Fundamentals of Standards and Conformity Assessment for Federal Agencies

A six-part seminar series sponsored by the National Institute of Standards and Technology Standards Coordination Office

Tuesday, February 22

The Big Picture of Standards and the Role of the USG

Wednesday, February 23

Fundamentals of Standards and Conformity Assessment

Thursday, February 24

Standards and Regulation

Tuesday, March 22

Domestic and International Standards Systems: U.S. Participation, Roles, and Responsibilities

Wednesday, March 23

Standards Development Organizations

Thursday, March 24

The Big Picture Revisited and Lessons Learned

All seminars will be held via Webex from 1:00-3:00 EST OPEN TO USG PERSONNEL ONLY

Seminars are free to attend but you must <u>register in</u> advance for each seminar using your USG email address.

Questions? Contact scotraining@nist.gov

AGENDA

Tuesday, February 22, 2022

Seminar #1 The Big Picture

1:00-3:00 PM EST | Welcome

Mary Jo DiBernardo, Program Manager, Standards Services, Standards Coordination Office (SCO), NIST

Brief Overview of NIST and the Standards Coordination Office

Warren Merkel, Leader, Standards Services, SCO, NIST

How Standards Impact (Most) Everything

From product design to the global market, standards protect health, safety, and the environment and promote interoperability. This talk will give participants a glimpse of the important relationships between manufacturing and innovation, standards, regulation, conformity assessment, trade, and more.

Gordon Gillerman, Director, SCO, NIST

Guidance to Federal Agencies

Federal Laws, Regulations, and Guidance on Standards and Standards Incorporated by Reference

A review of the laws, regulations, and guidance that collectively direct Federal agencies to participate in the development of voluntary consensus standards and to use nongovernment standards, whenever possible, to carry out policy objectives and meet their agency's missions.

Mary Donaldson, Program Manager, Standards Services, SCO, NIST

Wednesday, February 23, 2022

Seminar #2 Standards & Conformity Assessment 101

1:00-3:00 PM EST | Welcome

Mary Jo DiBernardo, Program Manager, Standards Services, Standards Coordination Office (SCO), NIST

Fundamentals of Standards

This talk will focus on the fundamentals of documentary standards, the different types of standards, the role of standards in regulation, the basics of the U.S. and international standards systems, key players, and the standards development process. It also includes an overview of the history of standardization and health, safety, environmental, and economic considerations over time.

Jennifer Marshall, Program Manager, Standards Services, SCO, NIST Cassy Robinson, Physical Scientist, Standards Services, SCO, NIST

Basics of Conformity Assessment

ISO/IEC 17000:2020, Conformity Assessment – Vocabulary and General Principles, defines conformity assessment as the demonstration that specified requirements are fulfilled. But what does this really mean? Learn more about general conformity assessment terms, such as testing, inspection, certification, accreditation, attestation, and more, and the use of conformity assessment to facilitate trade in both voluntary and regulatory environments.

Accreditation

A brief overview including accreditation of test and calibration laboratories, product certification organizations, and personnel certification.

Warren Merkel, Leader, Standards Services, SCO, NIST Gordon Gillerman, Director, SCO, NIST

Thursday, February 24, 2022

Seminar #3 Standards & Regulation

1:00-3:00 PM EST | Welcome

Mary Jo DiBernardo, Program Manager, Standards Services, Standards Coordination Office (SCO), NIST

Warren Merkel, Leader, Standards Services, SCO, NIST

Perspectives on Meeting Agency Missions with Regards to Standards Development and Use, Staff Participation in Standards Development Activities, and Working with SDOs

Updating Standards and Conformity Assessment Practices in a Well- Established Program

This presentation will highlight the challenges and opportunities associated with taking a fresh look at a program with decades of history and success.

Chris Thompson, Branch Chief, Dairy Standardization Branch, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture

FDA's Center for Devices and Radiological Health, Standards and Conformity Assessment Program

FDA will discuss their Standards and Conformity Assessment Program (S-CAP), which seeks to promote patient safety, advance regulatory science, and support a least burdensome regulatory framework. S-CAP fosters a collaborative approach to standards development and application by drawing upon expertise from across the product development, conformity assessment, and standards communities.

Stacy Cho, Senior Policy Analyst, Standards and Conformity Assessment Program, CDRH, U.S. Food and Drug Administration

Standards, Procurement, and the U.S. EPA's Environmentally Preferable Purchasing Program.

Learn about how U.S. EPA's Environmentally Preferable Purchasing Program helps federal government purchasers utilize private sector standards and ecolabels to identify and procure environmentally preferable products and services, providing a convenient and streamlined way to make sense of the often complex sustainable products marketplace by coordinating U.S. government technical input into the development of voluntary consensus product sustainability standards; issuing Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing across several key purchase categories; and helping federal agencies to procure products meeting the recommended specifications, standards, and ecolabels.

Holly Elwood, Senior Advisor, Environmentally Preferrable Purchasing Program, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Program

Tuesday, March 22, 2022

Seminar #4

Domestic and International Standards Systems: U.S. Participation, Roles, and Responsibilities

1:00-3:00 PM EST

Welcome

Mary Jo DiBernardo, Program Manager, Standards Services, Standards Coordination Office (SCO), NIST

The American National Standards Institute (ANSI) and Their Unique Role in the U.S. Standards System

The American National Standards Institute administers and coordinates the U.S. private sector-led voluntary standards and conformity assessment system. Founded in 1918, the Institute works in close collaboration with stakeholders from industry and government to identify and develop standards- and conformance-based solutions to national and global priorities. Together, standards and technical regulations impact up to 93% of global trade. Globally relevant standards and the conformance measures that assure their effective use help to increase efficiency, open markets, boost consumer confidence, and reduce costs. And ANSI is the U.S. leader in fostering that potential for the benefit of businesses across every industry and consumers around the world.

Mary Saunders, Vice President for Government Relations and Public Policy, ANSI

Kelley Cox, Director of Business and Membership Development, ANSI **Anne Caldas**, Senior Director, Procedures and Standards Administration, ANSI

Katie Calder, Senior Director, Accreditation Systems Integrity, ANSI National Accreditation Board (ANAB)

Leslie McDermott, Senior Director, International Development, ANSI

Comparison of Different Standardization Systems

The presentation will describe and compare characteristics of the standardization systems used in the United States, Europe, China, and Mexico. Differences in the systems will be highlighted as well as why and when they are important to consider.

Leslie McDermott, ANSI

Everything You Always Wanted to Know About Standards and International Obligations (But Were Afraid to Ask)

What would you do if the regulation you've been working on for months were suddenly declared to be in conflict with an international agreement that you had never heard of? Since 1994, the United States has been taken to dispute settlement 12 times in the World Trade Organization (WTO) for perceived violations of the WTO Technical Barriers to Trade Agreement. The most recent cases were related to product labeling, country of origin, and cigarette formulation. The TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. How do countries around the globe find the balance? How do agencies regulate and adhere to the principles of the Agreement? This talk will give a brief overview of the TBT Agreement, the Committee that works to implement and enforce the Agreement, and what agencies need to consider with regards to regulations, policy, standards, and conformity assessment.

Kent Shigetomi, Acting Assistant U.S. Trade Representative, Office of WTO and Multilateral Affairs, Office of the United States Trade Representative (USTR)

Wednesday, March 23, 2022

Seminar #5 Standards Development

1:00-3:00 PM EST | Welcome

Mary Jo DiBernardo, Program Manager, Standards Services, Standards Coordination Office (SCO), NIST

Standards Development Organizations

Learn about some of the similarities and differences between voluntary consensus standards, codes, and open standards.

ASTM International

ASTM International is a globally recognized leader in the development and delivery of voluntary consensus standards. Today, over 12,000 ASTM standards are used around the world to improve product quality, enhance health and safety, strengthen market access and trade, and build consumer confidence.

Jeff Grove, Vice-President, Global Policy and Communications, ASTM International

U.S. Representation in the International Organization for Standardization (ISO)

ANSI is the sole U.S. representative and full member of ISO. Learn about ISO's standards development process and how you can get involved.

Steven Cornish, Senior Director, International Policy and Strategy, American National Standards Institute (ANSI)

U.S. Representation in the International Telecommunications Union (ITU)

A discussion on the ITU process and governance, including the growing interest in standards development in countries such as China and Korea.

Paul Najarian, Foreign Affairs Officer, U.S. Department of State

Open Geospatial Consortium (OGC)

OGC is a not-for-profit international organization that pulls together a global community of geospatial experts to develop and promote open consensus-based standards for geospatial information and services. With location being at the center of everything nowadays, OGC's standards and best practices are critical to data integration in a variety of domains like Environment, Disaster management & response, Health, Defense, Agriculture, Digital twins, Meteorology and more. Our 550+ government, industry and academia members are building the future of Location and making geospatial information FAIR (Findable Accessible Interoperable and Reusable).

Nadine Alameh, CEO, OGC

Scott Simmons, Chief Standards Officer, OGC

International Code Council (ICC)

The ICC develops model codes and standards used in the design, build, and compliance process to construct safe, sustainable, affordable, and resilient structures. Members include state, county and municipal code

enforcement and fire officials, architects, engineers, builders, contractors, elected officials, manufacturers, and others in the construction industry.

Gabe Maser, Senior Vice President of Government Relations and National Strategy, ICC

Thursday, March 24, 2022

Seminar #6 The Big Picture Revisited and Lessons Learned

1:00-3:00 PM EST | Welcome

Warren Merkel, Leader, Standards Services, SCO, NIST

Case Study #1: Barrier Face Coverings in Response to COVID-19
Jennifer Marshall, Program Manager, Standards Services, SCO, NIST

Case Study #2: Ballistic-Resistant Shields

Cassy Robinson, Physical Scientist, Standards Services, SCO, NIST

Choosing and Using Standards

A discussion on the attributes of standards and standards development processes for federal agency consideration in the context of carrying out their mission in determining if a standard(s) is "fit for purpose."

Gordon Gillerman, Director, SCO, NIST

Q&A and Closing Remarks

Warren Merkel, Leader, Standards Services, SCO, NIST