 9/24/2003)	US Consensus
ISO 13926-02/Ed.1	Pen systems -- Part 2: Plungers and discs for pen-injectors for medical use, 22-Apr-99	Final (Due for review 4/22/2004)	US Consensus
ISO 13926-02/Ed.2	Pen systems -- Part 2: Plungers stoppers for pen-injectors for medical use, 23-Feb-10	Draft (DS/DIS-1)	US Consensus
ISO 13926-03/Ed.1	Pen systems -- Part 3: Seals for pen-injectors for medical use, 10-Mar-09	NWIP	US Consensus
ISO 15378/Ed.1	Primary packaging materials for medicinal products -- Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP), 01-Mar-06	Final (Due for review 3/1/2011)	US Consensus
ISO 15378/Ed.2	Primary packaging materials for medicinal products -- Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP), 17-Feb-09	Draft (DS/DIS-1)	US Consensus
ISO 3826-01/Ed.1	Plastics collapsible containers for human blood and blood components -- Part 1: Conventional containers, 13-Nov-03	Final (Due for review 11/13/2008)	US Consensus
ISO 6710/Ed.1	Single-use containers for venous blood specimen collection, 03-Aug-95	Final (Due for review 8/3/2000)	US Consensus
ISO 8362-03/Ed.2	Injection containers and accessories -- Part 3: Aluminium caps for injection vials, 20-Dec-01	Final (Due for review 12/20/2006)	US Consensus
ISO 8362-04/Ed.2	Injection containers and accessories -- Part 4: Injection vials made of moulded glass, 25-Jul-03	Final (Due for review 7/25/2008)	US Consensus
ISO 8362-07/Ed.2	Injection containers and accessories -- Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part, 19-Apr-06	Final (Due for review 4/19/2011)	US Consensus
ISO 8536-01/Ed.3	Infusion equipment for medical use -- Part 1: Infusion glass bottles, 23-Mar-06	Final (Due for review 3/23/2011)	US Consensus
ISO 8536-04/Ed.5	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed, 14-Jul-09	Draft (DS/DIS-1)	US Consensus
ISO 8871-01/Ed.1	Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 1: Extractables in aqueous autoclavates, 19-Sep-03	Final (Due for review 9/19/2008)	US Consensus

ISO 8871-02:2003/A1/Ed.1	Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 2: Identification and characterization, Amendment 1, 22-Jul-05	Final (Due for review 7/22/2010)	US Consensus
ISO 8871-04/Ed.1	Elastomeric parts for parenterals and for devices for pharmaceutical use -- Part 4: Biological requirements and test methods, 14-Jun-06	Final (Due for review 6/14/2011)	US Consensus
ISO 9187-01/Ed.3	Injection equipment for medical use -- Part 1: Ampoules for injectables, 19-Apr-06	Final (Due for review 4/19/2011)	US Consensus
ISO 9187-01/Ed.4	Injection equipment for medical use -- Part 1: Ampoules for injectables, 15-Aug-09	Draft (DS/DIS-1)	US Consensus
ISO 9187-02/Ed.1	Injection equipment for medical use -- Part 2: One-point-cut (OPC) ampoules, 17-Jun-93	Final (Due for review 6/17/1998)	US Consensus
ISO 9187-02/Ed.2	Injection equipment for medical use -- Part 2: One-point-cut (OPC) ampoules, 15-Jul-09	Draft (DS/DIS-1)	US Consensus

Endnote: This list includes new work items for which a project record has not yet been set up in the AAMI database, either because the NWIP is still under consideration or for some other reason (staff can supply more information about why an item is on this list on request). Also on this list are any projects that AAMI has followed for some reason (eg, AAMI submitted comments to the US TAG administrator) but which are assigned to a ballot committee that AAMI deals with so seldomly that it has not entered the committee into the AAMI database.

## **Other Committees (No Active Projects at Present)**

AAMI/AP, Apnea Monitoring Committee  
AAMI/BE/WG 05, Cytotoxicity  
AAMI/BE/WG 09, Effects on blood  
AAMI/BE/WG 10, Implantation  
AAMI/BE/WG 13, Toxicokinetics study  
AAMI/EC/WG 07, Signal averaging WG  
AAMI/EC/WG 08, Standard communications protocol WG  
AAMI/EQ, Medical Equipment Management Committee  
AAMI/EV/WG 12, Luminaires sub-TAG  
AAMI/EV/WG 13, Lens removal and vitrectomy devices for ophthalmic surgery sub-TAG  
AAMI/HF, High Frequency Therapeutic Device Committee  
AAMI/II, Infant Incubator Committee  
AAMI/MC, Mechanical Circulatory Support Systems Committee  
AAMI/NS/WG 02, Implantable neurostimulator WG  
AAMI/QM/WG 02, General aspects stemming from the application of quality principles to medical  
AAMI/SP, Sphygmomanometer Committee  
AAMI/ST, Sterilization Standards Committee  
AAMI/ST/WG 05, Sterilization Terminology WG  
AAMI/ST/WG 11, General criteria for sterilization processes  
AAMI/ST/WG 12, Instructions for reusable device reprocessing  
AAMI/ST/WG 60, EO sterilization hospital practices WG  
AAMI/ST/WG 62, Hospital EO sterilizer WG  
AAMI/ST/WG 63, Sterilization residuals WG  
AAMI/ST/WG 83, Reusable surgical textiles processing WG  
AAMI/ST/WG 92, Process challenge devices WG  
AAMI/WV, Waveform Testing Committee