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***Optical Diagnostics and Sensing XII:
Toward Point-of-Care Diagnostics; and
Design and Performance Validation of
Phantoms Used in Conjunction with
Optical Measurement of Tissue IV***

Robert J. Nordstrom

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Editors

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Introduction

The fourth meeting of the Design and Performance Validation of Phantoms used in Conjunction with Optical Measurements of Tissues was held on January 21 and 21, 2012. Nine countries were represented in the oral and poster presentations of this conference. While several papers continued the early conference tradition of discussing design and construction challenges in phantom fabrication, a majority of the papers showed how phantoms were being used to validate performance characteristics of optical devices.

The first session, "Phantom Fabrication, Testing, and Validation", was started by an invited talk from Dr. Steve Jacques who set the tone for phantom validation by speaking on confocal reflectance microscopy as a way to specify the scattering and anisotropy coefficients of tissue phantoms. Other presentations in that session discussed performance assessments, calibrations, and characterization issues dealing with optical phantoms for various tissues.

The second session, "Phantoms for Microscopy, Hyperspectral Imaging, and Other Optical Methods", focused on a variety of biomedical uses to which optical methods are being put. The need for phantoms of all levels of sophistication was the theme in this session. Dr. Calum MacAulay gave an invited presentation on the design of specific calibration slides useful for quantitative absorbance microscopy.

Finally, optical coherence tomography (OCT), a technique making rapid inroads into the commercial arena, was the topic of the third session of this conference. With its ability to record high resolution depth imaging in tissue, OCT requirements for phantoms are different from phantom requirements for other optical methods. Topics in phantom construction and performance for OCT were presented.

This year, for the first time, a joint session between this conference and the conference on Design Quality for Biomedical Technologies, chaired by Dr. Ramesh Raghavachari, Dr. Rongguang Liang, and Dr. Joshua Pfefer was held. Invited presentations, from NIST, FDA, and industry set the stage for a spirited panel discussion that followed. Central to the discussion was the theme of quality control and validation, and issues concerning where standards for biomedical optical device performance may one day come. Reference was made to other imaging modalities such as MRI and PET, and the professional organization surrounding them. These organizations promote standards in imaging modalities, so the question can be asked regarding the appropriate professional society in which standards for optical devices can be vetted.

Another twist to the discussion brought up the fact that industries are not often eager to comply with externally imposed standards when market share and patent positions are at stake. It may be appropriate to let the marketplace sort out which standards are viable and which are not, much the same way that VHS and Beta standards did in the video recording industry years ago. Of

course, with biomedical devices, the FDA will play an important role in the areas of safety and efficacy.

The available time was all too short to cover the depth of interest in this topic. A suggestion was made that this panel discussion continue again next year, and that perhaps a published text or journal could be initiated to bring the issues to a broader audience.

Robert J. Nordstrom