



USNC Conformity Assessment Policy Coordination Committee  
DRAFT MINUTES

Hosted by Association for the Advancement of Medical Instrumentation  
901 N. Glebe Road, Suite 300  
Arlington, VA 22203

Tuesday, 17 September 2019  
9:00 am – 4:00 pm (EDT)  
(Meeting #30)

**Members Participating**

Tim Duffy – USNC VP CA, Chair  
Steve Margis – USNC CAPCC Vice-Chair  
Wynn Bowman  
Dan Brake  
Elisabeth George  
Paul Green  
George Kelly  
Paul Kelly  
Bill Lawrence  
Evans Massey  
Edward Mikoski  
Paul Moliski  
Amy Phelps  
Joel Solis  
Joan Sterling  
Jianchao Zeng  
Kevin Lippert, USNC President  
Sonya Bird, USNC VP - Technical  
Steven Rood, USNC VP - Finance  
Tony Zertuche, General Secretary

Rockwell Automation  
UL  
Star Associates International  
NextEra Energy  
Philips  
Intel  
ARESCA  
UL  
FM Approvals LLC  
ABB Incorporated  
ECIA  
Intertek  
NIST  
NEMA  
Intertek  
FDA  
Eaton  
UL  
Legrand, North and Central America  
USNC / ANSI

**Guests Participating**

Hae Choe  
Bill Fiske  
Kazimier Gawrzyjal  
Adelana Gladstein  
Megan Hayes  
Byron Horak  
Jennifer Kitchen  
Bob Kretschmann+  
Dave Osborn  
Kristen Palma  
Kevin Robinson

AAMI  
Intertek  
Dell Technologies  
USNC/ANSI  
NEMA  
Intertek  
GE  
Rockwell Automation  
Philips  
USNC/ANSI  
OSHA

## **Members Not Participating**

Gabriel Alsenas	Florida Atlantic University
Don Baker	CTrends
Jonathan Colby	Verdant Power
Ed Donahue	Mutual Cornell Environmental
Ryan Franks	CSA Group
Lane Hallenbeck	ANSI
Ben Johnson	Thermon Industries
F. Scott Kiddle	ABB Incorporated
Richard McDermott	ECC Corp
Kevin Wolf	Intertek
Michael Woodford	AHRI

+ = Part Time

## **Section 1 – Welcome, Opening Remarks and Introductions**

### **1.1 Welcome, Opening Remarks, Introductions**

Mr. Tim Duffy called the meeting to order at 9:00 AM (EDT). Mr. Duffy thanked everyone for attending. Ms. Jen Padberg welcomed all to AAMI and then provided meeting and venue logistics.

Mr. Duffy noted that this will be his last CAPCC meeting as Vice President – Conformity Assessment and Chair of the committee.

He also drew attention to and congratulated the following ANSI Award Winners and IEC 1906 Award Winners of the USNC Constituency:

- Finegan Standards Medal awarded to William Lawrence
- George S. Wham Leadership Medal awarded to Captain Scott Colburn
- Gerald H. Ritterbusch Conformity Assessment Medal awarded to Paul Moliski
- Maureen Breitenberg Conformity Assessment Research Medal awarded to Amy Phelps
- Meritorious Service Awards awarded to Hae Choe, Jonathan Colby, Robert Kretschmann, Florence Otieno, Peter Pondillo, and Evans Massey
- IEC 1906 Winners include Daniel Delaney, Jeffrey Hall, and Wallace Eber

Mr. Tony Zertuche drew attention to the newly updated [USNC webpages](#). He thanked Anna Zeng, the USNC’s summer intern for her time and dedication to getting this longstanding project done.

### **1.2 Approval of Draft Agenda**

Mr. Duffy drew attention to the meeting's agenda, **USNC/CAPCC 243A**. No comments were offered. It was moved, seconded and

**VOTE #1 To Approve the Agenda (USNC/CAPCC 243A)  
(This motion was approved unanimously)**

#### **1.2.1 Approval of Consent Agenda**

(a) **Approval of the Minutes**

Mr. Duffy drew attention to the minutes from the April 2019 meeting at Rockwell Automation in Milwaukee, WI. No comments were offered. It was moved, seconded and

**VOTE #2 To Approve the Minutes from the CAPCC Meeting at Rockwell Automation in April 2019 (USNC/CAPCC 242)  
(This motion was approved unanimously)**

**1.2.2 Value of Participation in the USNC CAPCC**

Mr. Duffy discussed **USNC/CAPCC 246**, the document of questions regarding what is the value of participation in the USNC CAPCC. These questions will be distributed as a survey to the CAPCC membership (**ACTION ITEM #2019-09-01**).

**Section 2 – Outstanding Action Items**

The USNC Officers would like the USNC Staff will create a spreadsheet of the USNC policy committees (Council, TMC, & CAPCC) action items (**ACTION ITEM #2019-09-02**).

**#2018-01-04** – The USNC Staff completed the first draft of the USNC Meeting Guide. This guide will be distributed shortly for review by the CAPCC, Council and TMC.

**Status: Completed**

**#2018-04-01** – Ms. Amy Phelps will reach out to Mr. Gordon Gillerman of NIST for more information regarding possible workshops or information sessions on electronic labeling and its possible implementation by federal agencies.

**Status: Completed**

**#2019-04-02** – The Draft Harmonized Operating Procedures for the US CA Systems will be circulated to membership for comment for 30 days.

**Status: Completed**

**#2019-04-03** – The USNC CAPCC Communications Working Group’s Terms of Reference will be circulated for comment.

**Status: Completed**

**#2019-04-04** – The USNC Staff will circulate the call for the position of CAPCC Vice-Chair and CAB Alternate.

**Status: Completed**

**Section 3 – OSHA Nationally Recognized Testing Laboratory (NRTL) Directive**

Mr. Kevin Robinson provided a status update on the OSHA Nationally Recognized Testing Laboratory (NRTL) Directive. This update of the existing NRTL directive will be aligned with 17025 and 17065. Mr. Robinson noted that OSHA will be assisting with the transition into the new directive. There will be an informational meeting for all of the NRTLs to review and receive clarification on the new directive on October 24<sup>th</sup> following the American Council for Electrical Safety meeting at NEMA headquarters.

Mr. Robinson noted that there will be revisions and incremental updates at about three years following the distribution of the new directive.

#### **Section 4 – ASCA Pilot Program Overview Strategy**

Mr. Jianchao Zeng provided an overview, **USNC/CAPCC 248**, on the Accreditation Scheme for Conformity Assessment (ASCA) pilot program.

Following the presentation, Mr. Zeng addressed concerns regarding effective communication with test labs (TL) by noting that FDA is working with regional affairs professionals (RAPS) to make sure that the ASCA pilot program is understood.

For additional questions and concerns regarding accreditation body requirements, implications of an accreditation body or testing laboratory, and the Declaration of Conformity – please see the guidance document at the following [link](#).

#### **Section 5 – USNC CAPCC Subcommittee on the USNC Conformity Assessment Mirror Committee Operating Procedures**

Mr. Steve Margis reported on the activities of the CAPCC Subcommittee. The resolution of comments will be submitted with the final draft USNC Conformity Assessment Mirror Committee Operating Procedures, **USNC/CAPCC 249**, and Supplement, **USNC/CAPCC 250 (ACTION ITEM #2019-09-03)**. The USNC Staff will send out the draft USNC CA Mirror Committee Operating Procedures for a two week ballot (**ACTION ITEM #2019-09-04**).

It was stated that any supplement not submitted and approved by 1 January 2020 will require the corresponding USNC Mirror Committee to default to the basic operating procedures. Each mirror committee is encouraged to modify the supplement to fit their needs.

On this topic, USNC/IECEX noted that they are looking to add a status of Member Emeriti. As an example of process, the committee may include the renewable membership role into their supplement. That resulting document will then be reviewed by the Subcommittee on USNC CA Mirror Committee Operating Procedures for alignment, and then will be submitted for USNC CAPCC approval.

#### **Section 6 – USNC CAPCC Terms of Reference**

Mr. Margis reported on the draft USNC CAPCC Terms of Reference, **USNC/CAPCC 251**, to be approved as part of the USNC Rules of Procedures (ROP).

Mr. Margis drew attention the draft ROP, and noted that under Annex A, Section C, Membership - Subsection c, it is noted that the “chair of each system is ex-officio member of USNC Council”. The USNC Staff will resolve the statement under draft USNC Rules of Procedure, Annex A, Section C, Membership - Subsection c (**ACTION ITEM #2019-09-05**).

#### **Section 7 – Status Report on the USNC CAPCC Regulatory Labeling Task Force**

Mr. Richard McDermott provided a written report, **USNC/CAPCC 252**, on the USNC CAPCC Regulatory Labeling Task Force.

The members present began a discussion on the purpose and goals of the task force. There was also discussion around where and how U.S. input was being developed for ISO JTC 1/ SC 31/ WG 8. It was also raised that there are new different version types for the CD 22603 standard. Amongst the group there was expressed concern over who is keeping track of new information as it is circulated. The USNC Staff will schedule a USNC CAPCC Regulatory Labeling Task Force meeting to address the purpose and questions raised at the September USNC CAPCC meeting (**ACTION ITEM #2019-09-06**).

#### **Section 8 – Status Report on USNC CAPCC Communications Working Group**

Mr. Jonathan Colby provided a written report, **USNC/CAPCC 253**, on the CAPCC Communications Working Group.

The USNC Communications Working Group will have the Conformity Assessment 101 by the end of the year. Mr. Paul Moliski will replace Mr. Gary Schrempp as the presenter in the webinar. The working group will continue to coordinate with our federal colleagues in order to get appropriate help and input for and from the webinar.

## **Section 9 – Liaison Reports**

**9.1 ANSI Conformity Assessment Policy Committee (CAPC)** – The last ANSI CAPC meeting will take place on 8 November 2019. The purpose and agenda of this meeting has not yet been identified, and a new ANSI conformity assessment body has not yet been formed.

**9.2 ANSI International Conformity Assessment Committee (ICAC)** – Mr. Duffy announced to the committee that ICAC will become an ANSI TAG. Mr. Keith Mowry will also be stepping down as the chair of ICAC following this transition period for the committee to become a TAG.

Mr. Duffy drew attention to an ICAC Summary of CASCO Ballots and Resolutions, **USNC/CAPCC 244**, which was distributed with the agenda for the CAPCC meeting.

## **Section 10 – Reports on the Conformity Assessment Systems**

**10.1 IECRE and USNC/IECRE** – Mr. Bob Sherwin provided a report, **USNC/CAPCC 254**, on the activities of IECRE and the USNC/IECRE.

Mr. Sherwin drew attention to a few major points in his presentation, including:

- Continued upset by committee membership over the U.S. supplemental invoices due to the financial issues at IECRE
- ARESA published a whitepaper on Conformity Assessment in the Wind Energy Industry. The USNC Staff will circulate ARESA's link and whitepaper on Conformity Assessment in the Wind Energy Industry (**ACTION ITEM #2019-09-07**). This whitepaper will also be published in the USNC Current.
- The 2021 W-OMC meetings will be hosted by USNC/IECRE

**10.2 IECEE and USNC/IECEE** – Mr. Duffy provided a status report on the activities of the IECEE and the USNC/IECEE. Mr. Duffy drew attention to the distributed USNC/IECEE report, **USNC/CAPCC 255**. The next IECEE CMC meeting will take place in Montego Bay, Jamaica in June of 2020.

**10.3 IECEx and USNC/IECEX** – Mr. Evans Massey provided a status report on the activities of the IECEx and the USNC/IECEX. Mr. Massey drew attention to the distributed USNC/IECEX report, **USNC/CAPCC 256**. He noted that Mr. F. Scott Kiddle is leading an effort in user outreach.

**10.4 IECQ and USNC/IECQ** – Mr. Ed Mikoski and Mr. Wynn Bowman reported on the activities of the IECQ and the USNC/IECQ, **USNC/CAPCC 257**. It was noted that IEC CA Systems may need to decouple their logos from the IEC logo.

## **Section 11 – Status Report on US Government Activities Related to Conformity Assessment**

Ms. Amy Phelps reported on US Government activities related to conformity assessment.

She noted that NIST held a workshop on cyber standards, and that the outcome and next steps will be shared with committee members as necessary.

## **Section 12 – IEC Conformity Assessment Board Issues**

### **12.1 Review of CAB Decision List, CAB/1877/DL, from Meeting on 18 June 2019 in Geneva, Switzerland** – Mr. Duffy drew attention to a few items from the Decision List including:

- That each IEC CA System Supplement has been approved for the Harmonized Basic Rules IEC CA 01
- CAB Decision 45/14 – Proposal for clarification in IEC CA 01 concerning officer positions
- The CAB ahG created to review CAB/1840/DC and CAB/1840A/CC will have their next meeting in December

### **12.2 Review of IEC CAB October 2019 Agenda** – Mr. Duffy reviewed the IEC CAB Agenda, CAB/1899/DA, for the October 2019 meeting in Shanghai.

### **12.3 IEC CAB Elections**

1. As noted in C/2215/INF, appointment by Council in Shanghai of two “Automatically Appointed Members” of the Conformity Assessment Board (CAB) for a three-year term of office (2020-2022):
  - a. **Mr Pierre SELVA** (France)
  - b. **Ms Joan STERLING** (United States)
2. As noted in C/2216/INF, election/re-election by Council in Shanghai of 2 members of the Conformity Assessment Board (CAB) for a three-year term of office (2020-2022):
  - a. **Mr Gustavo KUSTER** (Brazil)
  - b. **Mr Rafael Luis NAVA Y URIBE** (Mexico)

## **Section 13 – IEC 83rd General Meeting on 22 October 2019 in Shanghai**

- **IEC International Symposium - Using IEC standardization work to support medical device regulation**
  - Saturday, 19 October 2019Mr. Margis raised that there will be an invite-only IEC 2019 Regulators Symposium, he relayed that he will report out on the events at the next CAPCC meeting. The USNC Staff will distribute the IEC 2019 Regulators Symposium Flyer & Agenda (**ACTION ITEM #2019-09-08**).
- **Tri-National Meeting and Reception**
  - Sunday, 20 October 2019 (with Canada and Mexico)The USNC Staff will circulate the Cvent for the Tri-National Meeting and Reception taking place at the 2019 IEC GM (**ACTION ITEM #2019-09-09**).
- **Asia Pacific Reception**
  - Tuesday, 22 October 2019

- **Bilateral Meetings**

Mr. Zertuche drew attention to the countries that the USNC will have bilateral meetings with. He encouraged everyone to submit agenda topics, and reminded all to have a comprehensive request or topics that can lead to productive conversation. CAPCC Members must submit agenda topics for bilateral meetings (**ACTION ITEM #2019-09-10**).

- Australia
- CENELEC
- Germany
- China
- Japan
- South Korea
- USNC/IEC Officers

#### **Section 14 - Conformity Assessment Issues in the Americas**

Mr. Paul Moliski provided a brief update to CAPCC about CA issues from his perspective as the Chair of the ANSI RSC-Americas.

Mr. Moliski noted that there will be tentative outputs from Brazil through the World Trade Organization's Technical Barriers to Trade in an effort to identify bureaucratic issues.

The members around the room also discussed the Philippines' development of their own Safety Mark (PS). CAPCC members present have submitted the following informational links on the Philippine Safety Mark:

- [https://www.tuv.com/market-access-services/en/certification-filter/philippine-standard-\(ps\)-certification-mark.html](https://www.tuv.com/market-access-services/en/certification-filter/philippine-standard-(ps)-certification-mark.html)
- <http://www.bps.dti.gov.ph/index.php/product-certification/list-of-products-under-mandatory-certification>
- <https://www.export.gov/article?id=Philippines-Labeling-Marking-Requirements>

#### **Section 15 – USNC Interface with Other Regional & International Organizations**

Mr. Zertuche provided regional updates:

##### **14.1 FINCA – 25-27 September 2019**

The USNC will be hosting FINCA in 2020. The USNC is open to interested hosts and sponsors for this next meeting.

##### **14.2 APCF at the IEC GM**

##### **14.3 German NC Bilateral Meeting – Held in Hamburg 19-20 August 2019**

The USNC had a successful meeting with German counterparts. The main issue that was discussed was the IEC governance review. Mr. Zertuche recognized that an important current event for the USNC and the other national committees is the hiring of the new General Secretary. Mr. Jim Shannon relayed that there will be a governance review for the new General Secretary to make a comprehensive assessment of the existing IEC structure. Mr. Zertuche also let the group know that

there will be German bilateral meeting on Thursday, October 24<sup>th</sup>, at night in Shanghai.

### **14.3 USNC Country Mentoring Program – Vietnam and CROSQ**

#### **(a) CROSQ collaboration with 2020 IECEE Meeting**

Mr. Zertuche announced that there will be a collaboration between the IECEE and CROSQ in Jamaica, before the IECEE CMC on 1 – 2 June 2020.

### **Section 16 – USNC and CAPCC/CAB Meeting Schedule 2019 and Beyond**

Mr. Duffy reviewed the upcoming USNC and international meeting schedule for the 2019 year and beyond. Mr. Zertuche brought special attention to the USNC Young and Emerging Professionals Summit which will take place on Friday, November 8 in Washington, DC at the National Housing Center, from 8:30 am to 5:00 pm ET.

### **Section 17 – Adjournment**

Mr. Duffy thanked all those in attendance and adjourned the CAPCC meeting at 4:06 PM (EDT).