Laboratory Quality Management System Plan

For the Laboratories and Laboratory Testing at Emory Decatur Hospital, Emory Hillandale Hospital and Emory LTAC

Quality Management System Plan

- Required by College of American Pathologists (CAP)

College of American Pathologists

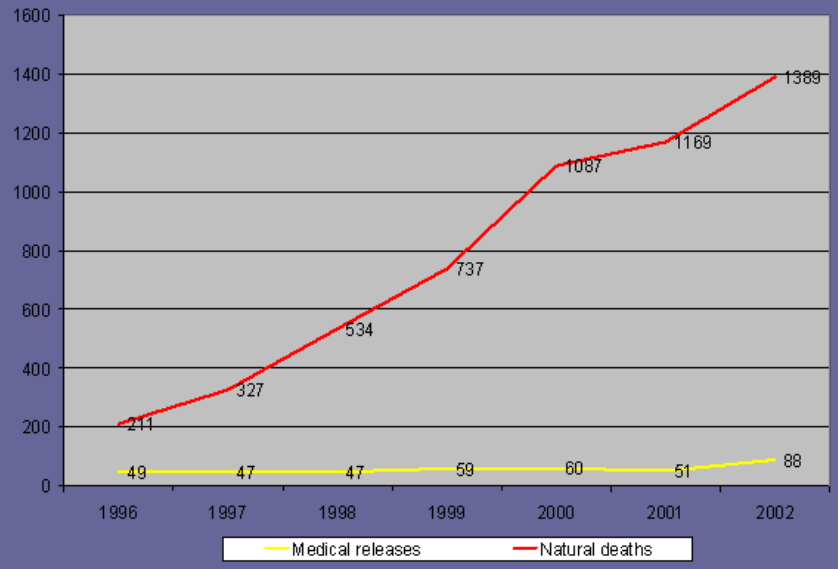
- Describes how we will establish and maintain quality in the tasks and services we provide

- Quality-focused tasks are not something we do in addition to our jobs, but that is incorporated into our daily routine.

- Who is responsible? All partners must have knowledge of and participate in the Quality Management System Plan.

Goals of the Quality Management Plan

- Designed to decrease error
- Give credibility to results
- Improve product safety and quality
- Improve productivity and reduce costs
- Emphasis is placed on preventing errors rather than detecting after the fact



12 Quality System Essentials

- Quality System Essentials (QSEs for short)
- QSEs are building blocks for quality and services
- QSEs help us determine if our laboratory goals are being met and when improvement is needed
- The laboratory management team is responsible for defining the building blocks; the entire laboratory team is responsible for using the building blocks to provide high-quality services.

12 QSEs

- QSE 1: Documents and Records
- QSE 2: Organization
- QSE 3: Personnel
- QSE 4: Equipment
- QSE 5: Purchasing and Inventory
- QSE 6: Process Control
- QSE 7: Information Management
- QSE 8: Occurrence Management
- QSE 9: External and Internal Assessment
- QSE 10: Process Improvement
- QSE 11: Customer Service
- QSE 12: Facilities and Safety

QSE 1: Documents and Records

This QSE outlines how documents and records in the laboratories are handled from creation to destruction. Includes:

- Approved plan for receiving incoming documents and records
- Creating and gaining approval for all necessary documents and forms (e.g., pathologist's signature on procedures)
- Ensuring staff have immediate access to current copies of the documents needed to perform work (e.g., procedures and forms)

QSE 1:Documents and Records, continued

Includes (continued):

- Overseeing the accurate and complete creation of records (e.g., test results)
- Storage and retrievability of all required documents and records (e.g., physician orders)
- Consistently and correctly documenting tasks, events, services and testing as defined by processes and procedures

QSE 2: Organization

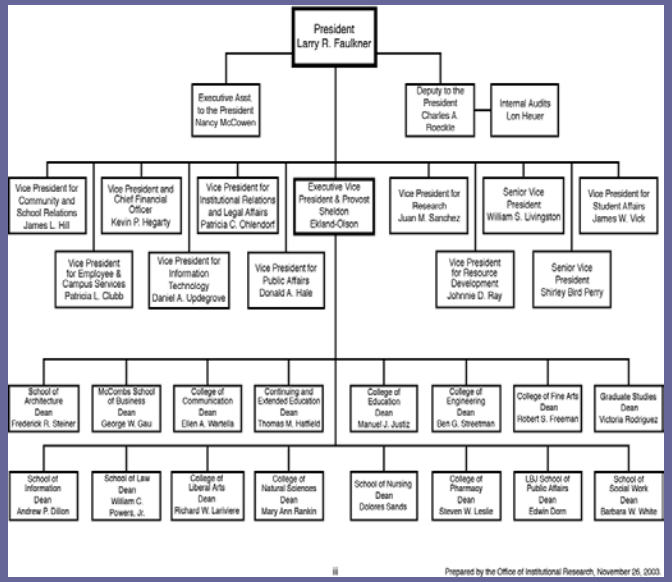
This QSE describes the organizational structure of the laboratories. It includes supervisory and lab team responsibilities as they relate to:

- Strategic planning
- Quality planning
- Responsible use of staffing and supplies

QSE 2: Organization, continued

The organizational chart is an important part of this QSE. It establishes reporting relationships and responsibilities among:

- Administration
- Medical Directors
- Laboratory Administrative Director
- Laboratory Leadership Personnel



QSE 3: Personnel

This QSE outlines how the laboratories will design and define job tasks, hire partners, orient, train, assess, and develop partners. Includes:

- Job descriptions
- Performance appraisals
- Training and documentation
- Competency assessment and documenta
- Continuing education and professional development activities

QSE 4: Equipment Control

This QSE outlines how laboratories manage equipment selection, implementation, maintenance, and disposal. Includes:

- Defining an Equipment Selection Team (laboratory partners, supervisory staff) who are responsible for the assessment.
- Contacting vendors, scheduling site visits, establishing timetables, and presenting final recommendations to the laboratory administrative staff.
- Coordination of equipment delivery and biomedical checks
- New equipment calibration, validation, and parallel studies
- Troubleshooting, vendor technical support, notification of delays in testing and use of equipment

QSE 5: Purchasing and Inventory

This QSE outlines how the laboratories manage the supplies and materials we need to perform our job. Includes how we:

- Determine what materials and supplies are needed
- Decide which vendor to purchase from
- Order materials and supplies
- Receive materials and supplies
- Inventory materials and supplies

QSE 6: Process Control

This QSE outlines the manner in which the laboratories will control work processes, testing, and service-related activities. Includes:

- Validation or verification (e.g., new equipment)
- Process control (e.g., our procedures)
- Quality control program
- Process change (e.g., new patient service area)
- Participation of the entire laboratory team

QSE 7: Information Management

This QSE outlines how the laboratories communicate information correctly and efficiently.

When we think of laboratory information, we think of all computer systems within the hospital, and those we communicate with outside the facility.

This QSE is the backbone for managing patient information.

QSE 7: Information Management, continued

Includes:

- Privacy and confidentiality of patient-related information (e.g., security access to patient information)
- Data transmission, security, and integrity (e.g., correct test results transmit to the correct patient record)
- Downtime and recovery of data (e.g., our downtime plan and entering information after downtime)
- Billing compliance (e.g., the patient gets charged correctly for the work performed)

QSE 8: Occurrence Management

This QSE outlines how the laboratories provide direction for documenting, investigating, and taking action on situations affecting quality and safety in our laboratory. Includes:

- Mislabeled specimens
- Incorrect test ordered
- Tests ordered that are not performed
- Incorrectly performed tests
- Erroneous test reporting
- Reagent, equipment, or supply failure
- Complaints from internal and external customers

QSE 8: Occurrence Management, continued

It is the responsibility of the entire laboratory team to report and document errors or problems that occur, not to retaliate against others, but out of sincere and professional concern for our patients.

QSE 9: Internal and External Assessments

This QSE describes the laboratories' participation in internal and external assessments to ensure operational and quality standards are met. Includes:

- Internal assessments by Environment of Care Committee, other hospital safety based committees, and internal departmental audits

- External assessments/inspections by regulatory and accrediting agencies.
  - **College of American Pathologists (CAP)**
  - **The Joint Commission (TJC)**
  - **Georgia Department of Community Health (DCH)**
  - **American Association of Blood Banks (AABB)**
  - **Food and Drug Administration (FDA)**

QSE 10: Process Improvement

This QSE outlines how the laboratories provide a mechanism for preventive and corrective action. Includes:

- A system that encourages the reporting of errors or potential errors to supervisory staff.
- Investigation to determine the cause and development of solutions so that the error or problem does not occur again (corrective action)
- Analysis of assessments leading to a change in process or procedure (preventive action).

QSE 10: Process Improvement, continued

Laboratory partners play a key role in identifying processes or procedures that can improve the quality of laboratory services.

- Partners should first report quality or safety concerns immediately to laboratory management.
- Partners may also communicate concerns directly to CAP (see CAP Compliance Concerns poster).
- Partners may communicate compliance concerns to the Emory Healthcare Trust Line by using the hotline number.

QSE 11: Customer Service

This QSE outlines how the laboratories' customer satisfaction is measured and how the data is used to make improvements. Includes:

- Identification of internal and external customers
- Identification of customer expectations
- Determining customer needs for new processes or programs
- Mechanism to record and resolve complaints

QSE 12: Facilities and Safety

This QSE outlines how the laboratories provide for a safe workplace with adequate environmental conditions, meeting or surpassing local, state, and federal regulations. Includes:

- Sufficient space to meet the needs of the laboratory without compromising quality and safety of personnel.
- Storage of dangerous materials and safe disposal of hazardous waste is provided.
- Required safety training for all staff (e.g., laboratory fire drills, PPE).
- DMC safety policies, both hospital and laboratory-specific policies on Life Safety, Fire Safety, Biosafety, Chemical Hygiene Plan, Infection Control and Bloodborne Pathogen, and more.

Summary

We can meet the goals of the Quality Management System Plan through the commitment, knowledge, and action of all laboratory partners.