

# Quality Qorner

## From Theory to Application

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We can credit the blood banking community with the important transition from QC and QA to quality management systems, which began in the mid-1990s as a response to the issue of HIV and the blood supply. Shortly after the AABB introduced the first blood bank Quality System Essentials (QSEs) in 1997, a few laboratory professionals recognized their value beyond transfusion medicine into clinical and anatomic pathology. Thus began the process of developing guidelines for laboratory-wide QSE implementation through the NCCLS (now the Clinical and Laboratory Standards Institute, CLSI) consensus development process ([www.clsi.org](http://www.clsi.org)).

I've spent the past 15 years of my career developing learning programs and materials about the value of the QSEs in managing blood banks, medical laboratories, and patient safety and delivering these to anyone who would listen. I've presented innumerable audioconferences, workshops, breakout sessions, breakfast roundtables, and keynote speeches at countless local, state, national, and international meetings. I've published many articles, chapters, and books and have worked as a volunteer on several NCCLS/CLSI guidelines, all designed to introduce the basic concepts of quality management systems to both staff and management level laboratory professionals. The essence of all these programs and materials has been to introduce the theory behind the QSEs and the rationale for using them as the basis for managing any size laboratory of any scope, of any specialty, anywhere in the world. I truly love what I do and I'm privileged to have the opportunity to contribute to our chosen profession in this way.

But there's one thing that I have not been able to contribute. When I left the daily work environment of the hospital laboratory to teach others full time, I left behind the opportunity to actively do what I preached to others; I could not develop a laboratory document control system, create laboratory process flowcharts, design an occurrence management reporting system, or prepare quarterly laboratory quality reports for management review. As a teacher and consultant, I've only been able to show others what needs to be done and hope they carry forth and do it for their own laboratories.

It's one thing to learn about the QSEs, another thing for a laboratory to actually implement them, and a completely different thing for someone from that laboratory to publicly share QSE experiences with others. It's taken over a decade but I'm happy to report an increasing incidence of laboratory professionals stepping forth to describe how they've used one or more of the QSEs—or all of them—to improve some aspect of their respective laboratories. The QSEs have been in place for over 10 years, but skeptical laboratory professionals only consider this approach as valid when others actually implement quality management and then also step forth to tell what happened when they did it. The good news is that our laboratory community is finally experiencing the important and necessary transition from programs on QSE theory to those about QSE application.

Look at what's being offered now in the catalogs of the laboratory professional meetings. Last month's ASCP Leadership Exchange offered programs on Lean process improvement, preparing for unannounced inspections, and training and competence assessment—by laboratory professionals involved in these projects. The late March CLMA meeting is providing programs on Lean in the anatomic pathology laboratory, shared laboratory good practices, specific quality monitors using the QSEs, the use of the QMS as continued readiness for unannounced inspections, and a successful Six Sigma study. The CLSI Leadership Conference in April is featuring programs on quality management system applications in African laboratories and in non-instrumented waived testing. The September COLA Quality Symposium program will include some “testimonials” about how laboratories are using the QSEs to improve quality and patient safety.

Futurist Joel Barker had a groundbreaking video in the 1990s called “The Paradigm Pioneers.” In it he described the pioneers as “the guys with the arrows in their backs”—that is, those bringing forth new concepts and weathering the inevitable backlash. Then come the early followers: those who see the new paradigm as good and take off running. Then come the late followers: those who cautiously wait to hear from the early followers before making their move. The last to arrive (or not) are the institutional terrorists and they should—in the words of a visionary pathologist who embraces quality concepts—“be invited to find a new work address.” With respect to the QSEs, where is your laboratory on this continuum?

I applaud both the early and late followers who are now sharing their quality management experiences with fellow laboratorians. We need to hear more from you! In my previous column, *Toot Your Horn (Lab Med. 38;12:713)*, I implored you to showcase your laboratory in your own institution. This time I ask that more of you brave souls submit proposals for audioconferences, breakouts, and workshops and write articles about your experiences with the QSEs and quality management. I can spew all the theory I'm invited to but only you can share the experiences of application!

### *This Month's Quality Quote:*

“Anything that isn't good for everybody is no good at all.”  
—Henry Ford

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