

## Invited Editorial

# Association for the Advancement of Medical Instrumentation/International Organization for Standards: Key to Perfusion Quality Management and Safety One Patient at a Time

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The Association for the Advancement of Medical Instrumentation (AAMI), a not-for-profit organization, writes standards for medical devices and is a country member of the International Organization for Standards (ISO). AAMI standards are reference guidelines for the United States Food and Drug Administration (FDA) and medical device manufacturers for the performance of all perfusion products' submission for FDA approval for product sales. Depending on the sophistication of the product, steps may involve in vitro bench testing (with fluid and/or animal blood), in vivo animal testing, approval for clinical testing pre-market approval (PMA), and final approval for general market release.

Historically, the FDA had virtually a non-participant role, but used AAMI standards as the paradigm for approval of products, which allowed manufacturers, clinicians, and independent experts to produce the details of the standards. Currently, however, there has been a major shift in the FDA philosophy. They have moved from a virtual non-involvement role to extensive participation. For example, one of their initiatives is that the bubble detector is a mandated part of a heart-lung machine and no longer is considered an accessory or can be sold separately. This shift in philosophy can be positive if it is balanced with active participation by clinicians and users. The FDA lacks the expertise to fully understand perfusion practice, but is taking aggressive stands in initiating standards that affect perfusion practice. They also have changed their focus on how the devices should perform to how the performer should perform. Recently, the FDA initiated the adoption of a checklist for extracorporeal circulation.

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As a member of the Blood/Gas Exchangers Working Group, the American Society of ExtraCorporeal Technology liaison accepted the task of producing the checklist document and co-authored the technical document. It is the first technical document ever with an itemized rationale for each checklist item allowing many clinicians and experts in the professional and standards organizations around the world to efficiently process the document. The delicate balance between the FDA and the clinicians was preserved in this case. The FDA's role remained the same with manufacturers. However, the recent decline in the number of representatives to the Working Group from manufacturers is a concern.

Another effect on perfusion practice is the constant pressure from manufacturers to downgrade a device classification with FDA. The oxygenator, for example, was a Class III device (the most difficult level for the approval process). In the mid-1980s, there was a strong movement initiated by the manufacturers, with reliable academic support, to attempt to downgrade the classification. While working for a manufacturer during that period, I was in a precarious position to petition against that movement. However, I was able to participate, along with an international group of perfusionists, in successfully stopping that movement, and the oxygenator classification remained Class III. I left the standards committees in 1990. Upon my return to the standards committees which included Blood/Gas Exchangers after a hiatus of 13 years in 2003, to my disappointment, the oxygenator had been downgraded to Class II.

In the dominant era of bubble oxygenators several decades ago, one of the most successful oxygenator companies experienced a massive number of randomly occurring oxygenator failures. Apparently, defoaming performance break down occurred unpredictably at the onset of cardiopulmonary bypass with their high performance oxygenator without rhyme or reason. The company devoted considerable resources but all the standard quality management

testing did not yield any clues. This extraordinary testing was carried out using blood collected from an entire battalion of Marines down the road in El Toro, but this effort yielded no clues. Eventually, it was discovered that the defoaming material from a supplier had undergone a slight change in formulation and some patients' blood reacted and aggregated causing defoaming breakdown instantaneously! The company acted responsibly, survived, and totally recovered from this debacle. The oxygenator was a Class III device at that time. Internal quality management protocol was modified to assure this event would not repeat itself. Expertise gained by the company eventually resulted in producing appropriate language into the Blood/Gas Exchanger standard. Defoamer is still a major component of many devices being used by perfusionists today.

Sometimes, perfusionists like to think of themselves as the gatekeepers and the guardians of the cardiac patient. Every time a patient safely comes off bypass, there is a feeling of satisfaction and gratification that can only be understood and appreciated by another perfusionist. We believe we have control of the destiny and safety of cardiac patients for a few hours. However, the enormous, daily,

hourly contributions of perfusionists in the operating room is not enough to safeguard the well being of cardiac surgery patients. Over the years this has been accomplished by our professional society's vigilant active participant through representation in AAMI and ISO. By participating in AmSECT through membership and volunteering perfusionists have a voice and an influence. This is the avenue for us to fulfill our professional obligation to protect patients.

There are 4000 perfusionists in the United States and 6000 more in the rest of the world. American Society of ExtraCorporeal Technology is the largest perfusion organization in the world making an impact on standards that affect cardiac surgery patients all over the world. Next time you open that package containing an oxygenator, be sure to look at the standard designation of ISO 7199 replacing the AAMI designation. Almost all our devices have ISO designations. We are the world. Careful monitoring and giving input to perfusion device standards will allow us to continue to take care of one patient at a time and maybe help us go to our beds knowing that we did our best to keep the "Device Failure Monsters" away from under our beds.