May 13, 2019

ISO/TC 215 Secretariat (via email): Rachel Hawthorne <rhawthorne@ansi.org> Kristen Califra <KristenCalifra@ansi.org>

This letter is in response to resolution 2019-28 from the recent Gothenburg meeting as follows:

2019- 28: Regarding IEEE and ISO 11073 series

ISO/TC 215 recommends that IEEE and ISO review the ISO/IEEE 11073 series in order to align the titles in this series. ISO/TC 215 assigns IEEE 11073 Standards Committee leadership in ISO/TC 215 to develop a document to provide justification for this recommendation and submit it to the ISO/TC 215 secretariat by 15 May 2019.

The IEEE 11073 Standards Committee proposes the following approach:

- 1. Substitute the mentions of "Point of care medical device communication" or "Personal health device communication" with the term "Device interoperability" in the title.
- 2. Move the mentions of "Point of care medical device communication" or "Personal health device communication" to directly after the "Part xxxxx:" in the title.

The following is an example (additional examples can be found in Annex A).

- Current:
 - ISO/IEEE 11073-10101:2004 -- Health informatics Point-of-care medical device communication Part 10101: Nomenclature
- <u>Proposed:</u>
 - ISO/IEEE 11073-10101:2004 -- Health informatics Device interoperability Part 10101: Point-of-care medical device communication Nomenclature

Our rationale is as follows:

- 1. "Device interoperability" is a simple series title that works for both the medical device and health device contexts.
- 2. "Interoperability" is an inclusive term that accurately covers the entire 11073 scope
- 3. Part titles can be mapped directly from the IEEE version in a way that maintains clarity (e.g., MDC vs. PHD) and continuity if you are used to looking at the IEEE project title then see the ISO/CEN title ... there shouldn't be any dissonance

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Please let me know if you have any questions or issues with this proposal. Best regards,

Ken Fuchs Chair – 11073 Standards Committee

Cc: Jodi Haasz, Tom Thompson, Todd Cooper, Elliot Sloane, Daidi Zhong, Michael Kirwan, John Rhoads, John Garguilo

Annex A

ISO/IEEE 11073 Titles - Current and Proposed

"PHD - Personal Health Device" examples

- <u>Current:</u> ISO/IEEE 11073-20601:2016 -- Health informatics -- Personal health device communication -- Part 20601: Application Profile - Optimized Exchange Protocol
- <u>Proposed:</u> ISO/IEEE 11073-20601:2016 -- Health Informatics Device interoperability -- Part 20601: Personal health device communication -- Application Profile Optimized Exchange Protocol
- <u>Current:</u> ISO/IEEE 11073-10404:2010 -- Health informatics -- Personal health device communication -- Part 10404: Device specialization -- Pulse oximeter
- <u>Proposed:</u> ISO/IEEE 11073-10404:2010 -- Health informatics Device interoperability -- Part 10404: Personal health device communication -- Device specialization -- Pulse oximeter
- <u>Current:</u> ISO/IEEE 11073-10425:2019 -- Health informatics--Personal health device communication -- Part 10425: Device Specialization -- Continuous Glucose Monitor (CGM)
- <u>Proposed:</u> ISO/IEEE 11073-10425:2019 -- Health informatics—Device interoperability -- Part 10425: Personal health device communication -- Device Specialization -- Continuous Glucose Monitor (CGM)

"MDC - Point of Care" examples

- <u>Current:</u> ISO/IEEE 11073-10101:2004 -- Health informatics Point-of-care medical device communication Part 10101: Nomenclature
- <u>Proposed:</u> ISO/IEEE 11073-10101:2004 -- Health informatics Device interoperability -- Part 10101: Point-of-care medical device communication -Nomenclature
- <u>Current:</u> ISO/IEEE 11073-10102:2014 -- Health informatics Point-of-care medical device communication -- Part 10102: Nomenclature - Annotated ECG
- <u>Proposed:</u> ISO/IEEE 11073-10102:2014 -- Health informatics Device interoperability -- Part 10102: Point-of-care medical device communication -- Nomenclature Annotated ECG
- <u>Current:</u> ISO/IEEE 11073-10201:2004 -- Health informatics Point-of-care medical device communication -- Part 10201: Domain information model
- <u>Proposed:</u> ISO/IEEE 11073-10201:2004 -- Health informatics -- Device interoperability -- Part 10201: Point-of-care medical device communication -- Domain information model

- <u>Current:</u> ISO/IEEE 11073-20101:2004 -- Health informatics Point-of-care medical device communication - Part 20101: Application profile - Base standard
- <u>Proposed:</u> ISO/IEEE 11073-20101:2004 -- Health informatics Device interoperability -- Part 20101: Point-of-care medical device communication -- Application profile Base standard

"SDC - Service-Oriented (Point of Care)" examples

- <u>Current:</u> ISO/IEEE 11073-10207:2019 -- Health informatics -- Personal health device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication (Note that the current ISO title is incorrect it should refer to Point of care medical device communication rather than Personal health device communication.)
- <u>Proposed:</u> ISO/IEEE 11073-10207:2019 -- Health informatics Device interoperability-- Part 10207: Point-of-care medical device communication -- Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication
- <u>Current:</u> ISO/IEEE 11073-20702:2018 -- Health informatics Point-of-care medical device communication - Part 20702: Medical Devices Communication Profile for Web Services
- <u>Proposed:</u> ISO/IEEE 11073-20702:2018 -- Health informatics Device interoperability -- Part 20702: Point-of-care medical device communication -- Medical Devices Communication Profile for Web Services