

SPEAKER BIOS

LCDR Scott A. Colburn

LCDR Scott A. Colburn, MS, BSN, RN is the Director of the Standards Program at the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). Since joining FDA in January of 2004, LCDR Colburn has served in numerous roles as a nurse consultant in the area of premarket review and voluntary consensus standards development within the General Hospital Devices Branch/Office of Device Evaluation. He has held the positions of lead reviewer and Acting Chief of the General Hospital Devices Branch and since August 2009 has served as Deputy Director of the CDRH Standards Program. Scott is a member to numerous national and international medical device standards working groups and is the convener to both the U.S. Technical Advisory Group (TAG) and International ISO/IEC Joint Working Group (ISO TC210 JWG4/IEC SC62D JWG10) charged with developing a manufacturing standard to address the risks associated with medical device small bore misconnections that lead to adverse and fatal events for patients. Scott has been appointed to the ANSI Executive Standards Council (ExSC), the ANSI Government Member Forum (GMF), the Interagency Committee on Standards Participation (ICSP) and the AAMI Standards Board.

Prior to coming to FDA, Scott completed his bachelor's degree in Nursing from Marquette University and was commissioned in the US Army Nurse Corps where he served four years at the Walter Reed Army Medical Center in D.C. Since coming to the FDA, he has earned a Masters of Science in Biomedical Technology Development and Management from Georgetown University and Virginia Polytechnic Institute and State University.

LCDR Colburn transferred to the U.S. Public Health Service Commissioned Corps in January 2004. Prior to his commission into the USPHS, Scott was enlisted in the Army as a combat medic prior to his Commission in the US Army Nurse Corps in 1999.

Mary Jo DiBernardo

Ms. DiBernardo joined the National Institute of Standards and Technology (NIST) in June 2000. She manages workshops and training in what is now known as the Standards in Trade Program at NIST.

Prior to this, she was responsible for NIST's implementation activities under the U.S.-EU Mutual Recognition Agreement (MRA) for Electromagnetic Compatibility and Telecommunications Equipment and the Organization of American States Inter-American Telecommunications

Commission (CITEL) MRA. Ms. DiBernardo also served as the NIST lead for negotiating the U.S.-Japan MRA for Telecommunications Equipment. She has worked with the National Voluntary Conformity Assessment System Evaluation (NVCASE) Program on NIST's recognition of U.S. accreditation bodies and has been trained as an ISO 9001 Lead Assessor.

Prior to joining NIST, Ms. DiBernardo was the Staff Director for Conformity Assessment at the American Council of Independent Laboratories (ACIL) in Washington, DC. She represented the laboratory community on issues involving testing, certification, and accreditation. Before locating to the Washington, DC metro area, Ms. DiBernardo was employed by the New York State Legislature and the New York State Economic Development Council.

Ms. DiBernardo holds a Masters Degree in Public Administration from the Rockefeller College of Public Affairs and Policy at the State University of New York (SUNY) at Albany and a B.A. in Political Science and Economics from SUNY Albany. She has a graduate certificate in International Studies from Johns Hopkins University's School of Advanced International Studies in Washington, DC and a graduate certificate in Negotiation and Dispute Resolution from Georgetown University's Center for Professional Development. Ms. DiBernardo was the recipient of the American National Standards Institute's Next Generation Award in 2004. She also graduated from NIST's Building the Next Generation leadership program in 2006.

Ginny Fitzner

Ginny Fitzner is the director of the Office of Safety Systems in the Directorate of Standards and Guidance of the Occupational Safety and Health Administration within the Dept. of Labor. Ginny's directorate is responsible for the development of safety and health standards that are published in part 29 of the Code of Federal Regulations. She served as an Occupational Safety and Health manager for over 15 years in several states before settling in the DC area and accepting a position with OSHA. Her decision to transition from safety and health management to regulatory development was inspired by desire to take real-life safety experience and apply it in the rulemaking process. During her time at OSHA she has enjoyed working with many safety professionals who are passionate about protecting America's workers from exposure to recognizable hazards.

Gordon Gillerman

Gordon Gillerman is the Director of Standards Services, Standards Coordination Office at the National Institute of Standards and Technology (NIST). Gordon has extensive experience in coordinating standards policy and development across a wide range of sectors critical to the U.S. including homeland security, safety, health and protection of the environment.

Gordon has been the NIST lead in designing and implementing conformity assessment programs as well as assisting in the development of performance standards to meet other federal agency and industry needs and fulfill NIST's role in coordinating standards and conformity assessment in the U.S. Gordon is the Public Sector Co-Chair of the American National Standards Institute's (ANSI) Homeland Security Standards Panel, a member of the Toy Industry Association, Toy Safety Certification Program's Oversight Council and a sought after lecturer on standards, conformity assessment and regulation.

Previous positions include leading government affairs for the largest U.S. product safety certification and standard development organization, Underwriters Laboratories (UL) in Washington, DC, and Staff Engineer for the medical device and information technology sectors at UL's Northbrook, IL headquarters. Gordon has worked collaboratively within the standards community to enhance health, safety, the environment and security throughout his career. In 2008 Gordon received an Environmental Protection Agency Gold Medal. He has also received a Department of Commerce Bronze Medal and the ANSI Meritorious Service Award for his work in standards and conformity assessment.

Gordon received a Bachelor's Degree BSEET from Bradley University in Peoria, IL.

Pat Harris

Pat Harris is an International Standards Specialist. She brings to Standards Services extensive experience in the standards development arena at the national and international levels. For twenty years Pat managed an ANSI-accredited standards setting organization and was directly involved in international standards development through the ISO. As secretariat for an ISO Subcommittee and the U.S. Technical Advisory Group to an ISO Technical Committee she gained valuable insights into standards development processes and systems. In her career, Pat has engaged in a number of standards activities that have demonstrated the value of standardization to enabling innovations in information technology, including standardization of the file structures for the CD-ROM and eBooks. She is a graduate of the Randolph Macon Woman's College, holds an M.S. from the University of North Carolina-Chapel Hill, and currently

serves on the Board of Visitors to the UNC-Chapel Hill School of Information and Library Science.

MaryAnn Hogan

MaryAnn Hogan is a Technical Information Specialist in the U.S. WTO TBT Inquiry Point located in the National Center for Standards and Certification Information (NCSCI), part of the Standards Services Group at NIST. She conducts research and provides assistance regarding standards and regulatory and conformity assessment information. She is also an administrator for the website of the Standards Services Group, Global Standards Information (GSI): <http://gsi.nist.gov/global/index.cfm>. Between 2007 and late 2010, MaryAnn served as a Research Librarian with the NIST Research Library.

MaryAnn earned a Bachelor of Arts magna cum laude in German and Anthropology and a Master of Library Science degree from the University of Maryland.

Erik Puskar

Erik Puskar leads global standards information activities within Standards Services, Standards Coordination Office at NIST.

Erik provides technical information related to standards and supports Federal agencies by monitoring developments in standards and conformity assessment internationally. Erik also lead SSG's impact analysis efforts of voluntary consensus standards as well as NIST's efforts on education about standardization. He is a member of the ANSI Committee on Education and represents NIST on the International Cooperation for Education About Standardization (ICES).

In addition to standards, he has experience in the fields of information technology, funding innovative high-risk technology and fiscal affairs/taxation. Previous to SSD, Erik was a program manager with the Advanced Technology Program (now Technology Innovation Program) of NIST and has held other positions with the U.S. Government, international development organizations, and consulting.

Erik holds a degree in Economics from Rutgers University and a Masters Degree in Public Management and Policy from Carnegie-Mellon University.

Ileana Martinez

Ileana Martinez is International Affairs Advisor, Standards Coordination Office at the National Institute of Standards and Technology (NIST). She also serves as International Affairs Advisor to the National Voluntary Laboratory Accreditation Program (NVLAP) at NIST and is Vice Chair of the Inter American Accreditation Cooperation (IAAC).

Ms. Martinez has expertise in the U.S. approach to standards, regulations, conformity assessment, laboratory accreditation, as well as in the National Technology Transfer and Advancement Act (Public Law 104-96), U.S. trade obligations under the World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT), the U.S. Inquiry Point, and related topics.

From 1996 through 2000, Ms. Martinez served as the NIST Regional Standards Attaché at the U.S. Embassies in Buenos Aires, Argentina and in Brasilia, Brazil, with standards-related responsibilities for South America, seeking to reduce technical barriers to trade in the region. Ms. Martinez earlier worked as a Standards Engineer in a variety of industrial sectors for both U.S. and overseas organizations gaining hands-on experience in national, regional and international standardization and conformity assessment activities.

Ms. Martinez earned a bachelor degree in Mechanical Engineering from the Catholic University of America in Washington, D.C. and did graduate work at American University in Washington, D.C. in Science/Technology Policy.

Mary Saunders

Mary Saunders currently serves as Director, Standards Coordination Office, NIST. In this capacity, she represents NIST and its significant interests in the standards and conformity assessment community and advises NIST leadership on policy and strategy as they relate to NIST's role in standardization. Her responsibilities include serving as a central point of focus for standards and conformity assessment policy for NIST, coordinating with the private sector and other federal agencies on standardization activities, leading interagency standards coordination, and leading NIST's standards interactions with foreign governments.

Prior to her return to NIST, Ms. Saunders served as Deputy Assistant Secretary for Manufacturing and Services, where she managed the day-to-day operations of the International Trade Administration's (ITA) Manufacturing and Services division of more than 200 industry specialists, economists and international trade experts. She helped strengthen the competitive position of U.S. industries in the U.S. and world markets by coordinating Commerce

Department strategies, policies and programs with U.S. industries in mind. At NIST, she served in a variety of positions during a 15 year career, including Chief, Standards Services Division. In that capacity, she administered a range of standards-related programs to provide solutions to regulatory and industry needs and increase trade opportunities. Over the course of her Commerce career, Ms. Saunders has managed programs to advance U.S. business and technology interests in the European Union, Russia and the Newly Independent States, China and Japan. She has worked with a broad range of sectors on competitiveness and market access issues, including information and communications technologies, telecommunications, medical devices, oil and gas equipment, construction equipment, energy technologies and consumer goods.

Ms. Saunders has been in federal service since 1979, serving in a variety of positions with the Department of the Army, including the Office of Institutional Research, U.S. Military Academy, before joining ITA in 1986. In ITA, she served as a special assistant in the Office of Capital Goods and as Team Leader, Internal Market Staff, in the Office of European Community Affairs, where she was a member of the U.S. team that negotiated the U.S.-European Union Mutual Recognition Agreement.

She has received the Department's Silver and Bronze Medals for outstanding achievements on several occasions during her Commerce career. She received her

B.A. from Vanderbilt University and an M.P.A. from the Woodrow Wilson School of Public and International Affairs, Princeton University

Peter Shebell

Mr. Peter Shebell has been with the Department of Homeland Security (DHS) since its inception. He is currently the standards policy manager in the Science and Technology Directorate (S&T) where he develops policy and guidance on the use of voluntary consensus standards and conformity assessment systems used by the department. Mr. Shebell works closely with the Components and has been involved with developing standards to support the National Incident Management System and supports the Federal Emergency Management Agency with the PS-Prep™ program. Mr. Shebell established the DHS Standards Council and serves as its secretariat. He represents DHS on the Interagency Standards Policy Committee, American National Standards Institutes (ANSI) Executive Standards Committee, and ANSI-ASQ National Accreditation Board (ANAB) Accreditation Council. Prior to transitioning to DHS headquarters, Mr. Shebell was a physicist Environmental Measurement Laboratory where he was involved in the Countermeasures Testbed Project and the development of radiation detector standards for homeland security.

David Wollman

Dr. David Wollman is one of NIST's smart grid team leads, managing NIST's smart grid standards and research efforts and overseeing Smart Grid Interoperability Panel activities. Before joining the Smart Grid and Cyber-physical Systems Program in the NIST Engineering Laboratory, he managed efforts within the Physical Measurement Laboratory to maintain and advance the Nation's electrical standards and metrology supporting the electric power industry. He has worked closely with a variety of standards development organizations, and he is the NIST official representative on the Board of Directors at the North American Energy Standards Board (NAESB), an ANSI-accredited SDO whose standards are often referenced by the Federal Energy Regulatory Commission (FERC). In addition, he has served in several other positions at NIST, including Scientific Advisor in the Electronics and Electrical Engineering Laboratory, Program Analyst in the NIST Director's Program Office, and bench-level scientist in Boulder, Colorado developing advanced high-resolution x-ray detectors. Before joining NIST, Dr. Wollman received his Ph.D. from the University of Illinois at Urbana-Champaign in the areas of superconducting electronics and device micro/nanofabrication. He has given numerous invited talks at international conferences, and holds three U.S. patents. He has received many awards, including the U.S. Department of Commerce Gold Medal and the NIST Applied Research Award.