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Laboratory Quality Management: A Roadmap

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"Total quality management is a journey, not a destination."
Thomas Berry [1]

How do you view activities related to laboratory quality management? Do you perceive these activities as being of special value in your everyday laboratory life? Do you perceive these activities as additional, often burdensome work that is necessary only because it is required by regulatory and accreditation organizations?

Unfortunately, the latter misperception is still prevalent a full 18 years after the College of American Pathologists first introduced Q-PROBES to acquire national laboratory performance data on selected quality performance measurements [2]. It seems that a large segment of the medical laboratory community has yet to understand that quality must be built into, not inspected into, work processes to ensure quality and patient safety [3]. Many laboratories miss out by focusing on their destination (ie, passing an accreditation inspection) instead of more carefully mapping out and enjoying their journey.

If any journey begins with a single step, then the journey toward total quality management must begin with an understanding of the relationship between medical laboratory quality activities that should be designed and supported by laboratory management and the technical activities that produce laboratory results for patient care. Fortunately, this dual relationship is very simple, can be described graphically, and can become the fundamental basis for quality management and quality improvement in any medical laboratory of any size, scope, or specialty anywhere in the world.

It has taken a while for the dual managerial relationship between medical laboratory quality management activities and technical work to become

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comprehensively mapped out. It began in the United States in 1992, when the Food and Drug Administration (FDA) convened a public workshop to solve the quality problems inherent in dealing with the HIV-AIDS virus contaminating the nation's blood supply. The FDA's concern spurred blood bank laboratories first to take notice of the dual quality management activities/technical procedural activities relationship.

The FDA workshop ultimately produced a guidance document for blood bank quality assurance [4] designed to complement FDA good manufacturing practice requirements [5,6]. The American Association of Blood Banks responded to the FDA guidance with publication of *The Quality Program* [7]. It was in this program that the relationship between the quality management activities mandated by the FDA in good manufacturing practice requirements and the blood bank technical activities was first conceptualized, graphically.

Laboratory personnel working in hospital-based transfusion services soon realized that the relationship between quality management and laboratory technical activities extended far beyond the transfusion service to all other specialty disciplines in clinical and anatomic pathology laboratories. In 1999, an NCCLS[1] subcommittee, representing laboratory, industry, and government perspectives, produced the first medical laboratory-specific quality management system (QMS) model [8]. They based this salient model on the regulations, accreditation requirements, and laboratory standards that existed at that time. In 2004, the CLSI published the most recent update to their QMS model [9,10] with a new edition scheduled for 2008.

Parallel to the CLSIs synthesis of laboratory quality management activities in the late 1990s, a group of international representatives from laboratory accrediting organizations, academia, and public and private laboratories also began transforming an already extent international standard for nonmedical industrial laboratories [11] for use in the medical laboratory environment. The initial result was the international medical laboratory standard *ISO 15189, Medical laboratories—Particular requirements for quality and competence* [12]. This international standard, first published in 2003, calls for medical laboratories worldwide to implement a QMS that provides the level of laboratory quality and performance deemed necessary for ensuring minimally acceptable patient care and safety. This standard addresses, in detail, the elements of both quality management and laboratory technical activities necessary for reaching this overall goal. Several countries have adopted this document as their national standard and have developed laboratory accreditation programs based on the requirements in the standard (Canada is one example) [13].

[1] In 2005, the NCCLS was renamed the Clinical and Laboratory Standards Institute (CLSI). The abbreviation, CLSI, is used throughout the rest of this article.

Laboratories in the United States are subject to so many national, state, and local requirements that it has been extremely difficult and time consuming to track compliance with every individual organization's listed requirements. Fortunately, the CLSI QMS model provides a means for aggregating all like requirements from different regulatory, accreditation, and standards-setting organizations into an easily understandable matrix. This helpful framework allows laboratories to develop quality and technical policies, processes, and procedures that meet all current regulatory requirements. In return for the effort, these documents describe the laboratory's QMS. Understanding the modular framework and using it to implement the activities necessary to meet requirements is the laboratory's best and easiest means to "build quality into" its daily work in the interests of patient care and safety.

The remainder of this article discusses the individual elements of the QMS model and how laboratories can use the model to build a QMS that covers all regulatory and accreditation requirements, prepares laboratories for unannounced inspections, and provides the means for the laboratory to make its best contribution to patient care and safety.

A simple model for a laboratory quality system

Medical laboratory work is composed of the technical activities that produce laboratory results for patient care and the management activities that support the technical work. It is the job of the laboratory technical staff to perform preanalytic activities (blood sample collection, receiving, accessioning); analytic activities (testing, examinations, interpretation); and postanalytic activities (reporting results, archiving samples, charge capture) that transform a clinician's order for a laboratory test or examination into the results used by the clinician to diagnose and treat patients.

Likewise, it is the job of the laboratory supervisory and managerial staff to design and implement the supportive infrastructure that is necessary for the technical work to proceed unimpeded. An integrated coordination between technical and managerial activities is essential for the continuous, unimpeded realization of high-quality, error-free, efficient, and effective laboratory operations. Fig. 1 depicts this important relationship between technical and managerial activities. Importantly, this figure also represents a QMS model that can be used in the medical laboratory environment.

The "quality system essentials" (QSEs), first introduced by the American Association of Blood Banks [14] and later adopted by the NCCLS-CLSI [8], are fundamental, generic management infrastructure elements that support the laboratory's technical work. Each QSE consists of a collection of essential information that characterizes a major managerial activity. Each QSE needs to function properly for the laboratory's technical work to be performed successfully.

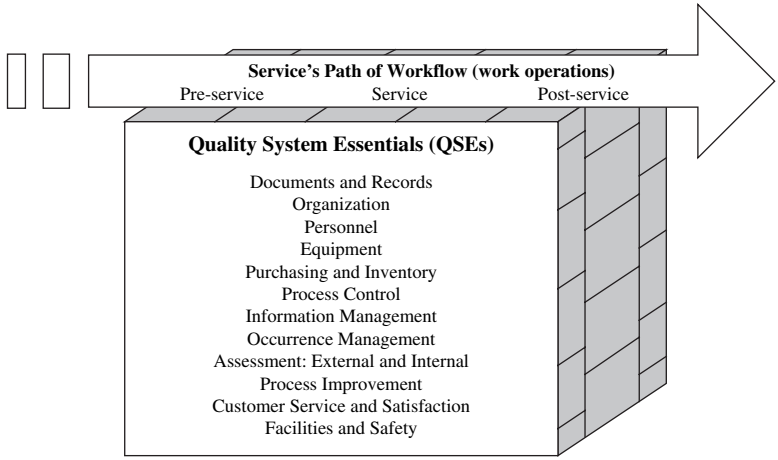

Fig. 1. A simple generic model for a quality management system. (*From* CLSI. CLSI approved guideline HS1: a quality system model for health care. 2nd edition. Wayne (PA): 2004. p. 4; with permission.)

The information gathered for each of the 12 QSEs stems directly from regulatory, accreditation, and standards requirements for laboratories and blood banks. The composition of each QSE was first prepared by sorting all the then-current (circa 1997) requirements into their respective QSE topic. Each item of the following was assigned to the most appropriate QSE:

- Clinical Laboratory Improvement Amendments of 1988
- FDA good manufacturing practice regulations
- Joint Commission laboratory standards
- College of American Pathologists inspection checklists
- American Association of Blood Banks standards
- Commission on Office Laboratory Accreditation standards

This compilation was published [15] and subsequently served as the basis for the original NCCLS-CLSI guideline [8].

CLSI regularly updates the QSEs by assigning each newly published regulatory, accreditation, or standards requirement to its respective QSE. Expanding the contributory base, CLSI included in their most recent QSE publication items that were not present in United States–based requirements but had been published as requirements in the international medical laboratory standard ISO 15,189:2003 [9]. Accrediting organizations are slowly adding items from the international standard to their respective requirements.

CLSI guideline HS1-A2 [9] presents the requirements-derived content of each of the 12 QSEs, and additional information about how to implement a QMS. CLSI guideline GP26-A3 [10] presents the requirements-derived content for the medical laboratory's path of preanalytic, analytic, and

postanalytic workflow activities. Laboratories can use both documents to verify whether they are performing and documenting all required management and technical activities.

These two CLSI laboratory QMS documents are not, themselves, standards; they are guidelines derived from published requirements. This distinction is important: the CLSI QMS model imposes no additional regulatory laboratory requirements other than those to which United States laboratories are already subjected. The model merely sorts given requirements into single, specific topics for which a laboratory can then design its policies, processes, and procedures. Consequently, the model provides a simplified means of understanding and implementing a QMS that meets all laboratory regulatory and accreditation requirements.

Another benefit of the QMS model is that it accommodates any requirement or standard that has ever been written or will be forthcoming. The QMS perpetually renews and updates itself. The laboratory merely incorporates each new requirement into its respective QSE and then reviews present laboratory policies, processes, and procedures to identify any additions or changes needed to fulfill the new requirement.

Implementing a quality management system

Most laboratories are already performing management activities that comprise components of a QMS. Without a standardized QMS in place, however, not all necessary management activities are practiced in every laboratory and those that are may not be practiced uniformly within a single laboratory. The resulting variation in management practice causes inefficiencies in the use of resources and ineffectiveness in meeting accreditation and regulatory requirements. The QMS is a uniform, systematic means for any laboratory to ensure that requirements are being continuously met each time, every time, in every laboratory section, every day.

Throughout the remainder of this article, the QSEs are discussed from the perspective of either creating a new laboratory that has not existed before or managing an existing laboratory that plans to offer a new service. For illustrative purposes, the following text uses the adding of a new testing service to an existing clinical laboratory. Please note that this approach, however, does not preclude any laboratory from reorganizing its current activities into a QMS.

Before the new testing can be performed, laboratory management must implement a number of critical infrastructural elements in a logical sequence and ensure they are solidly in place.

- First, the specific preanalytic, analytic, and postanalytic work processes and procedures for the new testing need to be identified.
- Next, the laboratory must determine the responsibilities and reporting relationships of all the people involved in the new service.

- Then, it needs to identify its potential customers and determine their needs and expectations for the new service.
- Next, adequate facilities, people, equipment, and materials need to be identified, sought, obtained, and put in place for the new service.
- The specific preanalytic, analytic, and postanalytic work processes and procedures need to be developed, validated, and documented.
- Staff needs to be trained and their initial competence assessed.
- The laboratory needs to determine the means by which patient results and reports will be managed for the new service.
- There is need to determine the laboratory's means for capturing complaints and nonconformances for the new service.
- The laboratory needs to determine how it will measure its performance to determine if goals, objectives, and customer expectations are being met for the new service.
- The laboratory needs to determine the means by which quality reports will be periodically prepared for the new service.
- Last, the laboratory needs to determine how management will review and identify opportunities for process improvement and prioritize and initiate improvement activities.

Only after all these elements are finally in place and functioning, may the new service testing finally begin.

One way to depict this important sequence of managerial events is by slightly modifying the QMS model as first shown in Fig. 1. This modification is shown in Fig. 2, which depicts the QSEs as divided into three groups: (1) laboratory, (2) work, and (3) measurements. These three groups sequentially embody the entire laboratory as a dynamic, whole organization. Every essential component needs to be in place for the laboratory to create and maintain its complete structural integrity.

The laboratory can implement its entire QMS by establishing the policies, processes, and procedures for the QSEs shown in Fig. 2, following the prescribed sequence of the three groupings. This sequential approach is also effective when planning any new laboratory service, or when regionalizing

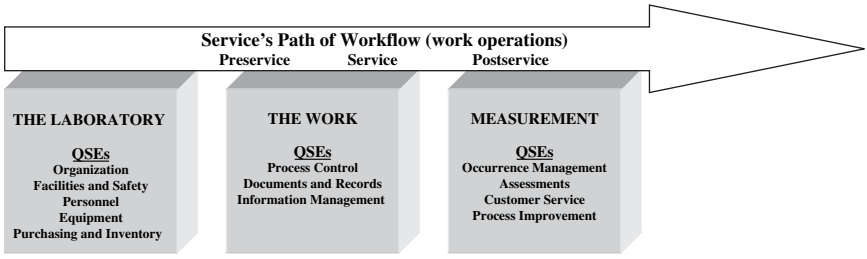

Fig. 2. Arrangement of the quality system essentials of the QMS model into logical groupings. (*Adapted from* CLSI. CLSI approved guideline HS1: a quality system model for health care. 2nd edition. Wayne (PA): 2004; with permission.)

any two or more laboratories within the same health system, or when creating a new entity through mergers.

To clarify the QMS sequential model further, the elements of each QSE are individually described next. Each element represents a laboratory requirement, as specified by regulatory agencies, accreditation organizations, or in published standards.

The laboratory quality system essentials

Organization

The laboratory needs to be legally identifiable and have a documented organizational plan and structure that ensures the delivery of quality services to patients and all clinical personnel responsible for patient care and ensures patient safety [12]. This plan and structure should include:

- Scope
- Roles, responsibilities, and reporting relationships
- Quality planning and risk assessment
- Budgeting of resources
- Quality review and assessment
- Management review

The scope of all of the laboratory's services should be clearly documented, with a description of all testing services provided and all customers served. All personnel roles, responsibilities, and reporting relationships need to be documented and communicated so that all staff members are aware of their respective places in the organization. Quality planning and risk assessment should be undertaken to ensure that all applicable accreditation and regulatory requirements are met with the laboratory's current, modified, or new processes and procedures. Allocation (ie, budgeting) of facility, human, equipment, and material resources is necessary for ensuring that resources provide adequate capability to meet customer needs. A QMS requirement is that laboratory management periodically reviews the effectiveness of the QMS in meeting customer needs, stated goals and objectives, and applicable requirements [12,16–18]. This last activity, management review, should culminate in the laboratory's prioritization of opportunities for improvement, allocation of resources to carry out the improvements, and monitoring of improvement activities to ensure their effectiveness.

Facilities and safety

The laboratory needs to have adequate space and facilities that are designed and constructed or renovated to optimize work efficiency; minimize the risk of injury and occupational illness; protect workers, visitors, and patients from recognized hazards; and meet governmental or industry

standards for facilities and environment. Listed next are several structural and nonstructural elements of laboratory design that affect the planning, layout, and safety of the laboratory [19].

- Space
- Workflow
- Casework
- Equipment placement
- Classifications
- Ventilation
- Lighting
- Plumbing
- Electrical
- Communications

Arrangements are needed for routine maintenance to keep the facility in a functional, reliable, and safe condition. Ensuring clean work areas and good housekeeping involves laboratory staff and ancillary services provided by the larger organization. The laboratory should have adequate space for storage of consumable supplies; reagents and chemicals; patient samples; and materials derived from patient samples, such as tissue blocks and retained slides.

Physical and procedural safety is an inseparable adjunct to the physical facility. Several safety programs that are required in the laboratory are

- Emergency preparedness (fire, weather, disaster)
- Universal precautions [20]
- Hazardous waste [21]
- Chemical hygiene [20]
- Infection control [22]
- Occupational injury and illness [20,23]
- Radiation safety (where applicable) [24]
- Ergonomics [17]

Supportive safety training is required in each respective program for each staff member as is applicable to his or her respective job tasks.

Personnel

Once the organization structure and responsibilities have been established and the laboratory's physical space needs have been addressed, the laboratory's personnel is the next important resource to be established. Certainly, without qualified, trained, and competent staff performing the work processes, quality laboratory performance cannot be ensured.

The Clinical Laboratory Improvement Amendments of 1988 regulation [25] specifies the minimum requirements for the qualifications and responsibilities for personnel performing provider-performed, moderate-complexity,

and high-complexity laboratory testing. The job titles for which these national personnel standards exist are shown in Table 1.

Laboratories and their parent organizations may set additional or higher qualifications and responsibilities, if so desired. Qualifications and responsibilities for the laboratory director, consulting pathologists, and technical consultants (for which the laboratory is assessed at its periodic unannounced inspections) have been published by the College of American Pathologists [26]. All personnel qualifications and responsibilities can be documented in the laboratory's job descriptions, which must be kept current and available to all staff.

The laboratory should provide an induction for all new laboratory staff. Suggested elements for laboratory orientation are as follows:

- Laboratory quality policy
- Laboratory's vision and mission
- Laboratory values
- Laboratory goals and objectives
- Personnel qualifications and responsibilities
- Laboratory culture

All staff needs training in the work processes and procedures that comprise their respective job tasks, whether or not new staff members arrive with previous experience. The required ways to ensure that competence of staff is assessed and documented initially after training and periodically thereafter are listed as follows [17,25]:

- Direct observation of routine work processes and procedures
- Direct observation of equipment maintenance and function checks
- Monitoring the recording and reporting of test results
- Review of work records
- Assessment of problem solving skills
- Use of specially provided samples, such as those from previously tested patients, interlaboratory comparison materials, or split samples.

Table 1
Job titles for which there are Clinical Laboratory Improvement Amendments of 1988 personnel standards

Provider-performed microscopy	Moderate-complexity testing	High-complexity testing
Laboratory director	Laboratory director	Laboratory director
Testing personnel	Technical consultant	Technical supervisor
	Clinical consultant	Clinical consultant
	Testing personnel	General supervisor
		Testing personnel
		Cytology general supervisor
		Cytotechnologist

To ensure that laboratory staff remains current in job and professional knowledge, laboratories are required to provide programs for continuing education and professional development [12,17]. Records of the laboratory's continuing education program are required. Records of personnel participation in internal and external continuing education and development should be maintained in personnel files.

In addition to the processes described previously, laboratory staff must also collaborate with the parent organization's human resources department for other required activities, such as occupational immunizations, accident reporting, and wage and payroll registration.

Equipment

Once the laboratory's organization, facility, and personnel are in place, the laboratory needs to acquire the equipment necessary for delivering its desired testing services. The processes, programs, and procedures described for this QSE refer to the laboratory's general equipment, instruments and analytical systems, and computer systems hardware and software.

The laboratory should establish selection criteria for each piece of equipment it needs to acquire, and should determine which vendors can meet those criteria. Before equipment is selected, the laboratory needs to verify that the laboratory's physical facility can meet the equipment's needs for space and load bearing; electricity, ventilation, humidity, and temperature; water type and quality; and any other special requirements. After arrival, and before use, each piece of equipment needs to be installed and initially verified as meeting the manufacturer's stated performance characteristics.

After the onset of the actual testing, the equipment must also be verified as functioning as intended in the actual work processes in which it is used. Laboratory schedules and procedures that follow manufacturer's instructions are required for ongoing preventive maintenance, calibrations, and calibration verification; performance records provide objective evidence of outcomes of these required activities. Troubleshooting, service, and repair records are also required. Reconstruction of the history of each piece of equipment from acquisition to decommission should be traceable from the equipment records.

Purchasing and inventory

Before any testing in any new laboratory or new process can begin, the laboratory needs to identify and purchase all related materials and reagents. The laboratory may also need to purchase services, such as equipment maintenance and service contracts and referral laboratory testing. For these purposes, the laboratory should formalize its needs and requirements in documented agreements with vendors that specify each party's responsibilities. These agreements should be periodically reviewed to determine the vendor's ability to meet the laboratory's needs, and adjusted as necessary.

Efficient laboratory operations require the uninterrupted availability of reagents, supplies, and services. The laboratory needs to maintain a cost-effective disposable supply inventory and have the support of an adequate materials purchasing program. Critical reagents and materials need to be received, evaluated, and tested as necessary (before use) to ensure that necessary quality requirements have been fulfilled.

The work quality system essentials

Process control

Control of the laboratory's preanalytic, analytic, and postanalytic work processes is crucial to the quality of the laboratory's test results. Such process control begins with identifying and documenting the laboratory's many work operations. A concise guide of laboratory processes with examples is available [10]. Use of properly constructed process flowcharts efficiently identifies the activities for which procedures (ie, instructions) are needed for the laboratory staff to perform their assigned job tasks. Such process analysis expedites the writing of individual procedure documents. Together, the process and procedure documents conveniently form the basis of the technical procedures manuals [27].

Before any process is executed in the live environment, the process needs to be verified as meeting its intended outcome. Verification consists of creating a plan that allows the technical staff to challenge the process as initially developed, document the results, and determine if the pre-established criteria set for the process have been met and whether the needs of the customers of the process have been met. In processes where laboratory testing is performed, test method verification is also required. Also, the laboratory must verify that the manufacturer's stated specifications are being met with the laboratory's own processes, equipment, personnel, and materials. Several guidelines are available to assist laboratories in such verification of test methods [28–35].

Quality control programs are a means of controlling patient testing processes at the bench level. Laboratories must meet the established requirements for quality control of test methods; both the minimum required quality control [25] and any manufacturer's requirements must be followed. The use of statistical tools provides a visual means to understand quality control data so that timely action can be taken when method problems are detected [12].

Documents and records

At the heart of the laboratory's QMS are the policy, process, and procedure documents that tell staff what to do and how to do it and the records that provide objective evidence of the results of performing the processes

and procedures. Audits often reveal that laboratory documents and records are missing, incomplete, outdated, or contain incorrect information; all these problems can cause errors that could compromise patient safety. Laboratories are now required to control their documents and records through the processes listed next [12,17,18]:

Document control elements
- Document identification
- Creation, review, and approval of new documents
- Document master files
- Review and approval of changes to approved documents
- Periodic review of unchanged documents
- Master index of documents
- Document distribution
- Archiving, storage, and retention of obsolete documents

Record control elements
- Record identification
- Creation and legibility
- Records reviews
- Record indexing
- Records access
- Changes to recorded information
- Record storage and retention
- Record disposal

Either or both paper or electronic document control systems are acceptable, provided that only the most current documents are available to all staff at the locations where they are needed for staff to perform their assigned job tasks.

Information management

The requirements contained in this QSE concern the laboratory's management of the information contained in its paper-based or computer-based record systems. This includes patient demographics, test results and interpretations, reports, other laboratory data and information, and how that information is disseminated to users or other computer systems. The laboratory needs to have policies, processes, and procedures that address information access and security; requests for information; confidentiality of information; information transfer (eg, electronic interfaces and data transfer); and data integrity (eg, report readability and accuracy).

Also, there needs to be a downtime program for managing the availability of patient results and information when the computer system is not functioning. In addition, this QSE contains the requirements for the processes to ensure against Medicare and Medicaid charging and billing fraud and abuse [36].

The measurement quality system essentials

Up to this point, eight QSEs (presented in sequential terms of "laboratory" and "work") have described the actions needed to prepare for the laboratory's production of testing and examination result reports. The remaining four measurement QSEs shift the focus to asking and answering the question of how well the laboratory's processes are performing in meeting the quality goals and objectives set in QSE: Organization, the requirements imposed by regulatory agencies and accreditation organizations, and the needs of the laboratory's customers. These are the QSEs of "measurement."

Occurrence management

Now referred to as "nonconforming event management," this QSE consists of the requirements for documenting and investigating events that do not conform to the laboratory's established policies, processes, or procedures, or other imposed requirements. The program captures and analyzes information about nonconforming events and complaints to identify underlying systematic problems and gain management's commitment to removing the causes. A nonconforming event management program contains the following elements [37]:

- Identification and reporting
- Remedial action
- Investigation and documenting
- Action plan
- Classification
- Analysis and presentation
- Management review and follow-up

This QSE also includes the recently established requirement for the laboratory to have a process for employees to communicate concerns about quality and safety to laboratory management [17].

Assessments: external and internal

The laboratory cannot improve the quality of its services without measuring its current performance. Both external and internal assessments provide objective evidence of the laboratory's performance compared with established goals.

The laboratory should be participating in three types of external assessments: (1) licensing or accreditation, (2) proficiency testing, and (3) performance comparison. First, all laboratories are subject to external assessment by licensing agencies (eg, Centers for Medicare and Medicaid Services, under the Clinical Laboratory Improvement Amendments of 1988) or accreditation organizations, such as the Joint Commission, College of American

Pathologists, or Commission on Office Laboratory Accreditation. These organizations assess the laboratory against their respective published requirements and issue deficiencies for identified nonconformances that require subsequent corrective action for the laboratory to maintain the license or accreditation.

The second type of external assessment is proficiency testing, where the laboratory tests or examines sample materials prepared and sent by an outside organization, the results of which are compared with other laboratories with similar methods and instrumentation [25].

The third type of external assessment involves the laboratory's comparison of its performance on selected process measurements against other laboratories of similar size and scope. The College of American Pathologists maintains two such programs: Q-PROBES and Q-TRACKS [38,39].

Routinely, laboratories should practice two types of internal assessments: quality indicator measurements and laboratory audits. Quality indicators are measurements of process performance that are tracked using graphical tools, such as control charts. One example is the number and source of received samples that do not meet the laboratory's established acceptance criteria; another is turnaround time. Ideally, the laboratory identifies one or more indicators to measure the performance of its preanalytic, analytic, and postanalytic work processes. Many examples of laboratory indicators are available [10,17].

A laboratory audit is the process of comparing observations of actual conditions with requirements and presenting an evaluation of the results to management [40]. In the laboratory environment, any preanalytic, analytic, postanalytic, or management process can be audited to determine its conformance to the laboratory's established policies, processes, and procedures, and external regulatory and accreditation requirements. College of American Pathologists inspectors are using auditing techniques to "follow the sample" through the laboratory's processes during unannounced laboratory inspections [17]. Audit findings point to process problems that need corrective action.

Customer service

The laboratory provides phlebotomy services to patient customers and provides test results, interpretations, and reports to its clinical caregiver customers. Adequate measurement and monitoring of laboratory performance requires feedback being actively, routinely solicited from these customers regarding their satisfaction with the laboratory services they have received [17]. Also, laboratories that perform referral testing have other laboratories as external customers. The referral laboratory should routinely assess these other laboratory customers' satisfaction with its referral services that includes the performance of any couriers, call centers, and reports involved. The satisfaction of the laboratory's internal (employee) customers should also be periodically assessed, with feedback provided.

Process improvement

Measurement and monitoring of laboratory process performance points to opportunities for improvement. All measurement activities, such as quality control, proficiency testing, nonconforming events, external assessments, internal quality indicators, performance comparisons, quality audits, and customer satisfaction feedback provide information that points to preanalytic, analytic, and postanalytic processes that are currently problematic or have the potential to become problematic if no preventive action is taken.

The laboratory needs to prepare information from measurement activities into a periodic report that is reviewed by laboratory management, with prioritization of problems for improvement and allocation of resources for these improvements. Improvement teams should be convened and assigned to specific problems for solution. Several different quality tools are available for determining the root cause of the problems and identifying potential solutions.

Quality tools from the nonmedical manufacturing arena have been adapted to improve health care processes, including Failure Modes and Effects Analysis, Lean, and Six Sigma. Failure Modes and Effects Analysis is a tool used to analyze the activities in a process for points of vulnerability, potential and actual risks, or failures. Scores for likelihood of failure detection, probability of occurrence, and severity of outcome are assigned, calculated, and prioritized. Process adjustments are made to reduce or remove the risks and improve the outcome [41].

Lean is a work philosophy that strives to eliminate waste from a process, first practiced and then formalized into the Toyota Production System [42]. Medical device manufacturers and industry consultants now offer Lean consulting services because many laboratories realize that a more efficient throughput means an increase in the laboratory's capability for more testing, often without additional resources [43–46]. Lean tools and principles are also being actively applied to eliminate delays, overcrowding, and frustration associated with the existing health care system [47].

Six Sigma is a methodology that uses proved quality principles and techniques to reduce process variation and decrease errors toward the 6σ level of 3.4 defects per million opportunities, so that compliance with requirements and with factors critical to customer satisfaction can be achieved [48]. The five major activities of any Six Sigma project (define, measure, analyze, improve, and control) include measurements, statistical analysis, and tracking to tie together quality, cost, processes, people, and accountability. Six Sigma methodology has been successfully applied in the automated laboratory environment [49] and to health care in general [50]. Comparisons of error rates for selected laboratory preanalytic, analytic, and postanalytic processes demonstrate that laboratory processes have yet to achieve the Six Sigma goal [51,52].

Combinations of Lean and Six Sigma methods have been applied to both health care processes and the medical laboratory [53,54]. Applications of this subject continue to grow, as reported in health care journals, laboratory periodicals, and Internet reports. Numerous opportunities for individuals to become certified in Lean and Six Sigma methods are available for laboratorians so interested; an Internet search provides ample information.

Incremental quality tools versus systematic quality management

The 12 QSEs comprise a systematic approach to quality management that ensures the laboratory meets all applicable requirements as part of performing everyday preanalytic, analytic, and postanalytic activities. Unfortunately, there is a pervading assumption that Failure Modes and Effects Analysis, Lean, and Six Sigma alone solve the quality problems of both laboratory and health care services. These, however, are merely single tools for improving only one work process at a time. These three tools can also, and should be, applied in QSE process control when the laboratory develops a new process (eg, the example of adding a new testing service to diagnostic testing). Most laboratories use these quality tools only for identified problems, however, thereby missing the opportunity to have initially designed, documented, validated, and implemented the processes optimally to identify any and all problems that actually arise, before implementation.

Likewise, none of the Total Quality Management, continuous Quality Improvement, and Plan-Do-Check-Act programs popular in the 1990s have solved the problems of medical errors causing patient injury and death so clearly documented in recent history. It can be argued that the reason for these failures has not been within the tools themselves (used properly, the aforementioned tools do indeed effect improvements) but rather that these tools have been used in isolation, instead of being incorporated into a system for quality.

What many laboratories lack is a fundamental foundational approach to quality in which the desired level of quality and process performance are built into each laboratory process such that [55,56]

- All applicable requirements and customer needs are met—first time, every time.
- Measurement and monitoring activities provide objective evidence of process performance.
- Laboratory management actively reviews reports of process performance.
- Laboratory management takes visible, definable actions to remove root causes.

The approach that most successfully integrates all regulatory and accreditation requirements, customer considerations, patient safety, process design, measurement, monitoring, and improvement is that of implementing

a QMS, such as the previously described 12-QSE model, which supports the laboratory's entire path of preanalytic, analytic, and postanalytic workflow.

This model is generic and applicable to laboratories of any size, scope, or specialty anywhere in the world. It has also been deemed simple enough to have been adapted for use in African countries supported by the President's Emergency Program for AIDS Relief [57]. A number of United States and Canadian laboratories have successfully used the model for implementing quality management as a means to achieve process improvement and patient safety and readiness for unannounced laboratory inspections. These laboratories have reported significant decreases in the numbers of deficiencies found during accreditation inspections and decreases in the cost of process failures, such as errors made at sample receiving (Sutter Health Sacrament-Sierra region and University of Alberta, Edmonton, personal communications, May 2007).

Sustaining a culture of quality in the medical laboratory

From all accounts in the nonmedical industry, quality literature, and all testimonials of Malcolm Baldrige award-winning organizations, leadership is the key ingredient in organizational quality improvement. Leadership sets the tone and culture for quality in any organization. Staff looks to leadership for guidance and follow-through and, lacking either, quality becomes relegated to the minimum required practice.

Two types of leadership exist in most laboratories: medical leadership and administrative leadership. Both are needed to support a sustainable culture of quality management in the medical laboratory environment. Laboratory administrative management should focus on setting the policies, processes, and procedures for the QSEs, removing barriers that prevent staff from getting their respective tasks accomplished efficiently and effectively. The equally important role of the pathologist medical leadership is to ensure that the policies, processes, and procedures for the preanalytic, analytic, and postanalytic work flow meet technical requirements and produce clinically relevant, accurate results and interpretations to the laboratory's customers for the purposes of patient care.

QSE and path of workflow activities require the constant collaboration of both administrative and medical leadership. The QMS model described in this article and visualized in Fig. 2 provides the roadmap in which this collaboration can successfully provide the laboratory's best contribution to patient care and safety.

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