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23 September 2005

Elliot Sloane
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Re: P1073.0.2.1 - Health informatics - Point-of-care medical device communication -
Recommended practice - Profile template

Dear Elliot:

I am pleased to inform you that on 22 September 2005 the IEEE-SA Standards Board approved the above referenced project until 31 December 2009. A copy of the file can be found on our website at <http://standards.ieee.org/board/nes/projects/1073-0-2-1.pdf>.

Now that your project has been approved, please forward a roster of participants involved in the development of this project. This request is in accordance with the IEEE-SA Operations Manual, Clause 5.1.2i under Duties of the Sponsor which states:

"Submit annually to the IEEE Standards Department an electronic roster of individuals participating on standards projects"

For your convenience, an Excel spreadsheet for your use has been posted on our website at <http://standards.ieee.org/guides/par/roster.xls>. Please forward this list to me via e-mail at j.haasz@ieee.org no later than 21 December 2005.

Please visit our website, IEEE Standards Development Online (<http://standards.ieee.org/resources/development/index.html>), for tools, forms and training to assist you in the standards development process. Also, we strongly recommend that a copy of your draft be sent to this office for review prior to the final vote by the working group to allow for a quick review by editorial staff before sponsor balloting begins.

If you should have any further questions, please contact me at 732-562-6367 or by email at j.haasz@ieee.org.

Sincerely,

Jodi Haasz
Program Manager
International Stds Programs and Governance
Standards Activities
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CC: t.cooper@ieee.org, jan.wittenber@philips.com

PAR FORM

PAR Status: New PAR

PAR Approval Date: 2005-09-22

PAR Signature Page on File: Yes

1. Assigned Project Number: P1073.0.2.1

2. Sponsor Date of Request: 2005-08-12

3. Type of Document:

4. Title of Document:

Draft: Health informatics - Point-of-care medical device communication - Recommended practice - Profile template

5. Life Cycle: Full-Use

6. Type of Project:

6a. Is this an update to an existing PAR? No

6b. The Project is a: New Standard

7. Working Group Information:

Name of Working Group: Medical Device Communication General Committee

Approximate Number of Expected Working Group Members:7

8. Contact information for Working Group Chair:

Name of Working Group Chair: Todd H Cooper

Telephone: 858-484-8231 **FAX:** 858.538-6256

Email: t.cooper@ieee.org

9. Contact information for Co-Chair/Official Reporter, Project Editor or Document Custodian if different from the Working Group Chair:

Name of Co-Chair/Official Reporter, Project Editor or Document Custodian: Jan Wittenber

Telephone: 978-659-3593 **FAX:** 978-685-5579

Email: jan.wittenber@philips.com

10. Contact information for Sponsoring Society or Standards Coordinating Committee:
Name of Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society 1073 Committee

Name of Sponsoring Committee Chair: Elliot Sloane

Telephone: 610-519-6432 **FAX:** 610-519-5015

Email: ebsloane@villanova.edu

Name of Liaison Rep. (if different from the Sponsor Chair):

Telephone: **FAX:**

Email:

Name of Co-Sponsoring Society and Committee:**Name of Co-Sponsoring Committee Chair:****Telephone: FAX:****Email:****Name of Liaison Rep. (if different from the Sponsor Chair):****Telephone: FAX:****Email:****11. The Type of ballot is:** Individual Sponsor Ballot**Expected Date of Submission for Initial Sponsor Ballot:** June 2006**12. Projected Completion Date for Submittal to RevCom:** December 2006**Target Extension Request Information for a Modified PAR whose completion date is being extended past the original four-year life of the PAR:****13. Scope of Proposed Project:**

This document presents a set of recommended practices for creating communication profiles that leverage new or existing technology for application within an ISO/IEEE 11073 communication framework. A template is defined that specifies the component elements that need to be contained in a profile, as well as instructions for how it should be completed and documented, including the definition and completion of related protocol implementation configuration statements (PICS) needed by referenced standards.

Is the completion of this document contingent upon the completion of another document?

No

14. Purpose of Proposed Project:

As various organizations and system developers define communication profiles (or "stacks") for point-of-care medical devices, they require guidance for how ISO/IEEE 11073 component standards, as well as other non-ISO/IEEE 11073 standards may be combined and configured to achieve the primary design goal for the family of standards, namely real-time plug-and-play interoperability. Though there is information about protocol implementation conformance statements ("PICS") throughout the standards, there is no general guidance or "template" provided for how to create a complete profile. This document provides recommended practices for how to create these profiles using the specified template in such a manner as to properly use existing standards as well as to provide specifications that may become future standards within the ISO/IEEE 11073 family.

15. Reason for the Proposed Project:

There are many considerations that must be factored into any profiling activity for a medical device communications service. If all of these considerations are not properly evaluated, the result is a misuse of existing standards as well as difficulty in extending the family of ISO/IEEE 11073 standards to meet the challenges resulting from evolving technology and user needs. When these recommended practices and the defined template profile are used by organizations and system developers, they design goals of the ISO/IEEE 11073 family of standards shall be

achieved and extension of the standards to meet new demands shall be facilitated. Primary stakeholders for this project include medical device system developers, organizations that are developing or approving technical profiles for medical device communication, and ultimately healthcare provider organizations that are looking to have their needs met by systems that implement the ISO/IEEE 11073 standards.

16. Intellectual Property:

- a. Has the IEEE-SA policy on intellectual property been presented to those responsible for preparing/submitting this PAR?** Yes 2005-01-22
- b. Is the sponsor aware of copyright permissions needed for this project?** No
- c. Is the sponsor aware of trademarks that apply to this project?** No
- d. Is the sponsor aware of possible registration activity related to this project?** No

17. Are there other documents or projects with a similar scope? No

Similar Scope Project Information:

18. Is there potential for this document (in part or in whole) to be adopted by another national , regional or international organization? Yes

If yes, the following questions must be answered:

Organization Name? ISO TC215 WG7

**Technical
Committee**

International Todd H Cooper

Contact Breakthrough Solutions

Information? 15058 Midland Road
Poway, CA 92064-2974
t.cooper@ieee.org

19. Will this project result in any health, safety, or environmental guidance that affects or applies to human health or safety? No

If yes, please explain:

20. Sponsor Information

a. Is the scope of this project within the approved/scope/definition of the Sponsor's Charter? Yes

If no, please explain:

b. The Sponsor's procedures have been accepted by the IEEE-SA Standards Board Audit Committee? Yes

21. Additional Explanatory Notes: (Item Number and Explanation)