Quality for tomorrow: by design or by checking?

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The clinical laboratory has seen some major changes, a revolution if you will, in the quality of testing services over the past decade. Some of this change has come through a better understanding of statistical theory and its direct application to concepts of error detection and false rejection, resulting in a blossoming of applications in many different quality-control (QC) rules, as championed by James Westgard. Another noteworthy component of this quality revolution has come through advances in analytical technology. Test systems are becoming more automated and feature internal self-diagnostics. Discrete analyzers lend themselves to more extensive monitoring of each specific function. Also, automation is being extended to the preanalytical and postanalytical phases. A third element in this quality revolution is the broad-based awareness of total quality management throughout the diagnostics business, from manufacturers to laboratories to physicians and patients. All of these factors help define the quality of laboratory services today. Because of this quality revolution, the momentum of change appears to be bringing us new opportunities to manage and regulate quality today and to improve our quality tomorrow.

As we have developed a greater understanding of process variation or process capability, we have become more adept at relating process errors to departures in typical process variation and at identifying appropriate corrective actions. However, at the same time, we have encountered situations in which results are not explainable by that process variation. These can be classified as blunders or mistakes, which are outside the bounds of typical process variation. In the past, process capability might have been so imprecise that our ability to differentiate between blunders and process variation was not very good. Blunders often were blended into process variation, but today, with more-precise test systems, the blunders become more evident. As we progress in the continual improvement cycle, we must emphasize the distinction between process variation and blunders and design quality systems accordingly.

Just as most laboratories have progressed from the simple 1–2s QC rule to the use of test-specific rule(s) that are based on quality requirements as well as capabilities as a method for monitoring process variation, we too need to factor into our thinking the potential for the occurrence of blunders and the need to prevent them. By definition, we can monitor process variation because it is predictable. However, it is very difficult to detect blunders and prevent them from being reported. Using 100% quality checking or performing all tests at least twice would be very costly and reduce productivity. The most successful way to deal with the potential for blunders is to understand each step in a process and design each step in a way that prevents or does not allow an error to be made. Thus we come to the concept of designing-in quality into a test system, not only to minimize process variation, but also to prevent or minimize process blunders.

Designed-in quality presupposes some quality goal. Whether the goal is defined by medical need or by technical capabilities (limitations) is an issue that both the designing scientist and engineer must address. However, it can be stated safely that once designed and produced (manufactured), the quality of a system cannot be improved by even the most sensitive and specific QC program. The QC program, at best, can monitor only what is there, identifying only departures from the routine process variation or capability, however good or bad that might be, and then only for some fraction of the time.

We can achieve the greatest impact on the quality of a test system at the design state and in the implementation of that design in the manufacturing stage. Several manufacturers in a variety of industries are implementing this most fundamental principle. Rather than taking the point of view that quality is the responsibility of the laboratory, these manufacturers have taken ownership of the quality equation, right from the start, and both they and the laboratory benefit from that principle.

Laboratorians and healthcare professionals must develop a conscious awareness that quality is inherent in the design of a test system, then customize quality-monitoring programs accordingly to check the most likely causes for failure (variation). These checks might focus on

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changes in precision, or shifts, or even on a specific subcomponent by use of a representative check sample, rather than a specimen, but these quality-monitoring systems are not likely to detect blunders. More importantly, regulatory agencies must appreciate this principle, giving greater emphasis to system designs that, while minimizing process variability, also prevent blunders. Less emphasis should be given to how many QC samples are run per day. If one looks only at monitoring quality after the product has been designed and built, then it may be too late; even the best QC system will not make it better. Obviously, one size of shoe does not “fit all” when it comes to defining and monitoring the quality of a test system.

This is only the beginning of what we hope to discuss at this, our sixth Forum: “Quality for Tomorrow.”