

# Medical Devices Metrology and Standards Needs

*Tuesday 14th November 2006, Atlanta, GA*

---

---

*A U.S. Measurement System (USMS) Workshop*

---

---

Members of the staff from the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the University of Texas at Arlington (UTA) the National Institute of Standards and Technology (NIST) and ASTM have agreed to collaborate in order to document and prioritize the measurement and measurement related standards needs of a few categories of Medical Devices in cooperation with other government agencies, private industries and universities (<http://usms.nist.gov>). The ultimate goal of this identification initiative is to help direct NIST resources, or to create partnerships, in order to provide solutions to these needs.

Discoveries and technology developments during the 20<sup>th</sup> century made possible the development of a significant number of medical devices, which have radically transformed the way medical care is delivered today. These include the Computed Axial Tomography (CAT) machine in 1972, the Magnetic Resonance Imaging (MRI) machine in 1977, the Positron Emission Tomography (PET) machine, the implantable defibrillator in 1980, the artificial heart in 1982, the cochlear implant in 1985, Lasik eye surgery in 1990, Computer Assisted Surgery systems in 1986, Surgical Robots in 1990, Diagnostic Imagine Endoscopy Capsules in 2001, etc. Despite the tremendous progress though many problems exist in performance, standards, sensors and reliability.

This workshop will bring together experts in the fields of Medical Devices, metrology and standards in order to discuss and document the metrology and standards needs of a few categories of Medical Devices. Before the conclusion of the workshop these needs will be listed and ranked according to their importance. This workshop will not cover Medical Imaging as a Biomarker and Active Implantable Medical Devices Reliability, which have been the subjects of other NIST USMS needs workshops.

The scope of this workshop is focused on the Metrology and Standards Needs of Medical Devices. Suggested topics for discussion are:

- Anthropomorphic Phantom Devices
- Computer Assisted Navigation and Surgery
- Drug-delivery Devices
- Stimulation Devices
- Surgical Robots

Workshop participants should address the following questions with respect to the above topics:

- What technological innovations are at stake?
- What is the economic significance of the innovations?
- What technical barriers to the innovations impede progress to the marketplace?
- At what stages of innovation do the technical barriers appear?
- What parts of the technical barriers are measurement science or standards development?
- What are the potential solutions to the measurement and standards development problems?
- Who are potential providers of solutions?
- Are there critical roles for agencies of the federal government?

For more information about this workshop, please contact:  
Nicholas Dagalakis [nicholas.dagalakis@nist.gov](mailto:nicholas.dagalakis@nist.gov) , Tel.: 301-975-5845