November 15-16, 2004

Second Meeting of the ORF PnP Standardization Project

A multidisciplinary project to develop standards for communication and control of medical devices in the OR of the Future

[Note added 2009: The program was initially called "ORF PnP" and was renamed the Medical Device "Plug-and-Play" Interoperability Program, or "MD PnP" to more accurately reflect the scope of work.]

This meeting will focus on:
Developing Functional Requirements and **Assessing the Regulatory Model**

Hosted by: **Food & Drug Administration**
9200 Corporate Blvd, Room 020B, Rockville, Maryland

Monday, November 15

8:30 – 9:00am	Registration / Coffee
9:00 – 9:30	Welcome, Conference Overview, Current Status of ORF PnP Standardization Program *Julian M. Goldman, MD* Principal Investigator, ORF PnP Program CIMIT/Massachusetts General Hospital
9:30 – 12:00	**WG1: Clinical Requirements** *WG1 Leader: John Howse, MD, Kaiser Permanente*
9:30 – 10:00	Clinical Requirements of PnP Systems *James C. Fackler, MD* Director of Critical Care, Cerner Corporation Associate Professor, Anesthesiology/CCM, Johns Hopkins University School of Medicine
10:00 – 11:00	Breakout Session I: Identify Top Clinical Requirements & Clinical Use Scenarios *Facilitators and Scribes TBA*
11:00 – 12:00	Groups Report Back: Consolidate Requirements
12:00 – 1:00pm	Networking Lunch (sandwiches brought in)

Monday, November 15 (continued)

1:00 – 5:00pm	**WG2: Regulatory Requirements** *WG2 Leaders: Jennifer A. Henderson, JD, MPH, CIMIT* *Michael Husband, FDA*
1:00 – 1:20	Designing High-Assurance Complex Systems: Future Directions *D. Helen Gill, PhD* Director, Embedded & Hybrid Systems Program National Science Foundation
1:20 – 1:45	Current and Future States of Device Systems *Paul L. Jones, MSCE* Senior Systems/Software Engineer U.S. Food and Drug Administration Center for Devices and Radiological Health *Office of Science and Engineering Laboratories*
1:45 – 2:15	Regulatory Experience with Networked Medical Systems *John Murray, MSEE* Software & Electronic Medical Record ("Part 11") Compliance Expert U.S. Food and Drug Administration Center for Devices and Radiological Health, *Office of Compliance*
2:15 – 2:45	Future Models to Assure Safety and Effectiveness of ORF PnP Interconnected Systems *Brian Fitzgerald* Acting Deputy Division Director U.S. Food and Drug Administration Center for Devices and Radiological Health *Office of Science and Engineering Laboratories*
2:45 – 3:00	Break
3:00 – 4:15	Breakout Session II: Identify Top High-Level Regulatory Requirements (Performance, Functional, and Interface) and Suggestions for Alternate Approaches to Current Regulatory Framework *Facilitators and Scribes TBA*
4:15 – 5:00	Groups Report Back: Consolidate Requirements Wrap up

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Dinner on your own – network!

Tuesday, November 16

7:30 – 8:00am	Coffee
8:00 – 8:30	Roles for Clinical Engineering in Specifying IT Requirements *Rick Schrenker* Systems Engineering Manager Massachusetts General Hospital Dept of Biomedical Engineering
8:30 – 9:00	From Wishlist to QoS: The Process *Todd Cooper* Chair, IEEE 1073 General Committee
9:00 – 9:30	**WG3 Status Report: PnP System Architectures** *WG3 Leaders: Bill Seitz, IXXAT Inc.* *Jeff Robbins, LiveData Inc.*
9:30 – 9:45	Instructions to Breakout Groups *Julian M. Goldman, MD* *WG4 Leader: Dwayne R. Westenskow, PhD* *University of Utah Medical Center*
9:45 – 10:00	Break
10:00 – 11:00	Breakout Session III: IIIA: ORF PnP relationship to existing standards IIIB: **WG4 – User Interface Requirements**
11:00 – 12:00	Groups Report Back: Consolidate Requirements
12:00 – 1:00pm	Networking Lunch (sandwiches brought in)
1:00 – 2:00	Consolidate Requirements for WG1, WG2, WG4 – to be sent to WG3 for review and response
2:00 – 3:00	Defining the Scope of the ORF PnP Project: near- and long-term objectives of project plan Next Steps *Julian M. Goldman, MD*
3:00	Adjourn

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