Fundamentals of Standards and Conformity Assessment for Federal Agencies

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SPEAKER BIOS

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Dr. Nadine Alameh is the CEO of the Open Geospatial Consortium (OGC) – a collective problem-solving body convening the global community of geospatial experts and users that use open consensus-based standards, collaborative innovation projects, and industry partnerships to make Location information Findable, Accessible, Interoperable, and Reusable (FAIR). Dr. Alameh is a passionate leader with a mission of accelerating the impact of organizations using or producing geospatial/location information, with a proven track record in a multiple of domains including Aviation, Earth Observation, Public Safety, and Defense. Nadine sits on the board of the Private Sector Network (PSN) of the United Nations Committee of Experts on Global Geospatial Information Management (UN-GGIM); and on the board of the US National Geospatial Advisory Committee, a federal Advisory Committee sponsored by the US Department of Interior.

Prior to OGC, she held various roles in industry from the Chief Architect for Innovation in Northrop Grumman's Civil Solutions Unit; to CEO of an Aviation data exchange startup; to senior technical advisor to NASA's Applied Science Program.

Nadine graduated from MIT with a Ph.D. in Information Systems Engineering, and 2 Masters Degrees in Civil Engineering and Urban Planning with a concentration in Geospatial Information Systems. She holds a BS degree in Computer Engineering from the American University of Beirut.

Anne Caldas

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Anne Caldas is Senior Director, Procedures and Standards Administration at the American National Standards Institute (ANSI). Anne's primary roles relate to standards development activities. She is responsible for the implementation of the programs and committees that support the American National Standards (ANS) process and the procedures that govern the ANS process as well as US participation via ANSI at ISO. Program oversight responsibilities include the accreditation of standards developers and U.S. Technical Advisory Groups (TAGs) to ISO, the approval of standards as American National Standards, the ANSI Standards Developer Audit Program, the multi-level appeals process at ANSI, ANSI's nanotechnology standardization activities, and other special projects. She is a graduate of the University of Maryland, College Park and holds an MA in Urban Affairs and Policy Analysis from the New School for Social Research in New York City.

Katie Calder

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Katie Calder is Senior Director Accreditation Systems Integrity, of the new ANSI National Accreditation Board (ANAB), responsible for the implementation of the quality management system required by ISO/IEC 17011 for ANAB's conformity-assessment accreditation programs: Product Certification (ISO/IEC 17065), Personnel Certification (ISO/IEC 17024), Greenhouse Gas Validation and Verification (ISO 14065), Certificate Accreditation (ANSI/ASTM E2659), Management Systems Certification (ISO/IEC 17021), Testing and Calibration Labs (ISO/IEC 17025), Inspection Bodies (ISO/IEC 17020), Proficiency Test Providers (ISO/IEC 17043), and Reference Material Producers (ISO/IEC 17034). Ms. Calder oversees a team implementing management system procedures that address risk management, competence, document and record control, and internal corrective actions.

Ms. Calder holds a Juris Doctorate degree from the University of Baltimore School of Law, a Master of Arts in Teaching degree from Johns Hopkins University, and a Bachelor of Sciences degree from the University of Maryland. Prior to joining ANSI/ANAB, Ms. Calder audited ANSI-accredited standards development organizations for 13 years.

Stacy Cho

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Stacy Cho is a senior policy analyst with the Standards and Conformity Assessment Program (S-CAP) at the Center for Devices and Radiological Health. Stacy received her B.S. in Biological Sciences and Psychology from Carnegie Mellon University and received her M.A. in Psychological and Brain Sciences with a focus on fMRI studies from Johns Hopkins University. Stacy started her career at FDA in 2013 after spending several years as a neurophysiologist with hospitals in the DC metro area. At FDA, she served as a lead reviewer for radiological devices with premarket, compliance, and postmarket submissions; and she also led the Third Party 510(k) Premarket Program. Currently, she is the Accreditation Body Lead for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot program after spending several years establishing the program.

Steven P. Cornish

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Steven P. Cornish is ANSI's Senior Director of International Policy and Strategy. In this role, Steven is responsible for the organization and administration of the ANSI International Policy Advisory Group (IPAG) which overseas ANSI's efforts to address cross-cutting international and regional standardization and conformity assessment policy issues. Steven is also responsible for ANSI regional interfaces with Europe and the Pacific Rim, and for bilateral interfaces with a number of other national standards bodies in countries such as Canada, the United Kingdom, Germany, Japan, and Australia. The greatest percentage of Steven's responsibility is overseeing ANSI's engagement with the International Organization for Standardization (ISO) at the policy and governance levels. This involves interfacing with ISO, analyzing documentation and developing ANSI positions and comments based on input from ANSI stakeholders to ensure effective and successful engagement of ANSI representatives on policy and governance issues of the ISO General Assembly, ISO Council and its subgroups, ISO Technical Management Board and its subgroups, and the ISO Policy Committee for Developing Countries.

Steven serves as the ANSI representative on the ISO Technical Management Board, which overseas and coordinates the development of all ISO deliverables across many committees and sectors. During his time on the ISO Technical Management Board, Steven has led efforts related to the development of ISO's Global Relevance Policy, the policy on normative referencing of standards from organizations other than ISO and IEC, the policy on use of ISO standards to support public policy, guidance on effective engagement of ISO national members and liaisons, guidance on introduction of new work proposals, the process for addressing complaints regarding breaches of the ISO Code of Conduct to ensure ethics in ISO standards development, guidance on conducting effective virtual and hybrid ISO and IEC standards development meetings, and the ISO/IEC Joint Directives Maintenance Team that addresses revisions to improve the ISO and IEC rules for the drafting of standards.

Steven holds a Master's Degree from Columbia University and a Bachelor's Degree from the State University of New York at Oswego.

Kelley Cox

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Kelley A. Cox is director of business and membership development. Her work includes identifying new business and membership opportunities and building sustainable relationships with key partners for the Institute's intermediate and long-term growth.

Ms. Cox has extensive professional experience in all facets of business development, membership, and marketing. Most recently, she was executive director of business development at the U.S. Chamber of Commerce, where she identified and secured business partnerships with organizations that market to small business members by creating national marketing programs, local outreach, and innovative alliances tailored to organizational needs. She also designed and spearheaded strategies to improve and enhance revenue generation and membership fundraising activities.

She also served as an emergency response and family assistance consultant for Aviem International, Inc. and the Family Assistance Foundation, after spending a majority of her career

at American Airlines. Ms. Cox served in a variety of leadership positions at American, where she was instrumental in leading hundreds of employees and families during the local response effort on September 11th for the Boston Flight Service Department. Most notably, she developed the airline industry's first formal family assistance program known as CARE (Customer Assistance Relief Effort), which was adopted as the airline industry standard. Ms. Cox has also served on the board of directors for the Family Assistance Foundation.

Ms. Cox holds a B.S. degree (cum laude) from Salem State University, in Salem, Massachusetts. She also has an A.A. degree in business administration (cum laude) from North Shore Community College in Beverly, Massachusetts, where she received a Distinguished Alumni Award for her work on 9/11. She also earned her Certified Association Executive (CAE) from the American Society of Association Executives (ASAE), and the Institute for Organization Management (IOM) recognition from the U.S. Chamber of Commerce.

Mary Jo DiBernardo

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Ms. DiBernardo is responsible for the management, design, development, and delivery of a standards and conformity assessment training program for government agencies, including NIST's Standards Boot Camp. She also manages the Standards Services Curricula Development Cooperative Agreement Program, which provides support for the development of undergraduate and graduate curriculum designed to integrate standards and standardization information and content into courses, seminars, and learning resources.

She serves as the co-vice chair of ANSI's Committee on Education. She was the first recipient of ANSI's Next Generation Award in 2004 and will receive ANSI's Meritorious Service Award in 2022. Mary Jo received a MPA and BA from the State University of New York at Albany; a graduate certificate in International Studies from the Johns Hopkins University School of Advanced International Studies; and a certificate in Negotiation and Dispute Resolution from Georgetown University's Center for Professional Development.

Mary Donaldson

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Ms. Donaldson serves as the NIST contact for standards-related issues arising out of the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119. She serves as Executive Secretary for the Interagency Committee on Standards Policy (ICSP) and is responsible for content of a government website that supports the use of standards in government (www.standards.gov). She serves on the ANSI Executive Standards Council, ANSI Government Member Forum, and ANSI ISO Council.

Prior to joining NIST, Ms. Donaldson was an Economist at the U.S. Consumer Product Safety Commission (CPSC) where she conducted regulatory analyses of proposed Commission actions. Ms. Donaldson began her career with the US Army Laboratory Command where she served as the agency project manager for a program which evaluated foreign developments in science and technology.

Ms. Donaldson received her BS and MS degrees from the University of Maryland, College Park.

Gordon Gillerman

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Gordon Gillerman, Director, Standards Coordination Office at the National Institute of Standards and Technology (NIST) leads NIST's work in standards coordination including the National Voluntary Laboratory Accreditation Program. Gordon coordinates and advises federal agencies and other stakeholders on standards and conformity assessment policy. The Standards Coordination Office is the NIST focal point for federal government standards coordination, administers the NIST Standards Curricula Development Cooperative Agreement Program, operates the U.S. Inquiry Point for the World Trade Organization's Technical Barriers to Trade Agreement and is a key information source for US industry on standards related market access issues. Gordon leads NIST's work with federal agencies to develop standards and conformity assessment policy and programs.

Gordon has extensive standards experience across a wide range of critical issues including homeland security, safety, health, and protection of the environment. Gordon is an expert on conformity assessment systems system design and a sought-after lecturer on standards, conformity assessment and regulation and their nexus with regulatory and trade issues and. Gordon has collaborated across the standards community to enhance health, safety, the environment, and security throughout his career.

Prior experience includes 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 he received an Environmental Protection Agency Gold Medal, a Department of Commerce Bronze Medal, and the ANSI Meritorious Service Award. In 2010 Gordon received a Department of Commerce Gold Medal for leadership in enhancing the performance standards and certification program for law enforcement body armor and EPA's Award for Outstanding Leadership in Collaborative Problem-Solving for his work in guiding the development of a Green Clean-Up standard. In 2012 Gordon received the ANSI Gerald H. Ritterbusch Conformity Assessment Medal. In 2013 he received the Department of Commerce Silver Medal for leadership in opening access to China's compulsory certification system to U.S. certification organizations. Gordon is also a Society of Standards (SES) Professionals Fellow.

Gordon received a bachelor's degree BSEET from Bradley University in Peoria, IL.

Jeff Grove

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Jeff Grove is the Vice President for Global Policy and Industry Affairs at ASTM International, one of the largest standards and technical information providers in the world. Jeff directs ASTM's government affairs and communications functions and is responsible for worldwide interactions with regulators, trade negotiators, and the global business community to advance public policies that promote industrial competiveness and trade. Prior to joining the staff of ASTM in 2004, Jeff was the Director of the Washington office of the Association for Computing

Machinery. From 1993 to 2001, he held several staff positions in the U.S. Congress - including serving as Staff Director for the House Committee on Science and Technology.

Jeff has a Bachelor of Science degree from the University of Wisconsin (La Crosse) and a Master's degree in International Commercial Policy from George Mason University. He completed the Executive Leadership Program at Georgetown University and the Oxford Summer Residence Programme in Globalization and Trade at St. Peter's College, University of Oxford, United Kingdom.

Holly Elwood

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Holly is a Senior Advisor for the EPA's Environmentally Preferable Purchasing Program, helping federal agencies factor the environment into purchasing decisions. She coordinates EPA and interagency technical input into product sustainability standard development efforts and helps shape and maintain EPA's Recommendations of Standards and Ecolabels for Federal Procurement.

Holly received an Individual Leadership Award from the Sustainable Purchasing Leadership Council for her "...vision, leadership, and dedicated effort to the advancement of the sustainable purchasing movement" for the development of the EPA Recommendations. She also received an EPA Gold Award for her role in forming and implementing the White House's National Strategy for Electronics Stewardship, and was selected as a Fed 100, awarded to government and industry leaders who have "played pivotal roles in the federal government IT community".

Holly holds a Masters Degree in Environmental Sciences and Public Policy from Johns Hopkins University, and a B.A. in Political Science from Macalester College.

Jennifer Marshall

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Jennifer Marshall is a Physical Scientist/Program Manager for Public Safety Standards Coordination at the National Institute of Standards and Technology (NIST). She leads and coordinates standards development efforts across the federal interagency at various standards developing organizations that impact the EMS, fire, and law enforcement communities. Ms. Marshall has managed homeland security standards developing efforts spanning chemical, biological, chemical, radiological, and nuclear (CBRNE) detection equipment; personal protective and operational equipment (PPOE); urban search and rescue robots; and various security technologies. In addition, Ms. Marshall participates in international standards development efforts as a member of the US Technical Advisory Group for ISO TC 229 (Nanotechnologies) and is the USTAG secretary to IEC TC 45 (Nuclear Instrumentation).

Prior to arriving at NIST, Ms. Marshall worked for the DHS Science and Technology (S&T) Directorate from its early inception in 2003 where she developed multi-year research, development, test and evaluation (RDTE) plans for the CBRNE countermeasures, infrastructure protection, standards development programs that supported the Federal, state and local public safety community. Ms. Marshall has over 15 years' experience in technology and standards development in the public safety and homeland security community.

Gabe Maser

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Gabe Maser is the senior vice president of Government Relations and National Strategy for the Code Council, where he manages and directs its federal and national policy and legislative priorities agenda, and maintains and enhances the Code Council's advocacy presence in Washington, D.C. He also serves as the elected Chair of the High Performance Buildings Coalition. Maser brings an extensive background in government relations and federal policy to his role at the Code Council. Most recently, he served as a regional director for market expansion and policy at Renovate America.

Previously, he worked as the director of federal and state relations for the Commonwealth of Massachusetts, a legislative assistant for a member of Congress and an associate at Baker Botts L.L.P. Maser has a bachelor's degree in biology from McGill University and a juris doctorate from Georgetown University Law Center. He is a licensed lawyer in the District of Columbia and Massachusetts.

Leslie McDermott

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As Senior Director, International Development, Leslie McDermott leads ANSI's international development activities, including advocacy and program development to strengthen U.S. market access in China, India, and other emerging economies. Ms. McDermott manages the implementation of projects such as the Standards Alliance, a public-private partnership with USAID designed to assist developing countries in effectively implementing their commitments under the WTO's Technical Barriers to Trade (TBT) agreement. Acting as a liaison between stakeholders in standards bodies, government, industry, and other affected organizations, Ms. McDermott helps assure that projects affecting trade and infrastructure development in emerging economies have the most meaningful impact.

In addition, Ms. McDermott oversees the ANSI China Program which brings together technical, business and policy leaders to find solutions to issues impacting the U.S.-China trading relationship. The ANSI China Program has become recognized as a focal point in the standards and compliance space and underpins numerous other programs such as ANSI's business facilitation services that offer customized solutions to help companies prevent and resolve standards and compliance barriers in China.

Ms. McDermott holds a Master's Degree in International Relations from Royal Holloway, University of London, a Bachelor's Degree from Boston University, and she is certified as a Project Management Professional (PMP).

Warren Merkel

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Warren Merkel serves as Chief of Standards Services in the National Institute of Standards and Technology (NIST) Standards Coordination Office. He was also co-convener of ISO CASCO Working Group 44 on the revision of ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

Mr. Merkel was Chief of the NIST National Voluntary Laboratory Accreditation Program (NVLAP) from 2003 to 2006. After leaving NIST for six years to teach chemistry, he returned to serve as Chief of NVLAP from 2012 to 2015. From 1996 to 2003, Mr. Merkel was employed by the American Association for Laboratory Accreditation (A2LA), most recently as Technical Manager. From 1992 to 1996, he worked as an Investigative Chemist in the Defense Logistics Agency Analytical Product Testing Center in Philadelphia, PA.

Mr. Merkel holds a B.S. in Chemistry from Temple University and a M.Ed. in Curriculum and Instruction from Bloomsburg University.

Paul B. Najarian

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Paul Najarian is a Foreign Affairs Officer in the office of International Communications & Information Policy within State Department's Bureau of Economic and Business Affairs.

Mr. Najarian serves as vice-chair of CWG-LANG on the "Use of the six official languages of the Union", as well as vice-chair of the ITU-T Standardization Committee for Vocabulary (SCV) and the ITU-R Coordination Committee for Vocabulary (CCV).

In this context, Mr. Najarian is actively engaged in the implementation of Resolution 154 (Rev. Dubai, 2018) and Council Resolution 1386 regarding the joint ITU Coordination Committee for Terminology (CCT); and is a strong advocate for inter-sectoral coordination and collaboration.

Mr. Najarian is also fluent in 3 (out of the 6) languages of the Union.

He is actively involved in all 3 sectors of the International Telecommunication Union (ITU); but mainly serves as U.S. Head-of-Delegation to ITU's standardization activities on Cybersecurity, as well as international regulatory activities on terrestrial radiocommunications.

Mr. Najarian is the liaison rapporteur between ITU-R and the ITU's Collaboration on Intelligent Transport Systems (ITS) Communication standards; and has been involved with ITU-R activities dating back to 1985.

From 1996 to 2006, Paul Najarian was the Director of Telecommunications and Standards for the Intelligent Transportation Society of America (ITS) as a federal advisory body to the U.S. Department of Transportation. His main responsibilities included the spectrum allocation in the 5850 – 5925 Mhz for Dedicated Short Range Communications (DSRC), the assignment of the "511" telephone number for traveler information services, and several ITS public safety programs such as Next Generation 911. Mr. Najarian also served as international secretariat, as well as U.S. TAG administrator, for ISO/TC 204 on ITS.

Mr. Najarian began his professional career in 1985 as a systems analyst for the Air Force and the Department of Defense on satellite communications networks. His first interaction with the ITU was to analyze the impact of WARC-85 on the U.S. geostationary satellites; and has remained regularly active in domestic preparations for the ITU-R, the WARCs and the WRCs. By 1992, his career gradually transferred to Land Mobile communications, including VLF/LF propagation.

From 1992 to 1995, Mr. Najarian was a technical and operational analyst as part of the UN Special Commission on Iraq (UNSCOM) inspection teams. This activity provided a broader exposure to UN activities, including the IAEA and UNDP.

Since 1995, Mr. Najarian has been a regular participant in ITU-R activities and the WRCs, but mainly in Study Group 5 (formerly SG 8 as well as the activities of the JRG 8A-9B), as well as a number of activities in the ITU-T related to the collaboration among standards organizations including the Fully Networked Car.

This was followed by the Dept. of Commerce / National Telecommunication and Information Administration (NTIA), from 2006 to 2009; and at the U.S. State Department since 2009.

Mr. Najarian has authored many technical and regulatory papers on ITS radiocommunications, public safety, and land mobile communications. In 1998 and 1999, he served as President of the Land Mobile Communications Council (LMCC), which groups more than 22 organizations representing the frequency managers, manufacturers, systems integrators, and end-users of land mobile and public safety communications, before the FCC.

Mr. Najarian holds a Masters degree in Electrical Engineering from the University of Virginia, as well as a Masters degree in Business Administration (MBA) from the George Washington University (in Washington, DC) with a specialization in Finance and the Management of Science, Technology, and Innovation.

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Casandra Robinson is a physical scientist in the National Institute of Standards and Technology (NIST) Standards Coordination Office. She is responsible for leading the development of documentary standards and coordinating with NIST technical units, other federal agencies, industry, and relevant stakeholders in the development of standards and conformity assessment systems.

Prior to joining NIST in 2012, she was a Program Manager with the U.S. Department of Energy Savannah River National Laboratory. For the previous 5 years, she supported the National Institute of Justice's Standards and Testing Program with development of performance standards for public safety equipment.

She is a member of the ASTM International Board of Directors and serves as Chair for the ASTM E54 Committee on Homeland Security Applications. She is a member of the American National Standards Institute (ANSI) Executive Standards Council and is the Federal co-chair for the ANSI Homeland Defense and Security Standardization Collaborative. She has participated in standards development activities with ASTM International, Underwriters Laboratories, the Institute of Electrical and Electronics Engineers, and the National Fire Protection Association.

She has a Bachelor of Science in Electrical Engineering from Clemson University and a Master of Science in Industrial and Systems Engineering from the University of Alabama.

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Mary Saunders is Vice President for Government Relations and Public Policy at the American National Standards Institute (ANSI). Mary leads ANSI's efforts to advocate greater use of voluntary consensus standards and conformance programs by government agencies and broader participation by agency personnel in standards development. She works with ANSI members to create standardization-related outreach programs to legislators and to increase understanding of the private-sector standards community among agencies involved in trade and commerce issues. Mary is a key player at ANSI in fostering understanding among opinion leaders of the major role standards and conformance play in the international and domestic marketplace.

Ms. Saunders has extensive federal government executive-level experience and served in a variety of positions within the Department of Commerce prior to joining the ANSI staff, most recently as the Associate Director for Management Resources at the National Institute of Standards and Technology (NIST). As Director of NIST's Standards Coordination Office, she represented NIST and its significant interests in the standards and conformity assessment community, advising the NIST Director and other officials throughout the Administration on policy and strategy as they relate to the federal government's role in standardization.

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Kent Shigetomi is the Acting Assistant U.S. Trade Representative for WTO and Multilateral Affairs at USTR. He works on issues related to technical barriers to trade (TBT) and rules of origin. Kent serves as the U.S. lead to the APEC Subcommittee on Standards and Conformance, and as the Chair of the APEC Chemical Dialogue. He coordinates U.S. engagement in the WTO Committee on Rules of Origin. Prior to joining USTR, Kent served as a Foreign Service Officer with the U.S. Department of State.

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Mr. Simmons is OGC's Chief Standards Officer. In this role, he provides oversight and direction to the Consortium's technical and program operations and deliverables. Mr. Simmons also continues to lead the OGC Standards Program, where he ensures that standards progress through the organization's consensus process to approval and publication. Preceding his time as a member of OGC staff, Mr. Simmons was an active member of OGC, promoting best practices in 3D Information Management (3DIM) as chair of the OGC 3DIM Domain Working Group and chairing or participating in numerous OGC infrastructure, mobility, and web services working groups. His OGC-related research has focused on data lifecycle management, integration, and dissemination.

Mr. Simmons was formerly an Executive Director for CACI International, Inc. (CACI). At CACI, Mr. Simmons responsibilities included alignment of new business opportunities with fielded or researched capabilities in the geospatial domain. CACI acquired TechniGraphics, Inc. in 2010 where Mr. Simmons was the Chief Technology Officer. From 1993 to 2000, Mr. Simmons worked as a consulting geologist in the areas of structural geology, seismic risk, and geochemistry for GeoSyntec Consultants, where he also founded and managed the firm's geospatial operations.

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Chris Thompson serves as the Dairy Standardization Branch Chief of the Dairy Program within the U.S. Department of Agriculture's Agricultural Marketing Service. He has over 25 years of experience in implementing and managing dairy industry service and regulatory programs. In addition to working with domestic standards activities, Chris provides USDA leadership in putting forth US positions relating to international standards, and he regularly participates in export certificate negotiations and interagency market access activities on behalf of the U.S. dairy industry.

Education: BS Agriculture, 1988, MS Agriculture 1990, both from Western KY University.