

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	AP, Apnea Monitoring Committee			Anesthesia	[PRIMARY] Coursey, Derya C; OMPT/CDRH/ODE/DAGID/RPDB; [ALTERNATE] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP
AAMI	AR, Anaesthetic and Respiratory Committee		AR/TG01 - Conical Connectors	Anesthesia	[PRIMARY] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB; [TECHNICAL EXPERT] Scott, Pamela D; OMPT/CDRH/OCD
AAMI	AR, Anaesthetic and Respiratory Equipment		TG 01, Adoption of ISO 5356-1 with deviations	Anesthesia	[PRIMARY] Maloney, William C; OMPT/CDRH/OSB/DPS/MDR; [ALTERNATE] Scott, Pamela D; OMPT/CDRH/OCD
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121		Anesthesia	[PRIMARY] Courtney, Todd D; OMPT/CDRH/ODE/DAGID/ANDB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC1, WG 09, Anaesthetic systems	WG 01, Anaesthetic Systems	Anesthesia	[PRIMARY] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC2, Airways and related equipment and affiliated WGs 01, 02, 03, 04, 05, 06, 07, 08, 09, 10	WG 02, Airways and Related Equipment	Anesthesia	[PRIMARY] Lakhani, Deepika; OMPT/CDRH/ODE/DAGID/RPDB; [ALTERNATE] Maloney, William C; OMPT/CDRH/OSB/DPS/MDR; [TECHNICAL EXPERT] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC3, WG 03, Heat and moisture control; ISO/TC 121/SC3, WG 05, Gas flow measurement and control; ISO/TC 121/SC3, WG 13, Biocompatibility of respiratory gas pathways	WG 03, Respirator Gas Measurement, Control, and Biocompatibility	Anesthesia	[PRIMARY] Levelle, Amy K; OMPT/CDRH/ODE/DAGID/RPDB; [ALTERNATE] Lee, James S; OMPT/CDRH/ODE/DCD/IEDB; [TECHNICAL EXPERT] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC4, Terminology and semantics	WG 04, Anaesthetic Terminology and Semantics	Anesthesia	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Bahadori, Lila M; OMPT/CDRH/ODE/DAGID/RPDB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC6, Medical gas systems	WG 06, Medical Gas Systems	Anesthesia	[PRIMARY] Danielely, Jennifer E; OMPT/CDRH/OC/DMQ/CDB
AAMI	AR, Anaesthetic and Respiratory Equipment	US TAG for ISO/TC 121/SC8, Suction devices for hospital and emergency care use	WG 08, Suction Devices for Hospital and Emergency Care	Anesthesia	[PRIMARY] Lee, Morgan; OMPT/CDRH/ODE/DAGID/ANDB; [ALTERNATE] Mirza, Sidra J; OMPT/CDRH/ODE/DAGID/RPDB
AAMI	EV, Anaesthetic and Respiratory Committee	US sub-TAG for ISO/TC 121/SC1, JWG 1 & ISO/TC 121/SC3, JWG 5; IEC/SC 62D, JWG 2 & IEC/SC 62A, JWG 5	WG 01, Anesthesia Equipment Working Group	Anesthesia	[PRIMARY] Parvinian, Bahram; OMPT/CDRH/ODE/DAGID/ANDB; [ALTERNATE] Lee, James S; OMPT/CDRH/ODE/DCD/IEDB; [TECHNICAL EXPERT] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
AAMI	EV, Anaesthetic and Respiratory Committee	US sub-TAG for ISO/TC 121/SC1, JWG 6 & IEC/SC 62D/JWG 6, ISO/TC 121/SC3, JWG 1 & IEC/SC 62D, JWG 1, ISO/TC 121/SC3, JWG 10 & IEC/SC 62D, JWG 5, ISO/TC 121/SC3, JWG 12 & IEC/SC 62D, JWG 12	WG 09, Lung Ventilators Working Group	Anesthesia	[PRIMARY] Lee, James S; OMPT/CDRH/ODE/DCD/IEDB; [ALTERNATE] Levelle, Amy K; OMPT/CDRH/ODE/DAGID/RPDB; [TECHNICAL EXPERT] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB; [TECHNICAL EXPERT] Pfefer, Thomas J; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
ASME	Pressure Vessel for Human Occupancy (PVHO) Committee	Subcommittee on Medical Hyperbaric Chambers		Anesthesia	[PRIMARY] To, Nam; OMPT/CDRH/ODE/DAGID/ANDB
ASTM	F29 Anesthetic and Respiratory Equipment	F29.90 Executive		Anesthesia	[ALTERNATE] Colburn, Scott A; OMPT/CDRH/OCD
ISO	TC 121 Anaesthetic and respiratory equipment	AG 1, Connectors for respiratory therapy devices and accessories		Anesthesia	[PRIMARY] Maloney, William C; OMPT/CDRH/OSB/DPS/MDR; [ALTERNATE] Scott, Pamela D; OMPT/CDRH/OCD
ISO	TC 121 Anaesthetic and respiratory equipment	ISO/TC 121/SC 3-IEC/SC 62D WG	JWG 10, Pulse oximeters	Anesthesia	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB; [TECHNICAL EXPERT] Pfefer, Thomas J; OMPT/CDRH/OSEL/DBP
ISO	TC 121 Anaesthetic and respiratory equipment	SC 1 Breathing attachments and anaesthetic machines	WG 09, Anaesthetic systems	Anesthesia	[PRIMARY] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 121 Anaesthetic and respiratory equipment	SC 2 Airways and related equipment		Anesthesia	[PRIMARY] Lakhani, Deepika; OMPT/CDRH/ODE/DAGID/RPDB; [ALTERNATE] Maloney, William C; OMPT/CDRH/OSB/DPS/MDR; [TECHNICAL EXPERT] Patel, Neel J; OMPT/CDRH/ODE/DAGID/ANDB
ISO	TC 121 Anaesthetic and respiratory equipment	SC 4 Terminology and semantics		Anesthesia	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Bahadori, Lila M; OMPT/CDRH/ODE/DAGID/RPDB
ISO	TC 121 Anaesthetic and respiratory equipment	SC 6 Medical gas systems		Anesthesia	[PRIMARY] Danieleley, Jennifer E; OMPT/CDRH/OC/DMQ/CDB
ISO	TC 121 Anaesthetic and respiratory equipment	SC 8 Suction devices for hospital and emergency care use		Anesthesia	[PRIMARY] Lee, Morgan; OMPT/CDRH/ODE/DAGID/ANDB; [ALTERNATE] Mirza, Sidra J; OMPT/CDRH/ODE/DAGID/RPDB
NFPA-Fire	Committee on Hyperbaric and Hypobaric Facilities			Anesthesia	[PRIMARY] To, Nam; OMPT/CDRH/ODE/DAGID/ANDB
AAMI	BE, Biological Evaluation Committee		WG 01, Systematic approach to biological evaluation and terminology	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Bailey, Michael T; OMPT/CDRH/ODE/DRGUD/OGDB
AAMI	BE, Biological Evaluation Committee		WG 02, Degradation aspects related to biological testing	Biocompatibility	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC; [ALTERNATE] Guo, Ji; OMPT/CDRH/OSEL/DBCMS
AAMI	BE, Biological Evaluation Committee		WG 03, Animal protection aspects	Biocompatibility	[PRIMARY] Davis, Judith; OMPT/CDER/OND; [ALTERNATE] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB
AAMI	BE, Biological Evaluation Committee		WG 04, Clinical investigations of medical devices in humans	Biocompatibility	[PRIMARY] Santel, Fabienne J; OMPT/CDRH/OC; [ALTERNATE] Schroeder, Anna E; OMPT/CDRH/ODE/CTS/IDE; [TECHNICAL EXPERT] Hamilton, Martin D; OMPT/CDRH/OC/DBM/BCB II
AAMI	BE, Biological Evaluation Committee		WG 05, Cytotoxicity	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [ALTERNATE] Bancos, Simona; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
AAMI	BE, Biological Evaluation Committee		WG 06, Mutagenicity, cancerogenicity and reproductive toxicity	Biocompatibility	[PRIMARY] Elespuru, Rosalie K; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
AAMI	BE, Biological Evaluation Committee		WG 07, Systemic toxicity	Biocompatibility	[PRIMARY] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
AAMI	BE, Biological Evaluation Committee		WG 08, Irritation and sensitization	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [ALTERNATE] Virmani, Mridulika; OMPT/CDRH/ODE/DOED/CLRD
AAMI	BE, Biological Evaluation Committee		WG 09, Effects on blood	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [TECHNICAL EXPERT] Lu, Qijin; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Malinauskas, Richard A; OMPT/CDRH/OSEL/DAM
AAMI	BE, Biological Evaluation Committee		WG 10, Implantation	Biocompatibility	[PRIMARY] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Manhart-Byrnes, Karen L; OMPT/CDRH/ODE/DCD/VSDB
AAMI	BE, Biological Evaluation Committee		WG 11, Allowable limits for leachable substances	Biocompatibility	[PRIMARY] Hood, Alan; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB
AAMI	BE, Biological Evaluation Committee		WG 12, Sample preparation and reference materials	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [ALTERNATE] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	BE, Biological Evaluation Committee		WG 13, Toxicokinetics study	Biocompatibility	[PRIMARY] Potnis, Pushya A; OMPT/CDRH/ODE/DRGUD/ULDB; [ALTERNATE] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
AAMI	BE, Biological Evaluation Committee		WG 14, Material characterization	Biocompatibility	[PRIMARY] Isayeva, Irada S; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Zheng, Jiwen; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Rimmer, Ralph; OMPT/CDRH/ODE/DSD/PRSB1
AAMI	BE, Biological Evaluation Committee		WG 15, Strategic approach to biological assessment	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN
AAMI	BE, Biological Evaluation Committee		WG 16, Pyrogenicity	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
AAMI	BE, Biological Evaluation Committee	(Joint with Nanotechnology STG) Biocompatibility STG is Primary	WG 17, Nanomaterials	Biocompatibility	[PRIMARY] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1; [ALTERNATE] Betz, Martha; OMPT/CDRH/ODE/DRGUD/GEDB; [TECHNICAL EXPERT] Goering, Peter L; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
AAMI	BE, Biological Evaluation Committee (U.S. TAG for ISO TC 194)			Biocompatibility	[PRIMARY] Brown, Ronald P; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.16 Biocompatibility Test Methods		Biocompatibility	[PRIMARY] Nielsen, Joseph A.; OMPT/CDRH/ODE/DSD/PRSB1; [ALTERNATE] Mollo, Sarah B; OMPT/CDRH/ODE/DAGID/GHDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.16 Biocompatibility Test Methods	F04.16.01 Biological Response to Particle Debris	Biocompatibility	[PRIMARY] Kavlock, Katherine; OMPT/CDRH/ODE/DOD/ASDB; [ALTERNATE] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [TECHNICAL EXPERT] Sussman, Eric; OMPT/CDRH/OSEL/DBCMS
ASTM	F04 Medical and Surgical Materials and Devices	F04.16 Biocompatibility Test Methods	F04.16.05 Recovery of Foreign Particles from Tissue	Biocompatibility	[PRIMARY] Bittleman, Katelyn R; OMPT/CDRH/OC/DMQ/PMON-DDB; [ALTERNATE] Zhang, Min; OMPT/CDRH/ODE/DSD/PRSB2; [TECHNICAL EXPERT] Miller, Natalie; OMPT/CDRH/ODE/DCD/SHDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.16 Biocompatibility Test Methods	F04.16.08 Immunological Testing	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Mollo, Sarah B; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Mu, Ying; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Wood, Steven C; OMPT/CDRH/OSEL/DBCMS
ISO	TC 194 Biological evaluation of medical devices			Biocompatibility	[PRIMARY] Brown, Ronald P; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB
ISO	TC 194 Biological evaluation of medical devices		WG 01 Systematic approach to biological evaluation and terminology	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Bailey, Michael T; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 194 Biological evaluation of medical devices		WG 02 Degradation aspects related to biological testing	Biocompatibility	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC; [ALTERNATE] Guo, Ji; OMPT/CDRH/OSEL/DBCMS
ISO	TC 194 Biological evaluation of medical devices		WG 03 Animal protection aspects	Biocompatibility	[PRIMARY] Davis, Judith; OMPT/CDER/OND; [ALTERNATE] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB
ISO	TC 194 Biological evaluation of medical devices		WG 04 Clinical investigation of medical devices in humans	Biocompatibility	[PRIMARY] Santel, Fabienne J; OMPT/CDRH/OC; [ALTERNATE] Schroeder, Anna E; OMPT/CDRH/ODE/CTS/IDE; [TECHNICAL EXPERT] Hamilton, Martin D; OMPT/CDRH/OC/DBM/BCB II

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ISO	TC 194 Biological evaluation of medical devices		WG 05 Cytotoxicity	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Bancos, Simona; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
ISO	TC 194 Biological evaluation of medical devices		WG 06 Mutagenicity, carcinogenicity and reproductive toxicity	Biocompatibility	[PRIMARY] Elespuru, Rosalie K; OMPT/CDRH/ODE/DBCMS; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ISO	TC 194 Biological evaluation of medical devices		WG 07 Systemic toxicity	Biocompatibility	[PRIMARY] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
ISO	TC 194 Biological evaluation of medical devices		WG 08 Irritation, sensitization	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Virmani, Mridulika; OMPT/CDRH/ODE/DOED/CLRD
ISO	TC 194 Biological evaluation of medical devices		WG 09 Effects on blood	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [TECHNICAL EXPERT] Lu, Qijin; OMPT/CDRH/ODE/DAM
ISO	TC 194 Biological evaluation of medical devices		WG 10 Implantation	Biocompatibility	[PRIMARY] Crusan, Annabelle; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Manhart-Byrnes, Karen L; OMPT/CDRH/ODE/DCD/VSDB
ISO	TC 194 Biological evaluation of medical devices		WG 11 Allowable limits of leachable substances	Biocompatibility	[PRIMARY] Hood, Alan; OMPT/CDRH/ODE/DBCMS; [ALTERNATE] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB
ISO	TC 194 Biological evaluation of medical devices		WG 12 Sample preparation and reference materials	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1
ISO	TC 194 Biological evaluation of medical devices		WG 13 Toxicokinetic study	Biocompatibility	[ALTERNATE] Potnis, Pushya A; OMPT/CDRH/ODE/DRGUD/ULDB; [ALTERNATE] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
ISO	TC 194 Biological evaluation of medical devices		WG 14 Material characterization	Biocompatibility	[PRIMARY] Isayeva, Irada S; OMPT/CDRH/ODE/DBCMS; [ALTERNATE] Zheng, Jiwen; OMPT/CDRH/ODE/DBCMS; [TECHNICAL EXPERT] Rimmer, Ralph; OMPT/CDRH/ODE/DSD/PRSB1
ISO	TC 194 Biological evaluation of medical devices		WG 15 Strategic approach to biological assessment	Biocompatibility	[PRIMARY] Goode, Jennifer L; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN
ISO	TC 194 Biological evaluation of medical devices		WG 16, Pyrogenicity	Biocompatibility	[PRIMARY] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Zhang, Qin; OMPT/CDRH/ODE/DRGUD/GEDB
ISO	TC 194 Biological evaluation of medical devices	(Joint with Biocompatibility STG) Biocompatibility STG is Primary	WG 17 Nanomaterials	Biocompatibility	[PRIMARY] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1; [ALTERNATE] Betz, Martha; OMPT/CDRH/ODE/DRGUD/GEDB; [TECHNICAL EXPERT] Goering, Peter L; OMPT/CDRH/ODE/DBCMS; [TECHNICAL EXPERT] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
AAMI	BF, Blood Filter/Cell Salvaging Committee			Cardiology	[PRIMARY] Gaylord, Catherine P; OMPT/CDRH/ODE/DCD/CSDB
AAMI	BG, Blood/Gas Exchange Device Committee (US TAG to ISO/TC150/SC2/WG04)			Cardiology	[PRIMARY] Gaylord, Catherine P; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Lu, Qijin; OMPT/CDRH/ODE/DAM
AAMI	BP, Blood Pressure Monitoring Committee			Cardiology	[PRIMARY] Ho, Charles Shang Chan; OMPT/CDRH/ODE/DCD/CDDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	CV, Cardiac Valve Prostheses Committee (US TAG/Mirror Committee to ISO/TC 150/SC2/WG01)			Cardiology	[PRIMARY] Wu, Changfu; OMPT/CDRH/ODE/DCD/SHDB; [ALTERNATE] Neubrandner, Rachel E; OMPT/CDRH/ODE/DCD/SHDB; [TECHNICAL EXPERT] Johnson, Terri K; OMPT/CDRH/OSB/DBS/DSBII; [TECHNICAL EXPERT] Laschinger, John C; OMPT/CDRH/ODE/DCD/SHDB
AAMI	DF, Defibrillator Committee (US TAG/Mirror Committee to IEC/SC 62D/MT19)			Cardiology	[PRIMARY] Tovar-Calderon, Oscar H; FDA/OMPT/CDRH/ODE/DCD/IEDB; [ALTERNATE] Stohlman, Jayna M; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Galeotti, Lorian; OMPT/CDRH/ODE/DCD/CDDB; [TECHNICAL EXPERT] Quinn, Bradley Q; OMPT/CDRH/ODE/DCD/CDDB
AAMI	DP, Medical Device Particulates Committee			Cardiology	[PRIMARY] Patwardhan, Dinesh V; OMPT/CDRH/OSEL; [ALTERNATE] Chowdhury, Katharine J; OMPT/OSMP/OOPD
AAMI	EC, ECG Committee (US TAG/Mirror Committee to IEC/SC 62D/MT22)			Cardiology	[PRIMARY] Galeotti, Lorian; OMPT/CDRH/ODE/DCD/CDDB; [ALTERNATE] Makrodimitis, Konstantinos; OMPT/CDRH/ODE/DCD/CDDB; [TECHNICAL EXPERT] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDB; [TECHNICAL EXPERT] Ho, Charles Shang Chan; OMPT/CDRH/ODE/DCD/CDDB
AAMI	ISO/TC 150/SC 02, Cardiovascular Implants & Extracorporeal Systems (U.S. TAG for ISO/TC150/SC 02)			Cardiology	[PRIMARY] Wu, Changfu; OMPT/CDRH/ODE/DCD/SHDB; [ALTERNATE] Lu, Qijin; OMPT/CDRH/OSEL/DAM
AAMI	MC, Mechanical Circulatory Support Systems Committee (US TAG/Mirror Committee to ISO/TC 150/SC6/WG6)			Cardiology	[PRIMARY] Rinaldi, Jean E; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Wu, Changfu; OMPT/CDRH/ODE/DCD/SHDB; [TECHNICAL EXPERT] Herbertson, Luke; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Richardson, Eric E; OMPT/CDRH/ODE/DCD/CSDB
AAMI	PC, Cardiac Rhythm Management Device Committee		PC-WG01 - Transvenous Cardiac Leads - Perforation Propensity SG	Cardiology	[PRIMARY] Walsh, Donna L; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Patel, Hetal; OMPT/CDRH/ODE/DCD/IEDB; [TECHNICAL EXPERT] Duraiswamy, Nandini; OMPT/CDRH/OSEL/DIDS; [TECHNICAL EXPERT] Kazmierski, Robert T; OMPT/CDRH/ODE/DCD/IEDB
AAMI	PC, Cardiac Rhythm Management Device Committee		PC-WG01 Transvenous Cardiac Leads	Cardiology	[PRIMARY] Walsh, Donna L; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Patel, Hetal; OMPT/CDRH/ODE/DCD/IEDB; [TECHNICAL EXPERT] Duraiswamy, Nandini; OMPT/CDRH/OSEL/DIDS; [TECHNICAL EXPERT] Kazmierski, Robert T; OMPT/CDRH/ODE/DCD/IEDB
AAMI	PC, Cardiac Rhythm Management Device Committee		PC-WG02 EMC Test Protocols	Cardiology	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Hazelett, Matthew; OMPT/CDRH/ODE/DCD/IEDB
AAMI	PC, Cardiac Rhythm Management Device Committee		PC-WG03 MRI Compatibility	Cardiology	[PRIMARY] Viohl, Ingmar; OMPT/CDRH/ODE/DCD/IEDB; [ALTERNATE] Rajan, Sunder S; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Delfino, Jana G; OMPT/CDRH/OIR/DRH/MREP; [TECHNICAL EXPERT] Seidman, Seth; OMPT/CDRH/OSEL/DBP
AAMI	PC, Cardiac Rhythm Management Device Committee (US TAG/Mirror Committee to ISO/TC150/SC6 - IEC/SC 62D JWG1)			Cardiology	[PRIMARY] Paulsen, Jessica; OMPT/CDRH/ODE/DCD/IEDB; [ALTERNATE] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Kazmierski, Robert T; OMPT/CDRH/ODE/DCD/IEDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	SP, Sphygmomanometer Committee (US TAG/Mirror Committee IEC/SC 62D/JWG7 - ISO/TC 121/SC3 JWG7)			Cardiology	[PRIMARY] Ho, Charles Shang Chan; OMPT/CDRH/ODE/DCD/CDDDB; [ALTERNATE] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 01 Cardiac valves	Cardiology	[PRIMARY] Wu, Changfu; OMPT/CDRH/ODE/DCD/SHDB; [ALTERNATE] Duraiswamy, Nandini; OMPT/CDRH/OSEL/DIDSR; [ALTERNATE] Neubrandner, Rachel E; OMPT/CDRH/ODE/DCD/SHDB; [TECHNICAL EXPERT] Laschinger, John C; OMPT/CDRH/ODE/DCD/SHDB
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 03 Vascular prostheses	Cardiology	[PRIMARY] Abel, Dorothy B; OMPT/CDRH/ODE/DCD/VSDB; [ALTERNATE] Banik, Jhumur D; OMPT/CDRH/ODE/DCD/PIDB; [TECHNICAL EXPERT] Anderson, Nelson E; OMPT/CDRH/ODE; [TECHNICAL EXPERT] Morrison, Tina M; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Weaver, Jason D; OMPT/CDRH/OSEL/DAM
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 04 Blood gas exchangers	Cardiology	[PRIMARY] Gaylord, Catherine P; OMPT/CDRH/ODE/DCD/CSDB; [ALTERNATE] Lu, Qijin; OMPT/CDRH/OSEL/DAM
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 06 Vascular device/drug combination products	Cardiology	[ALTERNATE] Brothers, Kenya A; OMPT/CDRH/ODE/DCD/ICDB; [TECHNICAL EXPERT] Guo, Ji; OMPT/CDRH/OSEL/DBCMS
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 06 Active implants	WG 06 Circulatory support devices	Cardiology	[PRIMARY] Rinaldi, Jean E; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Wu, Changfu; OMPT/CDRH/ODE/DCD/SHDB
AAMI	TAG 150/SC 6 TC 150 Implants for Surgery	SC 06 Active implants		Cardiology	[PRIMARY] Kazmierski, Robert T; OMPT/CDRH/ODE/DCD/IEDB; [ALTERNATE] Krauthamer, Victor; OMPT/CDRH/OSEL/DBP
AAMI	VP, Vascular Prostheses Committee		WG1 Vascular device/Drug combination products (US TAG/Mirror Committee to ISO/TC150/SC2/WG06)	Cardiology	[PRIMARY] Goodsell, Nicole; OMPT/CDRH/ODE/DCD/ICDB; [ALTERNATE] Brothers, Kenya A; OMPT/CDRH/ODE/DCD/ICDB
AAMI	VP, Vascular Prosthesis Committee (US TAG/Mirror Committee to ISO/TC150/SC2/WG03)			Cardiology	[PRIMARY] Abel, Dorothy B; OMPT/CDRH/ODE/DCD/VSDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.30 Cardiovascular Standards		Cardiology	[PRIMARY] Rinaldi, Jean E; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Mistry, Hiren P; OMPT/CDRH/ODE/DCD/PIDB; [TECHNICAL EXPERT] Banik, Jhumur D; OMPT/CDRH/ODE/DCD/PIDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.30 Cardiovascular Standards	F04.30.06 Endovascular Test Methods Task Group	Cardiology	[PRIMARY] Donaldson, Finn; OMPT/CDRH/ODE/DCD/PIDB; [ALTERNATE] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Weaver, Jason D; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Whatley, Eleni M; OMPT/CDRH/ODE/DCD/PIDB
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 19 Requirements for Defibrillators	Cardiology	[PRIMARY] Stohlmán, Jayna M; OMPT/CDRH/OSEL/DBP
ISO/IEC	ISO TC 121 SC 03 JWG 07		Joint ISO/TC 121/SC 3-IEC/SC 62D JWG 07: Non-invasive blood pressure monitoring equipment	Cardiology	[PRIMARY] Ho, Charles Shang Chan; OMPT/CDRH/ODE/DCD/CDDDB; [ALTERNATE] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
ISO/IEC	ISO-IEC/TC150/SC6 and IEC/SC62D	ISO - JWG01 and IEC - JWG03 Cardiac pacemakers and implantable defibrillators		Cardiology	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO/IEC	TC 150 Implants for Surgery SC6 & IEC SC62D	ISO JWG01 & IEC JWG03 Cardiac Pacemakers and Implantable Defibrillators		Cardiology	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Kazmierski, Robert T; OMPT/CDRH/ODE/DCD/IEDB
ISO/IEC	TC 150 Implants for Surgery SC6 & IEC SC62D	ISO JWG01 & IEC JWG03 Cardiac Pacemakers and Implantable Defibrillators	ISO 14117 EMC Test Protocols	Cardiology	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Hazelett, Matthew; OMPT/CDRH/ODE/DCD/IEDB
AAMI	CI, Cochlear Implants Committee			Dental/Ear, Nose and Throat	[PRIMARY] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Nandkumar, Srinivas; OMPT/CDRH/ODE/DOED/ENTB; [TECHNICAL EXPERT] Beard, Brian B; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Krauthamer, Victor; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Regnault, William F; OMPT/CDRH/OSEL/DBCMS
ADA	ADA Standards Committee on Dental Products (ADA SCDP) (U.S. TAG for ISO/TC 106)			Dental/Ear, Nose and Throat	[PRIMARY] Steen, Andrew I; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB
ADA	SCDI - Standards Committee of Dental Informatics		WG 11.8 - Track and Trace for Implantable Devices	Dental/Ear, Nose and Throat	[PRIMARY] Steen, Leslie T; OFVM/CFSAN/ODSP/ERS; [ALTERNATE] Palmer, Tiffany L; OMPT/CDRH/OSB/DPS
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)	SC 08 Medical Device EMC Test Methods	WG 03 Hearing Aid Compatibility C63.19	Dental/Ear, Nose and Throat	[PRIMARY] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB; [TECHNICAL EXPERT] Beard, Brian B; OMPT/CDRH/OSEL/DBP
ASA	Accredited Standards committee on Bioacoustics S3			Dental/Ear, Nose and Throat	[] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB
ASA	Accredited Standards Committee on Bioacoustics S3		WG 36 Speech Intelligibility	Dental/Ear, Nose and Throat	[PRIMARY] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB
ASA	Accredited Standards Committee on Bioacoustics S3		WG 37 Coupler Calibration of Earphones	Dental/Ear, Nose and Throat	[PRIMARY] Nandkumar, Srinivas; OMPT/CDRH/ODE/DOED/ENTB
ASA	Accredited Standards Committee on Bioacoustics S3		WG 48 Hearing Aids	Dental/Ear, Nose and Throat	[PRIMARY] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB
ASA	Accredited Standards Committee on Bioacoustics S3		WG 80 Probe Tube Measurements of Hearing Aid Performance	Dental/Ear, Nose and Throat	[PRIMARY] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB
ASA	Accredited Standards committee on Bioacoustics S3		WG 81 Hearing Assistance Technologies	Dental/Ear, Nose and Throat	[PRIMARY] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB
ASA	US TAG for IEC TC 029 Electroacoustics			Dental/Ear, Nose and Throat	[PRIMARY] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Peng, Shu-Chen; OMPT/CDRH/ODE/DOED/ENTB
ASTM	F04 Medical and Surgical Materials and Devices	F04.37 Implantable Hearing Devices		Dental/Ear, Nose and Throat	[] Beard, Brian B; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB
ISO	TC 106 Dentistry		WG 10 Biological evaluation	Dental/Ear, Nose and Throat	[PRIMARY] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 106 Dentistry	SC 01 Filling and restorative materials		Dental/Ear, Nose and Throat	[PRIMARY] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Malshet, Vasant G; OMPT/CDRH/ODE/DOED/ENTB
ISO	TC 106 Dentistry	SC 02 Prosthodontic materials		Dental/Ear, Nose and Throat	[PRIMARY] Anderson, Joel M; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Adjodha, Michael E; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 106 Dentistry	SC 03 Terminology		Dental/Ear, Nose and Throat	[PRIMARY] Steen, Andrew I; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 106 Dentistry	SC 04 Dental instruments		Dental/Ear, Nose and Throat	[PRIMARY] Giles, Lauren; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Mendelson, Michael; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 106 Dentistry	SC 06 Dental equipment		Dental/Ear, Nose and Throat	[PRIMARY] Anderson, Joel M; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Woods, Phillip D; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 106 Dentistry	SC 08 Dental implants		Dental/Ear, Nose and Throat	[PRIMARY] Steen, Andrew I; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Anderson, Joel M; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 106 Dentistry	SC 09 Dental CAD/CAM systems		Dental/Ear, Nose and Throat	[PRIMARY] Steen, Andrew I; OMPT/CDRH/ODE/DAGID/DEDB; [ALTERNATE] Anderson, Joel M; OMPT/CDRH/ODE/DAGID/DEDB
ISO	TC 150 Implants for Surgery	SC 06 Active Implants	WG 03 Cochlear implants	Dental/Ear, Nose and Throat	[PRIMARY] Dasika, Vasant; OMPT/CDRH/ODE/DOED/ENTB; [ALTERNATE] Nandkumar, Srinivas; OMPT/CDRH/ODE/DOED/ENTB; [TECHNICAL EXPERT] Krauthamer, Victor; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Regnault, William F; OMPT/CDRH/OSEL/DBCMS
AAMI	CN, Small Bore Connectors Committee		WG 01, Small-bore connector actuated valves	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC76 WG 01	WG 01, Soft containers for blood, blood components and parenterals; Infusion, transfusion and blood processing equipment	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC76 WG 02	WG 02, Rigid container systems and related accessories for parenterals and injectables	Gen. Hospital/Plastic Surgery	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC76 WG 04	WG 04, Elastomeric parts and components and related secondary packaging components	Gen. Hospital/Plastic Surgery	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC76 WG 06	WG 06, Primary packaging materials for medicinal products	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 03	WG 23, Syringes for insulin and pen-injectors	Gen. Hospital/Plastic Surgery	[ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Mcmichael, John C; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 08	WG 28, Sharps containers	Gen. Hospital/Plastic Surgery	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 09	WG 29, Catheters	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Pandya, Purva U; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Silverstein, Joshua S; OMPT/CDRH/ODE; [TECHNICAL EXPERT] Valdes, Thelma I; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Wiese, Carla M; OMPT/CDRH/ODE/DCD/PIDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 10	WG 30, Needles	Gen. Hospital/Plastic Surgery	[PRIMARY] Vesnovsky, Oleg; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [TECHNICAL EXPERT] Ferguson, Janice; OMPT/CDRH/OSB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 11	WG 31, Syringes	Gen. Hospital/Plastic Surgery	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 12	WG 32, Needle-based injection system (NIS) - Accessibility for Visually Impaired Persons	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 13	WG 33, Bolus injectors	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Stevens, Alan M; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 14	WG 34, Needle-based injection system (NIS) - Electrotechnical requirements and test methods	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Vesnovsky, Oleg; OMPT/CDRH/OSEL/DAM
AAMI	DI, Medical Devices for Injections Committee	US TAG for ISO/TC84 WG 15	WG 35, Device Change Management	Gen. Hospital/Plastic Surgery	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	EV, Electromedical equipment	US sub-TAG for IEC/ TC62/ SC62D and ISO/TC173, JWG 4	WG 05, Hospital Beds sub-TAG	Gen. Hospital/Plastic Surgery	[ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
AAMI	EV, Electromedical equipment	US sub-TAG for IEC/ TC62/ SC62D, MT 27	WG 12, Luminaires sub-TAG	Gen. Hospital/Plastic Surgery	[PRIMARY] Kosoglu, Mehmet A; OMPT/CDRH/ODE/DSD/GSDB1
AAMI	EV, Electromedical equipment	US sub-TAG ISO/TC 121/ SC3 & IEC/ TC62/ SC62D, JWG 8	WG 06, Clinical Thermometers	Gen. Hospital/Plastic Surgery	[PRIMARY] Wang, Quanzeng; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Meyer, Robert; OMPT/CDRH/ODE/DCD/PIDB
AAMI	HF, High Frequency Therapeutic Device Committee	US sub-TAG for IEC/ TC62/ SC62D, MT 17		Gen. Hospital/Plastic Surgery	[PRIMARY] Chen, Long H; OMPT/CDRH/ODE/DSD/GSDB2; [ALTERNATE] Talley, David B; OMPT/CDRH/ODE/DSD/GSDB2
AAMI	ID, Infusion Device Committee	US sub-TAG for IEC/ TC62/ SC62D, MT 23		Gen. Hospital/Plastic Surgery	[PRIMARY] Mcmichael, John C; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR
AAMI	II, Infant Incubator Committee	US sub-TAG for IEC/ TC62/ SC62D, MT21		Gen. Hospital/Plastic Surgery	[PRIMARY] Weeks, Crystal L; OFVM/CFSAN/OM/SMS; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	IP, Implantable Infusion Pumps Committee	US sub-TAG for ISO/ TC150/ SC06/ WG04		Gen. Hospital/Plastic Surgery	[PRIMARY] Cochenour, Carolyn; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Vuniqu, Bleta; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [TECHNICAL EXPERT] Stevens, Alan M; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	PB, Protective Barriers Committee			Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Qian, Bifeng; OMPT/CDRH/ODE/DAGID/INCB
AAMI	RB, Robotics Committee	US sub-TAG for IEC/ TC62/ SC62D, JWG35 & ISO/ TC299, JWG5, Medical robots for surgery		Gen. Hospital/Plastic Surgery	[PRIMARY] Yen, Dwight; OMPT/CDRH/ODE/DSD/GSDB2; [ALTERNATE] Claiborne, Thomas E; OMPT/CDRH/ODE/DSD/GSDB2
ASTM	D11 Rubber	D11.40 Consumer Rubber Products		Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Lilly, Lauren M; OMPT/CDRH/ODE/DAGID/INCB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG (MAIN)	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Rios, Michelle; OMPT/CDRH/OSB/DPS/MDR; [TECHNICAL EXPERT] Segars, Katharine M; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Walsh, Donna L; OMPT/CDRH/OSEL/DAM
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK19318 New Test Method for Standard Test Method for Abrasion of Ambidextrous Medical Examination Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Findley, Keisha M; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK27438 New Specification for Antimicrobial Medical Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK28465 New Test Method for In Vitro to Assess Anti-Viral Efficacy of Medical Gloves against Transmission of Pathogen during Simulated Puncture	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK30532 New Test Method for Microbial Contact Transfer with Antimicrobial-Treated Examination Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK35153 New Test Method for Determination of Bactericidal Efficacy on the Surface of Medical Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK46896 New Specification for Standard Specifications for Radiation Attenuating Protective Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.02 Medical Gloves TG, WK49858 New Specification for Chemotherapy Gloves	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.03 Commercial Glove TG (MAIN)	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.04 Extraction Test Methods TG (MAIN)	Gen. Hospital/Plastic Surgery	[PRIMARY] Lucas, Anne D; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.04 Extraction Test Methods TG, WK25943 New Test Method for Immunological Assay to Quantify Guayule Proteins	Gen. Hospital/Plastic Surgery	[PRIMARY] Lucas, Anne D; OMPT/CDRH/OSEL/DBCMS
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.04 Extraction Test Methods TG, WK40304 New Test Method for Phthalate Detection	Gen. Hospital/Plastic Surgery	[PRIMARY] Lucas, Anne D; OMPT/CDRH/OSEL/DBCMS
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.05 Rubber Products TG (MAIN)	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.05 Rubber Products TG, WK28312 New Test Method for Quantitative of Powder on Dental Dams	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ASTM	D11 Rubber	D11.45 (US TAG to TC45 Rubber and Rubber Products)	Rubber and Rubber Products	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB
ASTM	F04 Medical and Surgical Materials and Devices	F04.32 Plastic and Reconstructive Surgery		Gen. Hospital/Plastic Surgery	[PRIMARY] Ngatha, George K; OMPT/CDRH/OC/DMQ/ASDB; [ALTERNATE] Zhang, Min; OMPT/CDRH/ODE/DSD/PRSB2
ASTM	F04 Medical and Surgical Materials and Devices	F04.32 Plastic and Reconstructive Surgery	F04.32.01 Mammary Implants	Gen. Hospital/Plastic Surgery	[PRIMARY] Arepalli, Sambasiva; OMPT/CDRH/ODE/DSD/PRSB2; [ALTERNATE] Ki, Tajanay R; OMPT/CDRH/ODE/DSD/PRSB1; [TECHNICAL EXPERT] Eustaquio, Trisha V; OMPT/CDRH/ODE
ASTM	F04 Medical and Surgical Materials and Devices	F04.33 Medical/Surgical Instruments		Gen. Hospital/Plastic Surgery	[PRIMARY] Chen, Long H; OMPT/CDRH/ODE/DSD/GSDB2; [ALTERNATE] Nosovskyy, Mykhaylo B; OMPT/CDRH/ODE/DSD/GSDB2
ASTM	F15 Consumer Products	ASTM F15.70 Adult Safety Products, Portable Bed Rails		Gen. Hospital/Plastic Surgery	[PRIMARY] Ferlo Todd, Joan; OMPT/CDER/OND/OHOP/DHOT; [ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ASTM	F23 Protective Clothing	F23.40 Biological		Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Qian, Bifeng; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ASTM	F23 Protective Clothing	F23.40 Biological	F23.40.07 Surgical Gowns Task Group	Gen. Hospital/Plastic Surgery	[PRIMARY] Cunningham, Terrell A; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Qian, Bifeng; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
IEC	TC 087 Ultrasonics		WG 7, Surgical and Therapeutic Devices	Gen. Hospital/Plastic Surgery	[PRIMARY] Maruvada, Subha; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Chen, Long H; OMPT/CDRH/ODE/DSD/GSDB2; [TECHNICAL EXPERT] Talley, David B; OMPT/CDRH/ODE/DSD/GSDB2
IEC	TC 62 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 17, High frequency surgical equipment	Gen. Hospital/Plastic Surgery	[PRIMARY] Chen, Long H; OMPT/CDRH/ODE/DSD/GSDB2; [ALTERNATE] Talley, David B; OMPT/CDRH/ODE/DSD/GSDB2
IEC	TC 62 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 21, Pediatric equipment	Gen. Hospital/Plastic Surgery	[PRIMARY] Weeks, Crystal L; OFVM/CFSAN/OM/SMS; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB
IEC	TC 62 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 23, Infusion pumps	Gen. Hospital/Plastic Surgery	[PRIMARY] Mcmichael, John C; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR
IEC	TC 62 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 27, Luminaires for surgery and diagnosis	Gen. Hospital/Plastic Surgery	[PRIMARY] Kosoglu, Mehmet A; OMPT/CDRH/ODE/DSD/GSDB1

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEC	TC 62 Electrical equipment in medical practice	SC 62D Electromedical equipment	WG 34, Ionized Gas Coagulation Equipment	Gen. Hospital/Plastic Surgery	[PRIMARY] Nosovskyy, Mykhaylo B; OMPT/CDRH/ODE/DSD/GSDB2
IEC/ISO	IEC/ TC62/ SC62D, JWG35 & ISO/ TC229/ JWG 5		JWG 35/5, Medical robots for surgery	Gen. Hospital/Plastic Surgery	[PRIMARY] Yen, Dwight; OMPT/CDRH/ODE/DSD/GSDB2; [ALTERNATE] Claiborne, Thomas E; OMPT/CDRH/ODE/DSD/GSDB2
ISO	TC 150 Implants for Surgery		WG 08 Breast Implants	Gen. Hospital/Plastic Surgery	[PRIMARY] Ki, Tajanay R; OMPT/CDRH/ODE/DSD/PRSB1; [ALTERNATE] Eustaquio, Trisha V; OMPT/CDRH/ODE
ISO	TC 150 Implants for Surgery	SC 06 Active Implants	WG 04 Implantable infusion pumps	Gen. Hospital/Plastic Surgery	[PRIMARY] Cochenour, Carolyn; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Vuniqui, Bleta; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [TECHNICAL EXPERT] Stevens, Alan M; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 76 Transfusion, Infusion and Injection Equipment for Medical or Pharmaceutical Use		WG 01, Soft containers for blood, blood components and parenterals; Infusion, transfusion and blood processing equipment	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS
ISO	TC 76 Transfusion, Infusion and Injection Equipment for Medical or Pharmaceutical Use		WG 02, Rigid container systems and related accessories for parenterals and injectables	Gen. Hospital/Plastic Surgery	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
ISO	TC 76 Transfusion, Infusion and Injection Equipment for Medical or Pharmaceutical Use		WG 04, Elastomeric parts and components and related secondary packaging components	Gen. Hospital/Plastic Surgery	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 76 Transfusion, Infusion and Injection Equipment for Medical or Pharmaceutical Use		WG 06, Primary packaging materials for medicinal products	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 03, Syringes for insulin and pen-injectors	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Mcmichael, John C; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 08, Sharps containers	Gen. Hospital/Plastic Surgery	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 09, Catheters	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Pandya, Purva U; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Silverstein, Joshua S; OMPT/CDRH/ODE; [TECHNICAL EXPERT] Valdes, Thelma I; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Wiese, Carla M; OMPT/CDRH/ODE/DCD/PIDB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 10, Needles	Gen. Hospital/Plastic Surgery	[PRIMARY] Vesnovsky, Oleg; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [TECHNICAL EXPERT] Ferguson, Janice; OMPT/CDRH/OSB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 11, Syringes	Gen. Hospital/Plastic Surgery	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 12, Needle-based injection system (NIS) - Accessibility for Visually Impaired Persons	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 13, Bolus injectors	Gen. Hospital/Plastic Surgery	[PRIMARY] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Stevens, Alan M; OMPT/CDRH/ODE/DAGID/GHDB
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 14, Needle-based injection system (NIS) - Electrotechnical requirements and test methods	Gen. Hospital/Plastic Surgery	[PRIMARY] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Vesnovsky, Oleg; OMPT/CDRH/OSEL/DAM
ISO	TC 84 Devices for administration of medicinal products and intravascular catheters		WG 15, Device Change Management	Gen. Hospital/Plastic Surgery	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [ALTERNATE] Brooks, Mary E; OMPT/CDRH/ODE/DAGID/GHDB
ISO/IEC	ISO/TC 121/ SC3 & IEC/ TC62/ SC62D		JWG 8, Clinical Thermometers	Gen. Hospital/Plastic Surgery	[PRIMARY] Wang, Quanzeng; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Meyer, Robert; OMPT/CDRH/ODE/DCD/PIDB
ISO/IEC	ISO/TC 173 & IEC/ TC62/ SC62D		JWG 4, Medical Beds	Gen. Hospital/Plastic Surgery	[ALTERNATE] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
USP			General Chapters–Futures Expert Panel	Gen. Hospital/Plastic Surgery	[PRIMARY] Colehour, Maegen; OMPT/CDRH/ODE/DSD/PRSB1
AAMI	AAMI University	Quality Systems Exam Development Committee	job task analysis (JTA) study	General (Policy)	[] Jariwala, Jay; OMPT/CDER/OC/OMQ/DDQI/GCBII; [] Wilbon, Tonya A; OMPT/CDRH/OIR
AAMI	Board Healthcare Administration Vice Chair			General (Policy)	[PRIMARY] Richter, Kimber C.; OMPT/CDRH/OC
AAMI	Board of Directors			General (Policy)	[MEMBER] Mitchell, Diane A; OMPT/CDRH/OCD
AAMI	Committee on Standards Strategy			General (Policy)	[] Colburn, Scott A; OMPT/CDRH/OCD
AAMI	Committe on Medical Device Sustainability			General (Policy)	[] Colburn, Scott A; OMPT/CDRH/OCD
AAMI	HTSI/Alarm Best PracticesGroup			General (Policy)	[PRIMARY] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDB
AAMI	HTSI/Clinical AlarmsSteering Committee			General (Policy)	[PRIMARY] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDB
AAMI	Risk Management			General (Policy)	[MEMBER] Mitchell, Diane A; OMPT/CDRH/OCD
AAMI	Risk Management			General (Policy)	[MEMBER] Brockman, Randall G; OMPT/CDRH/ODE
AAMI	Standards Board			General (Policy)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD
ANSI	Accreditation Committee			General (Policy)	[] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB
ANSI	Board of Directors (Under GMF Chair)			General (Policy)	[] Colburn, Scott A; OMPT/CDRH/OCD
ANSI	Council of the U.S. National Committee to IEC			General (Policy)	[] Zeng, Jianchao; OMPT/CDRH/OCD
ANSI	Executive Standards Council			General (Policy)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD
ANSI	Government Member Forum			General (Policy)	[] Colburn, Scott A; OMPT/CDRH/OCD
ANSI	ISO Council (AIC)			General (Policy)	[] Bell, Tammie J; OMPT/CDER/OSP; [MEMBER] Colburn, Scott A; OMPT/CDRH/OCD
ASTM	ASTM Committee on Technical Committee Operations (COTCO)			General (Policy)	[] Fitzgerald, Brian J; OMPT/CDRH/OSEL; [MEMBER] Woods, Terry O; OMPT/CDRH/OSEL/DAM
ASTM	Board Committee on Standards (COS)			General (Policy)	[PRIMARY] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2
ASTM	Board of Directors	Term Ended 12/31/2015		General (Policy)	[] Colburn, Scott A; OMPT/CDRH/OCD
ASTM	Nominating Committee			General (Policy)	[PRIMARY] Woods, Terry O; OMPT/CDRH/OSEL/DAM; [MEMBER] Demian, Hany W; OMPT/OC/OCS/ORSI/DSICT/
IECEE				General (Policy)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD; [MEMBER] Zeng, Jianchao; OMPT/CDRH/OCD

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 276 Biotechnology			General (Policy)	[] Lappalainen, Sharon K; OMPT/CDRH/OCD; [] Nalubola, Padmashri; OP/PDCS; [PRIMARY] Arcidiacono, Judith A; OMPT/CBER/OTAT; [MEMBER] Kaplan, David S; OMPT/CDRH/OSEL/DAM; [MEMBER] Oh, Steven; OMPT/CBER/OTAT/DCGT/CTB
USP	Convention	CDRH USP Rep		General (Policy)	[PRIMARY] Lightfoote, Marilyn M; OMPT/CDRH/OSEL
USP	Official CDRH Correspondent			General (Policy)	[PRIMARY] Lightfoote, Marilyn M; OMPT/CDRH/OSEL
AAMI	AL, Medical Device Alarms Committee			General I (QS/RM)	[PRIMARY] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDDB; [ALTERNATE] Scully, Christopher; OMPT/CDRH/OSEL/DBP
AAMI	CN, Small Bore Connectors (US TAG to ISO TC210JWG4)			General I (QS/RM)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD; [PRIMARY] Scott, Pamela D; OMPT/CDRH/OCD; [TECHNICAL EXPERT] Anderson, Nicholas P; OMPT/CDRH/OIR/DMGP/MPCB; [TECHNICAL EXPERT] Bacalocostantis, Irene; OMPT/CDRH/ODE/DRGUD/GEDB
AAMI	EQ, Medical Equipment Management Committee			General I (QS/RM)	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH
AAMI	HE, Human Factors Engineering Committee			General I (QS/RM)	[PRIMARY] Hoste, Shannon M; OMPT/CDRH/ODE/DAGID; [ALTERNATE] Feng, Xin; OMPT/CDRH/ODE/DAGID
AAMI	QM, Quality Management and Corresponding General Aspects for Medical Devices		WG 02 General aspects stemming from the application of quality principles to medical devices (US TAG to ISO TC210 WG 02)	General I (QS/RM)	[] Gutierrez, Alberto; OMPT/CDRH/OIR; [PRIMARY] Keith, Erin I; OMPT/CDRH/ODE/DAGID
AAMI	QM, Quality Management and Corresponding General Aspects for Medical Devices		WG 03 Symbols and nomenclature for medical devices (US TAG to ISO TC210 WG 03)	General I (QS/RM)	[] Jacobs, Evan D; OMPT/CDRH/OSB/DPS/IAB; [] Pressly, Nancy A; OMPT/CDRH/OCE
AAMI	QM, Quality Management and Corresponding General Aspects for Medical Devices		WG 04 Application of risk management to medical devices (US TAG to ISO TC210 JWG01)	General I (QS/RM)	[] Erikson, Lorie; OMPT/CDRH/OC/DMQ/CDB; [PRIMARY] Torres, Melissa A; OMPT/CDRH/ODE/POS/PMA; [ALTERNATE] Brown Smith, Kimberly E; OMPT/CDRH/OC
AAMI	QM, Quality Management and Corresponding General Aspects for Medical Devices (US TAG for ISO/TC 210)			General I (QS/RM)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD
AAMI	SM, Software and Information Technology Committee		CP Combination Products	General I (QS/RM)	[PRIMARY] Burns, Melissa B; OMPT/OSMP/OCP; [ALTERNATE] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [TECHNICAL EXPERT] Ryan, Jacqueline S; OMPT/CDRH/OC; [TECHNICAL EXPERT] Torres, Melissa A; OMPT/CDRH/ODE/POS/PMA
ASME	V&V 40 - Verification and Validation in Computational Methods for Medical Devices			General I (QS/RM)	[PRIMARY] Morrison, Tina M; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Hariharan, Prasanna; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Pathmanathan, Pras; OMPT/CDRH/OSEL/DBP
ASQ	Z1 Applications of Statistical Methods in Process Management			General I (QS/RM)	[PRIMARY] Tang, Rong; OMPT/CDRH/OSB/DBS/TSB1
IEC	TC 056 Dependability			General I (QS/RM)	[PRIMARY] Simone, Lisa K; OMPT/CBER/OBRR/DETTD/PRB
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 25 Ergonomics and graphical symbols	General I (QS/RM)	[] Feng, Xin; OMPT/CDRH/ODE/DAGID; [] Hoste, Shannon M; OMPT/CDRH/ODE/DAGID
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 27 Risk management	General I (QS/RM)	[] Brown Smith, Kimberly E; OMPT/CDRH/OC; [] Burns, Melissa B; OMPT/OSMP/OCP; [] Torres, Melissa A; OMPT/CDRH/ODE/POS/PMA

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEEE			WG 1858 Camera Phone Image Quality (CPIQ)	General I (QS/RM)	[PRIMARY] Wang, Quanzeng; OMPT/CDRH/OSEL/DBP
ISO	TC 042 Photography		WG 18 Electronic still picture imaging	General I (QS/RM)	[PRIMARY] Wang, Quanzeng; OMPT/CDRH/OSEL/DBP
ISO	TC 069 Applications of statistical methods			General I (QS/RM)	[PRIMARY] Tang, Rong; OMPT/CDRH/OSB/DBS/TSB1
ISO	TC 069 Applications of statistical methods	SC4 Applications of Statistical Methods in Process Management		General I (QS/RM)	[PRIMARY] Tang, Rong; OMPT/CDRH/OSB/DBS/TSB1
ISO	TC 176 Quality management and quality assurance			General I (QS/RM)	[ALTERNATE] Welch, Jacqueline B; OGROP/ORR/OO
ISO	TC 210 Quality management and corresponding general aspects for medical devices (US TAG-AAMI QM Committee)			General I (QS/RM)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD; [ALTERNATE] Trautman, Kimberly A.; OMPT/CDRH/OCD
ISO	TC 210 Quality management and corresponding general aspects for medical devices (US TAG-AAMI QM WG 01)		WG 01 Application of quality systems to medical devices	General I (QS/RM)	[PRIMARY] Winter, Marc-Henri; OMPT/CDRH/OC/DICO; [ALTERNATE] Welch, Jacqueline B; OGROP/ORR/OO
ISO	TC 210 Quality management and corresponding general aspects for medical devices (US TAG-AAMI QM WG 02)		WG 02 General aspects stemming from the application of quality principles to medical devices	General I (QS/RM)	[] Gutierrez, Alberto; OMPT/CDRH/OIR; [PRIMARY] Keith, Erin I; OMPT/CDRH/ODE/DAGID
ISO	TC 210 Quality management and corresponding general aspects for medical devices (US TAG-AAMI QM WG 03)		WG 03 Symbols and nomenclature for medical devices	General I (QS/RM)	[PRIMARY] Pressly, Nancy A; OMPT/CDRH/OCE; [ALTERNATE] Jacobs, Evan D; OMPT/CDRH/OSB/DPS/IAB
ISO	TC 210 Quality management and corresponding general aspects for medical devices (US TAG-AAMI QM WG 04)		JWG 01 Application of risk management to medical devices	General I (QS/RM)	[PRIMARY] Torres, Melissa A; OMPT/CDRH/ODE/POS/PMA; [ALTERNATE] Keith, Erin I; OMPT/CDRH/ODE/DAGID
ISO/IEC	ISO/TC 121/SC 03 - IEC/SC62A		JWG 02 Alarm systems	General I (QS/RM)	[PRIMARY] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDDB; [ALTERNATE] Scully, Christopher; OMPT/CDRH/OSEL/DBP
ISO/IEC	ISO/TC 210 - IEC/SC 62A		JWG 4 Medical devices - General requirements for safety and essential performance - Usability	General I (QS/RM)	[PRIMARY] Hoste, Shannon M; OMPT/CDRH/ODE/DAGID; [ALTERNATE] Feng, Xin; OMPT/CDRH/ODE/DAGID
ISO/IEC	ISO/TC 210 - IEC/SC 62D		JWG 04 Small Bore Connectors	General I (QS/RM)	[PRIMARY] Colburn, Scott A; OMPT/CDRH/OCD; [PRIMARY] Scott, Pamela D; OMPT/CDRH/OCD; [TECHNICAL EXPERT] Anderson, Nicholas P; OMPT/CDRH/OIR/DMGP/MPCB
ISO/IEC	JTC 1 Information Technology	SC 31 Automatic identification and data capture techniques	WG 2 Data structure	General I (QS/RM)	[] Quencer, Erin K; OMPT/CDRH/OSB; [] Zeng, Jianchao; OMPT/CDRH/OCD
AAMI	EM, Electromagnetic Compatibility Committee			General II (ES/EMC)	[PRIMARY] Guag, Joshua W; OMPT/CDRH/OSEL/DBP; [PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
AAMI	ES Electrical Safety Committee			General II (ES/EMC)	[PRIMARY] Ghods, Hamed; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Zeng, Jianchao; OMPT/CDRH/OCD
AAMI	HA, Medical Devices and Systems in Home Care Applications			General II (ES/EMC)	[PRIMARY] Brumbaugh, Joann F; OMPT/CDRH/OSB/DPS/PEBI; [ALTERNATE] Ross, Aftin M; OMPT/CDRH/OCD
AAMI	MP, Multi-parameter Patient Monitoring Equipment Committee			General II (ES/EMC)	[PRIMARY] Forrest, Shawn W; OMPT/CDRH/ODE/DCD/CDDDB
AAMI	QM, Quality Management and Corresponding General Aspects for Medical Devices		WG 01 Application of quality systems to medical devices (US TAG to ISO TC210 WG 01)	General II (ES/EMC)	[PRIMARY] Winter, Marc-Henri; OMPT/CDRH/OC/DICO; [ALTERNATE] Welch, Jacqueline B; OGROP/ORR/OO

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	SM, Software and Information Technology Committee		WG 06 Wireless	General II (ES/EMC)	[PRIMARY] Witters, Donald M; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Seidman, Seth; OMPT/CDRH/OSEL/DBP
AIM	US TAG for ISO/IEC JTC1SC31 committee			General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Beard, Brian B; OMPT/CDRH/OSEL/DBP
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)			General II (ES/EMC)	[PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)	SC 01 Techniques and Development		General II (ES/EMC)	[PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)	SC 05 Immunity Testing and Measurements		General II (ES/EMC)	[PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)	SC 07 Spectrum Etiquette		General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
ANSI	Accredited Standards Committee C63 - Electromagnetic Compatibility (EMC)	SC 08 Medical Device EMC Test Methods	WG 01 Medical Device Ad Hoc EMC Test	General II (ES/EMC)	[PRIMARY] Witters, Donald M; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP
ASTM	F30 Emergency Medical Services (EMS)	F30.01 EMS Equipment		General II (ES/EMC)	[PRIMARY] Kumar, Allison M; OMPT/CDRH/OCD; [ALTERNATE] Lang, Edith; OMPT/CDRH/OSEL/DBP
IEC	TC 021 Secondary cells and batteries	SC21A Secondary cells and batteries containing alkaline or other non-acid electrolytes	WG4 Safety and mechanical tests on secondary cells and batteries and maintenance of IEC 61959, 62133, 62188	General II (ES/EMC)	[PRIMARY] Ho, Charles Shang Chan; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Ghods, Hamed; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Kyprianou, Iacovos S; OMPT/CDRH/OCD
IEC	TC 062 Electrical equipment in medical practice			General II (ES/EMC)	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common Aspects of Electrical Equipment Used in Medical Practice		General II (ES/EMC)	[] Syed, Sajjad H; OMPT/CDRH/OSEL/DBP; [] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 23 Electromagnetic compatibility	General II (ES/EMC)	[] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [] Witters, Donald M; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 28 Electrical hazards	General II (ES/EMC)	[] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 29 Mechanical hazards	General II (ES/EMC)	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 30 Overheating, fire protection and additional hazards	General II (ES/EMC)	[] Yang, Andrew; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 22 Transcutaneous partial pressure monitoring equipment	General II (ES/EMC)	[PRIMARY] Pressly, Nancy A; OMPT/CDRH/OCE; [ALTERNATE] Gonzalez, Gema; OMPT/CDRH/OSEL/DBP
IEC	TC 065 Industrial Process Measurement and Control	SC 65A Systems Aspects	WG 04 EMC Requirements	General II (ES/EMC)	[PRIMARY] Schwartz, Naomi; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
IEC	TC 077 Electromagnetic compatibility			General II (ES/EMC)	[PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEC	TC 106 Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure			General II (ES/EMC)	[] Shrivastava, Devashish; OMPT/CDRH/OIR/DRH/MREP; [] Song, Ting; OMPT/CDRH/OIR/DRH/MREP
IEC	U. S. Coordinating committee on electromagnetic compatibility			General II (ES/EMC)	[PRIMARY] Silberberg, Jeffrey L; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Witters, Donald M; OMPT/CDRH/OSEL/DBP
IEC/ISO	IEC/TC 62 - ISO/TC 121	IEC/SC 62A - ISO/SC 3	JWG 06 Medical electrical equipment and medical electrical systems used in home care applications	General II (ES/EMC)	[PRIMARY] Brumbaugh, Joann F; OMPT/CDRH/OSB/DPS/PEBI; [ALTERNATE] Ross, Aftin M; OMPT/CDRH/OCD
IEEE	IEEE 802 LAN/MAN Standards Committee	IEEE 802.15 Working Group for Wireless Personal Area Networks	Task Group 6 Body Area Networks	General II (ES/EMC)	[PRIMARY] Witters, Donald M; OMPT/CDRH/OSEL/DBP
ISO/IEC	ISO/TC 121/SC 03 - IEC/TC62/SC 62D		JWG 12 Home respiratory equipment	General II (ES/EMC)	[] O'Brien, Robert M; OMPT/CDRH/OSB
ISO/IEC	ISO/TC 121/SC 1 & SC 3 - IEC/SC 62A		JWG 11 Emergency medical services equipment	General II (ES/EMC)	[] Ross, Aftin M; OMPT/CDRH/OCD
ISO/IEC	ISO/TC 299/SC 2 - IEC/SC62A		JWG 9 Safety for medical devices using robotic technology	General II (ES/EMC)	[] Broverman, Ian; OMPT/CDRH/ODE/DNPM/NDNB; [PRIMARY] Janda, Michel D; OMPT/CDRH/ODE/DOD/JFDB1; [PRIMARY] Parvinian, Bahram; OMPT/CDRH/ODE/DAGID/ANDB
ISO/IEC	JTC 1 Information Technology	SC 31 Automatic identification and data capture techniques		General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Beard, Brian B; OMPT/CDRH/OSEL/DBP
ISO/IEC	JTC 1 Information Technology	SC 31 Automatic identification and data capture techniques	WG 4 Radio frequency identification for item management	General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Beard, Brian B; OMPT/CDRH/OSEL/DBP
ISO/IEC	JTC 1 Information Technology	SC 31 Automatic identification and data capture techniques	WG 5 Real time locating systems	General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Beard, Brian B; OMPT/CDRH/OSEL/DBP
ISO/IEC	JTC 1 Information Technology	SC 31 Automatic identification and data capture techniques	WG 7 Security for item management	General II (ES/EMC)	[PRIMARY] Seidman, Seth; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Beard, Brian B; OMPT/CDRH/OSEL/DBP
CLSI	Board of Directors			In Vitro Diagnostics	[] Oliner, Kelly; OMPT/CDRH/OIR/DIHD
CLSI	Consensus Council			In Vitro Diagnostics	[MEMBER] Tezak-Fragale, Zivana; OMPT/CDRH/OIR
CLSI	Expert Panel on Clinical Chemistry and Toxicology			In Vitro Diagnostics	[MEMBER] Duan, Lili; OMPT/CDRH/OIR/DCTD/CRDB
CLSI	Expert Panel on Clinical Chemistry and Toxicology	Document Development Committee on Protocol for Establishment of Sample Stability in Clinical Chemistry and Toxicology; Draft Guideline (C55)		In Vitro Diagnostics	[MEMBER] Caposino, Paula V; OMPT/CDRH/OIR/DCTD/CRDB; [CONTRIBUTOR] Kondratovich, Marina; OMPT/CDRH/OIR; [CONTRIBUTOR] Lovell, Stephen J; OMPT/CDRH/OIR/DMD/VIR2
CLSI	Expert Panel on Evaluation Protocols			In Vitro Diagnostics	[MEMBER] Kondratovich, Marina; OMPT/CDRH/OIR
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Assessment of Equivalency of Specimen Types for Clinical Laboratory Methods (EP35)		In Vitro Diagnostics	[MEMBER] Kondratovich, Marina; OMPT/CDRH/OIR; [CONTRIBUTOR] Pampori, Nisar A; OMPT/CDRH/OIR/DIHD
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Characterization of Dilution and Spiking Recovery (EP 34)		In Vitro Diagnostics	[MEMBER] Fijalkowska, Iwona; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Evaluation of Linearity (EP06-A2)		In Vitro Diagnostics	[MEMBER] Kondratovich, Marina; OMPT/CDRH/OIR; [CONTRIBUTOR] Chan, Yung W; OGROP/OIP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Evaluation of Qualitative Test Performance (EP12-A3)		In Vitro Diagnostics	[MEMBER] Li, Qin; OMPT/CDRH/OSB/DBS/DSBII; [CONTRIBUTOR] Bell-Vlasov, Andrea K; OMPT/CDRH/OIR/DCTD/DDDB; [CONTRIBUTOR] Pennello, Gene A; OMPT/CDRH/OSB/DBS/DSBII
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Evaluation of Stability of In Vitro Diagnostic Reagents (EP-25)		In Vitro Diagnostics	[MEMBER] Whitaker, Kathleen B; OMPT/CDRH/OIR/DMD/VIR2; [CONTRIBUTOR] Li, Chester; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Evaluation Protocols	Document Development Committee on Interference Testing in Clinical Chemistry (EP07-A3)		In Vitro Diagnostics	[MEMBER] Rheinheimer, Douglas W; OMPT/CDRH/OIR/DCTD/CTXB; [CONTRIBUTOR] Chan, Sic Lung; OMPT/CBER/OBRR/DBCD/BPB
CLSI	Expert Panel on Hematology and Immunology and Ligand Assay	Document Development Committee on Collection, Transport, and Processing of Blood Specimens for Plasma-Based Coagulation Assays (H21)		In Vitro Diagnostics	[MEMBER] Monasterial, Jeb; OMPT/CDRH/OIR/DIHD/HEMB; [CONTRIBUTOR] Taylor-Bell, Takeesha; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Hematology, Immunology and Ligand Assay			In Vitro Diagnostics	[MEMBER] Taylor-Bell, Takeesha; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Hematology, Immunology and Ligand Assay	H62 Validation of Assays Performed by Flow Cytometry		In Vitro Diagnostics	[MEMBER] Cleary, Jacqueline; OMPT/CDRH/OIR/DIHD/IMFB
CLSI	Expert Panel on Microbiology			In Vitro Diagnostics	[MEMBER] Shawar, Ribhi; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Microbiology	Ad Hoc Working Group for the Revision of M02 and M07		In Vitro Diagnostics	[MEMBER] Wong, Alexandra T; OMPT/CDRH/OIR/DMD/BAC1; [CONTRIBUTOR] Conville, Patricia S; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Microbiology	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters (M23)		In Vitro Diagnostics	[MEMBER] Conville, Patricia S; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Microbiology	Document Development Committee on Detection of Anaerobes in Clinical Specimens (M55)		In Vitro Diagnostics	[MEMBER] Shawar, Ribhi; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Microbiology	Document Development Committee on Susceptibility Testing of Mycobacteria Nocardiae and other Aerobic Actinomycetes (M24 A3)		In Vitro Diagnostics	[MEMBER] Conville, Patricia S; OMPT/CDRH/OIR/DMD/BAC1; [CONTRIBUTOR] Washington, Janice A; OMPT/CDRH/OIR/DMD/BAC2
CLSI	Expert Panel on Microbiology	Subcommittee on Antifungal Susceptibility Tests		In Vitro Diagnostics	[MEMBER] Shea, Yvonne D; OMPT/CDRH/OIR/DMD/BAC2; [CONTRIBUTOR] Shawar, Ribhi; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Microbiology	Subcommittee on Antimicrobial Susceptibility Testing		In Vitro Diagnostics	[CONTRIBUTOR] Conville, Patricia S; OMPT/CDRH/OIR/DMD/BAC1; [CONTRIBUTOR] Shawar, Ribhi; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Molecular Methods			In Vitro Diagnostics	[MEMBER] Schetter, Aaron J; OMPT/CDRH/OIR/DMGP/MGB
CLSI	Expert Panel on Molecular Methods	Document Development Committee on Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods (MM13, 2nd Edition)		In Vitro Diagnostics	[MEMBER] Ghosh, Soma; OMPT/CDRH/OIR/DMGP/MPCB; [CONTRIBUTOR] Bijwaard, Karen E; OMPT/CDRH/OIR/DMGP/MPCB; [CONTRIBUTOR] Goodwin, David G; OMPT/CDRH/OIR/DMD/BAC1
CLSI	Expert Panel on Molecular Methods	Document Development Committee on Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications (MM21)		In Vitro Diagnostics	[MEMBER] Bijwaard, Karen E; OMPT/CDRH/OIR/DMGP/MPCB; [CONTRIBUTOR] Liang, Xueying; OMPT/CDRH/OIR/DMGP/MGB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
CLSI	Expert Panel on Molecular Methods	Document Development Committee on Molecular Diagnostic Methods for Nonhematological Cancers (MM23)		In Vitro Diagnostics	[MEMBER] Roscoe, Donna M; OMPT/CDRH/OIR/DMGP/MGB; [CONTRIBUTOR] Bijwaard, Karen E; OMPT/CDRH/OIR/DMGP/MPCB
CLSI	Expert Panel on Molecular Methods	Document Development Committee on Verification and Validation of Multiplex Nucleic Acid Assays (MM17)		In Vitro Diagnostics	[MEMBER] Liang, Xueying; OMPT/CDRH/OIR/DMGP/MGB; [CONTRIBUTOR] Bish, Himani; OMPT/CDRH/OIR/DMD/VIR1
CLSI	Expert Panel on Newborn Screening			In Vitro Diagnostics	[MEMBER] Kelm, Kellie B; OMPT/CDRH/OIR/DCTD/CRDB
CLSI	Expert Panel on Newborn Screening	Document Development Committee on Newborn Screening for Hemoglobinopathies		In Vitro Diagnostics	[MEMBER] Taylor-Bell, Takeesha; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Point of Care Testing			In Vitro Diagnostics	[MEMBER] Bell-Vlasov, Andrea K; OMPT/CDRH/OIR/DCTD/DDDB
CLSI	Expert Panel on Point-of-Care Testing	Document Development Committee on Emergency and Disaster POC Testing (POCT15)		In Vitro Diagnostics	[CONTRIBUTOR] Puri, Beena; OMPT/CDRH/OIR/DMD/VIR2; [CONTRIBUTOR] Roth, Kristian M; OMPT/CDRH/OIR/DMD/BAC2
CLSI	Expert Panel on Point-of-Care Testing	Document Development Committee on Point-of-Care In Vitro Diagnostics (IVD)Testing (Revision of POCT04-A2)		In Vitro Diagnostics	[MEMBER] Roth, Kristian M; OMPT/CDRH/OIR/DMD/BAC2; [CONTRIBUTOR] Kagan, Carolina; OMPT/CDRH/OIR/DIHD/IMFB
CLSI	Expert Panel on Point-of-Care Testing	Document Development Committee Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition (POCT-14)		In Vitro Diagnostics	[MEMBER] Taylor-Bell, Takeesha; OMPT/CDRH/OIR/DIHD/HEMB; [CONTRIBUTOR] Goehe, Rachel; OMPT/CDRH/OIR/DIHD/HEMB
CLSI	Expert Panel on Quality Management System and General	Document Development Committee QMS01: Quality Management System: A Model for Laboratory Services, 5th Edition		In Vitro Diagnostics	[MEMBER] Blyskun, Elaine H; OMPT/CDRH/OIR/DPOM; [CONTRIBUTOR] Galloway, Mary A; OMPT/CDRH/OIR/DMGP/MPCB
CLSI	Expert Panel on Quality Management System and General Practices			In Vitro Diagnostics	[] Hwang, Leory; OMPT/CDRH/OIR/DMD/VIR2
ISO	TC 212 on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (US TAG - CLSI)			In Vitro Diagnostics	[PRIMARY] Gutierrez, Alberto; OMPT/CDRH/OIR; [ALTERNATE] Tezak-Fragale, Zivana; OMPT/CDRH/OIR
ISO	TC 212 on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (US TAG - CLSI)		WG 1 Quality and competence in the medical laboratory	In Vitro Diagnostics	[PRIMARY] Maher, Kevin J; OMPT/CDRH/OIR/DIHD/IMFB; [ALTERNATE] Connors, Sheila A; OMPT/CDRH/OIR/DCTD/CHTB
ISO	TC 212 on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (US TAG - CLSI)		WG2 Reference systems	In Vitro Diagnostics	[PRIMARY] Kondratovich, Marina; OMPT/CDRH/OIR; [ALTERNATE] Garica, Maria; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 212 on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (US TAG - CLSI)		WG3 In vitro diagnostic products	In Vitro Diagnostics	[PRIMARY] Silk, Alain; OMPT/CDRH/OIR/DCTD/DDDB; [ALTERNATE] Landree, Leslie E; OMPT/CDRH/OIR/DCTD/DDDB
ISO	TC 212 on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems (US TAG -CLSI)		WG4 – Microbiology and Molecular Diagnostics	In Vitro Diagnostics	[PRIMARY] Schetter, Aaron J; OMPT/CDRH/OIR/DMGP/MGB; [ALTERNATE] Li, Li; OMPT/CDRH/OIR/DMD/VIR1
AAMI	TAG 150/SC 2 TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 07 Absorbable Vascular Implants	Materials	[PRIMARY] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Brothers, Kenya A; OMPT/CDRH/ODE/DCD/ICDB; [TECHNICAL EXPERT] Guo, Ji; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Liu, Jinrong (Jinny); OMPT/CDRH/ODE/DCD/ICDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	VI, Cardiovascular Absorbable Implants Committee (US TAG/Mirror Committee to ISO/TC 150/SC2/WG07)			Materials	[PRIMARY] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Brothers, Kenya A; OMPT/CDRH/ODE/DCD/ICDB
ASTM	F04 Medical and Surgical Materials and Devices			Materials	[PRIMARY] Melkerson, Mark N; OMPT/CDRH/ODE/DOD
ASTM	F04 Medical and Surgical Materials and Devices	F04.11 Polymeric Materials		Materials	[PRIMARY] Liu, Jinrong (Jinny); OMPT/CDRH/ODE/DCD/ICDB; [ALTERNATE] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2
ASTM	F04 Medical and Surgical Materials and Devices	F04.12 Metallurgical Materials		Materials	[PRIMARY] Saylor, David M; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Di Prima, Matthew A; OMPT/CDRH/OSEL/DAM
ASTM	F04 Medical and Surgical Materials and Devices	F04.13 Ceramic Materials		Materials	[PRIMARY] Allen, Peter G; OMPT/CDRH/ODE/DOD/JFDB1; [ALTERNATE] Sun, Limin; OMPT/CDRH/ODE/DOD/JFDB2
ASTM	F04 Medical and Surgical Materials and Devices	F04.15 Material Test Methods		Materials	[PRIMARY] Woods, Terry O; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Weaver, Jason D; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Haugen, Shanil P; OMPT/CDRH/ODE/DRGUD/ULDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.15 Material Test Methods	F04.15.11 MR Standards	Materials	[PRIMARY] Woods, Terry O; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP
ASTM	F42 Additive Manufacturing Technologies (Main Committee)			Materials	[PRIMARY] Di Prima, Matthew A; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Coburn, James; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	WG 45 Items within the controlled access area of Magnetic resonance equipment for human application	Materials	[PRIMARY] Woods, Terry O; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Delfino, Jana G; OMPT/CDRH/OIR/DRH/MREP
ISO	TC 150 Implants for Surgery		WG 10 Retrieval and analysis of implants	Materials	[PRIMARY] Coburn, James; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Nagaraja, Srinidhi; OMPT/CDRH/OSEL/DAM
ISO	TC 150 Implants for Surgery		WG 12 Implant Coatings	Materials	[PRIMARY] Sun, Limin; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Duraiswamy, Nandini; OMPT/CDRH/OSEL/DIDSR; [TECHNICAL EXPERT] Guo, Ji; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Gutowski, Stacie; OMPT/CDRH/ODE/DNPMD/NSDN; [TECHNICAL EXPERT] Lin, Joyce; OMPT/CDRH/ODE/DOED/ENTB
ISO	TC 150 Implants for Surgery		WG 13 Absorbable Metal Implants	Materials	[PRIMARY] Seog, Joonil; OMPT/CDRH/ODE/DNPMD/NIDB
ISO	TC 150 Implants for Surgery	SC 01 Materials	Main (Plastics, Metals, Ceramics)	Materials	[PRIMARY] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Guo, Ji; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Woods, Terry O; OMPT/CDRH/OSEL/DAM
ISO/IEC	ISO/TC 150/SC 06 & IEC/SC62B		JWG 2, Effects of magnetic resonance imaging on active implantable medical devices	Materials	[PRIMARY] Woods, Terry O; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Delfino, Jana G; OMPT/CDRH/OIR/DRH/MREP; [TECHNICAL EXPERT] Bassen, Howard I; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP
AAMI	BE, Biological Evaluation Committee	(Joint with Biocompatibility STG) Biocompatibility STG is Primary	WG 17 Nanomaterials	Nanotechnology	[PRIMARY] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1; [ALTERNATE] Betz, Martha; OMPT/CDRH/ODE/DRGUD/GEDB; [TECHNICAL EXPERT] Goering, Peter L; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ASTM	E56 Nanotechnology			Nanotechnology	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [ALTERNATE] Goering, Peter L; OMPT/CDRH/OSEL/DBCMS
ASTM	E56 Nanotechnology	E56.01 Informatics and Terminology		Nanotechnology	[PRIMARY] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
ASTM	E56 Nanotechnology	E56.02 Characterization: Physical, Chemical, and Toxicological Properties		Nanotechnology	[PRIMARY] Goering, Peter L; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Chen, Benita D; OMPT/CDRH/OSEL/DBCMS
ASTM	E56 Nanotechnology	E56.03 Environment, Health, and Safety		Nanotechnology	[PRIMARY] Ngatha, George K; OMPT/CDRH/OC/DMQ/ASDB; [ALTERNATE] Kagan, Carolina; OMPT/CDRH/OIR/DIHD/IMFB
IEC	TC 113 Nanotechnology standardization for electrical and electronic products and systems			Nanotechnology	[PRIMARY] Malghan, Subhaschan G; OMPT/CDRH/OSEL
ISO	TC 194 Biological Evaluation of Medical Devices	SC 1 Tissue Product Safety	WG 17 Nanomaterials	Nanotechnology	[] Betz, Martha; OMPT/CDRH/ODE/DRGUD/GEDB; [] Casey, Brendan J; OMPT/CDRH/ODE/DSD/PRSB1; [] Goering, Peter L; OMPT/CDRH/OSEL/DBCMS; [] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
ISO	TC 229 Nanotechnologies			Nanotechnology	[PRIMARY] Centeno, Jose ; ; OMPT/CDRH/OSEL/DBCMS
ISO	TC 229 Nanotechnologies		JWG 2 Measurement and characterization	Nanotechnology	[PRIMARY] Centeno, Jose ; ; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Zheng, Jiwen; OMPT/CDRH/OSEL/DBCMS
ISO	TC229 Nanotechnologies			Nanotechnology	[PRIMARY] Centeno, Jose ; ; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Nalubola, Padmashri; OP/PDCS
AAMI	NS, Neurosurgery Committee			Neurology	[PRIMARY] Bowsher, Kristen A; OMPT/CDRH/ODE/DNPMD/NSDN
AAMI	NS, Neurosurgery Committee		WG 01, Intra-cranial Pressure Devices Working Group	Neurology	[PRIMARY] Tang, Xiaorui; OMPT/CDRH/ODE/DNPMD/NSDB
AAMI	NS, Neurosurgery Committee		WG 02, Implantable neurostimulator (US TAG/Mirror Committee to ISO/TC 150/SC6/WG05)	Neurology	[PRIMARY] Bowsher, Kristen A; OMPT/CDRH/ODE/DNPMD/NSDN; [ALTERNATE] Doucet, John R; OMPT/CDRH/ODE; [TECHNICAL EXPERT] Seidman, Seth; OMPT/CDRH/OSEL/DBP
AAMI	NS, Neurosurgery Committee		WG 03, Transcutaneous electrical stimulator	Neurology	[PRIMARY] Hinckley, Stephen M; OMPT/CDRH/ODE/DNPMD/NSDP; [ALTERNATE] Chan Marsh, Dulciana D; OMPT/CDRH/OIR/DCTD/CHTB
ASTM	F04 Medical and Surgical Materials and Devices	F04.31 on Neurosurgical Standards		Neurology	[PRIMARY] Kittlesen, Gregg P; OMPT/CDRH/ODE/DNPMD/NDNB; [ALTERNATE] Raben, Samuel G; OMPT/CDRH/ODE/DNPMD/NIDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.93 Neurosurgical Implants		Neurology	[PRIMARY] Rinaldi, Jean E; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Woods, Terry O; OMPT/CDRH/OSEL/DAM
IEC/ISO	ISO/TC 184/SC 2 - IEC/SC62A		JWG 36 Medical Robots for Rehabilitation	Neurology	[PRIMARY] Franca, Eric W; OMPT/CDRH/ODE/DNPMD/NSDP; [ALTERNATE] Marcus, Ian P; OMPT/CDRH/ODE/DNPMD/PMDB; [TECHNICAL EXPERT] Pinto, Vivek J; OMPT/CDRH/ODE/DNPMD/PMDB; [TECHNICAL EXPERT] Saha, Devjani; OMPT/CDRH/ODE/DNPMD/PMDB
IEEE	EMB Standards		Working Group (WG) on EEG	Neurology	[PRIMARY] Dean, Heather; OMPT/CDRH/ODE/DNPMD/PMDB
ISO	TC 150 Implants for Surgery	SC 03 Neurosurgical implants		Neurology	[PRIMARY] Rinaldi, Jean E; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Woods, Terry O; OMPT/CDRH/OSEL/DAM

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 150 Implants for Surgery	SC 06 Active Implants	WG 05 Implantable neurostimulators (Mirror Committee with AAMI NS, WG02)	Neurology	[PRIMARY] Bowsher, Kristen A; OMPT/CDRH/ODE/DNPM/NSDN; [ALTERNATE] Doucet, John R; OMPT/CDRH/ODE; [TECHNICAL EXPERT] Seidman, Seth; OMPT/CDRH/OSEL/DBP
ISO	11040-4:2015 : prefilled syringes - glass barrels for injectables and sterilized sub-assembled syringes and 11040-7: sterile packaging			NONE	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [MEMBER] Kochman, Sheryl; OMPT/CBER/OD/ADRM
ISO	DIS 7886-1 (Sterile hypodermic syringes for single use —Part 1: Syringes for manual use)			NONE	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [MEMBER] Kochman, Sheryl; OMPT/CBER/OD/ADRM
ISO	ISO CD 7886-3 ISO/CD 7886-3 - Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization			NONE	[PRIMARY] Tejero Del Rio, Maria Isabel; OMPT/CDRH/OC/DPLC; [MEMBER] Kochman, Sheryl; OMPT/CBER/OD/ADRM
AAMI	RD, Renal Disease and Detoxification Committee (US TAG/Mirror Committee for ISO /TC 150/SC2 WG05)			OB-GYN/Gastroenterology	[PRIMARY] Gonzalez, Gema; OMPT/CDRH/ODE/DRGUD/RNDB; [ALTERNATE] Williams, Richard J; OMPT/CDRH/ODE/DRGUD/RNDB
ASTM	D11 Rubber	D11.40 Consumer Rubber Products	D11.40.01 Condoms TG (MAIN)	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS; [TECHNICAL EXPERT] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ASTM	D11 Rubber	D11.57 (US TAG to ISO TC157)	Condoms	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Schroeder, Robert J; OMPT/CDRH/OSB/DBS/TSBIII; [TECHNICAL EXPERT] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ASTM	F04 Medical and Surgical Materials and Devices	F04.34 Urological Materials and Devices		OB-GYN/Gastroenterology	[PRIMARY] Valdes, Thelma I; OMPT/CDRH/ODE/DRGUD/ULDB; [ALTERNATE] Pandya, Purva U; OMPT/CDRH/ODE/DRGUD/ULDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.35 GI Applications		OB-GYN/Gastroenterology	[PRIMARY] Soler-Garcia, Angel A; OMPT/CDRH/ODE/DRGUD/ULDB; [ALTERNATE] Silverstein, Joshua S; OMPT/CDRH/ODE
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 20 Hemodialysis equipment	OB-GYN/Gastroenterology	[PRIMARY] Gonzalez, Gema; OMPT/CDRH/ODE/DRGUD/RNDB; [ALTERNATE] Sullivan, David C; OMPT/CDRH/ODE/DRGUD/RNDB
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 24 Extra-corporeal lithotripsy equipment	OB-GYN/Gastroenterology	[PRIMARY] Maruvada, Subha; OMPT/CDRH/OSEL/DAM
ISO	TC 150 Implants for Surgery	SC 02 Cardiovascular implants and extracorporeal systems	WG 05 Renal replacement, detoxification and apheresis	OB-GYN/Gastroenterology	[PRIMARY] Gonzalez, Gema; OMPT/CDRH/ODE/DRGUD/RNDB; [ALTERNATE] Wildt-Celedon, Bridget E; OMPT/CDRH/ODE/DRGUD/RNDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics			OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Schroeder, Robert J; OMPT/CDRH/OSB/DBS/TSBIII; [TECHNICAL EXPERT] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 10 Minimum burst pressure and burst volume requirements	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 11 Packaging integrity	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Piao, Yunshang; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 12 Determination of the amount of lubricant	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 13 Stability assessment	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Piao, Yunshang; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 14 Guidance on the use of ISO 4074	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 15 Test methods for the effect of additional lubricants on physical properties of condoms	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Ondeck, Mariah; OMPT/CDRH/ODE/DRGUD/OGDB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 17 Synthetic condoms	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Schroeder, Robert J; OMPT/CDRH/OSB/DBS/TSBIII
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 18 Female condoms	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 19 Methods for hole detection	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 20 Clinical trials	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Schroeder, Robert J; OMPT/CDRH/OSB/DBS/TSBIII
ISO	TC 157 Non-systemic contraceptives and STI barrier prophylactics		WG 23 Natural rubber latex condoms	OB-GYN/Gastroenterology	[PRIMARY] Andrews, Sharon M; OMPT/CDRH/ODE/DRGUD/OGDB; [ALTERNATE] Roberts, Jason R; OMPT/CDRH/ODE/DRGUD/OGDB
ISO	TC 172 Optics and photonics	SC 5 Microscopes and endoscopes	WG 6 Endoscopes	OB-GYN/Gastroenterology	[PRIMARY] Wang, Quanzeng; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Bandukwala, Abbas; OMPT/CDRH/ODE/DSD/GSDB1
AAMI	EV, (U.S. sub-TAG for IEC SC62D Electromedical equipment, MT 27)		WG 13, Lens removal and vitrectomy devices for ophthalmic surgery sub-TAG	Ophthalmic	[PRIMARY] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 172 Optics and photonics (US TAG OEOSC)			Ophthalmic	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Kim, Do-Hyun; OMPT/CDRH/OSEL/DBP
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments		Ophthalmic	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments	WG 2 Spectacle frames	Ophthalmic	[PRIMARY] Brown Smith, Kimberly E; OMPT/CDRH/OC
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments	WG 3 Spectacle lenses	Ophthalmic	[PRIMARY] Brown Smith, Kimberly E; OMPT/CDRH/OC
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments	WG 6 Ophthalmic instruments and test methods	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Mokhtarzadeh, Maryam; OMPT/OSMP; [TECHNICAL EXPERT] Agrawal, Anant; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Lepri, Bernard P; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP; [TECHNICAL EXPERT] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments	WG 7 Ophthalmic implants	Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Bancos, Simona; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Eydelman, Malvina B; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Rorer, Eva M; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Shih, Ming Chuen; OMPT/CDRH/ODE/DOED/CLRD
ISO	TC 172 Optics and photonics (US TAG OEOSC)	SC 7 Ophthalmic optics and instruments	WG 9 Contact lenses	Ophthalmic	[PRIMARY] Hampton, Denise L; OMPT/CDRH/ODE/DOED/CLRD; [ALTERNATE] Green, Joffre A; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [TECHNICAL EXPERT] Hutter, Joseph C; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Lepri, Bernard P; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Robboy, Marc W; OMPT/CDRH/ODE/DOED/CLRD
ISO/IEC	ISO/TC 172/SC 07 & IEC/SC62D		WG 09 Lens removal and vitrectomy devices for ophthalmic surgery	Ophthalmic	[PRIMARY] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
TVC	Z 080 Ophthalmic Optics			Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Verna, Viky G; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 Methodology	WG 11 Optically-Induced Visual Phenomena Z80.32	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Beylin, Alexander; OMPT/CDRH/ODE/DOED/DSDB
TVC	Z 080 Ophthalmic Standards	Subcommittee 1 Prescription Spectacle Lenses	WG 1 Spectacle Lenses Z80.1 (active)	Ophthalmic	[PRIMARY] Brown Smith, Kimberly E; OMPT/CDRH/OC
TVC	Z 080 Ophthalmic Standards	Subcommittee 2 Sunglasses & Fashion Eyewear	WG 1 Sunglasses Z80.3 (active)	Ophthalmic	[PRIMARY] Verna, Viky G; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [ALTERNATE] Kamon-Brancazio, Jamie N; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 3 Spectacle Frames	WG 1 Frames Z80.5 (active)	Ophthalmic	[PRIMARY] Brown Smith, Kimberly E; OMPT/CDRH/OC

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TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 1 Intraocular Lenses Z80.7 (active)	Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Alexander, Kesia Y; OMPT/CDRH/ODE/DOED
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 2 Laser Systems Z80.11 (inactive)	Ophthalmic	[PRIMARY] Eydelman, Malvina B; OMPT/CDRH/ODE/DOED; [ALTERNATE] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 3 Multifocal IOLS Z80.12 (inactive)	Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 4 Phakic IOLS Z80.13 (inactive)	Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Eydelman, Malvina B; OMPT/CDRH/ODE/DOED; [ALTERNATE] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 6 Operating Microscopes Z80.15 (inactive)	Ophthalmic	[PRIMARY] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Miller, Sharon L; OMPT/CDER/OND/PMAS
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 7 Endoilluminators Z80.19 (inactive)	Ophthalmic	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 8 Glaucoma Shunts Z80.27 (active)	Ophthalmic	[PRIMARY] Alexander, Kesia Y; OMPT/CDRH/ODE/DOED; [ALTERNATE] Kim, Julie H; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Cunningham, Bradley S; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Rorer, Eva M; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Zheng, Xiaolin; OMPT/CDRH/ODE/DNPMD/NNDB
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG 9 Accomodative IOLS Z80.29 (active)	Ophthalmic	[PRIMARY] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD; [ALTERNATE] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Alexander, Kesia Y; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG10 Toric IOLS Z80.30	Ophthalmic	[PRIMARY] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [ALTERNATE] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 4 MedicalOphthalmic Devices	WG11 Extended Depth of Focus Lenses (Z80.35)	Ophthalmic	[PRIMARY] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD; [ALTERNATE] Nguyen, Tieuvi H; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Calogero, Don; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Kamon-Brancazio, Jamie N; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB
TVC	Z 080 Ophthalmic Standards	Subcommittee 5 Low VisionDevices	WG 1 Low Vision Devices Z80.9 (inactive)	Ophthalmic	[PRIMARY] Lepri, Bernard P; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 6 OphthalmicInstruments	WG 1 Tonometers Z80.10 (active)	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Schuchard, Ronald A; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
TVC	Z 080 Ophthalmic Standards	Subcommittee 6 OphthalmicInstruments	WG 2 Visual Acuity Charts Z80.21 (active)	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Zhao, Shulei; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 6 OphthalmicInstruments	WG 3 Corneal Topography Z80.23 (active)	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Zhao, Shulei; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 6 OphthalmicInstruments	WG 4 Focimeters Z80.17 (active)	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 6 OphthalmicInstruments	WG 5 Method for Reporting Optical Aberrations of Eyes Z80.28 (active)	Ophthalmic	[PRIMARY] Drum, Bruce A; OMPT/CDRH/ODE/DOED/DSDB; [ALTERNATE] Hammer, Daniel X; OMPT/CDRH/OSEL/DBP; [TECHNICAL EXPERT] Berman, Sheryl; OMPT/CDRH/ODE/DOED/DSDB; [TECHNICAL EXPERT] Hilmantel, Gene N; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 7 ContactLenses	WG 1 Contact Lenses Z80.20 (active)	Ophthalmic	[PRIMARY] Hampton, Denise L; OMPT/CDRH/ODE/DOED/CLRD; [ALTERNATE] Green, Joffre A; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Ghosh, Chandramallika; OMPT/CDRH/ODE/DNPMD/NSDN; [TECHNICAL EXPERT] Hutter, Joseph C; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Lepri, Bernard P; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Robboy, Marc W; OMPT/CDRH/ODE/DOED/CLRD
TVC	Z 080 Ophthalmic Standards	Subcommittee 7 ContactLenses	WG 2 Contact Lens Care Products Z80.18 (active)	Ophthalmic	[PRIMARY] Hampton, Denise L; OMPT/CDRH/ODE/DOED/CLRD; [ALTERNATE] Green, Joffre A; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Hutter, Joseph C; OMPT/CDRH/ODE/DOED/ICIB; [TECHNICAL EXPERT] Lepri, Bernard P; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Robboy, Marc W; OMPT/CDRH/ODE/DOED/CLRD
ASTM	F04 Medical and Surgical Materials and Devices	F04.21 Osteosynthesis		Orthopedics	[PRIMARY] Kim, Grace; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Peck, Jonathan H; OMPT/CDRH/ODE/DOD/PSDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.22 Arthroplasty		Orthopedics	[PRIMARY] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Allen, Peter G; OMPT/CDRH/ODE/DOD/JFDB1; [ALTERNATE] Demian, Hany W; OMPT/OC/OCS/ORSI/DSICT/
ASTM	F04 Medical and Surgical Materials and Devices	F04.25 Spinal Devices		Orthopedics	[PRIMARY] Peck, Jonathan H; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Bechtold, Stephanie; OMPT/CDRH/ODE/DOD/ASDB; [ALTERNATE] Melkerson, Mark N; OMPT/CDRH/ODE/DOD; [ALTERNATE] Nagaraja, Srinidhi; OMPT/CDRH/OSEL/DAM
ASTM	F04 Medical and Surgical Materials and Devices	F04.38 Computer AssistedOrthopaedic Surgical Systems		Orthopedics	[PRIMARY] Janda, Michel D; OMPT/CDRH/ODE/DOD/JFDB1; [ALTERNATE] Chen, Long H; OMPT/CDRH/ODE/DSD/GSDB2

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ASTM	F04 Medical and Surgical Materials and Devices	F04.39 Human Clinical Trials		Orthopedics	[PRIMARY] Devlin, Vincent J; OMPT/CDRH/ODE/DOD; [ALTERNATE] Dong, Li Ming; OMPT/CDRH/OSB/DBS/TSB1; [TECHNICAL EXPERT] Belmont, Philip; OMPT/CDRH/ODE/DOD/JFDB2; [TECHNICAL EXPERT] Moazzam, Caroline; OMPT/CDRH/ODE/DOD/PSDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.93 on US TAG ISO/TC150 - Implants for Surgery		Orthopedics	[PRIMARY] Melkerson, Mark N; OMPT/CDRH/ODE/DOD; [ALTERNATE] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2
ISO	TC 150 Implants for Surgery			Orthopedics	[PRIMARY] Melkerson, Mark N; OMPT/CDRH/ODE/DOD; [ALTERNATE] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2
ISO	TC 150 Implants for Surgery	SC 04 Bone and joint replacements		Orthopedics	[PRIMARY] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Demian, Hany W; OMPT/OC/OCS/ORSI/DSICT/
ISO	TC 150 Implants for Surgery	SC 04 Bone and joint replacements	WG 01 Mechanical testing of components	Orthopedics	[PRIMARY] Goode, John S; OMPT/CDRH/ODE/DOD/JFDB2; [ALTERNATE] Demian, Hany W; OMPT/OC/OCS/ORSI/DSICT/
ISO	TC 150 Implants for Surgery	SC 05 Osteosynthesis and spinal devices	WG 02 Spinal Implants	Orthopedics	[PRIMARY] Peck, Jonathan H; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Bechtold, Stephanie; OMPT/CDRH/ODE/DOD/ASDB; [TECHNICAL EXPERT] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM
RESNA	TC 173 Assistive products for persons with disability	SC 1 Wheelchairs	WG 01 Test methods	Physical Medicine	[PRIMARY] Demarco, Angela D; OMPT/CDRH/ODE/DNPMD/PMDB; [ALTERNATE] Marszalek, John E; OMPT/CDRH/OC/DICO/FEB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM
RESNA	TC 173 Assistive products for persons with disability	SC 1 Wheelchairs	WG 06 Wheelchair restraint systems	Physical Medicine	[PRIMARY] Shermer, Shawn M; OMPT/CDRH/ODE/DOD; [ALTERNATE] Delaurentis, Kathryn J; OMPT/CDRH/ODE/DNPMD/PMDB
RESNA	TC 173 Assistive products for persons with disability	SC 1 Wheelchairs	WG 10 Requirements and test methods for electro-technical systems for wheelchairs	Physical Medicine	[PRIMARY] Marszalek, John E; OMPT/CDRH/OC/DICO/FEB; [ALTERNATE] Demarco, Angela D; OMPT/CDRH/ODE/DNPMD/PMDB; [TECHNICAL EXPERT] Schwerin, Matthew R; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Witters, Donald M; OMPT/CDRH/OSEL/DBP
RESNA	TC 173 Assistive products for persons with disability	SC 1 Wheelchairs	WG 11 Wheelchair seating	Physical Medicine	[PRIMARY] Shermer, Shawn M; OMPT/CDRH/ODE/DOD; [ALTERNATE] Delaurentis, Kathryn J; OMPT/CDRH/ODE/DNPMD/PMDB
AAMI	EV, (U.S. sub-TAG for IEC 62D Electromedical equipment)		WG 04 Electro-optical equipment sub-TAG	Radiology	[PRIMARY] Ogden, Neil R P; OMPT/CDRH/ODE/DSD/GSDB1
AAMI	EV, (U.S. sub-TAG for IEC 62D Electromedical equipment)		WG 08 Ultrasound sub-TAG	Radiology	[ALTERNATE] Maruvada, Subha; OMPT/CDRH/OSEL/DAM
AAMI	WV, Waveform Testing Committee			Radiology	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
AIUM	AIUM/NEMA Joint Committee	Output Standards Subcommittee (OSS)		Radiology	[ALTERNATE] Maruvada, Subha; OMPT/CDRH/OSEL/DAM
AIUM	Bioeffects Committee			Radiology	[PRIMARY] Vaezy, Shahram; OMPT/CDRH/OIR/DRH/MUIS
AIUM	Technical Standards Committee			Radiology	[PRIMARY] Wear, Keith A; OMPT/CDRH/OSEL/DAM
ANSI	B 11.21 Laser Safety for Machine Tools			Radiology	[PRIMARY] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
ANSI	N 43 Radiation protection from equipment for nonmedical radiation applications			Radiology	[PRIMARY] Kassiday, Daniel F H; OMPT/CDRH/OIR/DRH/NMRT

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ANSI	N 43 Radiation protection from equipment for nonmedical radiation applications	N 43.16 Radiation Safety Standard for X-Ray and Gamma Radiation Security Non-Intrusive Inspection Systems		Radiology	[PRIMARY] Kassiday, Daniel F H; OMPT/CDRH/OIR/DRH/NMRT
ANSI	N 43 Radiation protection from equipment for nonmedical radiation applications	N 43.17 Radiation Safety for Personnel Security Screening Systems Using IR		Radiology	[PRIMARY] Kassiday, Daniel F H; OMPT/CDRH/OIR/DRH/NMRT
ANSI	N 44 Equipment and Materials for Medical Radiation Applications		(New Priority Score)	Radiology	[PRIMARY] Basu, Sankar P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee			Radiology	[PRIMARY] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Vogt, William; FDA/OMPT/CDRH/OSEL/DBP/
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-01 Safe Use of Lasers		Radiology	[PRIMARY] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-02 Safe Use of Lasers in Telecommunications		Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-03 Laser Safety in Health Care Facilities		Radiology	[PRIMARY] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-04 Laser Measurements		Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-05 Laser Safety in Educational Facilities		Radiology	[ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-06 Outdoor Lasers		Radiology	[PRIMARY] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Smith, L Dale; OMPT/CDRH/OIR/DRH/MREP
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-07 Laser Eye Protection and Barriers		Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-08 Laser Safety in Research and Testing Facilities		Radiology	[PRIMARY] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-09 Laser Safety in Manufacturing Facilities		Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
ANSI	Z 136 Safe Use of Lasers Committee	Z 136/SSC-10 Laser Safety in Entertainment, Displays and Exhibitions		Radiology	[PRIMARY] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Smith, L Dale; OMPT/CDRH/OIR/DRH/MREP
ANSI	Z 311 Photobiological Safety of Lamps and Lighting Systems Subcommittee			Radiology	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP
ASTM	F12 Security Systems and Equipment	F12.60 Controlled Access Security, Search and Screening Equipment	F12.63 Task Group on Weapons Detection	Radiology	[PRIMARY] Witters, Donald M; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Casamento, Jon P; OMPT/CDRH/OSEL/DAM
CIE	TC 1-92 Skin Colour Database			Radiology	[PRIMARY] Cheng, Wei-Chung; OMPT/CDRH/OSEL/DIDSR
ICRP				Radiology	[PRIMARY] Miller, Donald L; OMPT/CDRH/OIR
IEC	IEC TC 62	SC 62B	MT 39 Dental Imaging Equipment	Radiology	[PRIMARY] Hilohi, Mike C; OMPT/CDRH/OIR/DRH/DXRS; [ALTERNATE] Spelic, David C.; OMPT/CDRH/OIR/DRH/DXRS
IEC	TC 061 Safety of household and similar electrical appliances		MT 16 Ultra-violet radiation	Radiology	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 061 Safety of household and similar electrical appliances		WG 30 Beauty therapy appliances for household and commercial use	Radiology	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Felten, Richard P; OMPT/CDRH/ODE/DSD/GSDB1
IEC	TC 061 Safety of household and similar electrical appliances	SC 61B Safety of microwave ovens		Radiology	[PRIMARY] Song, Ting; OMPT/CDRH/OIR/DRH/MREP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment		Radiology	[PRIMARY] Chakrabarti, Kishalaya; OMPT/CDRH/OIR/DMQS/PMBR; [ALTERNATE] Kaczmarek, Richard V; OMPT/CDRH/OIR/DMQS/PMBR
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 30 Computed tomography	Radiology	[PRIMARY] Vaishnav, Jay Y; OMPT/CDRH/OIR/DRH/DXRS; [ALTERNATE] Burk, Laurel M; OMPT/CDRH/OIR/DRH/DXRS; [ALTERNATE] Zeng, Rongping; OMPT/CDRH/OSEL/DIDSR
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 31 Mammographic X-ray equipment	Radiology	[PRIMARY] Glick, Stephen J; OMPT/CDRH/OSEL/DIDSR; [ALTERNATE] Makeev, Andrey V; OMPT/CDRH/OIR/DMQS/PMBR
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 32 Requirements for X-ray source assemblies	Radiology	[PRIMARY] Kaczmarek, Richard V; OMPT/CDRH/OIR/DMQS/PMBR
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 34 Revision of 60601-2-37: Medical electric equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic	Radiology	[PRIMARY] Herman, Bruce A; OMPT/CDRH/OSEL/DAM
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 37 Medical electrical equipment	Radiology	[] Gonzalez, Scott C; OMPT/CDRH/OIR/DRH/DXRS; [PRIMARY] Miller, Donald L; OMPT/CDRH/OIR
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 40 Magnetic resonance equipment for medical diagnosis	Radiology	[PRIMARY] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Delfino, Jana G; OMPT/CDRH/OIR/DRH/MREP; [TECHNICAL EXPERT] Rajan, Sunder S; OMPT/CDRH/OSEL/DBP
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 41 Revision of IEC 60601-2-43	Radiology	[PRIMARY] Miller, Donald L; OMPT/CDRH/OIR; [ALTERNATE] Gonzalez, Scott C; OMPT/CDRH/OIR/DRH/DXRS
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 51 Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	Radiology	[PRIMARY] Badano, Aldo; OMPT/CDRH/OSEL/DIDSR; [ALTERNATE] Lam, Shing Chun Benny; OMPT/CDRH/OIR/DRH/MUIS
IEC	TC 062 Electrical equipment in medical practice	SC 62B Diagnostic imaging equipment	MT 52 Maintenance of the IEC 62464 series, Magnetic resonance equipment for medical imaging	Radiology	[PRIMARY] Delfino, Jana G; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Krainak, Daniel M; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Song, Ting; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 062 Electrical equipment in medical practice	SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry	WG 01 Beam teletherapy and particle accelerators	Radiology	[PRIMARY] Bhullar, Amarjeet; OMPT/CDRH/OIR/DRH/NMRT; [ALTERNATE] Wersto, Nancy; OMPT/CDRH/OIR/DRH/NMRT
IEC	TC 062 Electrical equipment in medical practice	SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry	WG 02 Nuclear medicine instrumentation	Radiology	[PRIMARY] Levine, Gary M; OMPT/CDRH/OIR/DRH/MUIS
IEC	TC 062 Electrical equipment in medical practice	SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry	WG 03 Performance of dosimeters	Radiology	[PRIMARY] Maloney, William C; OMPT/CDRH/OSB/DPS/MDR
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	MT 18 Therapy equipment	Radiology	[ALTERNATE] De Luca, Robert J; OMPT/CDER/OPQ/ONDP/DNDPII/NDPBV
IEC	TC 062 Electrical equipment in medical practice	SC 62D Electromedical equipment	PT 60601-2-62 High intensity therapeutic ultrasound (HITU) systems	Radiology	[PRIMARY] Liu, Yunbo; OMPT/CDRH/OSEL/DAM; [PRIMARY] Maruvada, Subha; OMPT/CDRH/OSEL/DAM
IEC	TC 076 Optical radiation safety and laser equipment			Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] James, Robert; OMPT/CDRH/OSEL/DBP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEC	TC 076 Optical radiation safety and laser equipment		WG 01 Optical radiation safety	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG 03 Laser radiation measurement	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] James, Robert; OMPT/CDRH/OSEL/DBP
IEC	TC 076 Optical radiation safety and laser equipment		WG 04 Safety of medical laser equipment	Radiology	[PRIMARY] Basu, Sankar P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG 05 Safety of fibre optics communications systems	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG 07 High power lasers	Radiology	[PRIMARY] Basu, Sankar P; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG 08 Development and maintenance of basic standards	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG 09 Non coherent sources	Radiology	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Basu, Sankar P; OMPT/CDRH/ODE/DSD/GSDB1
IEC	TC 076 Optical radiation safety and laser equipment		WG 10 Safety of lasers and laser equipment in an industrial materials processing environment (JWG w/ISO TC 172/SC9 WG3)	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 076 Optical radiation safety and laser equipment		WG12 Eye and face protection against laser radiation	Radiology	[PRIMARY] Miller, Sharon; OMPT/CDRH/OIR/DRH/MREP
IEC	TC 087 Ultrasonics			Radiology	[PRIMARY] Wear, Keith A; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Dar, David; OMPT/CDRH/OC/DICO/FEB
IEC	TC 087 Ultrasonics		WG 06 High Intensity Therapeutic Ultrasound (HITU) and Focusing Transducers	Radiology	[] Herman, Bruce A.; OMPT/CDRH/OSEL/DAM; [PRIMARY] Liu, Yunbo; OMPT/CDRH/OSEL/DAM
IEC	TC 087 Ultrasonics		WG 08 Ultrasonic field measurement	Radiology	[PRIMARY] Herman, Bruce A.; OMPT/CDRH/OSEL/DAM
IEC	TC 087 Ultrasonics		WG 09 Pulse-Echo Diagnostic Equipment	Radiology	[PRIMARY] Wear, Keith A; OMPT/CDRH/OSEL/DAM
IEC	TC 087 Ultrasonics		WG 14 Determination of ultrasound exposure parameters	Radiology	[PRIMARY] Liu, Yunbo; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Herman, Bruce A.; OMPT/CDRH/OSEL/DAM
IEC	TC 110 Flat panel display devices		WG6 3-Dimensional display devices	Radiology	[PRIMARY] Badano, Aldo; OMPT/CDRH/OSEL/DIDSR
IECEE	Committee of Testing Laboratories		Expert Task Force 11: Lasers	Radiology	[PRIMARY] Strzelecki, Wlodzimierz; OMPT/CDRH/OIR/DRH/MREP
IEEE	International Committee on Electromagnetic Safety (ICES) TC34	SC2 Wireless Handset SAR Certification	WG1 Experimental Techniques (New Priority Score)	Radiology	[PRIMARY] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Chang, Isaac A; OMPT/CDRH/OSB/DPS
IEEE	International Committee on Electromagnetic Safety (ICES) TC34	SC2 Wireless Handset SAR Certification	WG2 Computational Techniques (New Priority Score)	Radiology	[PRIMARY] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Chang, Isaac A; OMPT/CDRH/OSB/DPS
IEEE	International Committee on Electromagnetic Safety (ICES) TC95	Executive Committee	(New Priority Score)	Radiology	[PRIMARY] Bassen, Howard I; OMPT/CDRH/OSEL/DBP
IEEE	International Committee on Electromagnetic Safety (ICES) TC95	SC1 Measurements and computation	(New Priority Score)	Radiology	[PRIMARY] Bassen, Howard I; OMPT/CDRH/OSEL/DBP
IEEE	International Committee on Electromagnetic Safety (ICES) TC95	SC3 Safety levels to human exposure 0-3kHz		Radiology	[PRIMARY] Bassen, Howard I; OMPT/CDRH/OSEL/DBP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
IEEE	International Committee on Electromagnetic Safety (ICES) TC95	SC4 Safety levels to human exposure 3kHz-300GHz		Radiology	[PRIMARY] Bassen, Howard I; OMPT/CDRH/OSEL/DBP
ISO	TC 172 Optics and photonics	SC 9 Electro-optical systems		Radiology	[PRIMARY] Gould, Taylor C; OMPT/CDRH/OIR/DRH/MREP
ISO	TC 172 Optics and photonics	SC 9 Electro-optical systems	WG 1 Terminology and test methods for lasers	Radiology	[PRIMARY] Virani, Jitendra V; OMPT/CDRH/ODE/DSD/GSDB1; [ALTERNATE] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 172 Optics and photonics	SC 9 Electro-optical systems	WG 4 Laser systems for medical applications	Radiology	[PRIMARY] Chowdhury, Atiq; OMPT/CDRH/OIR/DPOM; [ALTERNATE] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 172 Optics and photonics	SC 9 Electro-optical systems	WG 5 Laser systems for general applications (Standby as of May 19, 2011)	Radiology	[] James , Robert; OMPT/CDRH/OSEL/DBP
ISO	TC 172 Optics and photonics	SC 9 Electro-optical systems	WG 6 Optical components and their test methods	Radiology	[PRIMARY] Gould, Taylor C; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Shi, Dexiu; OMPT/CDRH/ODE/DOED/DSDB
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee			Radiology	[PRIMARY] Krainak, Daniel M; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Kang, Yanna S; OMPT/CDRH/OIR/DRH/MUIS
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 11 Display Function Standard	Radiology	[PRIMARY] Jennings, Robert J; OMPT/CDRH/OSEL/DIDSR; [ALTERNATE] Chakrabarti, Kishalaya; OMPT/CDRH/OIR/DMQS/PMBR
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 13 Visible Light	Radiology	[PRIMARY] Cheng, Wei-Chung; OMPT/CDRH/OSEL/DIDSR
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 15 Digital Mammography and CAD	Radiology	[PRIMARY] Kang, Yanna S; OMPT/CDRH/OIR/DRH/MUIS; [ALTERNATE] Nosratieh, Anita; OMPT/CDRH/OIR/DRH/MUIS
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 16 Magnetic Resonance	Radiology	[PRIMARY] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP; [PRIMARY] Krainak, Daniel M; OMPT/CDRH/OIR/DRH/MREP
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 22 Dentistry	Radiology	[PRIMARY] Sauer, Robert A; OMPT/CDRH/OIR/DPOM
NEMA	Digital Imaging and Communications in Medicine (DICOM) Standards Committee		WG 28 Physics	Radiology	[PRIMARY] Fang, Yuan; OMPT/CDRH/OIR/DRH/DXRS
NEMA	NEMA/MITA	Magnetic Resonance	(New Priority Score)	Radiology	[PRIMARY] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Rajan, Sunder S; OMPT/CDRH/OSEL/DBP
NEMA	NEMA/MITA	Magnetic Resonance	Magnetic Resonance Technical Committee (New Priority Score)	Radiology	[PRIMARY] Rajan, Sunder S; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Kainz, Wolfgang; OMPT/CDRH/OSEL/DBP
NFPA-Fire	Laser Fire Protection		(New Priority Score)	Radiology	[PRIMARY] Hewett, Daniel J; OMPT/CDRH/OIR/DRH/MREP; [ALTERNATE] Hintz, Patrick J; OMPT/CDRH/OIR/DRH/MREP
AAMI	AAMI/UL Joint Committee on Medical Device Interoperability (UL 2800)			Software/Informatics	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Li, Catherine H; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB
AAMI	SM, Software and Information Technology Committee		WG 01 Medical device software	Software/Informatics	[PRIMARY] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB; [ALTERNATE] Muradyan, Naira ; OMPT/CDRH/OIR/DRH/MUIS; [TECHNICAL EXPERT] Fitzgerald, Brian J; OMPT/CDRH/OSEL
AAMI	SM, Software and Information Technology Committee		WG 01 Medical device software	Software/Informatics	[PRIMARY] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB; [ALTERNATE] Patel, Bakul; OMPT/CDRH/OC; [TECHNICAL EXPERT] Mathews, Binoy J; OMPT/CDRH/ODE/DNPMD/NSDP

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	SM, Software and Information Technology Committee		WG 02 Information technology networks incorporating medical devices	Software/Informatics	[PRIMARY] Li, Catherine H; OMPT/CDRH/ODE/DAGID/GHDB; [ALTERNATE] Fitzgerald, Brian J; OMPT/CDRH/OSEL; [TECHNICAL EXPERT] Gitterman, Steven R; OMPT/CDRH/OIR/DMD
AAMI	SM, Software and Information Technology Committee		WG 03 Interoperability	Software/Informatics	[PRIMARY] Agler, Heather; OMPT/CDRH/OCD; [ALTERNATE] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
AAMI	SM, Software and Information Technology Committee		WG 03 Interoperability	Software/Informatics	[PRIMARY] Weininger, Sandy; OMPT/CDRH/OSEL/DBP; [ALTERNATE] Zhang, Yi; OMPT/CDRH/OSEL/DIDSR
AAMI	SM, Software and Information Technology Committee		WG 04 Mobile applications	Software/Informatics	[PRIMARY] Patel, Bakul; OMPT/CDRH/OCD; [ALTERNATE] Zhang, Cheng; OMPT/CDRH/OIR/DIHD/HEMB
AAMI	SM, Software and Information Technology Committee		WG 05 Device security	Software/Informatics	[PRIMARY] Fitzgerald, Brian J; OMPT/CDRH/OSEL; [ALTERNATE] Simone, Lisa K; OMPT/CBER/OBRR/DETTD/PRB
AAMI	SM, Software and Information Technology Committee		WG 07 Software assurance case	Software/Informatics	[PRIMARY] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR; [ALTERNATE] Li, Catherine H; OMPT/CDRH/ODE/DAGID/GHDB
AAMI	SM, Software and Information Technology Committee		WG 08 Software defect classification	Software/Informatics	[PRIMARY] Simone, Lisa K; OMPT/CBER/OBRR/DETTD/PRB; [ALTERNATE] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB; [TECHNICAL EXPERT] Syed, Sajjad H; OMPT/CBER/OBRR/DETTD/PRB
ANSI	Healthcare Information Technology Standards Panel		(New Priority Score)	Software/Informatics	[PRIMARY] Witters, Donald M; OMPT/CDRH/OSEL/DBP
CLSI	Expert Panel on Automation and Informatics			Software/Informatics	[MEMBER] Anderson, Nicholas P; OMPT/CDRH/OIR/DMGP/MPCB
IEC	TC 062 Electrical equipment in medical practice	SC 62A Common aspects of electrical equipment used in medical practice	MT 31 Programmable electrical medical systems	Software/Informatics	[] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR
IEC	TC 065 Industrial Process Measurement and Control	SC 65A Systems Aspects	WG 10 Functional safety of programmable electronic systems	Software/Informatics	[PRIMARY] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR
IEC	TC 065 Industrial Process Measurement and Control	SC 65A Systems Aspects	WG 10 Functional safety of programmable electronic systems	Software/Informatics	[PRIMARY] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR
IEC/ISO	IEC/SC62A ISO/TC210JWG3		JWG 03 Medical Device Software IEC 62304 (New Priority Score)	Software/Informatics	[PRIMARY] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB; [ALTERNATE] Fitzgerald, Brian J; OMPT/CDRH/OSEL
IEC/ISO	IEC/SC62A ISO/TC215JWG7		JWG 07 Risk management for IT-Networks incorporating medical devices IEC/ISO 80001 (New Priority Score)	Software/Informatics	[PRIMARY] Fitzgerald, Brian J; OMPT/CDRH/OSEL; [ALTERNATE] Weininger, Sandy; OMPT/CDRH/OSEL/DBP
IEEE	11073 Personal Health Device (PHD) Working Group			Software/Informatics	[PRIMARY] Li, Catherine H; OMPT/CDRH/ODE/DAGID/GHDB
IICC	IVD Industry Connectivity Consortium		Semantic Interoperability Code Transmission Working Group	Software/Informatics	[PRIMARY] Waters, Michael; OMPT/CDRH/OIR/DMD/BAC1
ISCT	Automation and Data Processing Working Group			Software/Informatics	[PRIMARY] Jorgens, Joseph; OMPT/CDRH/OSEL/DIDSR
ISO	TC 215 Health Informatics		WG2 Systems and Device Interoperability	Software/Informatics	[PRIMARY] Gitterman, Steven R; OMPT/CDRH/OIR/DMD; [ALTERNATE] Zhang, Cheng; OMPT/CDRH/OIR/DIHD/HEMB
ISO/IEC	ISO JTC1/SC 07 TAG, Software Engineering			Software/Informatics	[PRIMARY] Murray, John F; OMPT/CDRH/OC/DAPO/ARMB
NONE	Diabetes Technology Society (DTS) Cybersecurity Standard for Connected Diabetes Devices			Software/Informatics	[MEMBER] Beck, Stayce E; OMPT/CDRH/OIR/DCTD/DDDB
UL	UL 1998	Standard for Software in Programmable Components		Software/Informatics	[PRIMARY] Jones, Paul L; OMPT/CDRH/OSEL/DIDSR

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
UL	UL Standards Technical Panel (STP) for Software Cybersecurity for Network-Connectable Products (STP 2900)			Software/Informatics	[PRIMARY] Fitzgerald, Brian J; OMPT/CDRH/OSEL
AAMI	ST, Sterilization Standards Committee		WG 01, Industrial EO sterilization	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Elliott, Steven T; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Randazzo, Salvatore N; OGROP/ORR/SE-FO/FLA-DO/FLA-CB
AAMI	ST, Sterilization Standards Committee		WG 02, Radiation sterilization	Sterility	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH; [ALTERNATE] Palmer-Ochieng, Dupeh G; OMPT/CDER/OPQ/OPF/DMA/MABIII
AAMI	ST, Sterilization Standards Committee		WG 03, Industrial moist heat sterilization	Sterility	[PRIMARY] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Fedorko, Daniel P; OMPT/CDRH/ODE/DOED/DSDB
AAMI	ST, Sterilization Standards Committee		WG 04, Biological indicators	Sterility	[PRIMARY] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Gonzalez, Elizabeth A; OMPT/CDRH/ODE/DRGUD/RNDB; [TECHNICAL EXPERT] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Tcheuko, Lucas; OMPT/CDRH/OSB/DBS
AAMI	ST, Sterilization Standards Committee		WG 05, Sterilization terminology	Sterility	[PRIMARY] Rodriguez, Victoria; OMPT/CDRH/ODE/DCD/SHDB
AAMI	ST, Sterilization Standards Committee		WG 06, Chemical indicators	Sterility	[PRIMARY] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Claverie, Elizabeth F; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 07, Packaging	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Lee, Hyung; OMPT/CDRH/ODE/DNPMD/NSDP; [TECHNICAL EXPERT] Soler-Garcia, Angel A; OMPT/CDRH/ODE/DRGUD/ULDB
AAMI	ST, Sterilization Standards Committee		WG 08, Microbiological methods	Sterility	[PRIMARY] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I; [ALTERNATE] Soler-Garcia, Angel A; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Brocious, Jeffery M; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Lee, Hyung; OMPT/CDRH/ODE/DNPMD/NSDP; [TECHNICAL EXPERT] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 09, Aseptic processing	Sterility	[ALTERNATE] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Arista, Thomas J; OGROP/ORR/OO/OMPTO/DMPTPO/MDTP; [TECHNICAL EXPERT] Trudel, Nicole K; OMPT/CBER/OCBQ/DMPQ
AAMI	ST, Sterilization Standards Committee		WG 10, Liquid chemical sterilization	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Dugard, Christopher; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 11, General criteria for sterilization processes	Sterility	[PRIMARY] Rodriguez, Allison A; OGROP/ORR/NE-FO/WEAC/WEAC-AB; [ALTERNATE] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	ST, Sterilization Standards Committee		WG 12, Instructions for reusable device reprocessing	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Haugen, Shanil P; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Smith, Myra K; OMPT/CDRH/ODE/DNPMD/NIDB
AAMI	ST, Sterilization Standards Committee		WG 13, Washer-disinfectors	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Elliott, Steven T; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 15 (90), Sterility Assurance Level (SAL) WG	Sterility	[PRIMARY] Smith, Myra K; OMPT/CDRH/ODE/DNPMD/NIDB; [ALTERNATE] Rodriguez, Victoria; OMPT/CDRH/ODE/DCD/SHDB; [TECHNICAL EXPERT] Cruz-Fisher, Maria I; OMPT/CDER/OPQ/OPF/DMA/MABI; [TECHNICAL EXPERT] Peters, Lori P; OMPT/CBER/OCBQ/DMPQ/BI
AAMI	ST, Sterilization Standards Committee		WG 40, Steam sterilization hospital practices	Sterility	[PRIMARY] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 42, Dry heat sterilization	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I
AAMI	ST, Sterilization Standards Committee		WG 43, Hospital steam sterilizer	Sterility	[PRIMARY] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Smith, Myra K; OMPT/CDRH/ODE/DNPMD/NIDB; [TECHNICAL EXPERT] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 60, EO Sterilization hospital practices	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB
AAMI	ST, Sterilization Standards Committee		WG 61, Chemical sterilants hospital practices	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Dugard, Christopher; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Barnett, Paola S; OMPT/CDRH/OC/DICO/FEB; [TECHNICAL EXPERT] Bittleman, Katelyn R; OMPT/CDRH/OC/DMQ/PMON-DDB; [TECHNICAL EXPERT] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 62, Hospital EO sterilizer	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB
AAMI	ST, Sterilization Standards Committee		WG 63, Sterilization residuals	Sterility	[PRIMARY] Lucas, Anne D; OMPT/CDRH/ODE/DBCMS; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 83, Reusable surgical textiles processing	Sterility	[ALTERNATE] Qian, Bifeng; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 84, Endoscope reprocessing WG	Sterility	[PRIMARY] Haugen, Shanil P; OMPT/CDRH/ODE/DRGUD/ULDB; [ALTERNATE] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Ali, Shumaya B; OMPT/CDRH/OC/DICO/FEB; [TECHNICAL EXPERT] Smith, Myra K; OMPT/CDRH/ODE/DNPMD/NIDB
AAMI	ST, Sterilization Standards Committee		WG 85, Human factors for device reprocessing WG	Sterility	[PRIMARY] Wiyor, Hanniebey D; OMPT/CDRH/ODE/DAGID; [ALTERNATE] Marin, Keith G; OMPT/CDRH/ODE/DAGID/GHDB; [TECHNICAL EXPERT] Ross, Aftin M; OMPT/CDRH/OC

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
AAMI	ST, Sterilization Standards Committee		WG 86, Quality systems for device reprocessing WG	Sterility	[PRIMARY] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I; [ALTERNATE] Cheung, Peter; OMPT/CDRH/ODE/DCD/ICDB; [TECHNICAL EXPERT] Weixel, Patrick B; OMPT/CDRH/OIR/DRH
AAMI	ST, Sterilization Standards Committee		WG 91, Resistometer	Sterility	[PRIMARY] Ortega, Cristina E; OMPT/CDRH/OC/DICO/IB; [ALTERNATE] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 92, Process challenge devices	Sterility	[PRIMARY] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 93, Cleaning of reusable medical devices	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Park, Sunny; OMPT/CDRH/ODE/DOED/ENTB
AAMI	ST, Sterilization Standards Committee		WG 94, Rigid sterilization container systems	Sterility	[PRIMARY] Elliott, Steven T; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Dugard, Christopher; OMPT/CDRH/ODE/DAGID/INCB
AAMI	ST, Sterilization Standards Committee		WG 95, Water quality for reprocessing medical devices	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Wen, Mary; OMPT/CDRH/ODE/DSD/GSDB2; [TECHNICAL EXPERT] Steffen, Scott E; OMPT/CDRH/ODE/DOED/CLRD
AAMI	ST, Sterilization Standards Committee		WG 96, Compatibility of materials subject to sterilization	Sterility	[PRIMARY] Lucas, Anne D; OMPT/CDRH/OSEL/DBCMS; [ALTERNATE] Cheung, Peter; OMPT/CDRH/ODE/DCD/ICDB
ASTM	E61 Radiation Processing			Sterility	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH; [ALTERNATE] Morehouse, Kim M; OFVM/CFSAN/ORS/DAC/MDB
ASTM	F02 Flexible Barrier Materials			Sterility	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH; [ALTERNATE] Das, Srilekha S; OMPT/CDRH/OSEL/DBCMS
ASTM	F02 Flexible Barrier Materials	F02.60 Medical Packaging		Sterility	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH; [ALTERNATE] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.15 Material Test Methods	WK31799 - New Guide for Designing Medical Devices for Cleanability	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Steffen, Scott E; OMPT/CDRH/ODE/DOED/CLRD; [TECHNICAL EXPERT] Anderson, Nicholas P; OMPT/CDRH/OIR/DMGP/MPCB; [TECHNICAL EXPERT] Bittleman, Katelyn R; OMPT/CDRH/OC/DMQ/PMON-DBB; [TECHNICAL EXPERT] Fedorko, Daniel P; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 198 Sterilization of health care products		WG 02, Radiation sterilization	Sterility	[PRIMARY] Weixel, Patrick B; OMPT/CDRH/OIR/DRH; [ALTERNATE] Palmer-Ochieng, Dupeh G; OMPT/CDER/OPQ/OPF/DMA/MABIII
ISO	TC 198 Sterilization of health care products		WG 03, Industrial moist heat sterilization	Sterility	[PRIMARY] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Fedorko, Daniel P; OMPT/CDRH/ODE/DOED/DSDB
ISO	TC 198 Sterilization of health care products		WG 04, Biological indicators	Sterility	[PRIMARY] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I; [ALTERNATE] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Gonzalez, Elizabeth A; OMPT/CDRH/ODE/DRGUD/RNDB; [TECHNICAL EXPERT] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Tcheuko, Lucas; OMPT/CDRH/OSB/DBS

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ISO	TC 198 Sterilization of health care products		WG 05, Sterilization terminology	Sterility	[PRIMARY] Rodriguez, Victoria; OMPT/CDRH/ODE/DCD/SHDB
ISO	TC 198 Sterilization of health care products		WG 06, Chemical indicators	Sterility	[PRIMARY] Murray, Clarence W; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Claverie, Elizabeth F; OMPT/CDRH/ODE/DAGID/INCB
ISO	TC 198 Sterilization of health care products		WG 07, Packaging	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Lee, Hyung; OMPT/CDRH/ODE/DNPMD/NSDP; [TECHNICAL EXPERT] Soler-Garcia, Angel A; OMPT/CDRH/ODE/DRGUD/ULDB
ISO	TC 198 Sterilization of health care products		WG 08, Microbiological methods	Sterility	[PRIMARY] Hitchins, Victoria M; OMPT/CDRH/ODE/DBCMS; [ALTERNATE] Lappalainen, Sharon K; OMPT/CDRH/OCD; [TECHNICAL EXPERT] Brocius, Jeffery M; OMPT/CDRH/ODE/DOED; [TECHNICAL EXPERT] Lee, Hyung; OMPT/CDRH/ODE/DNPMD/NSDP; [TECHNICAL EXPERT] Panguluri, Ramesh C; OMPT/CDRH/ODE/DAGID/INCB
ISO	TC 198 Sterilization of health care products		WG 09, Aseptic processing	Sterility	[ALTERNATE] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Arista, Thomas J; OGROP/ORO/OO/OMPTO/DMPTPO/MDTP; [TECHNICAL EXPERT] Trudel, Nicole K; OMPT/CBER/OCBQ/DMPQ
ISO	TC 198 Sterilization of health care products		WG 10, Liquid chemical sterilization	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Dugard, Christopher; OMPT/CDRH/ODE/DAGID/INCB
ISO	TC 198 Sterilization of health care products		WG 11, General criteria for sterilization processes	Sterility	[PRIMARY] Rodriguez, Allison A; OGROP/ORO/NE-FO/WEAC/WEAC-AB; [ALTERNATE] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB
ISO	TC 198 Sterilization of health care products		WG 12, Instructions for reusable device reprocessing	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Haugen, Shanil P; OMPT/CDRH/ODE/DRGUD/ULDB; [TECHNICAL EXPERT] Smith, Myra K; OMPT/CDRH/ODE/DNPMD/NIDB
ISO	TC 198 Sterilization of health care products		WG 13, Washer-disinfectors	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Elliott, Steven T; OMPT/CDRH/ODE/DAGID/INCB
ISO	TC 198 Sterilization of health care products		WG 14, Dry heat sterilization	Sterility	[PRIMARY] Mayhall, Elaine S; OMPT/CDRH/ODE/DAGID/INCB; [ALTERNATE] Perez, Cesar A; OMPT/CDRH/OC/DPLC/SEB I
ISO	TC 198 Sterilization Standards Committee		WG 01, Industrial EO sterilization	Sterility	[PRIMARY] Turtill, Steven E; OMPT/CDRH/ODE/DOD/PSDB; [ALTERNATE] Elliott, Steven T; OMPT/CDRH/ODE/DAGID/INCB; [TECHNICAL EXPERT] Randazzo, Salvatore N; OGROP/ORO/SE-FO/FLA-DO/FLA-CB
ISO	TC 209 Cleanrooms and Associated Controlled Environments			Sterility	[PRIMARY] Arista, Thomas J; OGROP/ORO/OO/OMPTO/DMPTPO/MDTP; [ALTERNATE] Brown, Christopher J; OMPT/CDRH/OC
AAMI	TS, Tissue Product Safety Committee		WG 04, TSE Elimination	Tissue Engineering	[PRIMARY] Asher, David M; OMPT/CBER/OBRR/DETTD/LBTSEA; [ALTERNATE] Mcnamee, Scott G; OMPT/CDRH/OC
AAMI	TS, Tissue Product Safety Committee	US TAG for ISO/TC194/SC1		Tissue Engineering	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC; [ALTERNATE] Asher, David M; OMPT/CBER/OBRR/DETTD/LBTSEA
ASTM	F04 Medical and Surgical Materials and Devices	F04.41 Classification and Terminology for TEMPs		Tissue Engineering	[PRIMARY] Moos, Malcolm C; OMPT/CBER/OTAT/DCGT/CTTB

SDOs	Level 1 (Committees)	Level 2 (SubCommittee)	Level 3 (WorkingGroup)	STG	Member
ASTM	F04 Medical and Surgical Materials and Devices	F04.42 Biomaterials and Biomolecules for TEMPs		Tissue Engineering	[PRIMARY] Kaplan, David S; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Panguluri, Rakhi; OMPT/CDRH/OC/DMQ/R/ENT/GH-ODB; [TECHNICAL EXPERT] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM
ASTM	F04 Medical and Surgical Materials and Devices	F04.43 Cells and Tissue Engineered Constructs for TEMPs		Tissue Engineering	[PRIMARY] Wensky, Allen K; OMPT/CBER/OCTGT/DCEPT/PTB; [ALTERNATE] Li, Shuliang; OMPT/CDRH/OC/D; [TECHNICAL EXPERT] Dreher, Maureen L; OMPT/CDRH/OSEL/DAM; [TECHNICAL EXPERT] Mcfarland, Richard D; OMPT/CBER/OTAT
ASTM	F04 Medical and Surgical Materials and Devices	F04.44 Assessment for TEMPs		Tissue Engineering	[PRIMARY] Arcidiacono, Judith A; OMPT/CBER/OTAT; [ALTERNATE] Kaiser, Aric D; OMPT/CDRH/ODE/DOD/RRDB
ASTM	F04 Medical and Surgical Materials and Devices	F04.46 Cell Signaling		Tissue Engineering	[PRIMARY] Moos, Malcolm C; OMPT/CBER/OTAT/DCGT/CTTB; [ALTERNATE] Hursh, Deborah A; OMPT/CBER/OTAT/DCGT/CTTB
ISO	TC 150 Implants for Surgery	SC 07 Tissue Engineered Medical Products		Tissue Engineering	[PRIMARY] Kaplan, David S; OMPT/CDRH/OSEL/DAM; [ALTERNATE] Yong, Carolyn; OMPT/CBER/OCTGT/DCGT/CTB
ISO	TC 194 Biological evaluation of medical devices	(Joint with Biocompatibility STG) Biocompatibility STG is Primary	WG 01 Risk assessment, terminology and global aspects	Tissue Engineering	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC
ISO	TC 194 Biological evaluation of medical devices	SC 01 Tissue product safety	WG 02 Sourcing controls, collection and handling	Tissue Engineering	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC
ISO	TC 194 Biological evaluation of medical devices	SC 01 Tissue product safety	WG 03 Elimination and/or inactivation of viruses and TSE agents	Tissue Engineering	[PRIMARY] Mcnamee, Scott G; OMPT/CDRH/OC
ISO	TC 194 Biological evaluation of medical devices	SC 01 Tissue product safety	WG 04 TSE Elimination	Tissue Engineering	[PRIMARY] Asher, David M; OMPT/CBER/OBRR/DETTD/LBTSEA; [ALTERNATE] Mcnamee, Scott G; OMPT/CDRH/OC
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