

# AAMI News

Association for the Advancement of Medical Instrumentation

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## The Inside Word

***“The realization that quality is an important function within an organization is being conveyed more and more in businesses.”***

**J. Brad Vance**



See story on page 11

### FDA Expert Says . . .

## One System for ISO 13485 and QS Regulation Sufficient

The new edition of ISO 13485:2003, which is expected to be approved in May and published in July or August, will not conflict with current FDA quality system (QS) regulations, so device manufacturers will not need to establish two different quality systems, according to Kimberly Trautman, FDA's Medical Device Quality Systems Expert.

In fact, the ISO 13485 standard and the QS regulation are complementary, Trautman said during the 13th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation.



Nearly 300 people attended the 13th AAMI/FDA Annual International Conference, packing each session to full capacity.

The shift from ISO 9001:2000 is fundamental and important. “The wording in 9001 was too loose for regulatory purposes,” Trautman said, whereas ISO 13485 is tailored to the medical device industry specifically.

The new edition of ISO 13485 is a

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### Like Father, Like Son . . .

## Keeping the BMET Profession in the Family

When David Michael Collings was growing up in the 1980s, he remembers watching his father fix equipment around the house and at work. It didn't matter what it was—a toaster, a television set, or a ventilator—his dad could make it work.

Despite his admiration for his father's talents, he wasn't persuaded to follow in his footsteps. “He had no interest in the field at all,” laughs his father, David W. Collings. “He didn't even like coming into the shop.”

Over time, however, his father's influence rubbed off. Today, father David and son David—who is better known as Mike—are proud to be certified biomedical equipment technicians.

At a time when hospitals are struggling to attract qualified BMETs to the profession, David and Michael Collings have come up with a simple way to get the job done: groom BMETs in the family. David and Mike



David Michael Collings (left) and David W. Collings—A BMET family.

are devoted not only to the BMET profession, but also to the U.S. military.

David, 56, is a retired Air Force Chief Master Sergeant and currently a civilian working as the chief of biomedical engineering at Wilford Hall Medical Center Lackland Air Force Base in Texas.

His son, Mike, 33, is an active duty Air Force Technical Sergeant based at the Air Force Academy Hospital in Colorado.

For David, the decision to join the Air Force was easy. It was during the height of the Vietnam War and, with an active draft in place, it was join or be joined. It didn't take long for him to find his niche in the service. He became certified as a BMET in 1974, and has been devoted to the profession and military ever since.

For Mike, the decision to join the military and become a BMET didn't come as easily. He aspired to be a graphic artist. It took

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■ **Early Bird Discount:** AAMI members can save \$100 off non-member rates by registering early for AAMI's Annual Conference and Expo, June 14–17 in Long Beach, CA. Members who register by May 17 will pay \$695 compared to the non-member rate of \$795. After May 17, registration fees will increase to \$750 for AAMI members and \$850 for non-members. For more information or to register, visit [www.aami.org](http://www.aami.org) or call (800) 332-2264, ext. 217.

■ **New Issue of *BI&T*:** The March–April issue of AAMI's peer-reviewed journal, *BI&T*, is now available.

This new issue features a cover story on how to assess candidates for job vacancies and how to survive a merger or outsourcing. You'll also find an IT acronym guide and an article examining the fundamentals of surgical microscopes.

In *BI&T*'s new "Quality Matters" column, author Tammy Pelnik discusses the importance of design reviews to improve product introductions.

## Like Father, Like Son

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years of subtle influence by his father to convince Mike to consider a career as a BMET. And sometimes, dad's advice didn't seem so subtle.

For example, Mike remembers sitting with his father and making a list of pros and cons about joining the service. The list, he laughs about now, was all pros and did not contain a single con.

"I always told him this was the best job in the Air Force," adds David.

David's persistence paid off in 1990 when Mike enlisted in the Air Force. Following his father's advice, Mike jumped at the first BMET opportunity that presented itself. He became certified as a BMET in 1994, almost exactly 20 years after his father.

The parallels between their two careers are striking. Aside from both having the same instructor, Mike's current boss was a subordinate under his father 18 years earlier.

"I have been plagued by people who know both of us," Mike jokes. "It is kind of funny to hear about my father from the other side."

Mike sees himself as a "worker bee" and his father as a managing bulldog. "My father is the first person who people go to if they want to get a job done," Mike says. "There is a lot of give and take with my father, but you can always count on him. He does not back down."

Self-described as dogmatic and authoritative, David is not surprised by the description. But he also thinks of himself as flexible, in that he allows and expects input from his entire team. David believes in setting goals, delegating authority, and allowing section leaders to take ownership of a project.

Technology and the responsibilities of a BMET have changed considerably since David joined the service nearly 30 years ago.

"When I first came into the service, I was working with vacuum tubes and transistors," says David. "Nowadays, everything is becoming digital. The line between BMETs and the IT folks is becoming thinner."

Both David and Mike agree that emerging technology is one of the biggest challenges today. Someone entering the field needs to be competent in many computer operating systems and interfaces. Coupled with the deployment needs of a potential war with Iraq and continued turmoil in the Middle East, a well-trained military force is a concern for both men.

Although David and Mike live in different states and have different daily responsibilities, Mike says his father—the man with 30 years of experience who started the BMET family tradition—is always there to help.

"We try not to talk about business too much, but he always offers advice. Even if I don't ask for it, he still gives it," Mike jokes. "I guess that is what a father is for." ■

## ABOUT AAMI NEWS

**AAMI News** is the official newsletter of the Association for the Advancement of Medical Instrumentation (AAMI), a unique alliance of the health care professions providing essential information on the development and use of medical instrumentation and technology.

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