

AAMI Standards Program (active projects only) – 2&3 January 2012

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 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.

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>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee:</i>			
	Standardized instructions for use (IFU) for medical devices	NWIP	
	Active implantable medical devices - Requirements for Universal Radio Frequency Identification (RFID) of implantable cardiac pacemakers and implantable cardioverter defibrillators (ICD)	NWIP	
	Sterilization packaging systems for reusable medical devices	NWIP	
	Human factors engineering design processes for medical software not considered a medical device	NWIP	
	Guidance on low- and intermediate-level disinfection	NWIP	
	Guidance for managing sterilization of loaner instrumentation	NWIP	
	Guidance for contextual enquiry	NWIP	
	Effectiveness testing for antimicrobial agents incorporated into medical devices and combination products	NWIP	
	Adhesion-to-skin guideline for medical tapes	NWIP	
AAMI MDI/Ed.1	Medical device interoperability	Project	Development and Adoption
<i>BallotCommittee: AAMI/AP, Apnea Monitoring Committee</i>			
AAMI TIR4/Ed.1	Apnea monitoring by means of thoracic impedance pneumography, 01-Dec-89	Final (Due for review 9/15/2011)	Development and Adoption
<i>BallotCommittee: 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>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/BE/WG 06, Mutagenicity, carcinogenicity and reproductive toxicity</i>			
AAMI/ISO 10993-03/Ed.3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, 04-Aug-11	Draft (AAMI/CDV-4)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/BE/WG 07, Systemic toxicity</i>			
AAMI/ISO TIR10993-20/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 2/13/2012)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/BE/WG 11, Allowable limits for leachable substances</i>			
AAMI/ISO 10993-17/Ed.1	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances, 27-Mar-03	Final (Due for review 12/3/2012)	US Consensus/Parallel Adoption
AAMI/ISO TIR29741/Ed.1	Development of Tolerable Intake Values for Di(2-ethylhexyl)phthalate (DEHP)	Project	US Consensus/Parallel Adoption
<i>BallotCommittee: 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
<i>BallotCommittee: AAMI/BE/WG 14, Material characterization</i>			
AAMI/ISO TIR10993-19/Ed.1	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials, 09-Aug-06	Final (Due for review 11/10/2011)	US Consensus/Parallel Adoption
<i>BallotCommittee: 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
<i>BallotCommittee: AAMI/BF, Blood Filter/Cell Salvaging Committee</i>			
AAMI BF64/Ed.2	Leukocyte reduction filters	Project	Development and Adoption
AAMI BF7/Ed.3	Blood transfusion micro-filters	Project	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee:</i> <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, 18-Apr-11	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/CI, Cochlear Implants Committee</i>			
AAMI CI86/Ed.1	Cochlear implants - Output characteristics and performance requirements	NWIP	Development and Adoption
<i>BallotCommittee:</i> <i>AAMI/CN/WG 02, Breathing systems and driving gases applications WG</i>			
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
<i>BallotCommittee:</i> <i>AAMI/CN/WG 03, Enteral applications</i>			
AAMI/ISO 80369-03/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	Project	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/CN/WG 05, Limb cuff applications</i>			
AAMI/ISO 80369-05/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications, 14-Dec-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/CN/WG 06, Neuraxial applications</i>			
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
<i>BallotCommittee:</i> <i>AAMI/CV, Cardiac Valve Prostheses Committee</i>			
AAMI/ISO 5840/Ed.5	Cardiovascular implants - Cardiac valve prostheses	Project	US Consensus/Parallel Adoption
AAMI/ISO 5840-03/Ed.1	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by minimally invasive techniques, 24-Feb-11	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/EC/WG 01, Ambulatory electrocardiograph WG</i>			
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, 18-Nov-11	Draft (AAMI/FDS-1)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/EC/WG 02, Arrhythmia monitoring WG</i>			
AAMI EC57/Ed.3	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms, 20-May-11	Draft (AAMI/CDV-1)	Development and Adoption
<i>BallotCommittee: AAMI/EC/WG 03, Cables and leads WG</i>			
AAMI EC53/Ed.2	ECG trunk cables and patient leadwires, 20-May-11	Draft (AAMI/CDV-1)	Development and Adoption
<i>BallotCommittee: AAMI/EC/WG 04, Cardiac monitor and diagnostic ECG WG</i>			
AAMI/IEC 60601-2-25/Ed.3	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs, 15-Nov-11	Draft (AAMI/FDSB-1)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/EC/WG 07, Signal averaging WG</i>			
AAMI TIR23/Ed.1	Signal averaging, 15-Jun-00	Final (Due for review 9/15/2011)	Development and Adoption
<i>BallotCommittee: AAMI/EC/WG 08, Standard communications protocol WG</i>			
AAMI EC71/Ed.1-Reaff2	Periodic review of ANSI/AAMI EC71:2001, Standard communications protocol - Computer assisted electrocardiography, 20-Dec-11	Periodic Review Ballot (AAMI/CDV-1)	Periodic Review
<i>BallotCommittee: AAMI/EM, Electromagnetic Compatibility Committee</i>			
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, 04-Mar-11	Draft (AAMI/CDV-1)	Intl Secretariat/Parallel Adoption
<i>BallotCommittee: AAMI/EQ, Medical Equipment Management Committee</i>			
AAMI EQ56/Ed.2	Recommended practice for a medical equipment management program, 11-Feb-11	Draft (AAMI/WD-1)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/ES, Electrical Safety Committee</i>			
AAMI ES60601-1:2005/A1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment 1, 11-Mar-11	Draft (AAMI/DS-1)	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR62296/Ed.2	Considerations of unaddressed safety aspects in the Second Edition of IEC 60601-1 and proposals for new requirements, 27-Apr-09	Final (Due for review 4/5/2012)	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR62348/Ed.1	Mapping between the clauses of the third edition of IEC 60601-1 and the 1988 edition as amended, 15-Aug-06	Final (Due for review 10/26/2012)	Intl Secretariat/Parallel Adoption
<i>BallotCommittee: AAMI/HA, Medical Devices and Systems in Home Care Applications</i>			
AAMI TIR(HA_1)/Ed.1	Design of training and instructional materials for medical devices used in non-clinical environments, 28-Oct-11	Draft (AAMI/WD-1)	Development and Adoption
AAMI TIR(HA_1)/Ed.1	Design of training and instructional materials for medical devices used in non-clinical environments, 11-Feb-11	NWIP	Development and Adoption
<i>BallotCommittee: AAMI/HE, Human Factors Engineering Committee</i>			
AAMI (HE_1)/Ed.1	Post-market surveillance (event detection) and complaint analysis for use error	NWIP	Development and Adoption
AAMI/IEC 62366/Ed.3	Medical devices - Application of usability engineering to medical device	Project	Intl Secretariat/Parallel Adoption
<i>BallotCommittee: AAMI/ID, Infusion Device Committee</i>			
AAMI ID26/Ed.4	Infusion Pumps - General requirements	NWIP	Development and Adoption
AAMI TIR38/Ed.1	Infusion devices - Assurance Case Report guidance	NWIP	Development and Adoption
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
AAMI/ISO 14708-04/Ed.2	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps	Project	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/IT, Information Technology Networks Incorporating Medical Devices</i>			
AAMI/IEC 82304-01/Ed.1	Healthcare software systems - Part 1: General requirement	Project	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR80001-2-1/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical application and examples, 23-Sep-11	Draft (AAMI/CDV-1)	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR80001-2-2/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the communication of medical device security needs, risks and controls, 23-Sep-11	Draft (AAMI/CDV-1)	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR80001-2-3/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks, 23-Sep-11	Draft (AAMI/CDV-1)	Intl Secretariat/Parallel Adoption
AAMI/IEC TIR80001-2-4/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-4: General implementation guidance for Healthcare Delivery Organizations	Project	Intl Secretariat/Parallel Adoption
<i>BallotCommittee: AAMI/MC, Mechanical Circulatory Support Systems Committee</i>			
AAMI MC84/Ed.1	Mechanical circulatory support device evaluation - Preclinical testing	NWIP	Development and Adoption
<i>BallotCommittee: AAMI/MP, Multi-parameter Patient Monitoring Equipment Committee</i>			
AAMI/IEC 60601-2-49/Ed.1	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment, 10-Jan-11	Draft (AAMI/FDS-1)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/NS/WG 02, Implantable neurostimulator WG</i>			
AAMI/ISO 14708-03/Ed.2	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators	Project	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/NS/WG 03, Transcutaneous electrical stimulator WG</i>			
AAMI NS4/Ed.2	Transcutaneous electrical stimulators, 01-Feb-96	Draft (AAMI/WD-1)	Development and Adoption
<i>BallotCommittee: AAMI/PB, Protective Barriers Committee</i>			
AAMI PB70/Ed.2	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, 17-Jun-11	Draft (AAMI/CDV-2)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee:</i> <i>AAMI/PC, Cardiac Rhythm Management Device Committee</i>			
AAMI PC76/Ed.1	Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	NWIP	Development and Adoption
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 PC88/Ed.1	Implants for surgery - Active implantable medical devices - Pacemaker magnet mode response to a suitable magnetic flux density; the uniform magnet mode response, 04-Jan-12	Draft (AAMI/CDV-2)	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/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
AAMI/ISO PC14708-06/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), 22-Nov-10	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/QM/WG 01, Application of quality systems to medical devices</i>			
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
<i>BallotCommittee:</i> <i>AAMI/QM/WG 02, General aspects stemming from the application of quality principles to medical devices</i>			
AAMI/ISO TIR16142/Ed.2	Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices, 08-Mar-06	Final (Due for review 11/10/2011)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/QM/WG 03, Symbols and nomenclature for medical devices</i>			
AAMI/IEC TIR60878/Ed.1	Graphical symbols for electrical equipment in medical practice, 03-Jun-04	Final (Due for review 2/23/2012)	Adoption Only
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 TIR19218-01:2011/A1/Ed.1	Medical devices - Hierarchal coding structure for adverse events - Part 1: Event type codes - Amendment 1 (Examples), 13-Sep-11	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO TIR19218-02/Ed.1	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation code, 01-Jun-11	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/QM/WG 04, Application of risk management to medical devices</i>			
AAMI/ISO TIR24971/Ed.1	Guidance on the application of ISO 14971	Project	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/RD, Renal Disease and Detoxification Committee</i>			
AAMI RD47/Ed.4	Reprocessing of hemodialyzers, 13-Jun-08	Final (Due for review 5/8/2012)	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.5	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, 03-Dec-10	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO 8637:2010/A1/Ed.1	Cardiovascular implants and extracorporeal systems -- Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, Amendment 1, 18-Jan-12	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/SP, Sphygmomanometer Committee</i>			
AAMI TIR(SP1)/Ed.1	Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact, 27-May-11	Draft (AAMI/CDV-1)	Development and Adoption
AAMI TIR(SP1)/Ed.1	Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact, 01-Nov-10	NWIP	Development and Adoption
AAMI/IEC 80601-2-30:2009/A1/Ed.1	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, Amendment 1, 17-Dec-10	Draft (AAMI/CD-1)	US Consensus/Parallel Adoption
AAMI/ISO 81060-01/Ed.1	Non invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type, 11-Jun-08	Final (Due for review 5/1/2012)	US Consensus/Parallel Adoption
AAMI/ISO 81060-02/Ed.2	Non-invasive sphygmomanometers - Clinical validation of automated measurement type, 02-Dec-11	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption

BallotCommittee: AAMI/ST/WG 01, Industrial EO sterilization WG

AAMI TIR(STW1_1)/Ed.1	EO sterilization using gas diffusion systems	Project	Development and Adoption
AAMI TIR14/Ed.2	Contract sterilization using ethylene oxide, 15-May-09	Final (Due for review 3/17/2012)	Development and Adoption
AAMI TIR15/Ed.2	Physical aspects of ethylene oxide sterilization, 02-Mar-10	Final (Due for review 9/3/2012)	Development and Adoption
AAMI TIR16/Ed.2	Microbiological aspects of ethylene oxide sterilization, 08-Apr-10	Final (Due for review 12/31/2012)	Development and Adoption
AAMI TIR28/Ed.2	Product adoption and process equivalence for ethylene oxide sterilization, 27-May-09	Final (Due for review 3/17/2012)	Development and Adoption
AAMI/ISO 11135/Ed.5	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices, 15-Sep-11	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/ST/WG 02, Radiation sterilization WG</i>			
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, 14-Dec-11	Draft (AAMI/CDV-2)	Development and Adoption
AAMI TIR40/Ed.1	Sterilization of health care products - Radiation - Guidance on dose setting utilizing a Modified Method 2, 19-Mar-10	Final (Due for review 9/3/2012)	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 TIR13004/Ed.1	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method Vdmax	NWIP	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/ST/WG 03, Industrial moist heat sterilization WG</i>			
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
AAMI/ISO 17665-01/Ed.3-Reaff	Periodic review of ANSI/AAMI/ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices, 21-Dec-10	Periodic Review Ballot (AAMI/CDV-1)	Periodic Review
AAMI/ISO TIR17665-02/Ed.3	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1, 14-Jul-09	Final (Due for review 6/18/2012)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/ST/WG 04, Biological indicators WG</i>			
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
AAMI/ISO 16342/Ed.1	Sterilization of health care products - Biological indicators - Method for validation of a reduced incubation time for a biological indicator, 18-Nov-11	Draft (AAMI/WD-1)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/ST/WG 05, Sterilization Terminology WG</i>			
AAMI/ISO TIR11139/Ed.2	Sterilization of health care products - Vocabulary, 21-Apr-06	Final (Due for review 12/18/2011)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
BallotCommittee: AAMI/ST/WG 06, Chemical indicators WG			
AAMI/ISO 11140-01/Ed.3	Sterilization of health care products - Chemical indicators - Part 1: General requirements, 19-Dec-11	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
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 11140-03/Ed.1-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 11140-3:2007, Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test, 06-Oct-11	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
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 11140-04/Ed.1-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 11140-4:2007, 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, 06-Oct-11	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
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 11140-05/Ed.2-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 11140-5:2007, Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests, 06-Oct-11	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
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
AAMI/ISO 15882/Ed.4	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results, 14-Jan-09	Final (Due for review 12/4/2012)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
BallotCommittee: <i>AAMI/ST/WG 07, Packaging</i>			
AAMI/ISO 11607-01:2006/A1/Ed.1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging, Amendment 1, 25-Oct-11	Draft (AAMI/CD-1)	US Consensus/Parallel Adoption
AAMI/ISO 11607-02:2006/A1/Ed.1	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes, Amendment 1, 25-Oct-11	Draft (AAMI/CD-1)	US Consensus/Parallel Adoption
AAMI/ISO 16775/Ed.1	Packaging for terminally sterilized medical devices - Part 3: Guidance on the application of ISO 11607-1 and ISO 11607-2, 25-Oct-11	Draft (AAMI/CD-2)	US Consensus/Parallel Adoption
BallotCommittee: <i>AAMI/ST/WG 08, Microbiological methods WG</i>			
AAMI TIR(ST08_1)/Ed.1	Environmental monitoring for the manufacture of terminally sterilized healthcare products	NWIP	Development and Adoption
AAMI TIR39/Ed.1	Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices, 23-Nov-09	Final (Due for review 9/3/2012)	Development and Adoption
BallotCommittee: <i>AAMI/ST/WG 09, Aseptic processing WG</i>			
AAMI/ISO 13408-01:2008/A1/Ed.1	Aseptic processing of health care products - Part 1: General requirements, Amendment 1, 29-Sep-11	Draft (AAMI/CDV-1)	US Consensus/Parallel Adoption
AAMI/ISO 13408-03/Ed.1	Aseptic processing of health care products - Part 3: Lyophilization, 21-Jan-09	Final (Due for review 10/14/2012)	US Consensus/Adoption
AAMI/ISO 13408-04/Ed.1	Aseptic processing of health care products - Part 4: Clean-in-place technologies, 21-Jan-09	Final (Due for review 10/14/2012)	US Consensus/Adoption
AAMI/ISO 13408-05/Ed.1	Aseptic processing of health care products - Part 5: Sterilization in place, 21-Jan-09	Final (Due for review 10/14/2012)	US Consensus/Adoption
AAMI/ISO 13408-06:2005/A1/Ed.1	Aseptic processing of health care products - Part 6: Isolator systems, Amendment 1, 29-Sep-11	Draft (AAMI/CD-1)	US Consensus/Parallel Adoption
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-Feb-11	Draft (AAMI/CDV-2)	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/ST/WG 13, Washer-disinfectors</i>			
AAMI ST15883-01:2009/A1/Ed.1	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests, Amendment 1	Project	US Consensus/Parallel Adoption
AAMI ST15883-01:2009/A2/Ed.1	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests, Amendment 2, 09-Dec-11	Draft (AAMI/CDV-1)	Development and Adoption
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>BallotCommittee: AAMI/ST/WG 40, Steam sterilization hospital practices WG</i>			
AAMI ST79:2010/A3.02/Ed.1	Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, Amendment 3.2, 09-Mar-11	Draft (AAMI/CDV-1)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 43, Hospital steam sterilizer WG</i>			
AAMI ST8/Ed.6	Hospital steam sterilizers, 04-Aug-11	Draft (AAMI/WD-1)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 60, EO sterilization hospital practices WG</i>			
AAMI ST41/Ed.4	Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 01-Nov-08	Final (Due for review 7/31/2012)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 61, Chemical sterilants hospital practices WG</i>			
AAMI ST58/Ed.3	Chemical sterilization and high-level disinfection in health care facilities, 01-Apr-11	Draft (AAMI/WD-2)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/ST/WG 63, Sterilization residuals WG</i>			
AAMI/ISO 10993-07/Ed.3	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, 16-Jan-09	Final (Due for review 12/19/2012)	US Consensus/Parallel Adoption
AAMI/ISO 10993-07/Ed.3-Reaff	Proposed reaffirmation of ANSI/AAMI/ISO 10993-7:2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, 05-Dec-11	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
<i>BallotCommittee: AAMI/ST/WG 83, Reusable surgical textiles processing WG</i>			
AAMI ST65/Ed.2	Processing of reusable surgical textiles for use in health care facilities, 02-Apr-09	Final (Due for review 12/4/2012)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 84, Endoscope reprocessing WG</i>			
AAMI TIR(ST84)1/Ed.1	Processing of flexible and semi-rigid scopes	NWIP	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 85, Human factors for device reprocessing WG</i>			
AAMI TIR(ST85)1/Ed.1	Human factors engineering for cleaning instructions for reusable medical devices	NWIP	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 92, Process challenge devices WG</i>			
AAMI TIR31/Ed.2	Process challenge devices/test packs for use in health care facilities, 12-Jan-09	Final (Due for review 11/20/2011)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 94, Rigid sterilization container systems WG</i>			
AAMI ST77/Ed.2	Containment devices for reusable medical device sterilization, 30-Nov-11	Draft (AAMI/CDV-1)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 95, Water quality for reprocessing medical devices</i>			
AAMI TIR34/Ed.2	Water for the reprocessing of medical devices, 16-Sep-11	Draft (AAMI/WD-2)	Development and Adoption
<i>BallotCommittee: AAMI/ST/WG 96, Compatibility of materials subject to sterilization</i>			
AAMI TIR17/Ed.2	Compatibility of materials subject to sterilization, 20-Nov-08	Final (Due for review 8/26/2011)	Development and Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee: AAMI/SW, Medical Device Software Committee</i>			
AAMI TIR(SW1)/Ed.1	Guidance on the use of agile practices in the development of medical device software	NWIP	Development and Adoption
AAMI TIR32/Ed.1	Medical device software risk management, 15-Feb-05	Final (Due for review 3/21/2011)	Development and Adoption
AAMI/IEC 62304/Ed.1-Reaff	Proposed reaffirmation of ANSI/AAMI/IEC 62304:2006, Medical device software - Software life cycle processes, 27-Sep-11	Proposed Reaffirmation (AAMI/DS-1)	Reaffirmation
AAMI/IEC 62304/Ed.2	Medical device software - Software life cycle processes	Project	US Consensus/Parallel Adoption
AAMI/IEC TIR80002-01/Ed.1	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software, 24-Dec-09	Final (Due for review 10/26/2012)	US Consensus/Parallel Adoption
AAMI/ISO TIR80002-02/Ed.1	Medical device software - Part 2: Validation of software for regulated processes	Project	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/SW/WG 01, Medical device data systems WG</i>			
AAMI SW87/Ed.1	Application of Quality Management System concepts to Medical Device Data Systems (MDDS), 03-Jan-12	Draft (AAMI/CDV-1)	Development and Adoption
<i>BallotCommittee: AAMI/TS, Tissue Product Safety Committee (US TAG for ISO/TC 194/SC 1)</i>			
AAMI/ISO 13022/Ed.1	Medical products containing viable human cells -- Application of risk management and requirements for processing practices, 30-Sep-10	Draft (AAMI/CDV-3)	US Consensus/Parallel Adoption
<i>BallotCommittee: AAMI/VI, Cardiovascular Absorbable Implants Committee</i>			
AAMI/ISO 17137/Ed.1	Cardiovascular absorbable implants	Project	US Consensus/Parallel Adoption

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
<i>BallotCommittee:</i> <i>AAMI/VP, Vascular Prosthesis Committee</i>			
AAMI/ISO 25539-01/Ed.2	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses	Project	US Consensus/Parallel Adoption
AAMI/ISO 25539-02/Ed.2	Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents	Project	US Consensus/Parallel Adoption
AAMI/ISO 25539-03/Ed.1	Cardiovascular implants - Endovascular devices - Part 3: Vena Cava Filters, 15-Nov-11	Draft (AAMI/FDSB-1)	US Consensus/Parallel Adoption
AAMI/ISO 7198/Ed.2	Cardiovascular implants - Tubular vascular prostheses	Project	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/VP/WG 01, Vascular device/Drug combination products</i>			
AAMI/ISO 12417/Ed.1	Cardiovascular implants and extracorporeal systems -- Vascular device-drug combination products	Project	US Consensus/Parallel Adoption
<i>BallotCommittee:</i> <i>AAMI/WV, Waveform Testing Committee</i>			
AAMI TIR24/Ed.1	Acquisition and use of physiologic waveform databases for testing of medical devices, 27-Oct-00	Final (Due for review 9/15/2011)	Development and 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 (US TAG for ISO/TC 173/SC 3)

<i>BallotCommittee:</i>	<i>ISO/TC 173/SC 3</i>	<i>Secretariat:</i>	<i>SIS</i>
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 12505-01/Ed.1	Skin barrier for ostomy aids - Test methods - Part 1: Size, surface pH and water-absorbency, 20-Jul-11	Draft (FDS/FDIS-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

BallotCommittee:	ISO/TC 194	Secretariat:	DIN
Project	Title	Item	AAMIActivity
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

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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 06, Mutagenicity, carcinogenicity and reproductive toxicity

<i>BallotCommittee: ISO/TC 194</i>		<i>Secretariat: DIN</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10993-03/Ed.3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity, 04-Aug-11	Draft (DS/DIS-1)	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 09, Effects on blood

<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

TAG: AAMI/BE/WG 10, Implantation

BallotCommittee: ISO/TC 194		Secretariat: DIN	
Project	Title	Item	AAMIActivity
ISO 10993-06/Ed.2	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation, 04-Apr-07	Final (Due for review 4/4/2012)	US Consensus/Parallel Adoption

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

BallotCommittee: ISO/TC 194		Secretariat: DIN	
Project	Title	Item	AAMIActivity
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

BallotCommittee: ISO/TC 194		Secretariat: DIN	
Project	Title	Item	AAMIActivity
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

BallotCommittee: ISO/TC 194		Secretariat: DIN	
Project	Title	Item	AAMIActivity
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

TAG: AAMI/BE/WG 15, Strategic approach to biological assessment

BallotCommittee: ISO/TC 194		Secretariat: DIN	
Project	Title	Item	AAMIActivity
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

BallotCommittee:	<i>ISO/TC 194</i>	Secretariat:	<i>DIN</i>
Project	Title	Item	AAMIActivity
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

BallotCommittee:	<i>ISO/TC 150/SC 2</i>	Secretariat:	<i>AAMI (ANSI)</i>
Project	Title	Item	AAMIActivity
ISO 11658/Ed.1	Cardiovascular implants and extracorporeal systems - Blood-contact coatings for extracorporeal perfusion systems, 18-Apr-11	Draft (DS/DIS-1)	US Consensus/Parallel Adoption
ISO 7199:2009/A1/Ed.1	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators). Amendment 1, 18-Apr-11	Draft (DS/DIS-1)	Parallel Adoption
ISO TS 23810/Ed.2	Cardiovascular implants and artificial organs - Checklist for preoperative extracorporeal circulation equipment setup, 02-May-11	Draft (CDV/CD-1)	US Consensus/Parallel Adoption

TAG: AAMI/CI, Cochlear Implants Committee

BallotCommittee:	<i>ISO/TC 150/SC 6</i>	Secretariat:	<i>AAMI (ANSI)</i>
Project	Title	Item	AAMIActivity
ISO 14708-07/Ed.1	Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems, 31-Oct-11	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/CN/WG 02, Breathing systems and driving gases applications WG

BallotCommittee:	<i>ISO/TC 210</i>	Secretariat:	<i>AAMI (ANSI)</i>
Project	Title	Item	AAMIActivity
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

TAG: AAMI/CN/WG 03, Enteral applications

BallotCommittee:	<i>ISO/TC 210</i>	Secretariat:	<i>AAMI (ANSI)</i>
Project	Title	Item	AAMIActivity
ISO 80369-03/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications, 16-Jul-10	NWIP	US Consensus/Parallel Adoption

TAG: AAMI/CN/WG 05, Limb cuff applications

<i>BallotCommittee: ISO/TC 210</i>		<i>Secretariat: AAMI (ANSI)</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 80369-05/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications, 14-Dec-10	Draft (CDV/CD-1)	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, 17-Dec-10	Draft (CD-1)	US Consensus/Parallel Adoption

TAG: AAMI/CN/WG 06, Neuraxial applications

<i>BallotCommittee: ISO/TC 210</i>		<i>Secretariat: AAMI (ANSI)</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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/CN/WG 07, Luer fittings and small bore connectors for parenteral and vascular applications

<i>BallotCommittee: ISO/TC 210</i>		<i>Secretariat: AAMI (ANSI)</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 80369-07/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 7 - Connectors with 6% (Luer) taper for intravascular or hypodermic applications, 31-Dec-10	NWIP	US Consensus/Parallel Adoption
ISO 80369-07/Ed.1	Small-bore connectors for liquids and gases in healthcare applications - Part 7 - Connectors with 6% (Luer) taper for intravascular or hypodermic applications, 14-Dec-10	NWIP	US Consensus/Parallel Adoption

TAG: AAMI/CV, Cardiac Valve Prostheses Committee

<i>BallotCommittee: ISO/TC 150/SC 2</i>		<i>Secretariat: AAMI (ANSI)</i>	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 5840-03/Ed.1	Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by minimally invasive techniques, 24-Feb-11	Draft (DS/DIS-1)	US Consensus/Parallel Adoption

TAG: AAMI/DF, Defibrillator Committee

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62A/TR 61288-01/Ed.1	Cardiac defibrillators - Cardiac defibrillators-monitors, Part 1: Operation, 01-Oct-93	Final (Due for review 11/15/2011)	AAMI Comments
IEC 62A/TR 61288-02/Ed.1	Cardiac defibrillators - Cardiac defibrillators-monitors, Part 2: Maintenance, 01-Oct-93	Final (Due for review 11/15/2011)	AAMI Comments

TAG: AAMI/DI, US TAG for ISO/TC 76 and ISO/TC 84

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 11040-01/Ed.1	Prefilled syringes -- Part 1: Glass cylinders for dental local anaesthetic cartridges, 19-Nov-92	Final (Due for review 7/30/2012)	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 13926-01/Ed.3	Pen systems -- Part 1: Glass cylinders for pen-injectors for medical use, 02-Nov-04	Final (Due for review 7/30/2012)	US Consensus
ISO 3826-03/Ed.1	Plastics collapsible containers for human blood and blood components -- Part 3: Blood bag systems with integrated features, 22-Sep-06	Final (Due for review 9/22/2011)	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 8536-05/Ed.2	Infusion equipment for medical use -- Part 5: Burette infusion sets for single use, gravity feed, 19-Jan-04	Final (Due for review 7/30/2012)	US Consensus
ISO 8536-08/Ed.1	Infusion equipment for medical use -- Part 8: Infusion equipment for use with pressure infusion apparatus, 12-Aug-04	Final (Due for review 7/30/2012)	US Consensus

ISO 8536-09/Ed.1	Infusion equipment for medical use -- Part 9: Fluid lines for use with pressure infusion equipment, 14-Oct-04	Final (Due for review 7/30/2012)	US Consensus
ISO 8536-10/Ed.1	Infusion equipment for medical use -- Part 10: Accessories for fluid lines for use with pressure infusion equipment, 12-Oct-04	Final (Due for review 7/30/2012)	US Consensus
ISO 8536-11/Ed.1	Infusion equipment for medical use -- Part 11: Infusion filters for use with pressure infusion equipment, 12-Oct-04	Final (Due for review 7/30/2012)	US Consensus
ISO 8536-12/Ed.1	Infusion equipment for medical use -- Part 12: Check valves, 30-Mar-07	Final (Due for review 3/30/2012)	US Consensus
ISO 8536-12:2007/A1/Ed.1	Infusion equipment for medical use - Part 12: Check valves, Amendment 1, 28-Nov-11	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

BallotCommittee: ISO/TC 84

Secretariat: DS

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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 594-01/Ed.1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements, 01-Jan-86	Final (Due for review 11/20/2011)	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 595-01/Ed.1	Reusable all-glass or metal-and-glass syringes for medical use - Part 1: Dimensions, 01-Jan-86	Final (Due for review 11/20/2011)	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
ISO 8537/Ed.2	Sterile single-use syringes, with or without needle, for insulin, 01-Oct-07	Final (Due for review 10/1/2012)	US Consensus

BallotCommittee: ISO/TC 84/SC 1 **Secretariat:** BSI

Project	Title	Item	AAMIActivity
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 6009/Ed.3	Hypodermic needles for single use - Colour coding for identification, 01-Jan-92	Final (Due for review 12/20/2012)	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 7886-04/Ed.1	Sterile hypodermic syringes for single use - Part 4: Syringes with reuse prevention feature, 22-Sep-06	Final (Due for review 9/22/2011)	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, Soft containers for blood, blood components and parenterals; Infusion, transfusion and blood processing equipment

BallotCommittee: ISO/TC 76 **Secretariat:** DIN

Project	Title	Item	AAMIActivity
ISO 3826-01/Ed.2	Plastics collapsible containers for human blood and blood components -- Part 1: Conventional containers, 14-Oct-10	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/DI/WG 02, Rigid container systems and related accessories for parenterals and injectables

BallotCommittee: ISO/TC 76 **Secretariat:** DIN

Project	Title	Item	AAMIActivity
ISO 11040-04/Ed.3	Prefilled syringes -- Part 4: Glass barrels for injectables, 22-Dec-10	NWIP	US Consensus
ISO 11040-06/Ed.1	Prefilled syringes -- Part 6: Plastics barrels for injectables, 10-Nov-10	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/DI/WG 04, Elastomeric parts and components and related secondary packaging components

BallotCommittee:	<i>ISO/TC 76</i>	Secretariat:	<i>DIN</i>
Project	Title	Item	AAMIActivity
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.3	Prefilled syringes -- Part 5: Plunger stoppers for injectables, 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

TAG: AAMI/DI/WG 05, Blood collection systems

BallotCommittee:	<i>ISO/TC 76</i>	Secretariat:	<i>DIN</i>
Project	Title	Item	AAMIActivity
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 6710/Ed.1	Single-use containers for venous blood specimen collection, 03-Aug-95	Final (Due for review 8/3/2000)	US Consensus

TAG: AAMI/DI/WG 23, Insulin syringes and pen injectors for drugs

BallotCommittee:	<i>ISO/TC 84</i>	Secretariat:	<i>DS</i>
Project	Title	Item	AAMIActivity
ISO 11608-01/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods - Part 1: Needle-based injection systems, 04-Nov-10	Draft (DS/DIS-1)	US Consensus
ISO 11608-02/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles, 28-Oct-10	Draft (DS/DIS-1)	US Consensus
ISO 11608-03/Ed.2	Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Container closures, 02-Dec-10	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/DI/WG 24, Needle-free injectors

BallotCommittee:	<i>ISO/TC 84</i>	Secretariat:	<i>DS</i>
Project	Title	Item	AAMIActivity
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/DI/WG 26, Auto-injectors

<i>BallotCommittee:</i> ISO/TC 84		<i>Secretariat:</i> DS	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 11608-05/Ed.1	Needle-based injection systems for medical use -- Requirements and test methods -- Part 5: Automated functions, 28-Oct-10	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/DI/WG 28, Sharps containers

<i>BallotCommittee:</i> ISO/TC 84		<i>Secretariat:</i> DS	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 23907/Ed.1	Sharps injury protection -- Requirements and test methods -- Sharps containers, 04-Nov-10	Draft (DS/DIS-1)	US Consensus

TAG: AAMI/DI/WG 29, Catheters

<i>BallotCommittee:</i> ISO/TC 84		<i>Secretariat:</i> DS	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 10555-01/Ed.2	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements, 02-Oct-11	Draft (DS/DIS-1)	US Consensus
ISO 10555-03/Ed.2	Sterile, single-use intravascular catheters -- Part 3: Central venous catheters, 02-Oct-11	Draft (DS/DIS-1)	US Consensus
ISO 10555-04/Ed.2	Intravascular catheters -- Sterile and single-use catheters - Part 4: Balloon dilatation catheters, 09-Oct-11	Draft (DS/DIS-1)	US Consensus
ISO 10555-05/Ed.2	Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters, 09-Oct-11	Draft (DS/DIS-1)	US Consensus

<i>BallotCommittee:</i> ISO/TC 84/SC 1		<i>Secretariat:</i> BSI	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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

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

<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/60601-2-47/Ed.2	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems, 18-Nov-11	Draft (FDS/FDIS-1)	US Consensus/Parallel Adoption

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

<i>BallotCommittee:</i> <i>See Endnote</i>		<i>Secretariat:</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
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 03, EMG and evoked response equipment sub-TAG

<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/60601-2-40/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 1/1/2011)	US Consensus	

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

<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/60601-2-03/Ed.3	Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment, 13-Jan-12	Draft (FDS/FDIS-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, 17-Sep-10	Draft (CDV/CD-1)	US Consensus	
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 07, Transc. partial pressure monit. equip. sub-TAG

<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/60601-3-01/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 1/1/2011)	US Consensus	

TAG: AAMI/EV/WG 08, Ultrasound 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>
IEC 62D/60601-2-36/Ed.2	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy, 24-Jun-11	Draft (CD-1)	Intl Secretariat Only
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, 23-Dec-11	Draft (CDV/CD-1)	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 80601-2-67/Ed.1	Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment, 13-May-11	Draft (CD-1)	Intl Secretariat/AAMI Comments
ISO 80601-2-69/Ed.1	Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment, 24-Jun-11	NWIP	Development and Adoption
ISO 80601-2-69/Ed.1	Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment, 16-Dec-11	Draft (CD-1)	Development and Adoption
ISO 80601-2-70/Ed.1	Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment, 08-Jul-11	NWIP	Development and Adoption
ISO 80601-2-70/Ed.1	Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment, 16-Dec-11	Draft (CD-1)	Development and Adoption

<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/EV/WG 12, Luminaires 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>
IEC 62D/60601-2-41:2009/A1/Ed.1	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis, Amendment 1, 06-May-11	NWIP	US Consensus
IEC 62D/60601-2-41:2009/A1/Ed.1	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis, Amendment 1, 24-Jun-11	Draft (CDV/CD-1)	US Consensus

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

<i>BallotCommittee:</i> ISO/TC 150/SC 6		<i>Secretariat:</i> AAMI (ANSI)	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 14708-04/Ed.2	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps	NWIP	US Consensus/Parallel Adoption

TAG: AAMI/NS/WG 02, Implantable neurostimulator WG

<i>BallotCommittee:</i> ISO/TC 150/SC 6		<i>Secretariat:</i> AAMI (ANSI)	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 14708-03/Ed.2	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators	NWIP	US Consensus/Parallel Adoption

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

<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/60601-2-10/Ed.2	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators, 17-Sep-10	Draft (CDV/CD-1)	US Consensus

TAG: AAMI/PC, Cardiac Rhythm Management Device Committee

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 11318/Ed.2	Cardiac defibrillators - Connector assembly for implantable defibrillators - Dimensions and test requirements, 15-Aug-02	Final (Due for review 1/15/2013)	US Consensus
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 (DS/DIS-1)	US Consensus/Parallel Adoption
ISO 14708-02/Ed.2	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers, 31-Mar-11	Draft (DS/DIS-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, 16-Nov-10	Draft (DS/DIS-1)	US Consensus
ISO 5841-02/Ed.3	Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads	NWIP	US Consensus
ISO 5841-03/Ed.3	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers	NWIP	US Consensus

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

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 13485/Ed.2	Medical devices - Quality management systems - Requirements for regulatory purposes, 25-Aug-03	Final (Due for review 11/1/2012)	US Consensus/Parallel Adoption
ISO 13485:2003/C1/Ed.1	ISO 13485:2003, Corrigendum 1, 01-Aug-09	Final (Due for review 11/1/2012)	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

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
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

<i>BallotCommittee:</i> ISO/TC 210		<i>Secretariat:</i> AAMI (ANSI)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
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	
ISO TS 19218-01:2011/A1/Ed.1	Medical devices - Hierarchal coding structure for adverse events - Part 1: Event type codes - Amendment 1 (Examples)	NWIP	US Consensus/Parallel Adoption	
ISO TS 19218-02/Ed.1	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation code, 01-Jun-11	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	

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

<i>BallotCommittee:</i> ISO/TC 210		<i>Secretariat:</i> AAMI (ANSI)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO TS 24971/Ed.1	Guidance on the application of ISO 14971, 10-Dec-10	NWIP	US Consensus/Parallel Adoption	
ISO/IEC Guide 63/Ed.2	Guide to the development and inclusion of safety aspects in International Standards for medical devices, 03-Sep-10	Draft (DS/DIS-1)	US Consensus	

TAG: AAMI/RD, Renal Disease and Detoxification 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/60601-2-16/Ed.4	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, Amendment 1, 03-Dec-10	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	
IEC 62D/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, Amendment 1, 23-Dec-11	Draft (FDS/FDIS-1)	US Consensus/Parallel Adoption	
IEC 62D/60601-2-39/Ed.2	Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment, 27-Nov-07	Final (Due for review 11/1/2012)	US Consensus	
IEC 62D/TR 62653/Ed.1	Guideline for the safe use of medical products in dialysis treatment (proposed technical report), 13-Jan-12	Draft (CDV/CD-1)	US Consensus	

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

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 8637:2010/A1/Ed.1	Cardiovascular implants and extracorporeal systems -- Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, Amendment 1	NWIP	US Consensus/Parallel Adoption

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/80601-2-30:2009/A1/Ed.1	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, Amendment 1, 17-Dec-10	Draft (CD-1)	US Consensus/Parallel Adoption
ISO 81060-01/Ed.1	Non invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type, 19-Nov-07	Final (Due for review 11/19/2012)	US Consensus
ISO 81060-02/Ed.2	Non-invasive sphygmomanometers - Clinical validation of automated measurement type, 02-Dec-11	Draft (CDV/CD-1)	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 11135/Ed.3	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices, 15-Sep-11	Draft (DS/DIS-1)	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 11137-01:2006/A1/Ed.1	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices, Amendment 1	NWIP	US Consensus/Parallel Adoption
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	Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose - Method Vdmax, 25-Apr-08	NWIP	US Consensus/Parallel Adoption

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

BallotCommittee:	<i>ISO/TC 198</i>	Secretariat:	<i>AAMI (ANSI)</i>	
Project	Title	Item	AAMIActivity	
ISO 17665-3/Ed.1	Sterilization of health care products - Steam sterilization - Part 3: Product families, 14-Dec-11	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	

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

BallotCommittee:	<i>ISO/TC 198</i>	Secretariat:	<i>AAMI (ANSI)</i>	
Project	Title	Item	AAMIActivity	
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 06, Chemical indicators WG

BallotCommittee:	<i>ISO/TC 198</i>	Secretariat:	<i>AAMI (ANSI)</i>	
Project	Title	Item	AAMIActivity	
ISO 11140-01/Ed.3	Sterilization of health care products - Chemical indicators - Part 1: General requirements, 19-Dec-11	Draft (CDV/CD-1)	US Consensus/Parallel Adoption	
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

BallotCommittee:	<i>ISO/TC 198</i>	Secretariat:	<i>AAMI (ANSI)</i>	
Project	Title	Item	AAMIActivity	
ISO 11607-01:2006/A1/Ed.1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging, Amendment 1, 25-Oct-11	Draft (CD-1)	US Consensus/Parallel Adoption	
ISO 11607-02:2006/A1/Ed.1	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes, Amendment 1, 25-Oct-11	Draft (CD-1)	US Consensus/Parallel Adoption	
ISO 16775/Ed.1	Packaging for terminally sterilized medical devices - Part 3: Guidance on the application of ISO 11607-1 and ISO 11607-2, 25-Oct-11	Draft (CD-2)	US Consensus/Parallel Adoption	

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

<i>BallotCommittee:</i> ISO/TC 198		<i>Secretariat:</i> AAMI (ANSI)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO 13408-01:2008/A1/Ed.1	Aseptic processing of health care products - Part 1: General requirements, Amendment 1, 29-Sep-11	Draft (DS/DIS-1)	Parallel Adoption	
ISO 13408-06:2005/A1/Ed.1	Aseptic processing of health care products - Part 6: Isolator systems, Amendment 1, 29-Sep-11	Draft (CD-1)	Parallel Adoption	
ISO 13408-07/Ed.1	Aseptic processing of health care products - Part 7: Aseptic qualification of solid medical devices and combination medical devices, 25-Feb-11	Draft (DS/DIS-1)	US Consensus/Parallel Adoption	
ISO 13408-08/Ed.1	Aseptic processing of health care products - Part 8: Cell based health care products, 29-Mar-11	Draft (WD-1)	US Consensus	

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

<i>BallotCommittee:</i> ISO/TC 198		<i>Secretariat:</i> AAMI (ANSI)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO 15883-01:2006/A1/Ed.1	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests, Amendment 1	NWIP	Parallel Adoption	
ISO 15883-07/Ed.1	Washer-disinfectors - Part 7: Requirements and tests for general purpose washer-disinfectors employing chemical disinfection for bedframes, bedside tables, transport carts, containers, surgical tables, furnishings and surgical clogs	NWIP	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/SW, Medical Device Software Committee

<i>BallotCommittee:</i> ISO/TC 210		<i>Secretariat:</i> AAMI (ANSI)		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
ISO TR 80002-02/Ed.1	Medical device software - Part 2: Validation of software for regulated processes, 01-Apr-11	NWIP	US Consensus/Parallel Adoption	
ISO TR 80002-02/Ed.1	Medical device software - Part 2: Validation of software for regulated processes, 29-Mar-11	NWIP	US Consensus/Parallel Adoption	

TAG: AAMI/TS, Tissue Product Safety Committee (US TAG for ISO/TC 194/SC 1)

<i>BallotCommittee:</i> ISO/TC 194/SC 1		<i>Secretariat:</i> DIN	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 13022/Ed.1	Medical products containing viable human cells -- Application of risk management and requirements for processing practices, 30-Sep-10	Draft (DS/DIS-1)	US Consensus/Parallel Adoption
ISO 22442-01/Ed.1	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management, 27-Nov-07	Final (Due for review 11/27/2012)	US Consensus/Parallel Adoption
ISO 22442-02/Ed.1	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling, 27-Nov-07	Final (Due for review 11/27/2012)	US Consensus/Parallel Adoption
ISO 22442-03/Ed.1	Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents, 27-Nov-07	Final (Due for review 11/27/2012)	US Consensus/Parallel Adoption

TAG: AAMI/VI, Cardiovascular Absorbable Implants Committee

<i>BallotCommittee:</i> ISO/TC 150/SC 2		<i>Secretariat:</i> AAMI (ANSI)	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 17137/Ed.1	Cardiovascular absorbable implants	NWIP	US Consensus/Parallel Adoption

TAG: AAMI/VP, Vascular Prostheses Committee

<i>BallotCommittee:</i> ISO/TC 150/SC 2		<i>Secretariat:</i> AAMI (ANSI)	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 25539-02/Ed.2	Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents	NWIP	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

<i>BallotCommittee:</i> ISO/TC 150/SC 2		<i>Secretariat:</i> AAMI (ANSI)	
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
ISO 12417/Ed.1	Cardiovascular implants and extracorporeal systems -- Vascular device-drug combination products	NWIP	US Consensus/Parallel Adoption

<i>BallotCommittee: IEC/SC 62A</i>		<i>Secretariat: AAMI (USNC)</i>		
<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>	
IEC 60601-1-06:2010/A1/Ed.	Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, Amdt 1, 09-Jan-12	Draft (CD-1)	Intl Secretariat/AAMI Comments	
IEC 62A/60601-1/Ed.3	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, 15-Dec-05	Final (Due for review 12/15/2012)	Intl Secretariat/Parallel Adoption	
IEC 62A/60601-1:2005/A1/Ed.1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment 1, 11-Mar-11	Draft (DS/DIS-1)	Intl Secretariat/Parallel Adoption	
IEC 62A/60601-1:IS/Ed.1	Official Interpretations to IEC 60601-1:2005, 01-Apr-08	Final (Due for review 4/1/2012)	Intl Secretariat/AAMI Comments	
IEC 62A/60601-1:IS/Ed.1	Official Interpretations to IEC 60601-1:2005, 01-Jan-09	Final (Due for review 4/1/2012)	Intl Secretariat/AAMI Comments	
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)	US Consensus/Parallel Adoption	
IEC 62A/60601-1-08/Ed.2	Medical electrical equipment, Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, 25-Oct-06	Final (Due for review 10/25/2011)	Intl Secretariat/AAMI Comments	
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, Amdt 1, 17-Jun-11	Draft (CDV/CD-1)	Intl Secretariat/AAMI Comments	
IEC 62A/60601-1-12/Ed.1	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for ME equipment and ME systems used in the emergency medical services environment, 13-Jan-12	Draft (CDV/CD-1)	Intl Secretariat/AAMI Comments	
IEC 62A/62304/Ed.2	Medical device software - Software life cycle processes, 23-Jul-11	NWIP	US Consensus/Parallel Adoption	
IEC 62A/62353/Ed.2	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment, 10-Dec-10	NWIP	Intl Secretariat/AAMI Comments	
IEC 62A/62366/Ed.2	Medical devices - Application of usability engineering to medical device	NWIP	Intl Secretariat/Adoption	
IEC 62A/82304-01/Ed.1	Healthcare software systems - Part 1: General requirement, 07-Nov-10	NWIP	Intl Secretariat/Parallel Adoption	
IEC 62A/TR 60878/Ed.2	Graphical symbols for electrical equipment in medical practice, 01-Jul-03	Final (Due for review 7/1/2011)	Intl Secretariat/AAMI Comments	

IEC 62A/TR 80001-2-1/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical application and examples, 01-Oct-10	NWIP	Intl Secretariat/Parallel Adoption
IEC 62A/TR 80001-2-2/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the communication of medical device security needs, risks and controls, 01-Oct-10	NWIP	Intl Secretariat/Parallel Adoption
IEC 62A/TR 80001-2-3/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks, 01-Oct-10	NWIP	Intl Secretariat/Parallel Adoption
IEC 62A/TR 80001-2-4/Ed.1	Application of risk management for IT-networks incorporating medical devices - Part 2-4: General implementation guidance for Healthcare Delivery Organizations, 28-May-11	NWIP	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 9/1/2011)	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: *See Endnote* **Secretariat:**

<i>Project</i>	<i>Title</i>	<i>Item</i>	<i>AAMIActivity</i>
IEC 62A/795/NP	Health informatics - Guidance on standards for enabling safety in health software, 06-Jan-12	NWIP	
IEC 62D/966/NP	Medical electrical equipment - Part 2-xx: Particular requirements for the basic safety and essential performance of functional oximeter equipment, 25-Nov-11	NWIP	
IEC 62D/978/NP	IEC New Work Item Proposals (unassigned), 13-Jan-12	NWIP	

TAG: US TAG for IEC/SC 62D, Electromedical Equipment

BallotCommittee:	<i>IEC/SC 62D</i>	Secretariat:	<i>AAMI (USNC)</i>	
Project	Title	Item	AAMIActivity	
ISO 80601-2-60/Ed.1	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment, 25-Nov-11	Draft (FDS/FDIS-1)	US Consensus	

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

BallotCommittee:	<i>ISO/TC 150/SC 6</i>	Secretariat:	<i>AAMI (ANSI)</i>	
Project	Title	Item	AAMIActivity	
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, 18-Feb-11	Draft (CDV/CD-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/BE/WG 02, Degradation aspects related to biological testing
AAMI/BE/WG 03, Animal protection aspects
AAMI/BE/WG 04, Clinical investigations of medical devices in humans
AAMI/BE/WG 05, Cytotoxicity
AAMI/BE/WG 08, Irritation and sensitization
AAMI/BE/WG 09, Effects on blood
AAMI/BE/WG 10, Implantation
AAMI/BE/WG 13, Toxicokinetics study
AAMI/BP, Blood Pressure Monitoring Committee
AAMI/CN, Small Bore Connectors Committee
AAMI/DF, Defibrillator Committee
AAMI/DI/WG 06, Primary packaging materials for medicinal products
AAMI/DI/WG 27, Safety issues for needles
AAMI/DP, Medical Device Particulates Committee
AAMI/EC/WG 04, Cardiac monitor and diagnostic ECG WG
AAMI/EC/WG 06, ECG Electrode WG
AAMI/EV/WG 04, Electro-optical equipment sub-TAG
AAMI/EV/WG 05, Hospital beds 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/MP, Multi-parameter Patient Monitoring Equipment Committee
AAMI/NS/WG 01, ICP device WG
AAMI/ST, Sterilization Standards Committee (US TAG for ISO/TC 198)
AAMI/ST/WG 05, Sterilization Terminology WG
AAMI/ST/WG 08, Microbiological methods WG
AAMI/ST/WG 10, Liquid chemical sterilization WG
AAMI/ST/WG 11, General criteria for sterilization processes
AAMI/ST/WG 12, Instructions for reusable device reprocessing
AAMI/ST/WG 42, Dry heat sterilization WG
AAMI/ST/WG 62, Hospital EO sterilizer WG
AAMI/ST/WG 63, Sterilization residuals WG
AAMI/ST/WG 90, Sterility Assurance Level (SAL) WG
AAMI/ST/WG 91, Resistometer WG
AAMI/ST/WG 93, Cleaning of reusable medical devices
AAMI/TS/WG 04, TSE elimination