Time to Reboot: New Software Standard to Replace SW68

Kurt Larrick

Software's unbridled growth as an integral part of medical device technology shows no signs of slowing down, and a new AAMI standard will play an important role in helping the next generation of software-dependent medical devices reach new heights in patient treatment and safety.

The new American National Standard ANSI/AAMI/IEC 62304:2006, *Medical device software—Software life cycle processes* updates the 2001 AAMI/American National Standard of the same name (previously designated SW68). The new standard is an identical adoption of a new International Electrotechnical Commission (IEC) standard that was largely based on the AAMI SW68 standard. The path may seem a bit circular, but the end result—international harmonization that provides manufacturers with a single set of guidelines for stand-alone medical device software as well as software that is an embedded or integral part of a medical device—is an important achievement.

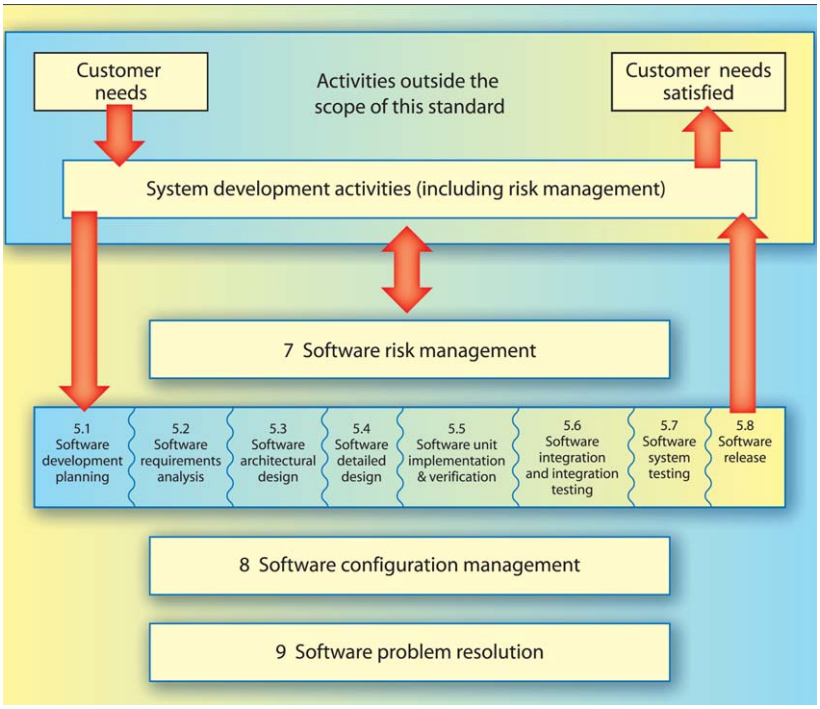

Figure 1. *In AAMI's new software standard, the development process is broken down into its core activities. A similar approach is used for the software maintenance process.*

"While the development of 62304 began using the AAMI SW68 standard as its starting point, several significant changes and additions are important to note," said Alan Kusinitz of SoftwareCPR in Winchester, MA. "The first significant difference to be aware of is that, while SW68 established minimum life cycle requirements for software of minor and moderate concern, 62304 also addresses minimum requirements for software of major levels of concern."

The second important difference, according to Kusinitz, who is a member of the AAMI Medical Device Software Committee and a faculty member for AAMI programs including Software Validation Requirements and Industry Practice, is that "62304 requires identification of the risk of each software component into one of three levels defined in the standard, and defines different minimum life cycle requirements for each component based on risk level."

The three software safety classes identified in 62304 are based on the possible effects on the patient, operator, or other people resulting from a hazard to which the software system can contribute. Manufacturers are required to assign a software safety class to each software system.

Class A: No injury or damage to health is possible
Class B: Non-serious injury is possible
Class C: Death or serious injury is possible

Kurt Larrick is AAMI's director of technical publishing and marketing.

Check Points

The new AAMI/American National Standard ANSI/AAMI/IEC 62304:2006, *Medical device software—Software life cycle processes* is now available from AAMI:

- ✓ The new standard was largely based on the AAMI SW68 standard.
- ✓ It provides manufacturers with a single set of guidelines for stand-alone medical device software as well as software that is an embedded or integral part of a medical device.

Specific processes and tasks are then required for each software safety class, for example the Section 5.5.2 establishes basic requirements for unit verification that apply to all safety classes; Section 5.5.3 requires unit test acceptance criteria for software in classes B and C only; and 5.5.4 requires additional unit test acceptance criteria and only applies to Class C. A table is provided in the standard identifying requirements by safety class.

The new standard does not differentiate between primary and supporting processes, as SW68 did. Two processes—documentation and verification—that were included in SW68 were removed from the new standard. Some requirements that were in these processes were moved to other processes where they applied.

With a number of software standards already available, and with AAMI SW68, ISO 12207, UL 1998, and several others already formally recognized by the U.S. Food and Drug Administration, was a new standard really needed?

According to Kusinitz, it was. "All but AAMI SW68 are general software standards not tailored to aspects central to safe and effective medical devices, and AAMI SW68 is a national, not an international, standard. The strategy in development of SW68 was to develop a U.S. national standard that FDA could recognize, and then use that as a basis for longer term development of an international standard. That is exactly what has occurred, and SW68 is now superseded and replaced by 62304. I believe that 62304 will become a *de facto*, and in some countries *de jure*, requirement for medical device software. The Japanese regulatory authority has already announced it will require use of 62304 and it is expected that 62304 will become a harmonized standard in Europe." ■

AAMI Software Guidance

■ ANSI/AAMI/IEC 62304:2006, *Medical device software—Software life cycle processes*. Specifies life cycle processes including software development, software maintenance, software risk management, software configuration management, and software problem resolution requirements for medical device software. Also requires manufacturers to assign one of three defined safety classes to the software system, and makes normative reference to ANSI/AAMI/ISO 14971, *Application of risk management to medical devices*. List price/member discount price: $95/$50. Order code: 62304. PDF Order code: 62304-PDF

■ ANSI/AAMI/ISO 14971:2000, *Medical devices—Application of risk management to medical devices*. Specifies a procedure for the manufacturer to identify the hazards associated with medical devices and their accessories, estimate and evaluate the risks, control these risks, and monitor the effectiveness of the control. List price/member discount price: $90/$45. Order code: 14971. PDF Order Code: 14971-PDF.

■ AAMI TIR32:2004, *Medical device software risk management* provides information for performing effective software risk management in the context of ISO 14971 and AAMI SW68. TIR32 should be regarded as a reference for developing safe software systems to be used in medical devices. The information that it contains provides a framework within which experience, insight, and judgment are applied systematically to reduce medical device risks. List price/member discount price: $95/$50. Order code: TIR32. PDF Order Code: TIR32-PDF.