QUALITY ASSURANCE PLANNING
A Practical Approach to Quality Management Systems

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OBJECTIVES

• Describe the purpose of a Quality Assurance (QA) plan
• List the components of an effective QA plan
• Discuss the benefits of incorporating Quality System Essentials and other Quality Management System principles into a laboratory QA plan
• Identify tools to use when developing an effective QA planning process
QUALITY TERMINOLOGY

- Quality control
- Quality assurance
- Quality improvement
- Quality indicators
- Quality management
QUALITY TERMINOLOGY

- Quality management systems
- Quality planning
- Quality system essentials
DEFINITIONS : QUALITY CONTROL

- A system designed to increase the probability that each result reported is valid and can be used with confidence by the physician
- Refers to activities that evaluate, monitor or regulate services
- QC procedures are designed to detect error
  - If acceptable, proceed with results
  - If unacceptable, evaluate test method and re-run test
EXAMPLES OF QUALITY CONTROL

- Running control samples
- Control charts
- Quality control statistics
DEFINITIONS:
QUALITY ASSURANCE

• A system for monitoring and evaluating all the various aspects of a service
• A set of activities designed to ensure that processes are adequate to meet testing objectives
• Includes pre-analytical and post-analytical components of service
EXAMPLES OF QUALITY ASSURANCE

- Quality Assurance plan
- Customer satisfaction survey
- Sample adequacy and collection data
- Turn around time
QUALITY IMPROVEMENT (CQI)

- A formal approach to the analysis of performance and systematic efforts to improve it.
- Involves prospective and retrospective reviews
- Focuses on systems or processes, not people
EXAMPLES OF QUALITY IMPROVEMENT

• Plan, Do, Check, Act (PDCA) cycle
• Six Sigma
• Process Improvement
• Continuous Quality Improvement (CQI)
QUALITY INDICATORS

- Observations, statistics, or other data defined by the organization that typified the performance of given work
- Must be measurable and objective
EXAMPLES OF QUALITY INDICATORS

- Turn around time
- Workload
- Productivity
QUALITY MANAGEMENT

• A way to continuously improve performance at every level of the organization

• All activities of the overall management function that determine quality policy objectives, implementing them by means such as quality assurance, and quality improvement within the system (NCCLS)
QUALITY MANAGEMENT

- Ensures that both the customer requirements and the organization’s requirements are met
- Reviews interrelated processes within an organization
EXAMPLES OF QUALITY MANAGEMENT

- Cross cutting work teams
- Audits
- Quality monitoring
- Root cause analysis
- Proficiency testing
- Quality management review
QUALITY MANAGEMENT SYSTEMS (QMS)

- Management system to direct and control an organization with regard to quality
- All systems stress participation, communication, rewards and acknowledgment
EXAMPLES OF QUALITY MANAGEMENT SYSTEMS

- Total Quality Management (Deming)
- Six sigma (Motorola)
QUALITY SYSTEM ESSENTIALS (QSE’S)

- The management infrastructure necessary to support any health care organization
- Tools of a Quality Assurance Plan
QUALITY PLANNING

• The part of a quality management system focused on setting quality objectives and specifying operational processes

• Reflected in the document, the "Quality Plan"
  • Procedures, resources
PURPOSE OF A QA PLAN

- Process improvement
- Regulatory compliance
- To meet customer expectations
- Reduce costs by eliminating waste
- Improve laboratory performance by identifying sources of error
RELATIONSHIP OF STRATEGIC AND QA PLANS

• QA planning is a component of Strategic planning
• Quality plan has a shorter term focus, usually up to a year
• Strategic plan has a long range focus, usually 3-5 years
QA PLAN– A COOPERATIVE EFFORT

- Need support from administration, pathologists, technologists, and all staff
- Need clearly defined outcomes and responsibilities
- Need to build trust for a QA plan to be effective
BENEFITS OF A QA PLAN

- Improved test accuracy and performance
- Increased profitability
- Increased customer satisfaction
- Increased employee satisfaction
ATTRIBUTES OF A QA PLAN

- Clearly defined goals
- Realistic and feasible goals
- Cost effective planning process (keep it simple)
- A measurable positive effect on quality
- Flexibility
ATTRIBUTES OF A QA PLAN

- Assigns responsibility
- Contains statement of how you will measure performance
- To be used for process improvement. Not to be used or confused with competency assessment and performance evaluation
COMPONENTS OF A QA PLAN

- Indicators of performance
- Criteria for each indicator
- Standard for each indicator
- Remedial action to be taken for each indicator
POTENTIAL INDICATORS

- What is required by law?
- What have the traditional indicators used by the laboratory?
- What are the most important customer service indicators?
- What are the important fiscal indicators?
- How are process improvements monitored?
MOST IMPORTANT INDICATORS

- Impact on patient care
- Impact on customer satisfaction
- Compliance with legal or regulatory requirements
- Feasibility of monitoring
NUMBER OF INDICATORS

- Based on resources available
- What information can be used effectively
- What indicators are absolutely necessary

**IT IS NOT FEASIBLE TO MONITOR EVERYTHING**
CRITERIA AND DATA COLLECTION

• Defines how data will be collected
• Defines who will be collecting the data
• Defines how calculations will be made
• Explains terms used in the indicator
• Explains who has access to this data
LABORATORY STANDARDS

- Precisely defines expected performance
- Standards are based on objective data whenever possible
- Can be reviewed and adjusted as additional data is collected
REMEDIAL ACTIONS

• Identify actions that will correct the problem

• Use continuous quality improvement tool (for example the Plan, do, check, act cycle) to evaluate actions

• Be prepared to take additional steps as needed
PDCA CYCLE

- **Planning** identifies indicators, criteria and standards
- **Doing** is the process of implementing a QA plan monitor
- **Checking** is comparing outcomes with expected standards
- **Acting** is taking steps to correct the problem
PDCA CYCLE
CONTROL CHARTS

• Consists of points that represent a statistic of measurement
• The mean of this statistic is calculated
• Standard error (deviation) is calculated
• Upper and lower control limits are defined that indicate output that is likely. Usually 2 or 3 standard deviations
WHAT IS A QUALITY ASSURANCE PLANNING?

- Quality Assurance is a “system for evaluating performance, as in the delivery of services or the quality of products provided to consumers, customers, or patients”
- Quality Assurance plan is a component of a Quality system
- A tool to make the plan operational
QUALITY MANAGEMENT SYSTEM TOOLS

• Processes that provide a comprehensive approach to quality
  • Quality System essentials (Clinical and Laboratory Standards Institute)
  • ISO 15189 (The International Organization for Standardization)
QUALITY SYSTEM ESSENTIALS

- CLSI (NCCLS) document “Application of a Quality System Model for Laboratory Services (GP26-A3)
- Model uses 12 essential services based on the 20 quality system elements in ISO 9001
- Simplifies; uses language familiar to laboratories
12 QUALITY SYSTEM ESSENTIALS

- Documents and records
- Organization
- Personnel
- Equipment
- Purchasing and inventory
- Process control
- Information management
- Occurrence management
- Assessments—internal and external
- Process improvement
- Facilities and safety
Documents and Records

- Identifies records and documents required for use in a quality management system.
- This information is described in the Laboratory Quality Manual.
- Includes systems for controlling documents and records.
EXAMPLES OF DOCUMENTS AND RECORDS

- Quality manual
- Procedure manuals
- Lab wide policy statements
- Records management
  - Identification
  - Storage and retrieval
  - Retention and disposal
DOCUREH MANAGEMENT

• Documents management involvement in the quality process
• Includes quality planning
• Tracking and follow up systems
• Quality officer/ quality assurance staff
EXAMPLES OF ORGANIZATION

- Organizational chart, including levels of authority
- Quality Plan
  - Reviewed and approved by technical supervisor
  - Coordinated with overall laboratory and/or institution plan
  - Visible participation of management
PERSONNEL

• A laboratory’s most valuable and costly resource

• Includes policies and processes for obtaining and retaining highly qualified personnel
EXAMPLES OF PERSONNEL

- Qualifications (transcript, CV)
- Position (job) descriptions
- Position (job) qualifications
- Training records/continuing education
- Competency assessments
- Recruitment and retention records
EQUIPMENT

• Process for the selection and acquisition of equipment
• Process for assuring the instrument is working properly
• Process for assurance maintenance of the instrument
EXAMPLES OF EQUIPMENT

• Selection and acquisition process
• Calibration records
• Validation and verification records
• Maintenance records
• Equipment inventory
PURCHASING AND INVENTORY

- Provides for an efficient, cost-effective operation
- Prevents interruption of services by identifying critical supplies and services
EXAMPLES OF PURCHASING AND INVENTORY

- Identification of critical supplies and services
- Vendor qualifications
- Purchase agreement review
- Inventory management
- Storage and handling
- Reference lab selection
PROCESS CONTROL

• Analysis and design of work processes
• Process documentation
• Process validation
• Incorporation of regulations, quality control, and outcome measures
EXAMPLES OF PROCESS CONTROL

- Flowcharts of processes
- Validation or verification studies
- Written procedures
- Process (statistical) control
INFORMATION MANAGEMENT

- Defines processes for receiving and handling patient information
  - Accessibility, security, and privacy for both paper and electronic records
- Defines the hardware and software needs
- Data tracking systems
EXAMPLES OF INFORMATION MANAGEMENT

- HIPAA records
- Computer security
- Computer system downtime
- Provision for downtime operation
- Defined authority levels
OCCURRENCE MANAGEMENT

- A process for the laboratory that allows anyone on staff to document and report problems or issues that may interfere with patient care services

- Focuses on analysis and trending of events, root cause analysis, and process improvement
EXAMPLES OF OCCURRENCE MANAGEMENT

- Practitioner or patient complaints
- Nonconforming QC events
- Nonconforming external assessments
- Reagent, supply, or instrument problems
- Safety issues
- PT failures
ASSESSMENTS- EXTERNAL AND INTERNAL

- **External assessments** are activities that evaluate the quality management system conducted outside the organization.

- **Internal assessments** are activities that evaluate the quality management system conducted within the organization.
EXAMPLES OF ASSESSMENTS - EXTERNAL AND INTERNAL

• External
  • Accreditation assessments
  • PT

• Internal
  • Monitoring of quality indicators
  • Internal audits
PROCESS REVIEW

- Collection of information from varied resources to identify opportunities for improvement
- Analysis of information and development of a process improvement plan
- Continuous quality Improvement
EXAMPLES OF PROCESS REVIEW

- Customer surveys results
- Feedback from employees
- Assessments, both internal and external
- Occurrence management
- Proficiency test results
CUSTOMER SERVICE

- Identification of internal and external customers
- Evaluation of customer needs
- Capture customer feedback
EXAMPLES OF CUSTOMER SERVICE

• Identification of both external and internal customers
• Customer survey
• Meeting with physicians to determine needs
• Meetings with internal laboratory staff to determine needs
FACILITIES AND SAFETY

• Need to maintain a safe work environment that provides safety for all staff
• Organization of space to assure optimal workflow
• Ergonomic design
• Remodeling/safety updates/ safety inspections
EXAMPLES OF FACILITIES AND SAFETY

- Space allocation
- Facility design
- Maintenance of facility
- Safety program
- Ergonomics
- Safety audits
INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

- Provides requirements for competence and quality
- Have been an industry standard for many years.
- In 2000, ISO published ISO 15189-guidelines for the Medical Laboratory
ISO STANDARDS

• ISO 9000 Quality management systems
• ISO 14000 Environmental quality
• ISO 13485 Quality management for medical devices
• ISO 17025 Competence of testing and calibration laboratories
• ISO 15189 Quality and competence in the medical laboratory
ISO 9000

- 8 principles
  - Customer focus
  - Leadership
  - Involvement of people
  - Process approach
  - System approach to management
  - Continual improvement
  - Factual approach to decision making
  - Mutually beneficial supplier relationships
**ISO 17025**

- Based on ISO 9000 requirements
- Used by laboratories to develop their quality, administrative, and technical systems
- Applies for laboratory testing outside medical laboratory
- Document was used to develop ISO 15189
ISO 15189-2007

- Mandatory in some countries (Europe)
- Voluntary in the U.S.
- Evolved from ISO 9000
- Scope extends beyond the internal activities of the laboratory
- Focuses on prevention of error
ISO 15189 Management Requirements

- Organization and management
- Quality management
- Document control
- Review of contracts
- Examination by reference laboratories
- External services and supplies
- Advisory services
ISO 15189 Management Requirements (continued)

- Resolution of complaints
- Identification and control of nonconformities
- Corrective action
- Preventive action
- Continual improvement
- Quality and technical records
- Internal audits
- Management review
ISO 15189 Management Requirements

- Focuses on what a laboratory should do
- Does not tell you how to do it
- Does not pose specific questions, as found in the CAP checklist
ISO 15189 Technical Requirements

- Personnel
- Accommodation and environmental requirements
- Laboratory equipment
- Pre-examination process
• Examination procedures
• Assuring the quality of examination procedures
• Post-examination procedures
• Reporting of results
ISO 15189 Management Requirements

- When reading the ISO 15189 requirements
  - The “shall” statements are critical. These must be done
  - Note that there are areas where records are mandatory
  - Assigns management responsibilities
  - Defines role of quality manager
Summary

- Successful laboratory professionals will require a diverse skill set
- The decision of where testing will be performed is not pre-determined. It will go where there is the best chance of success
- Sound understanding of regulatory requirements as well as QA/QC/QM improves chances for success
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