AAMI-UL Joint Committee 2800 Update To IEEE 11073 Standards Committee

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1. Overview of AAMI-UL 2800 Standard
2. Current Status of Standards Development
3. Forward Outlook
4. IEEE 11073 Committe–Specific Implications

AAMI-UL Joint Committee 2800 Update To IEEE 11073 Standards Committee: Overview of AAMI-UL 2800 Standard

AAMI/UL 2800 is intended to provide a set of safety and security requirements that support component safety claims in the context of system safety claims, related to multi-vendor, plug-and-play interoperability of components assembled within an architectural framework and ecosphere designed to satisfy the declared system safety objectives:

1. Horizontal Standards (application-agnostic safety and security requirements)
   - General Requirements (system safety and security requirements and performance objectives): AAMI/UL 2800-0
   - Minimum Requirements for Specifying and Submitting a Medical System Interoperability Architecture: AAMI/UL 2800-1 **New!**
   - ICE Safety and Security Architecture Standard (ICE architecture-specific safety and security requirements): AAMI/UL 2800-1-1

2. Vertical Standards (Intended use-specific safety and security system and test requirements, test protocol requirements)
   - ICS PCA Safety and Security Requirements: AAMI/UL 2800-3-1-1

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- **Draft standards deliverables** targeted for the June 2015 Joint Committee Meeting are outlined on the previous slide.
- **Multiple work products** in support of the standard have been created and distributed to develop the language of the standard. For example (not exhaustive):
  - List of ICS PCA-specific hazardous situations and hazards; Generalized list of fault types
  - List of "existing interoperable clinical scenarios"
  - Glossary of terms and automated tool to manage this glossary
  - List of safety and essential performance objectives; list of minimum system security requirements
  - Shared requirements from CMIT as captured in the Serena requirements management database
- **Memoranda of Understanding** is intended between AAMI, UL, ASTM, and IEEE.
- **Standards requirements and terminology** within the standards parts are being harmonized.
- **Modeling is proposed** for the particular instantiation of the PCA Interlock System.

AAMI-UL Joint Committee 2800 Update To IEEE 11073 Standards Committee: Forward Outlook (not confirmed)

- **Next JC2800 Committee Meeting (week of June 8, Denver, CO) focus:**
  - Review of draft standards content (including specific comments submitted through CSDS)
  - External communications of JC2800 status
  - Going forward plans of JC2800 Work Groups

- **Joint Plenary Meeting: JC2800 and AAMI SWIT (week of June 8, Denver, CO) focus:**
  - High level inter-group informational reports

- **JC2800 Committee Work Group Leadership Webinar (est. Mar. 2015) *anticipated focus*:**
  - Work Group updates

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- There is significant overlap in scope between AAMI/UL 2800 and IEEE 11073 as well as IHE PCD[/HL7] (and Open SDC[/WS]); relative mutual value potentials:
  - General: Access to/referential use of requirements definitions, particularly in computational (i.e. DB) form.
  - Upper Layers (UL):
    - MDDL: Domain Information Model (DIM) and Nomenclature—significant positive potential w.r.t. reuse (of 11073 by AAMI/UL 2800);
    - MDAP: Application Profiles—apparently, not very promising and probably conflicting interoperability methodologies; see "Homologation" topic below;
  - Lower Layers (LL):
    - Internet/IEEE 802-series-based: most promising potential for CoTS-based CNS reuse;
    - Non-Internet-based data links: "CNS"-based non-Internet/802-based data links have significant potential for leverage by AAMI/UL 2800-based implementations.
- Activities have mostly addressed applications and MDDL-level harmonization; more structured interaction, such as recent F2F with Open SDC on this subject, should be pursued but may require dedicated tCon series
- There is no formalized standards organizational relationship, i.e. @ MoU, which should be addressed in future, since
  - Homologation of IEEE 11073 and AAMI/UL 2800 would require significant resourcing, well beyond the capability of 11073 as presently constituted, probably including new 11073 Application Profiles addressing Internet-based "peer to peer" middle- and lower-layers standards, which is also true for homologation of 11073 and Open SDC, but perhaps less so w.r.t. SDC and ICE/DDS.

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THANK YOU FOR YOUR ATTENTION