



**USNC COUNCIL  
DRAFT MINUTES**

**Hosted by the Association for the Advancement  
of Medical Instrumentation  
901 North Glebe Road  
Arlington, VA 22203**

**Thursday, 19 September 2019  
9:00 am – 4:00 PM (EDT)  
(Meeting #57)**

**Members Participating**

Kevin Lippert, USNC President	Eaton
Steven Rood, USNC VP – Finance	Legrand North America
Tim Duffy, USNC VP – Conformity Assessment	Rockwell Automation
Sonya Bird, USNC VP – Technical	UL
Tony Zertuche, General Secretary	USNC/ANSI
Randy Dollar	Siemens
Kazimier (Kaz) Gawrzyjal	Dell
Elisabeth George	Philips
Veronica Lancaster	CTA
Angus Low	Rockwell Automation
Alan Manche	Schneider
Edward Mikoski	ECIA
Paul Moliski	Intertek
Jennifer Padberg	AAMI
Amy Phelps	NIST
Joan Sterling	Intertek
Karen Willis	NEMA
Jianchao Zeng	FDA

**Guests Participating**

Larry Albert+	Stanley, Black & Decker
David Bain	TIA
Ethan Biery*+	Lutron Electronics
Hae Choe	AAMI
Wallace Ebner+	ARESCA
Paul Green	Intel Corp
Jeffrey Hall+	UL
Donald Heirman	Don Heirman Consultants
Patrick Hughes+	NEMA
Mark Klerer+	Independent
Robert Kretschmann	Rockwell Automation
William Lawrence	FM Approvals
Yan Lu+	NIST

Steve Margis	UL
Evans Massey	ABB
Joe Musso	UL
Frank O'Brien+	O'Brian Compliance Management
Dave Osborn	Philips
Florence Otieno	TIA
Gowri Rajappan+	Doble Engineering Company
Lars Samuelsson+	ABS
Robert Sherwin	EAPC Wind
Roger Wicks+	DuPont
Adelana Gladstein	USNC/ANSI
Cara Magoon	USNC/ANSI

**Members Not Participating**

Joe Bhatia	ANSI
Mazen Chmaytelli	Qualcomm
Mark Earley	NFPA
Amy Marasco	Microsoft
James Marquedant	FM Approvals
Richard McDermott	ECC Corporation
Himanshu Patni	US DoD
Peter Pondillo	Corning Incorporated

\* = **Via Teleconference**

+ = **Part Time**

**Section 1 – Organizational Matters**

**1.1 Welcome and Introductions**

Mr. Kevin Lippert, USNC President and Council Chair, called the meeting to order at 9:00 AM (EDT) and thanked AAMI for hosting. Mr. Robert Jensen, AAMI President & CEO, provided a welcome to the Council meeting participants. Ms. Jennifer Padberg reviewed the logistics of the meeting space. Everyone in attendance provided introductions.

**1.2 Presentations of 1906 Awards**

Mr. Tony Zertuche reviewed the IEC 1906 Award recipients' accomplishments, while Mr. Lippert congratulated the recipients and presented the awards. Photos of the 1906 Award recipients were taken in the conference room and in the lobby.

**1.3 Approval of Agenda**

Mr. Lippert drew attention to the meeting agenda, and noted that the meeting would begin with Section 1.2 then revert to the listed order of agenda items. It was moved, seconded and

**VOTE #1 – To Approve the Council Agenda (USNC/Council 736)  
(This motion was approved)**

### **1.3.1 Approval of Consent Agenda**

Mr. Lippert drew attention to the consent agenda and the minutes from the USNC Council meeting on 2 May 2019 in Milwaukee, WI (USNC/Council 735). No comments were offered. It was moved, seconded and

**VOTE #2 – To Approve the Minutes from the Council Meeting in Milwaukee, WI (USNC/Council 735).  
(This motion was approved)**

### **1.3.2 Approval of Balance of Agenda**

No comments were offered.

## **Section 2 – Status of Outstanding Action Items**

Mr. Tony Zertuche reviewed the outstanding action items from the last Council meeting:

**ACTION ITEM #2019–2–1** – It was requested that the USNC staff look into how to put the list of USNC TAG Administrators and TAG officers back on the USNC website for easy access.

**Status: COMPLETED**

**ACTION ITEM #2019–2–2** – It was requested that the USNC staff look into developing an online calendar for all USNC meetings and events

**Status: PENDING**

**ACTION ITEM #2019–2–3** – The USNC Staff will circulate the FDA Discussion Paper on AI and Machine Learning in Software as a Medical Device.

**Status: COMPLETED**

*Secretary's Note: This action item was completed at the meeting. Please see **ATTACHMENT A** for additional information.*

**ACTION ITEM #2019–2–4** – The USNC Staff was asked to include a web link to ANSI's Code of Conduct policy on the USNC's Toolbox of Reference Documents webpage.

**Status: COMPLETED**

*Secretary's Note: This action item was reviewed and completed at the meeting.*

**ACTION ITEM #2019–2–5** – USNC Council members must submit their ballots for USNC Vice President – Conformity Assessment and USNC Nominations Committee Chair.

**Status: COMPLETED**

**ACTION ITEM #2019–1–9** – USNC members who are interested in hosting a set of USNC Management Meetings in 2020 at a US location are invited to contact Tony Zertuche.

**Status: COMPLETED**

*Secretary's Note: This action item was completed at the meeting as hosts and locations have been identified and confirmed for all of the Management Meetings in 2020.*

## **Section 3 – New IEC General Secretary and Governance Review**

Mr. Lippert led a discussion on the new IEC General Secretary and IEC governance and organizational structure. He noted that Mr. Jim Shannon, IEC President, has been as transparent as possible throughout the process of confirming the new General Secretary Mr. Philippe Metzger

**(ATTACHMENT B).** Mr. Shannon is proposing that there be a governance review team to make recommendations to the new General Secretary. Incoming IEC President, Dr. Yinbao Shu, will lead this effort. A USNC delegation met with their German counterparts in Hamburg, Germany for a bilateral meeting and the IEC governance review was the main topic discussed. One of the major action items was to the need to communicate with Mr. Shannon and Dr. Shu regarding the IEC governance review. Mr. Lippert reviewed the discussion topics with the Council members.

Mr. Zertuche noted that the IEC will send out invitations to the USNC to meet with Mr. Metzger at the 2019 General Meeting in Shanghai. USNC will also plan to invite Mr. Metzger to the US for a longer discussion – perhaps in New York.

#### **Section 4 – For Action – USNC Rules and Procedures Committee Report**

Mr. Angus Low reviewed the work of the Rules and Procedures Committee after the 25-26 July 2019 meeting focused on the revisions to the USNC Rules of Procedure (RoP) and the review of the draft USNC Council Operating Procedures from ANSI Legal. The next R&P Committee meeting has not been scheduled, but will likely be held in November or December 2019.

Mr. Low informed the Council that the R&P Committee reviewed the draft USNC Council Operating Procedures from ANSI Legal and had two main issues. The document quoted language that came out of various other USNC documents, such as Statutes and the Rules of Procedure. Mr. Low noted that R&P opted to add references to the documents as opposed to redundantly writing them again in the RoP.

Mr. Low then highlighted another issue within the document that needed to be reviewed by the Council extensively: the use of term “fiduciary responsibility.” Many USNC Council members felt that fiduciary responsibilities should end at the Board level instead of falling down to the Council or the Committees. The R&P Committee’s concerns and edits on these Council Operating Procedures were sent back to ANSI Legal. According to Ms. Patty Griffin, VP, General Counsel at ANSI, the document must retain language concerning the fiduciary responsibilities due to the revisions in the 2020 ANSI By-Laws.

The USNC staff will distribute the draft USNC Council Operating Procedures from ANSI Legal and the 2020 ANSI By-Laws to Council members (**ACTION ITEM #1**).

The Council drafted a list of questions for ANSI Legal regarding the fiduciary responsibility clause in the USNC Council Operating Procedures that were sent to Ms. Griffin for response.

Mr. Lippert, Mr. Low, and Mr. Zertuche indicated their desire to hold a teleconference with Ms. Griffin to discuss the extent of the fiduciary responsibilities further in detail.

#### **Section 5 – For Information – IEC Market Strategy Board (MSB) Report**

Mr. Scott Colburn submitted a written report. Mr. Jianchao Zeng provided a brief update on behalf of Mr. Colburn. For more information, please see **ATTACHMENT C**.

#### **Section 6 – For Information – IEC CAB / CAPCC Issues**

Mr. Tim Duffy, CAPCC Chair, provided a brief update on the CAPCC meeting held on 17 September 2019. Mr. Duffy highlighted several items including the value proposition of participating in the USNC and CAPCC. He also discussed the new format suggested for tracking CAPCC actions items. Mr. Duffy reported that the draft USNC CA Terms of Reference were sent to the R&P Committee and would be sent to Council for final approval. CAPCC discussed the OSHA Nationally Recognized Testing Laboratory (NRTL) Directive, which will be published in the next few weeks. Finally, the

CAPCC reviewed the upcoming CAB elections. For more information, please see **USNC/CAPCC 259 – Draft Minutes and Attachments**.

Mr. Lippert thanked Mr. Duffy for 7.5 years of service as Chair of the CAPCC and US CAB Member, Mr. Steve Margis for his service as Vice Chair and CAB Alternate, and welcomed Ms. Joan Sterling into the role USNC Vice President - Conformity Assessment.

#### **Section 7 – For Information – ASCA Pilot Program Overview**

Mr. Jianchao Zeng provided an overview on the Accreditation Scheme for Conformity Assessment (ASCA) pilot program (**ATTACHMENT D**). The draft guidance document will be published in a couple of weeks. There will be a public comment period and then a webinar to discuss this document in October 2019.

#### **Section 8 – For Information – IEC SMB / TMC Issues**

Ms. Sonya Bird, TMC Chair, provided a brief report on the TMC meeting held on 18 September 2019. Ms. Bird drew attention to multiple items reviewed at the TMC meeting, including the “In Some Countries” guidance document developed by a task force formed at the previous TMC meeting. She reported that the draft USNC TMC Terms of Reference were reviewed at the TMC meeting and will be sent to the R&P Committee for inclusion in the USNC Rules of Procedure. Ms. Bird noted the presentation offered by Mr. Philip Wennblom, Chair of JTC 1, and Ms. Lisa Rajchel, Secretary of JTC 1, on the structure and governance of JTC 1. Finally, Ms. Bird highlighted the discussion on CENELEC and requested that members share any issues that they may have had on technical committees with CENELEC. For more information, please see **USNC/TMC 1057 – Draft Minutes and Attachments**.

#### **Section 9 – For Information – USNC Communications Committee**

Mr. Ethan Biery, Vice Chair of the Communications Committee, provided a report on the activities of the group. Mr. Biery recognized the three winners of the USNC’s 2019 Young Professionals Competition. He also highlighted that the USNC YEP Summit will be held on Friday, November 8, 2019 in DC at the end of World Standards Week. Mr. Biery provided additional updates on the Communications Committee’s outreach activities and training. For more information, please see **ATTACHMENT E**.

#### **Section 10 – For Information/Action – Strategic Objectives Implementation Task Force**

On behalf of Mr. Peter Pondillo, Mr. Zertuche briefly provided an update on the Strategic Objectives Implementation TF. During the USNC Council meeting on 2 May 2019, Council members voted and approved of the dissolution of the Strategic Objectives Implementation TF.

#### **Section 11 – For Information/Action – USNC 2022 Planning Committee Update**

Mr. Steve Margis provided an update on the USNC's plans for the 2022 IEC General Meeting in San Francisco, CA. The Planning Committee (PlanCo) was scheduled to meet directly following the Council meeting. Mr. Margis drew attention to a 2022 GM venue visit that will likely be scheduled after the Management Meetings in May that will be held in Fremont, CA at UL’s offices. Mr. Zertuche noted that updates on tech sponsors for the 2022 GM would be shared at the PlanCo meeting.

#### **Section 12 – For Action/Information – USNC / IEC Finance Issues**

Mr. Steve Rood reviewed the USNC budget for 2020. Mr. Rood noted that the third Finance Committee (FinCo) meeting was held the day before this USNC Council meeting. FinCo moved their meeting from October to September in order to fully review the USNC 2020 budget before it was

officially submitted to ANSI. The Council reviewed the USNC 2020 budget by quarter (**ATTACHMENT F**). It was discussed, moved, seconded and

**VOTE #3 – To Approve the 2020 USNC Budget.  
(This motion was approved with two abstentions)**

Finally, Mr. Rood reviewed a presentation (**ATTACHMENT G**) on additional FinCo updates and the key takeaways from the IEC budget documents distributed with the agenda, including the Memo from the IEC Treasurer, the IEC Proposed Budget for 2020, Proposed National Dues for the Year 2020, and Multi-Year Budget Outlook.

Mr. Kevin Lippert to develop a (small) project outline to authorize for 2019 expenditure to pursue an initial proof of concept for a Database of members, their participation, terms, Chairs, etc. (**ACTION ITEM #2**).

**Section 13 – For Action – USNC Nominations Committee Report**

Elisabeth George, Nominations Committee Chair, provide a brief update on the USNC Nominations Committee, including an update on the latest winners of the ANSI awards and new Nominations Committee members. Thirteen USNC nominees are recipients of the ANSI awards for 2019. Ms. George also noted that the nominations committee has accepted five new members: Mr. Jonathan Colby, Ms. Karen Willis, Ms. Amy Phelps, Ms. Veronica Lancaster, and Mr. Peter Pondillo.

**Section 14 – For Action – 83<sup>rd</sup> IEC General Meeting – Shanghai, China**

Mr. Zertuche led a discussion on preparations for the IEC General Meeting in Shanghai, including information on bilateral meetings and logistics.

**14.1 Meeting Preparations:**

Mr. Zertuche issued a call for additional topics to discuss during the bilateral meetings. Council members who offer agenda items must be prepared to lead these discussions at the bilateral meetings.

The USNC staff will send the registration link and information for the Tri-National meeting and reception to the USNC Council, TMC, and CAPCC, and all USNC constituency registered for the 2019 General Meeting in Shanghai (**ACTION ITEM #3**).

Mr. Angus Low inquired as to why the USNC was not holding a bilateral meeting with the UK which led to a discussion on the current Chair issues with IEC/TC 65. The UK, which holds the Secretariat for TC 65 is nominating an individual from the UK as the next Chair. TCs can technically have the Chair and Secretary from the same country, but it is strongly discouraged. The deadline to submit a candidate in 22 November 2019. Ms. Bird noted that the USNC should have been identifying candidates earlier this year. The Council discussed US strategy in the context of the IEC leadership. The Council formed a new task force on USNC strategy to review USNC strategic interests and US leadership positions at the IEC level. USNC Strategy TF Chair: Angus Low and members: Jennifer Padberg, Dan Brake, Steve Margis, Ed Mikoski, Sonya Bird, Tim Duffy, Bob Kretschmann, and Karen Willis (**ACTION ITEM #4**).

**14.2 IEC Council Meeting at GM**

Mr. Lippert highlighted a hot topic discussion from the last Council Board meeting on the sales policy agreement. At issue is whether the royalties on national adoptions

should be listed as “0%” or “N/A” was debated. Ultimately, “0%” was approved by the IEC Council Board.

Finally, Mr. Lippert indicated that he would have to make a formal commitment at the upcoming IEC Council Meeting in Shanghai for the USNC to host the 2022 General Meeting in San Francisco. It was discussed, moved, seconded and

**VOTE #4 – To Endorse USNC President Kevin Lippert to formally make the commitment at the IEC Council Meeting for the USNC to host the 2022 General Meeting in San Francisco.  
(This motion was approved)**

Council members requested an itinerary of meetings and events for the 2019 General Meeting in Shanghai. The USNC staff will circulate the finalized USNC schedule of events for the 2019 General Meeting with Council members (**ACTION ITEM #5**).

### **14.3 IEC Elections:**

Mr. Lippert reviewed the elections that would take place during the IEC General Meeting:

- The re-election of the Chair of the SMB and Vice-President of the IEC for a three-year term of office (2020-2022). Dr. Ralph Sporer (Germany) is the only candidate. He just completed his first term as Chair of the SMB. The USNC Council agreed to support the candidate.
- The election/re-election of five financial Group A Council Board (CB) members by Council in Shanghai for a three-year term of office (2020-2022). The candidates are Mr. Haimo Huhle (Germany), Mr. Kevin Lippert (United States), Mr. Gilles Nativel (France), Dr. Naoto Nishida (Japan), Mr. Rodney Turtle (United Kingdom). This would be the second term for both Mr. Lippert and Dr. Nishida. The USNC Council agreed to support all five candidates.
- The re-appointment of six “Automatically Appointed Members” of the Standardization Management Board (SMB) for a three-year term of office (2020-2022). The candidates are Mr. Emmanuel Petit (France), Mr. Michael Teigeler (Germany), Mr. Ivan Visintainer (Italy), Mr. Tadashi Ezaki (Japan), Mr. Andrew Evans (United Kingdom), and Ms. Sonya Bird (United States). Ms. Bird will begin her second term.
- The election/re-election of three members of the Standardization Management Board (SMB) for a three-year term of office (2020-2022). The candidates are Ms. Kareen Riley-Takos (Australia), Mr. Israel Guratti (Brazil), Mr. Carlos Perez Munguia (Mexico), Mr. Willem Wolf (Netherlands), and Mr. Thomas Korsell (Sweden). Ms. Sonya Bird highlighted that there are five candidates running for three positions on SMB. Mr. Perez Munguia and Mr. Korsell are completing their first term, Mr. Wolf has been the alternate on the SMB, and Ms. Riley-Takos and Mr. Guratti are new candidates. The TMC’s recommendations were made to Mr. Lippert as the US Council Board members.

- The election/re-election by Council in Shanghai of two members of the Conformity Assessment Board (CAB) for a three-year term of office (2020-2022). The candidates are Mr. Gustavo Kuster (Brazil) and Mr. Rafael Luis Nava y Uribe (Mexico). Mr. Nava y Uribe is completing his first term. The USNC Council agreed to support Mr. Nava y Uribe.
- The 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). The candidates are Mr. Pierre Selva (France) and Ms. Joan Sterling (United States). This will be Ms. Sterling’s first term.

### **Section 15 – For Action – USNC Young and Emerging Professionals**

Mr. Zertuche provided an update on behalf of Ms. Carin Stuart. He again highlighted the fact that Ms. Carrie Schmaus was voted as one of the IEC Young Professional Leaders, a position not held by an American in a number of years. He noted that Ms. Schmaus is also leading efforts on the USNC YEP Summit to be held on 8 November 2019 in Washington, DC at the end of ANSI World Standards Week.

### **Section 16 – For Action – IEC Country Mentoring Program**

Mr. Zertuche provided an update on the USNC's participation in the IEC’s Country Mentoring Program with both CROSQ and Vietnam. The CROSQ workshop will be held in Montego Bay, Jamaica in June 2020 in conjunction with the IECEE CMC meeting. Mr. Zertuche suggested that the Vietnam National Committee potentially attend one of the USNC Management Meetings in 2020. The Council was amenable to this suggestion. The USNC will likely hold a workshop in Vietnam in 2021.

### **Section 17 – For Action / Information – Interface with International Organizations**

Mr. Zertuche provided an update on the USNC’s regional outreach initiatives:

- **German NC Bilateral Meeting** – Held in Hamburg 19-20 August 2019  
Mr. Lippert emphasized that the USNC had a successful meeting with German counterparts. The main issue that was discussed was the IEC governance review. Additional discussion focused on XML, Digital TC Champion, JTC 1 concerns, the Lord Kelvin Award, and the Standards Australia Incubator. USNC staff will distribute bullet point highlights from German bilateral meeting in August 2019 to USNC Council (**ACTION ITEM #6**).
- **APCF** – APCF meeting will be held in Shanghai at the 2019 GM. The Asia Pacific reception is on Tuesday evening, which will be hosted by the Chinese, the United States, and Australian NCs.
- **FINCA** – Next meeting will be in September 2019 in Lima, Peru (hosted by the Canadian National Committee)

Canada is hosting the FINCA meeting in Lima, Peru, since Peru is a new IEC member. It is the United States’ turn to host the FINCA meeting in 2020. Suggestions on where to host FINCA in US in September 2020 were discussed, including Miami (American Welding Society), San Antonio, Dallas, New Orleans, and Atlanta.

### **Section 18 – Future Meeting Dates**

Mr. Zertuche reviewed the following dates, hosts, and locations for 2020 Management Meetings:



- January 14-16 – hosted by Corning in Charlotte, NC
- May 5-7 – hosted by UL in Fremont, CA (USNC PlanCo would like to tie in a tour of the IEC GM venue in San Francisco ahead of 2022 General Meeting)
- September 1-3 – hosted by FM Approvals in Norwood, MA

Mr. Zertuche reviewed the new webpages and demonstrated how to navigate through the site. Mr. Zertuche highlighted Ms. Anna Zeng's, Mr. Zeng's daughter, hard work on the webpages during her internship and asked Mr. Zeng to pass along the USNC's gratitude.

Mr. Lippert reviewed the remaining 2019 meeting schedule and other important dates.

### **Section 19 – Adjournment**

Mr. Lippert again thanked AAMI for hosting these meetings and the Council members and guests for their participation. Mr. Lippert adjourned the meeting at 3:16 PM (EDT).