Welcome to ANSI’s World Accreditation Day Webinar

PLEASE NOTE:
Everyone is MUTED; please send questions via “Questions” option

Q&A follows the presentations
Thanks for Your Participation

- Lane Hallenbeck, ANSI VP Accreditation Services is your host today
  - All webinar participants are muted
  - If you are participating via laptop, you may need to adjust the sound on your computer
  - If you hear an echo, please hang up and dial in again
  - If the webinar slides do not display, please check that you have installed the software correctly - you may need to reinstall
Webinar Protocol

- **Questions**
  - Will be answered as time allows at the end of the presentation
  - Use the “Q&A” option and type a brief question
  - All other questions may be sent to kcalder@ansi.org

- If anyone has a problem during the webinar, please send an email to kcalder@ansi.org
The ANSI Federation represents more than **125,000 companies and organizations** and **3.5 million professionals** worldwide.

**Members of the ANSI Federation include . . .**

- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations
- Professional Societies
- Service Organizations
- Standards Developers
- Consumer and Labor Interests
- and many more
World Accreditation Day
9 June 2015

Confidence
Accreditation
Competence
Action
Trust
Value
Consistency
Acceptance
Health
Party
Environment
System
Specification
Cost
Reliability
Regulation
Conformity
Interoperability
Personnel
Improvement
Improvement
Risk
1st
Cost
Safety
2nd
Cost
Assurance
Cost
3rd
Trust
Cost
Preventive
Verification
Harmonization
Validation
Certification
Declaration
Standard
Process
Product
Benefit
Procedure
ANSI Collaboratives and Workshops

1994
Information Infrastructure Standards Panel

2003
Homeland Defense and Security Standardization Collaborative

2004
Nanotechnology Standards Panel

2005
Healthcare Information Technology Standards Panel

2006
ID Theft Prevention and ID Management Standards Panel

2007
Biofuels Standards Coordination Panel

2007
ANSI Network on Chemical Regulation

2009
Workshop Toward Product Standards for Sustainability

2009
ANSI-NIST Nuclear Energy Standards Coordination Collaborative

2010
The Financial Management of Cyber Risk

2011
ANSI Electric Vehicles Standards Panel

2012
ANSI Energy Efficiency Standards Coordination Collaborative

2013
ANSI Network on Smart and Sustainable Cities
World Accreditation Day
9 June 2015

Accreditation: Supporting the Delivery of Health and Social Care

Panelist:

Kathy Abusow
President and CEO
Sustainable Forestry Initiative
More Than a Standard
GOVERNANCE: SFI BOARD OF DIRECTORS

The Board has three chambers, representing environmental, social and economic sectors equally.

At every point in the supply chain, SFI has a relevant standard to support responsible forestry:

- SFI 2015-2019 Forest Management Standard
- SFI 2015-2019 Fiber Sourcing Standard
- SFI 2015-2019 Chain-of-Custody Standard
SFI Depends On Accreditation Bodies

- SFI relies on the International Accreditation Forum structure and processes
- Great value to SFI through independent oversight of certification bodies and audits
- Assurance of a credible audit and independent mechanism to handle complaints
Independent Certification Bodies

ACCREDITED CERTIFICATION BODIES DELIVERING AUDITS TO SFI STANDARDS

- Independent verification of conformance
- Credibility with stakeholders
- Transparency of audits disclosed in public summaries.
World Accreditation Day

9 June 2015

Accreditation: Supporting the Delivery of Health and Social Care

Panelist:

Scott Colburn

Director, CDRH Standards Program

U.S. Food and Drug Administration
Standards at USFDA/CDRH
Center for Devices and Radiological Health

- Food & Drug Administration Modernization Act
  - Enacted in 1997
  - Requires the “recognition” of standards to help expedite premarket review
  - Requires allowance for a “declaration of conformity” to standards

- 21 USC Section 514(c) Recognition of standard
  (1)(A)…”by publication in the FR, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket requirement or other applicable requirement under this chapter to which such standard is applicable”
Declaration of Conformity - What does it mean?

Conformance ≠ Equivalence
Conformance ≠ Clearance
Conformance ≠ Approval
Recognition of Standards

Since FDAMA, CDRH is currently “recognizing” ~ 1200 medical device related voluntary consensus standards.

CDRH is currently, participating in ~600 individual national and international standards committees/working groups.
Why Standards (besides the U.S. law)?

- Improve time to market for safe and effective medical devices and other health care products
- Facilitates product design and performance
- Continually raises the bar on safety and effectiveness
- Facilitates communication between regulators and industry
- Serves as education for FDA scientists

*FDA/CDRH believes that conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices.*

*Therefore, information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made.*
Panelist:

Dale R. Cyr

CEO

American Registry for Diagnostic Medical Sonography

Improving Global Health Using Medical Ultrasound
ARDMS

- Globally recognized in ultrasound certification;
- Founded in 1975;
- 90,000 Active Registrants/Certificants;
  - sonographers;
  - physicians;
- Testing in 28 countries;
- All test development and psychometrics are in-house;
Global Health and Ultrasound

Experts

Point-Of-Care
Global Health and the ISO 17024 Standard

- Assures patients in any healthcare environment and practice that providers have obtained valid and reliable (meaningful) certification(s);
- Demonstrating proficiency in the use of ultrasound in many clinical settings;
- Improves effectiveness of ultrasound diagnoses and efficiencies in clinical care;
- The ISO 17024 accreditation standard allows organisations to provide quality-based policies and procedures for consistency and scalability.
Professional society

- Those interested in health technology
- Not a trade association/no advocacy!

7,000+ members

- Industry, technology professionals, engineers, clinicians, academics, researchers, consultants, regulators, HDOs, companies

Accredited ANSI Standards Developer

- ~130 U.S. committees
- Twelve ISO or IEC Secretariats/21 TAGs
- 2000+ participants

AAMI Credentials Institute

- Seeking ANSI accreditation
- Certifies HTMs and industry professionals
- (Future) Accredit supporting education programs
AAMI Members

• Accredited by accreditation agencies (Joint Commission, HFAP, DNV)
• Accreditation required by CMS for reimbursement under Medicare/Medicaid

Healthcare providers

• Certify compliance with standards
• Self-certification or by third parties
• Certification of compliance sometimes required by regulation

Medical device manufacturers
Benefits of accreditation

Assurance of Competence

Public, Patients, Regulators, Professionals

Integrity

Safety & Efficacy

Reduction of Risk
Panelist:

Alicia Morton

Director

Office of the National Coordinator, Health Information Technology

U.S. Department of Health and Human Service
About ONC

The Office of the National Coordinator for Health Information Technology (ONC) is:

- at the forefront of the nation’s efforts to modernize healthcare.
- is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.

Coordinator, Convener & Enabler
ONC’s History

- **2004**: Executive Order establishes the Office of the National Coordinator for Health IT
- **2005**: Initial funding provided to create the Certification Commission for Health IT
- **2009**: ONC authority expands under the Health Information Technology for Economic and Clinical Health Act (HITECH)
- **2010**: First regulations governing the certification of Health IT are published
- **2012**: Update to certification rule published – focuses on health information exchange
ONC Health IT Certification Program Structure/Process

ONC reviews and posts certified product to CHPL

ONC “Scheme Owner” approves

ISO/IEC 17011

NIST NVLAP
National Voluntary Laboratory Accreditation Program accredits

ONC-AA
Approved Accreditor accredits

ISO/IEC 17065

ATL
Accredited Testing Laboratory performs testing against criteria

ONC-ACB
ONC-Authorized Certification Body certifies tested products

ISO/IEC 17025

NIST 150

NIST 150-31

Developer

Product successfully passes testing

Product successfully achieves certification

ANSI World Accreditation Day 2015 Webinar

Slide 28
Panelist:

Sharon Stanford

Director, Standards Administration

American Dental Association
American Dental Association - 
ANSI Accredited Standards Developing Organization

- The standards program supports the ANSI 
  accredited development of voluntary consensus 
  standards for safe and effective dental products
- Standards help members integrate with confidence 
  current/emerging technologies used in dental practice
- Levels the playing field in choosing the right products 
  for patients and ultimately lowers costs
- Facilitates interoperability necessary in today’s 
  healthcare environment to support data portability 
  across healthcare in the delivery of patient care in 
  complex multidisciplinary cases
Why Do We Support ANSI Accreditation?

- Assurance that...
  - Standards accurately represent the prevailing science and technology in the field
  - Standards provide appropriate requirements for safety and effectiveness facilitating the improvement and quality of oral health and the safety of dental care

- Partnerships and Collaboration
  - Provide wide stakeholder participation that improves information flow between manufacturers, the dental profession, academics and government regulators
  - Helps breaks down trade barriers thus making a wider range of products available to more people
Why Do We Support ANSI Accreditation?

Supply Chain Accountability

- Illegal products pose “a real risk to patients” as the counterfeit materials may not meet US safety standards
- By certifying to “accredited” standards, conformity assessment/regulatory bodies can be confident that those products meet the appropriate requirements necessary to ensure the integrity of today’s healthcare system
- Standards facilitate the availability of authentic materials and devices that meet important clinical requirements, stimulate development of improved products, and help ensure successful clinical outcomes
Panelist:

Patricia Tanabe

Executive Director

American Society for Clinical Pathology Board of Certification
2014-2015 Board of Governors

13 Examination Committees & 5 Qualification Work Groups
<table>
<thead>
<tr>
<th>BOC Sponsoring, Participating, and Collaborating Societies</th>
<th>Allied Health, Health Science &amp; Clinical Laboratory Science Educational Program Accreditation Agencies</th>
<th>Laboratory Accreditation Agencies</th>
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How does the accreditation support the delivery of health and social care?

Panelists:
- Kathy Abusow - Sustainable Forestry Initiative
- Scott Colburn - US FDA
- Dale Cyr - American Registry for Diagnostic Medical Sonography
- Joe Lewelling - Association for the Advancement of Medical Instrumentation
- Alicia Morton - Office of the National Coordinator, Health Information Technology
- Sharon Stanford - American Dental Association
- Patricia Tanabe - American Society for Clinical Pathology

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What are the benefits of accreditation?

Panelists:
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International aspects of accreditation

Panelists:
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Trends and growth opportunities

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For More Information:
www.ansi.org/accreditation

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