

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



World Accreditation Day

9 June 2015



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



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



Panelist:

Kathy Abusow

President and CEO

Sustainable Forestry Initiative

More Than a Standard

Accreditation: Supporting the Delivery of Health and Social Care



Sustainable Forestry Initiative

GOVERNANCE: SFI BOARD OF DIRECTORS

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

Environmental Sector	Social Sector	Economic Sector
 Ducks Unlimited Canada <small>Conserving Canada's Wetlands</small>	 Habitat for Humanity Habitat pour l'humanité <small>Canada</small>	 Time Inc.
 Canadian Council on Invasive Species	 UNIVERSITY OF TORONTO FACULTY OF FORESTRY	 MILLAR WESTERN
 MANOMET <small>Center for Conservation Science</small>	 UNITED STEELWORKERS USW WOOD COUNCIL	 Senwix Resources <small>A FIRST NATIONS COMPANY</small>
 WILDLIFE SOCIETY	 SFA	 Hancock Natural Resource Group®
 NatureServe®	 VIRGINIA DEPARTMENT OF FORESTRY	 GP Georgia-Pacific <small>Making Life's Simple Necessities.™</small>
	 Cypress Bay	 RMS <small>Resource Management Service, LLC</small>



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



Standards Council of Canada
Conseil canadien des normes

- 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

BM TRADA

BNQ
Bureau de normalisation
du Québec



DNV·GL

KPMG



ORI
Orion Registrar, Inc.
Thorough and Fair Auditing

pwc

QMI
SAI GLOBAL

SGS



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

World Accreditation Day

9 June 2015



Panelist:

Scott Colburn

Director, CDRH Standards Program

U.S. Food and Drug Administration

Accreditation: Supporting the Delivery of Health and Social Care



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 \neq Equivalence

Conformance \neq Clearance

Conformance \neq 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.*

World Accreditation Day

9 June 2015



Panelist:

Dale R. Cyr

CEO

American Registry for
Diagnostic Medical
Sonography

Improving Global Health
Using Medical Ultrasound

Accreditation: Supporting the Delivery of Health and Social Care



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;
- 2005: ANSI-ISO 17024 accreditation.

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

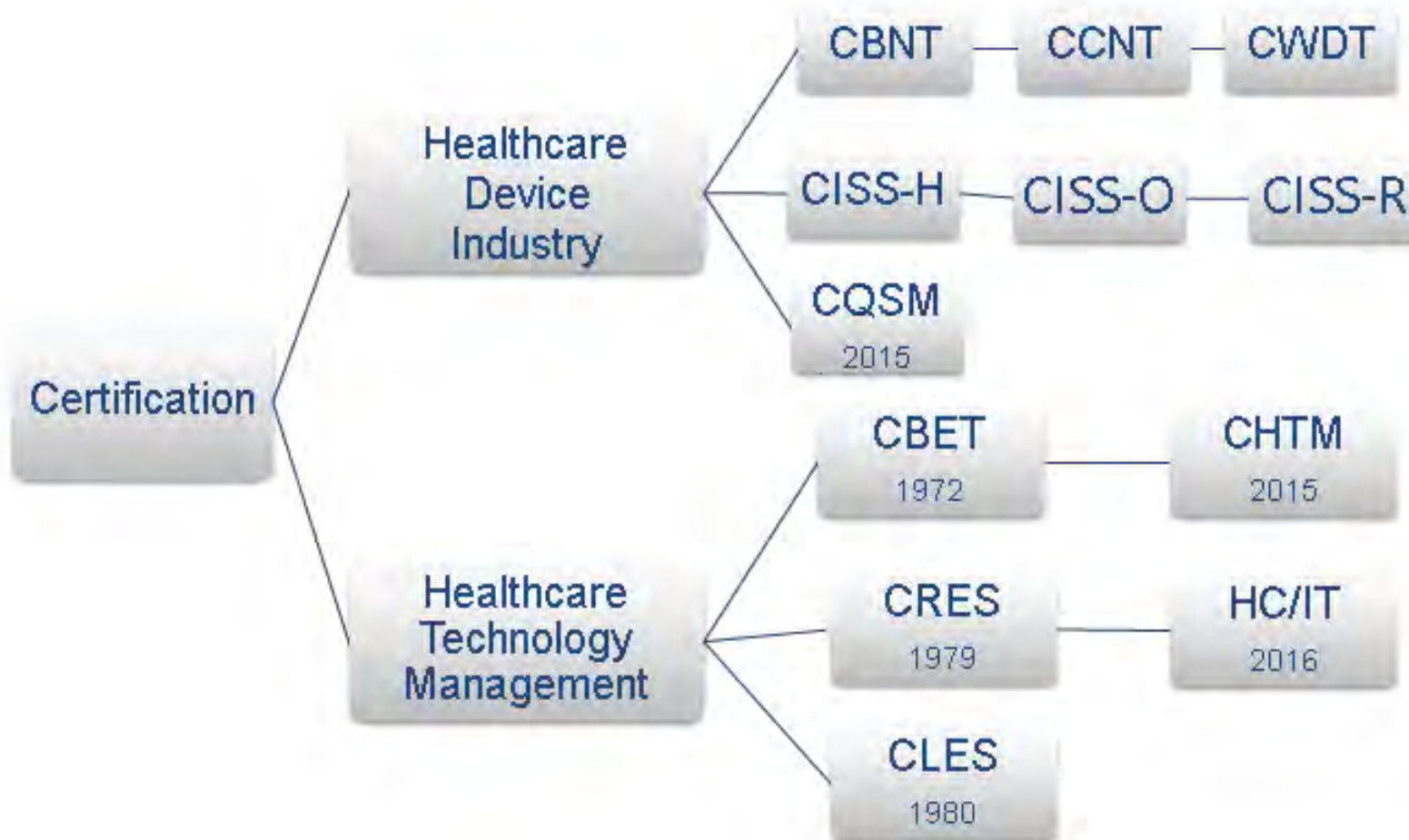
**AAMI Credentials
Institute**

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

ACI AAMI Credentials Institute

World
Accreditation Day

9 June 2015



AAMI Members



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

Healthcare providers



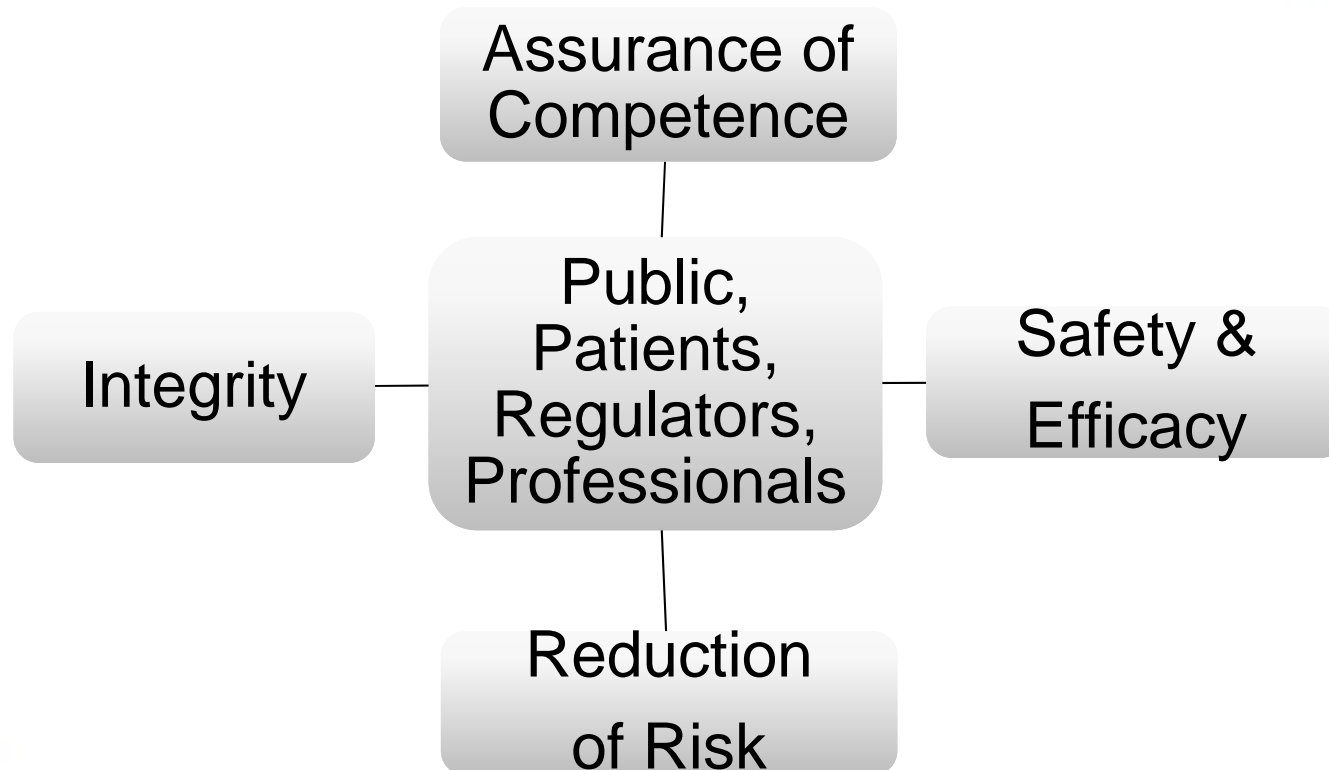
- Certify compliance with standards
- Self-certification or by third parties
- Certification of compliance sometimes required by regulation

Medical device manufacturers





Benefits of accreditation



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



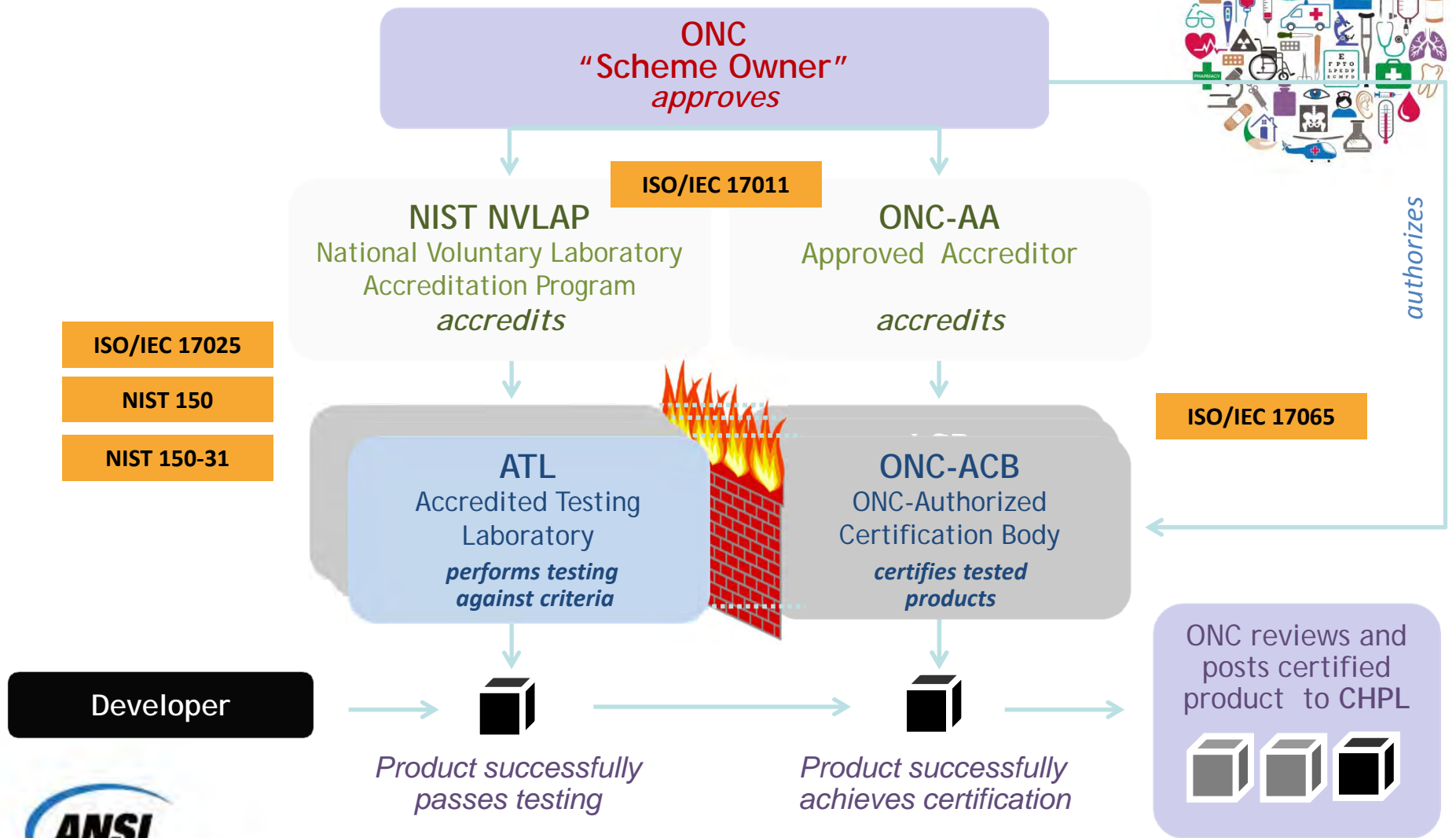
M
I
L
E
S
T
O
N
E
S



ONC Health IT Certification Program Structure/Process

World Accreditation Day

9 June 2015



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





ASCP
**BOARD OF
CERTIFICATION®**

**World
Accreditation Day**

9 June 2015



Pat Tanabe, MPA, MLS(ASCP)^{CM}
Executive Director

BOC Staff





ASCP
BOARD OF
CERTIFICATION®

World
Accreditation Day

9 June 2015



2014-2015 Board of Governors



13 Examination Committees & 5 Qualification Work Groups





ASCP
BOARD OF
CERTIFICATION®



BOC Sponsoring, Participating, and Collaborating Societies	Allied Health, Health Science & Clinical Laboratory Science Educational Program Accreditation Agencies	Laboratory Accreditation Agencies
  		
  	 <p>Commission on Accreditation of Allied Health Education Programs</p>	
  	 <p>National Accrediting Agency for Clinical Laboratory Sciences</p>	
 		

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

Questions?

- Use the “Q&A” option and type a brief description
- All other questions may be sent to kcalder@ansi.org

What are the benefits of accreditation?

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

Questions?

- Use the “Q&A” option and type a brief description
- All other questions may be sent to kcalder@ansi.org



International aspects of accreditation



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

Questions?

- Use the “Q&A” option and type a brief description
- All other questions may be sent to kcalder@ansi.org

Trends and growth opportunities



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

Questions?

- Use the “Q&A” option and type a brief description
- All other questions may be sent to kcalder@ansi.org



QUESTIONS?

- Use the “Q&A” option and type a brief description
- All other questions may be sent to kcalder@ansi.org

For More Information:
www.ansi.org/accreditation

World Accreditation Day

9 June 2015



Accreditation: Supporting the Delivery of Health and Social Care



American National Standards Institute

Lane Hallenbeck

Vice President, Accreditation Services

lhallenb@ansi.org

Katie Calder

Director, Accreditation Services

kcalder@ansi.org

ANSI Headquarters

1899 L Street, NW

11th Floor

Washington, DC 20036

T: 202.293.8020

F: 202.293.9287

