CAPCC e-Labeling Task Force
Draft Meeting Report

5 February 2021
10 a.m. ET
WebEx Meeting

Members On the Call

Richard McDermott (Task Force Chair)	ECC Corp
Bill Fiske	Intertek
Chuck Evanhoe	Evanhoe & Associates, Inc.
Joel Solis	NEMA
Megan Hayes	NEMA
Steve Margis	UL
Tim Schumann	SEW-Eurodrive, Inc.
Megan Pahl	ANSI

Members Not on the Call

Chris Selle	Emerson Automation Solutions
Don Baker	Component Trends
Elisabeth George	Philips
Jianchao Zeng	FDA
Joan Sterling	Intertek
Nora Moudiyne	ANSI/ANAB
Paul Green	Intel, Corp.
Zita Yurko	Philips

1. **Call to order**
   Dr. Richard McDermott called the meeting to order at 10:03 a.m. ET.

2. **Summary of USNC CAPCC e-Labeling Task Force January 19, 2021**
   22603-1 passed on the FD stage on January 29th and, according to the Convenor, 22603-2 will likely pass as well.

3. **ISO/IEC JDMT Meetings (Joint Directive Maintenance Team)**
   Dr. McDermott is working with Mr. Tony Zertuche to get clarification on this JDMT, though the current interpretation of this per the WG 8 Convener is that if WG 8 approves the ad hoc draft for 22603-3, it would take precedence over any other NP from an ISO TC 65. The desire is to approve the draft at the next ISO/IEC JTC1/SC31/WG 8 meeting on Feb 25. By doing so, the USNC would basically control what happens in the future for this standard.

Mr. Steve Margis shared that TC 65 has started some work on an e-labeling proposal (from Europe). The US can take ownership over the scope of this activity regardless. Mr. Joel Solis furthered, that the Europeans have a draft document that they are working from. This draft is limited; the Europeans are looking to use a QR code for the name plate. Dr. McDermott noted that if the USNC words it the proposal the right way, it would essentially consume what Europe is doing. This is how the scope would be managed so it's not redundant.

Mr. Margis suggested that Mr. Solis review the associated German document; at the beginning, it explains how the document was created. Mr. Margis recalls a fast-track process. This may be helpful to reference as we move forward with this topic.

Mr. Bill Fiske noted that these documents have not yet been shown to TC 31.

4. **Push IEC ND on 22603-3 before February 17 to start Balloting**

Dr. McDermott was informed by two members of the ad hoc committee (Mr. Rainer Schrundner and Mr. Gerold Klotz-Engmann) that they would provide a first draft of this working draft by the end of January; this did not happen. Mr. Solis subsequently exchanged e-mails with Mr Schrundner on February 17th **(ATTACHMENT A).** They indicated they will participate in the February 25th meeting by invitation from the Convener.

The DMT/JDMT meetings occur once a year, usually in November or December. During these meetings, changes to the ISO/IEC Directive are discussed and approved. The new versions are usually published in May following the Fall DMT/JDMT meeting.

As noted earlier in the meeting, the interpretation of this per the WG 8 Convener is that if WG 8 approves the ad hoc draft for 22603-3 it would take precedence over any other NP from an ISO TC 65. The desire is to approve the draft at the next ISO/IEC JTC1/SC31/WG 8 meeting on Feb 25.

Reference; JDNT/209/RM_ZOOM_2020-12 Doc. No. 209. These are the unconfirmed minutes for the ISO/IEC JDMT **(ATTACHMENT B1 and ATTACHMENT B2)**.

5. **Potential for 22603-4 Medical Devices/Applications**

For 22603-4: Medical Devices/Applications, the following relevant references have been provided:

- AHWP/WG1-WG2/F001:2017. Asian Harmonization Working Party: Regulations and treatment of e-IFU and e-Label of Medical Devices- Review of International Practices **(ATTACHMENT C)**.

- IMDRF/GRRP WG/N52 FINAL:2019. International Medical Device Regulators Forum: Principals of Labelling for Medical Devices and IVD Medical Devices **(ATTACHMENT D)**.

Mr. Chuck Evanhoe asked for clarification on the scope of 22603-4, specifically asking if the standard includes implantable or infusion pumps. Dr. McDermott responded that nearly anything in a hospital is considered a medical device. Mr. Evanhoe noted that in UDI (Unique Device Identifier) regulation almost everything that goes into a hospital, from implantable down to Band-Aids. Since the FDA published UDI regulation on this, the rest of the world follows what goes on in that UDI regulation.

The term for the WG 8 Chair is up. The US has put forth a candidate, Ms. Jeannie Ducket, who is likely to get the seat. At the appropriate time, Ms. Ducket should be brought into these conversations. The outgoing Chair had ideas that were not practical, which the e-labeling task force wants to avoid with Ms. Ducket. Mr. Evanhoe knows Ms. Ducket and will make an introduction for Dr. McDermott to meet Ms. Ducket, if appropriate.

6. **Next Meeting – Late February after next SC 31 WG 8 Meeting**
   The next meeting for SC 31/WG 8 is February 25. The next e-labeling meeting will be held after the SC 31/WG 8 gathering. USNC staff will send a Doodle poll.

7. **Adjournment**
   Dr. McDermott adjourned the meeting at 10:18 a.m. ET.