



Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices

V&V 40 - 2018

ASME introduces its first verification and validation standard for specific application to medical devices. Understand this new standardized approach for determining the credibility evidence needed to support use of a computational model and how it can impact the product lifecycle for medical devices.

This standard provides a framework for assessing the relevance and adequacy of completed V&V activities that establish credibility of a computational model. The credibility should be commensurate with the degree to which the computational model is relied on as evidence of device performance, functional characteristic, and/or safety to support a decision, and the consequences of an incorrect decision.

ASME V&V 40 will help users communicate the value of the completed V&V activities and establish the associated credibility of the computational model to support a decision. It also augments ASME V&V 20 and ASME V&V 10 standards, which present V&V methodologies. While this standard was developed specifically for medical devices, the V&V 40 Subcommittee considers this standard to be general enough to be applied to other disciplines.

ASME V&V 40 offers:

- ASME's first standard for specific application to medical devices
- Guidelines for assessing and quantifying the accuracy and credibility of computational models and simulations
- A framework for methodologies, implementation and best practices
- Standardized computational modeling techniques to aid in the design, testing, and regulatory review of medical devices

ASME V&V 40-2018 builds on the foundations of ASME standards V&V 20-2009, Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer, V&V 10.1-2012, An Illustration of the Concepts of Verification and Validation in Computational Solid Mechanics, and V&V 10-2006, Guide for Verification and Validation in Computational Solid Mechanics.

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