
Quality Qorner

Quality – A 3-Legged Stool

My dad loved to dabble in his woodworking hobby after a long day in the factory. He would make things for my brother and me—a rocking horse, wooden pull toys, a beanbag toss board, a toy box. One of my all-time favorite things was a small wooden stool, just the size for short toddler legs, brightly painted with my name on it.

Recently, I pondered a question that I am often asked, “How does a laboratory integrate the quality elements of administrative compliance, customer needs, and cost constraints?” It occurred to me that perhaps these aspects of quality were like my little 3-legged stool. That stool could not adequately perform its function without the equal support of all 3 legs (as I found out when, in a tussle with my brother, 1 of the legs was broken.) Likewise, quality is a “3-legged” balancing act between accomplishing compliance with requirements, meeting the needs of customers, and affording the cost of providing for both.

Accomplishing Compliance With Requirements: Laboratories and blood centers found to be significantly noncompliant with federal requirements have experienced sanction or closure. Lesser nonconformances have resulted in warning letters and increased federal scrutiny. The message is that it is imperative for laboratories and blood banks to comply with all federal, as well as state and local, regulatory requirements.

Although peer accreditation is optional in lieu of many governmental inspection programs, when a laboratory or blood bank facility chooses to be accredited by 1 or more such organizations, the understanding is that the facility also chooses to meet the documented accreditation requirements. External assessors and inspectors verify compliance with their organization’s requirements through on-site visits. Though occurring rarely, accreditation has been withheld or withdrawn from laboratories and blood banks that were found to be repeatedly or significantly noncompliant.

So, it looks like the compliance leg of the stool is essential to your facility’s ability to *exist* in a regulatory environment. Laboratories and blood banks need to design their managerial and technical work processes and procedures in a way that ensures that regulatory and accreditation requirements are actually met. This proactive philosophy is different from the usual approach of “This is how we do things, so let’s see if they can find anything on us.”

Meeting Customer Needs and Desires: We all know that physicians and nurses would like laboratory test results to be instantly available after sample collection. However, we all need to be more realistic, which requires knowledge of both customer and laboratory perspectives about what is reasonably achievable with the existing resources and work processes. What is quality for 1 customer may not be quality for another. From the physician customer’s perspective, it is not quality if the quantitative test result is accurate to the second decimal point but it takes 4 hours to get it when it was needed in 1 hour. Likewise, it is not quality for a transfusion service to delay provision of blood components so that clinically insignificant cold-reacting antibodies can be identified to the letter and antigen-negative units (that

will not react with the antibody anyway!) can be selected.

Therefore the customer leg of the stool is also essential. It represents your facility’s ability to provide necessary services that *make a difference to* and *add value for* varied laboratory customers. (For more on who is the laboratory’s customer, see last month’s *Quality Qorner*.) Laboratories and blood banks need to design their managerial and technical work processes and procedures in a way that ensures the customers’ needs are met. This philosophy is different from the usual approach of “This is how it’s done here, so they can just live with it.”

Affording Cost: The cost issue is an interesting circle. Many laboratory and blood bank processes are *ineffective*—that is, they don’t meet regulatory, accreditation, or customer requirements. Considerable effort and resources are invested in responses for inspection nonconformances and complaints; the human and material resources expended can be very costly. Worse yet, when the response does not include revising the process to remove the *root cause* of the problem, the resource expenditure *recurs each time* there is an assessment/inspection nonconformance or complaint!

In addition to being ineffective, many laboratory and blood bank processes are *inefficient*—that is, they consume an inordinate amount of human and material resources due to inherently bad design—“This is the way we’ve always done it (or had to do it).” As a result, samples need to be recollected, reports re-sent, tests repeated, or work redone. Supplies are not conveniently located; people trip over each other as they cross paths to complete a task; and everything takes longer than it should. A considerable portion of the laboratory’s costs is spent in ineffectiveness and inefficiency. We come full circle when we realize that we have no resources for improvement because they have already been spent on recurrent problems!

There is no doubt that the cost leg of the stool is essential. Laboratories and blood banks need resources to provide compliant products and services to their customers, but costs must be controlled.

So we’re back to the original question, “How does a laboratory balance customers, compliance, and cost?” The answer is simple, but not easy. Laboratories and blood banks need to re-

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design their managerial and technical work processes in such a way that both regulatory/accreditation requirements and customer needs can be met *when working in the process*. With this approach, the processes become more effective and efficient, thus releasing resources once spent in addressing unresolved problems to be available for further enhancements and improvements.

So what holds the 3 legs together? It is the seat of the stool—a quality management system, upon which the laboratory can safely rest, balancing compliance, customers, and cost.

This month's quality quote: *“Control the process, count on the results.”*