

Revised Standard Includes Biological Evaluation Framework

A recently revised AAMI/ISO standard provides additional new guidance on how to plan and implement biological evaluations of medical devices.

The standard—titled *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*—offers a framework for biological evaluations of medical

devices or materials.

The standard includes increased clarity regarding the overall framework of a risk management process for biological evaluations—which are conducted to determine whether a device or material will have an adverse effect on the patient.

“We tried to move the standard away from people using only the tests on charts and tables and nothing else,” says Jon Cammack, PhD, co-chair of AAMI’s Biological Evaluation of Medical Devices Committee.

“Just because you do all these tests in the chart doesn’t mean you have evaluated the safety of that device under the clinical use condition,” Cammack says. “You have to be able to say here is how this device is going to be used, and you have evaluated it under those end-use conditions.”

The standard has also been updated to make it easier to follow. “There is a flow chart that shows which questions to ask at discrete steps,” Cammack says. “There is also an enhanced glossary of terms.” ■

Biological Evaluation: A Primer

A biological evaluation is conducted to determine whether a device or material will have an adverse effect on the patient. Tests vary depending on the device. “As a device becomes more and more invasive, you need to do more tests to evaluate its safety,” says Cammack. “A device like a gauze bandage requires less biological testing versus a stent that is going in someone’s blood vessel.”

The tests for a biological evaluation vary from an *in vitro* test to a cell culture test. The tests are used to evaluate how a patient’s body will respond to the device or material. “If the device or material is causing cells to die like crazy then there is something not quite right about that material or device,” Cammack says. ■

ANSI/AAMI/ISO 10993-1:2009, *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*

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