International Conference on Medical Device Standards and Regulation

Software Engineering Standards Struggle to Keep Up with Rapid Technological Change

THE INCREASINGLY COMPLEX array of software used in medical devices make software engineering standards a critical component of today's regulatory environment. Session moderator John F. Murray, Jr. said the FDA's long-term goal is to create a regulatory environment that is so effective it eliminates the need for the premarket submission of software documentation for those choosing to use consensus standards. In addition, Murray said the software standards must address the needs of all customers and explained that this can best be achieved through global harmonization.

Alan Kusinitz, managing partner of SoftwareCPR, described the AAMI draft standard for medical device software. It is the AAMI Software Committee's intent that this standard will be recognized by FDA to be sufficient for low- and moderate-risk software. The standard will be useful for high-risk software, but FDA is expected to require additional software documentation for these devices. He said the AAMI Software Standards Committee has completed their balloting. Next steps will include public review and final approval. The committee also wishes to submit the document to FDA for recognition and to propose the standard as an international work item. Updated information on software standards is at **www.softwarecpr.com**.

Susan Gill, senior project engineer for Underwriter Laboratories Inc., was also on hand to present UL 1998, a standard for software in programmable components. It applies to embedded software in non-networked applications and addresses safety-related requirements that are implemented in software. The FDA software standards Technical Group has recommended that FDA recognize this standard. Conformance to this standard would reduce the software documentation required for premarket submission.

Carl Wyrwa, manager of software quality assurance for Beckman Coulter, Inc., then explained the Software Conformance Assessment Tool, now being developed by the Health Industry Manufacturers Association (HIMA). The new product was developed by the HIMA Software Quality Audits Working Group, whose goal was to develop a written guidance and/or tool that would assist manufacturers in performing objective assessments to determine their relative compliance with software development standards that are recognized by FDA. Wyrwa said firms that are in compliance with a standard may make a "declaration of conformity" to a standard and reduce the documentation that needs to be included. The tool, which is now in its third working draft version, is intended for both small and large companies and software teams that want to participate in a voluntary process.

During his presentation on global software standards, Sherman Eagles, technical fellow and senior principal software engineer for Medtronic, Inc., reminded the audience of the need to keep the ultimate goal in mind: delivering safe devices that help patients. He explained the many international software standards being developed and described some of the future issues related to medical device software. There is much more software available in medical devices and the software is evolving into new roles to accommodate the new functionality. Finally, he indicated that the Internet has set up a "tidal wave" of change in medical devices. He said future needs would include predictable and fast premarket reviews of software in medical devices, risk-based review criteria, and the evolution of software regulation to match the evolution of software uses in medical devices. The integration of medical devices and information technology is one example of an area that requires a new look at software regulation. ■

AAMI News

This article is reprinted from the April 2000 issue of *AAMI News*,