

# THE HIGH CONFIDENCE SOFTWARE AND SYSTEMS COORDINATING GROUP

## FEDERAL NETWORKING AND INFORMATION TECHNOLOGY RESEARCH AND DEVELOPMENT SUBCOMMITTEE, COMMITTEE ON TECHNOLOGY OF THE NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

### WORKSHOP ON HIGH CONFIDENCE MEDICAL DEVICE SOFTWARE AND SYSTEMS (HCMDSS) RESEARCH AND ROADMAP

JUNE 2 - 3, 2005

PHILADELPHIA, PA

<http://www.cis.upenn.edu/hcmdss/>

### CALL FOR POSITION PAPERS (VERSION 4-20)

#### INVITATION

The High Confidence Software and Systems (HCSS) Coordinating Group (CG) of the Federal Networking and Information Technology R&D (NITRD) Subcommittee, Committee on Technology of the National Science and Technology Council, invites you to submit a position paper for a workshop on *High Confidence Medical Device Software and Systems* (HCMDSS). The Federal government recognizes that the rapidly increasing software complexity of medical devices makes the development of high integrity medical device software and systems a crucial issue in public health. The purpose of the HCMDSS workshop is to provide an open, working forum for leaders and visionaries concerned with medical devices from industry, research laboratories, academia, and government with the goal of developing a roadmap to overcome crucial medical device software and systems issues and challenges facing the design, manufacture, certification, and use of medical devices.

Through this call for position papers, we solicit input that can be used by the HCMDSS Coordinating Group to help identify the research needs, challenges, and a roadmap for HCMDSS. The organizers will deliver a report to the Government that summarizes the workshop's findings. By submitting a position paper, you will have an opportunity to provide technical facts and information that potentially can help shape the future direction of HCMDSS. Due to the workshop's ambitious schedule, position papers are requested by Monday, April 11, 2005 (see below for late submission). The position papers will be used to select invitees to the workshop scheduled for June 2 and 3, 2005. Invitees will have the opportunity to provide further input to the HCMDSS roadmap.

#### WORKSHOP TOPICS

The following eight topics are considered critical in the development and production of future HCMDSS that are safe, secure, and reliable. (Subareas listed under each topic are meant to be indicative, rather than exhaustive.)

- Enabling Technologies for Future Medical Devices
  - Implantable regulatory devices, networked biosensors, telesurgery, robotic surgery
- Foundations for Integration of Medical Device Systems/Models
  - Component-based foundations for accelerated design and verifiable system integration
  - System of systems (including models, medical devices, care-givers, patients)
- Distributed Control & Sensing of Networked Medical Device Systems
  - Robust, verifiable, fault-tolerant control of uncertain, multi-modal systems
- Patient Modeling & Simulation
  - Large scale, high fidelity organ and patient models for design and testing

- Embedded, Real-Time, Networked System Infrastructures for MDSS
  - Architecture, platform, middleware, resource management, QoS (Quality of Service), PnP (Plug-and-Play) of MDSS
- High-Confidence Medical Device Software Development & Assurance
  - Care-giver requirements solicitation and capture, design and implementation V&V (Verification and Validation)
  - Heterogeneity in environment, architecture, platform in medical devices
- Medical Practice-driven Models and Requirements
  - User-centered design, risk understanding, and use/misuse modeling in medical practice
- Certification of MDSS
  - Quantifiable incremental certification of MDSS, role of design tools
  - COTS, non-deterministic and self-adaptive medical device systems

## **BACKGROUND AND SCOPE**

The medical sector represents about 20 cents of every dollar spent in the United States. The rapidly increasing use of software to control medical devices makes the development and production of medical device software and systems a crucial issue, both for the U.S. economy and to assure safe advances in health care delivery. Several Federal agencies are interested in identifying the research needs required to improve the design, certification, and operation (by both health care professionals and consumers) of medical device software and systems that will result in better and more cost-effective medical care.

To plan for the HCMDSS workshop, a one and a half day HCMDSS Workshop Planning Meeting (WPM) was held November 16-17, 2004 in Arlington, Virginia. The WPM was sponsored by the NITRD Program Federal agencies that participate in the HCSS Coordination Group (CG), including FDA, NIST, NSA, and NSF, plus the National Coordination Office for NITRD. Sixty experts participated in the WPM including those in government information technology and industry, software engineers, medical doctors, nurses, and academic researchers. (See <http://www.cis.upenn.edu/hcmdss-planning/>). The eight topics listed above resulted from the WPM.

The objective of this HCMDSS workshop is to build on the work accomplished at the WPM by further analyzing the challenges and approaches that can help address the findings resulting from this meeting, as well as identifying additional challenges and approaches from other communities. Our goal is to have a complete mix of the relevant stakeholders (including researchers, developers, certifiers, and users) who can help identify emerging systems and assurance needs. The workshop will result in a comprehensive research needs report that will prioritize recommendations with a roadmap to determine what, when, and how these priorities should be addressed over an identified time frame. The generation of the summary and roadmap report is preceded by this call for position papers to assist in identifying the topics, speakers, and report writers for the workshop.

## **WORKSHOP INVITATIONS**

The workshop is by invitation. Anyone interested in participating in the workshop is encouraged to submit a position paper on the several topics outlined above by April 11, 2005. Notice will be sent by April 25, 2005 to all those who will be invited to the workshop and will include information of the roles they will be asked to play. The workshop will be structured largely as a working meeting, with some participants invited to make presentations. Please indicate in your position paper if your participation requires not making such a public presentation.

Government representatives interested in being invited to attend as observers are asked to submit a brief bio with a few sentences describing your interest in HCMDSS.

## **POSITION PAPER SUBMISSION GUIDELINES**

Position papers should be at most three pages in length and printed in a 12-point font on 8-1/2 by 11 inch paper. Each position paper should address two to four of the workshop topics listed above. Each topic should answer each of the following three questions:

1. What are three most important challenges?
2. What are three most important information technology research needs?
3. What is a possible roadmap for the next 5 to10 years?

In addition, each position paper should include at most a half-page bio, organization/affiliation, e-mail address, and phone number for each author. Position papers should be addressed to the attention of the HCMDSS Workshop Program Committee and submitted to: <http://www.cis.upenn.edu/hcmdss/>, by Monday, April 11, 2005 (see below for late submission).

Note that submitted position papers will be available on-line and authors are advised not to include any proprietary information that they do not want to disseminate to public.

## **IMPORTANT DATES**

April 11, 2005: Submission deadline (*Please contact the organizer at [hcmdss@cis.upenn.edu](mailto:hcmdss@cis.upenn.edu) for late submission request*)

April 25, 2005: Notification of Acceptance/Rejection

June 2-3, 2005: Workshop

## **VENUE**

The workshop will be held at the Warwick Hotel in Philadelphia, PA 19104. The hotel is located one block from the Rittenhouse Square in downtown Philadelphia.

## **INFORMATION**

The workshop Web site <http://www.cis.upenn.edu/hcmdss/> provides up-to-date information. For more information or if you wish to be put on the workshop mailing list, please contact the workshop organizers at [hcmdss@cis.upenn.edu](mailto:hcmdss@cis.upenn.edu).

## **WORKSHOP ORGANIZERS**

Insup Lee	University of Pennsylvania (Chair)
George J. Pappas	University of Pennsylvania
Janos Sztipanovits	Vanderbilt University
Doug Schmidt	Vanderbilt University
Shankar Sastry	University of California-Berkeley

## **PROGRAM COMMITTEE**

See the workshop Web site for the latest list.

## **SPONSORING AGENCIES**

National Science Foundation  
National Institute of Standards and Technology  
Food and Drug Administration  
National Security Agency  
National Coordination Office for Information Technology Research and Development (NCO/ITRD)

## **COOPERATING PROFESSIONAL ORGANIZATIONS**

ACM SIGBED (Special Interest Group in Embedded Systems)  
IEEE Computer Society TC-RTS (Technical Committee on Real-Time Systems)