Laboratory Quality Management:

A Roadmap

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“Total quality management is a journey,

not a destination.”

(Thomas Berry. Managing the total quality transformation. New York: McGraw-Hill; 1990)

- Self assessment

- 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 misperception is still prevalent**

(Howanitz PJ. Quality assurance measurements in departments of pathology and laboratory medicine. Arch Pathol Lab Med 1990;114:112–5)

- Many laboratories miss out by focusing on their destination

(ie, passing an accreditation inspection) instead of more carefully mapping out and enjoying their journey.

- Any journey begins with a single step,
- Then the journey toward total quality management must begins with an **understanding of the relationship** between medical laboratory

1. quality activities & laboratory management
2. quality activities & the technical activities that produce laboratory results for patient care.

- Fortunately, this dual relationship is very simple,
- It’s the fundamental basis for quality management and quality improvement in any medical laboratory of **any size, scope, or specialty anywhere in the world**.

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.

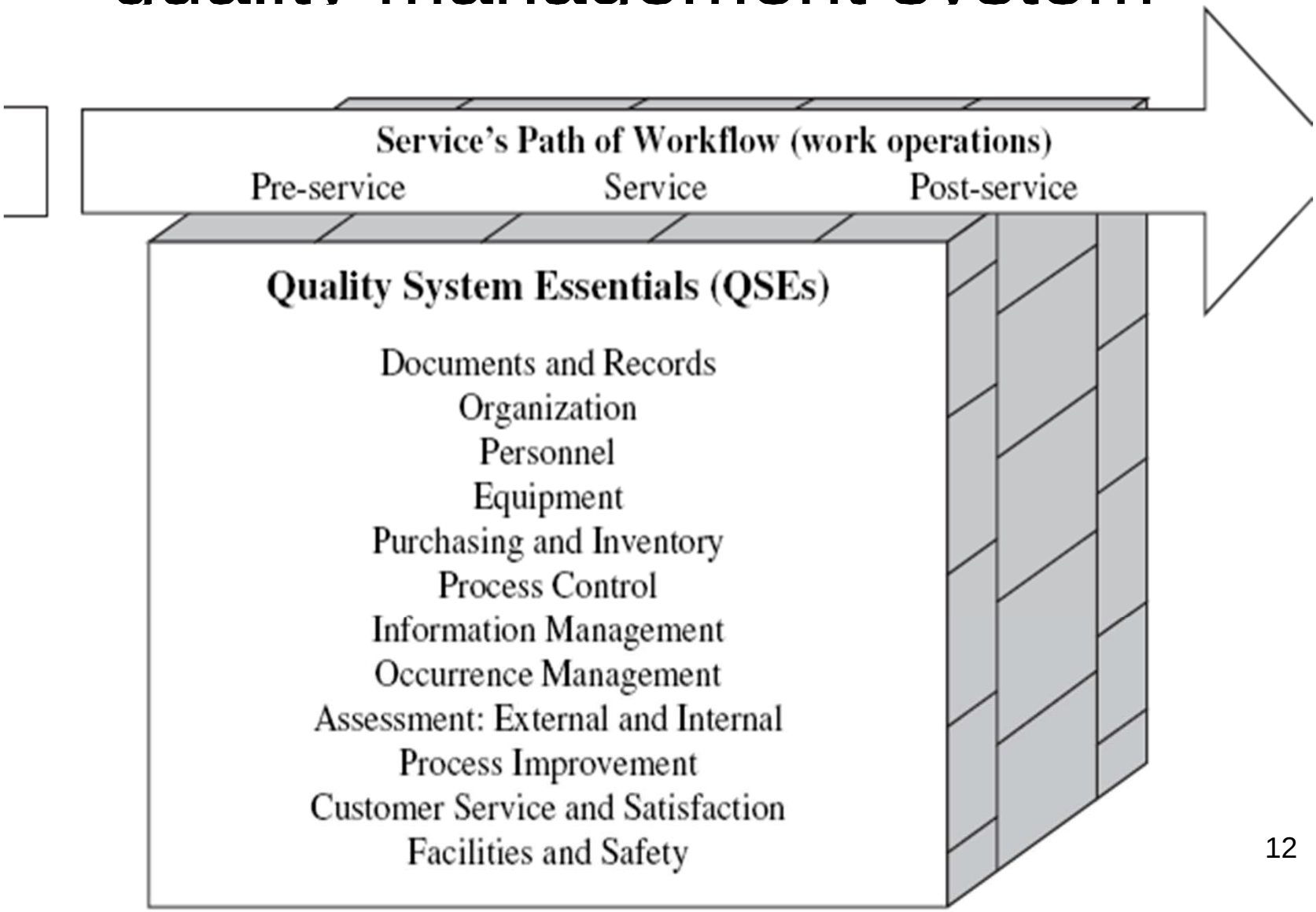
- Likewise, it is the job of the laboratory supervisory and managerial staff

- To design and implement the supportive infrastructure that is necessary for the technical work to proceed unimpeded.

  (no disturbance, no blocking, non-stop)

- 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.

A simple generic model for a quality management system



Quality System Essentials

1. Document and records
2. Organization
3. Personnel
4. Equipment
5. Purchasing and inventory
6. Process control
7. Information management

Quality System Essentials

- 8. Occurrence management
- 9. Assessment : External and internal
- 10. Process improvement
- 11. Customer service and satisfaction
- 12. Facilities and safety

- 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.

“The adding of a new testing service to an existing clinical laboratory”

- 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.

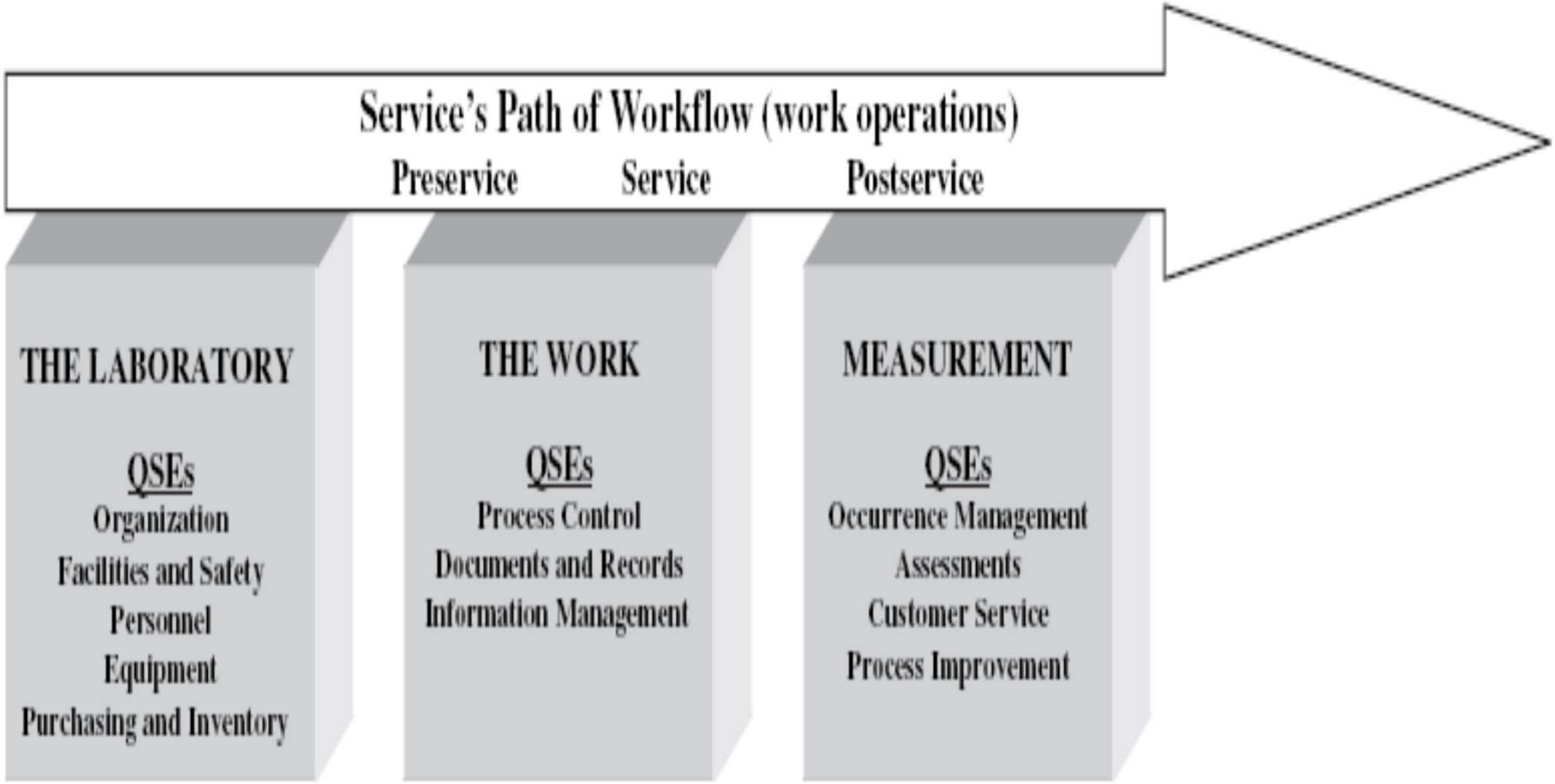
- Staff needs to be trained and their initial competence assessed.

- The laboratory needs to determine 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 *p*rioritize and initiate improvement activities.

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


Service's Path of Workflow (work operations)
Preservice
Service
Postservice
THE LABORATORY
QSEs
Organization
Facilities and Safety
Personnel
Equipment
Purchasing and Inventory
THE WORK
QSEs
Process Control
Documents and Records
Information Management
MEASUREMENT
QSEs
Occurrence Management
Assessments
Customer Service
Process Improvement

THE LABORATORY QSEs

1. Organization
2. Facility and safety
3. Personnel
4. Equipment
5. Purchasing and inventory

THE WORK QSEs

- 1. Process control
- 2. Documents and records
- 3. Information management

MEASUREMENT QSEs

- 1. Occurrence management
- 2. Assessments
- 3. Customer service
- 4. Process improvement

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

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.

- 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.

- 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
- Hazardous waste
- Chemical hygiene
- Infection control
- Occupational injury and illness
- Radiation safety (where applicable)
- Ergonomics

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

Personnel

- Certainly, without qualified, trained, and competent staff performing the work processes, quality laboratory performance cannot be ensured.

- 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.

- 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.

- To ensure that laboratory staff remains current in job and professional knowledge, laboratories are required to provide programs for continuing education and professional development

- 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.

- 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 QSEs

- 1. Process control
- 2. Documents and records
- 3. Information management

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.

- 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

- 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 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

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.

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).

MEASUREMENT QSEs

- 1. Occurrence management
- 2. Assessments
- 3. Customer service
- 4. Process improvement

The measurement quality system essentials

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:

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

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 or accreditation organizations,

- These organizations assess the laboratory against their respective published requirements and issue deficiencies for identified non- conformances 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

- 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.

- 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.

- A laboratory audit is the process of comparing observations of actual conditions with requirements and presenting an evaluation of the results to management.

- 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.
- 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.

- 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.

Sustaining a culture of quality in the medical laboratory

- Two types of leadership exist in most laboratories:
- Medical leadership & 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.

References

- [1] Berry T. Managing the total quality transformation. New York: McGraw-Hill; 1990.
- [2] Howanitz PJ. Quality assurance measurements in departments of pathology and laboratory medicine. Arch Pathol Lab Med 1990;114:112–5.

- [3] Food and Drug AdministrationDepartment of Health andHuman Services.Guideline on general principles of process validation. Bethesda (MD): Food and Drug Administration; 1987.
- [4] Food and Drug Administration, Department of Health and Human Services. Guideline for quality assurance in blood establishments; Docket No. 91N-0450, July 11, 1995. Rockville (MD): Food and Drug Administration; 1995.
- [5] Food and Drug Administration, Department of Health and Human Services. Code of Federal Regulations, Title 21, Parts 210 and 211. Washington DC: U.S. Government Printing Office, published annually.
- [6] Food and Drug Administration, Department of Health and Human Services. Code of Federal Regulations, Title 21, Parts 606, 610, 630, and 640. Washington, DC: U.S. Government Printing Office, published annually.

- [7] Robbins J, editor. The quality program. Bethesda (MD): American Association of Blood Banks; 1994.
- [8] NCCLS. A quality system model for health care; approved guideline GP26-A. Wayne (PA): NCCLS; 1999.
- [9] CLSI [Formerly NCCLS]. CLSI document HS1dA quality system model for health care; approved guideline. 2nd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2004.
- [10] CLSI [Formerly NCCLS]. CLSI document GP26dApplication of a quality system model to laboratory services; approved guideline. 3rd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2004.

- [11] ISO. ISO standard 17025: General requirements for competence of testing and calibration laboratories. Geneva, Switzerland: International Organization for Standardization; 1999.
- [12] ISO. ISO standard 15189: Medical laboratoriesdParticular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2003.
- [13] Ontario Laboratory Accreditation Division. Ontario laboratory accreditation requirements, version 3. Toronto: Quality Management ProgramdLaboratory Services; 2005.
- [14] AABB. Quality program implementation; Association bulletin 97–4. Bethesda (MD): AABB; 1997.
- [15] Nevalainen DE, Berte LM. A laboratory quality system from clinical laboratory regulations and accreditation standards. Abbott Park (IL): Abbott Quality Institute; 1997. [out of print].
- [16] ISO. ISO standard 9001: Quality management systemsdrequirements. Geneva, Switzerland: International Organization for Standardization; 2001.
- [17] Laboratory Accreditation Program. Laboratory general checklist. Northfield (IL): College of American Pathologists; 2006.
- [18] Silva MA, editor. Standards for blood banks and transfusion services. 24th edition. Bethesda (MD): AABB; 2006.

- [19] CLSI. CLSI document GP18dLaboratory design; approved guideline. 2nd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2007.
- [20] Occupational Safety and Health Administration. Code of Federal Regulations, Title 29, Part 1910. Washington DC: U.S. Government Printing Office, published annually.
- [21] CLSI [Formerly NCCLS]. CLSI/NCCLS document GP5dClinical laboratory waste management; approved guideline. 2nd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2002.
- [22] CLSI [Formerly NCCLS]. CLSI/NCCLS document M29dProtection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue; approved guideline. 4th edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2003.
- [23] Centers for Disease Control and Prevention. Public health service guidelines for the management of occupational exposures to HBC, HCV, and HIV, and recommendations for postexposure prophylaxis. Morb Mortal Wkly Rep 2001;50:1–52.
- [24] Radiation safety manual. Urbana-Champaign (IL): University of Illinois, 2006. Available at: http://phantom.ehs.uihc.edu/rss/manuals/radiationmanual/pdf/manual.pdf. Accessed on May 15, 2007.

- [25] Centers for Medicare and Medicaid Services, Department of Health and Human Services. Code of Federal Regulations, Title 42, Parts 430 to end. Washington DC: U.S. Government Printing Office, published annually.
- [26] Laboratory Accreditation Program. Team leader assessment of director and quality checklist. Northfield, IL: College of American Pathologists; 2006.
- [27] CLSI. CLSI document GP2dLaboratory documents: development and control; approved guideline. 5th edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2006.
- [28] CLSI. CLSI document EP5dEvaluation of precision performance of quantitative measurement methods; approved guideline. 2nd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2004.
- [29] CLSI. CLSI document EP6dEvaluation of the linearity of quantitative measurement procedures; approved guideline. Wayne (PA): Clinical and Laboratory Standards Institute; 2003.
- [30] CLSI. CLSI document EP9dMethod comparison and bias estimation using patient samples; approved guideline. 2nd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2002.
- [31] CLSI. CLSI document EP10dPreliminary evaluation of quantitative clinical laboratory measurement procedures; approved guideline. 3rd edition. Wayne (PA): Clinical and Laboratory Standards Institute; 2006.

- [32] CLSI. CLSI document EP12dUser protocol for evaluation of qualitative test performance; approved guideline. Wayne (PA): Clinical and Laboratory Standards Institute; 2002.
- [33] CLSI. CLSI document EP15dUser verification of performance for precision and trueness; approved guideline. 2nd edition.Wayne (PA):Clinical and Laboratory Standards Institute; 2006.
- [34] CLSI. CLSI document EP18dProtocols for determination of limits of detection and limits of quantitation; approved guideline. Wayne (PA): Clinical and Laboratory Standards Institute; 2004.
- [35] CLSI. CLSI document EP21dEstimation of total analytical error for clinical laboratory methods; approved guideline. Wayne (PA): Clinical and Laboratory Standards Institute; 2003.
- [36] Department of Health and Human Services. Office of the inspector general compliance program guideline for clinical laboratories. Federal Register. Available at: www.oig.hhs.gov/ authorities/docs/coglab.pdf. Accessed on May 15, 2007.
- [37] CLSI. CLSI document GP32dManagement of nonconforming events; provisional guideline. Wayne (PA): Clinical and Laboratory Standards Institute; 2007.
- [38] Q-PROBES. Northfield (IL): College of American Pathologists. Available at: www.cap.org. Accessed May 14, 2007.

- [39] Q-TRACKS. Northfield (IL): College of American Pathologists. Available at: www.cap.org. Accessed May 14, 2007.
- [40] Russell JP, editor. The ASQ auditing handbook. 3rd edition. Milwaukee (WI): American Society for Quality Press; 2006.
- [41] Stamatis DH. Failure mode and effect analysis: from theory to execution. 2nd edition. Milwaukee (WI): American Society for Quality Press; 2003.
- [42] Liker J. The Toyota way: 14 management principles from the world's greatest manufacturer. New York: McGraw-Hill; 2004.
- [43] Condel JL, Sharbaugh DT, Raab SS. Error-free pathology: applying lean production methods to anatomic pathology. Clin Lab Med 2004;24(4):865–99.
- [44] McDowell J. Getting the fat out of labs. Clinical Laboratory News 2005;31(3):1–6.
- [45] Joseph TP. Design a lean laboratory layout. Med Lab Obs 2006;38(2):24–31.
- [46] Joseph TP. Design of lean work cells: a lean laboratory layout (Part II). Med Lab Obs 2006; 38(8):24–32.
- [47] Zidel TG. A lean guide to transforming healthcare: How to implement lean principles in hospitals, medical offices, clinics, and other healthcare organizations. Milwaukee (WI): American Society for Quality Press; 2007.

- [48] Brassard M, Finn L, Ginn D, et al. The Six Sigma Memory Jogger II. Salem (NH): GOALQPC; 2002.
- [49] Riebking N, Tria L. Six Sigma project reduces analytical errors in an automated lab. Med Lab Obs 2005;37(6):20–3.
- [50] Barry R, Murcko AC, Brubaker CE. The Six Sigma book for healthcare. Chicago: Health administration Press; 2002.
- [51] Nevalainen D, Berte L, Kraft C, et al. Evaluating laboratory performance on quality indicators with the Six Sigma scale. Arch Pathol Lab Med 2000;124:516–9.
- [52] Berte LM. Patient safety: Getting there from here. Clinical Laboratory Management Review 2004;18(6):311–5.

- [53] Daley AT. Pro: Lean Six Sigma revolutionizing health care of tomorrow. Available at: www. clma.org/files/pubfiles/clmr/PDF/Sep-Oct_2006/daley.pdf. Accessed on May 15, 2007.
- [54] Caldwell C, Brexler J, Gillem T. Lean Six Sigma for healthcare: A senior leader guide to improving cost and throughput. Milwaukee (WI): American Society for Quality Press; 2005.
- [55] Landek D. Con: Six Sigma is not always the right answer in the clinical laboratory. Available at: www.clma.org/files/pubfiles/clmr/PDF/Sep-Oct_2006/landek.pdf. Accessed on May 15, 2007.
- [56] Berte LM. Managing laboratory quality: A systematic approach. Lab Med 2004;35(10): 621–4.
- [57] Available at: http://enews.clsi.org/clsi/issues/2007-04-01/3.html. Accessed on May 15, 2007.

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