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QUALITY ASSURANCE PLANNING

A Practical Approach to Quality Management Systems

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Produced by University Communications

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

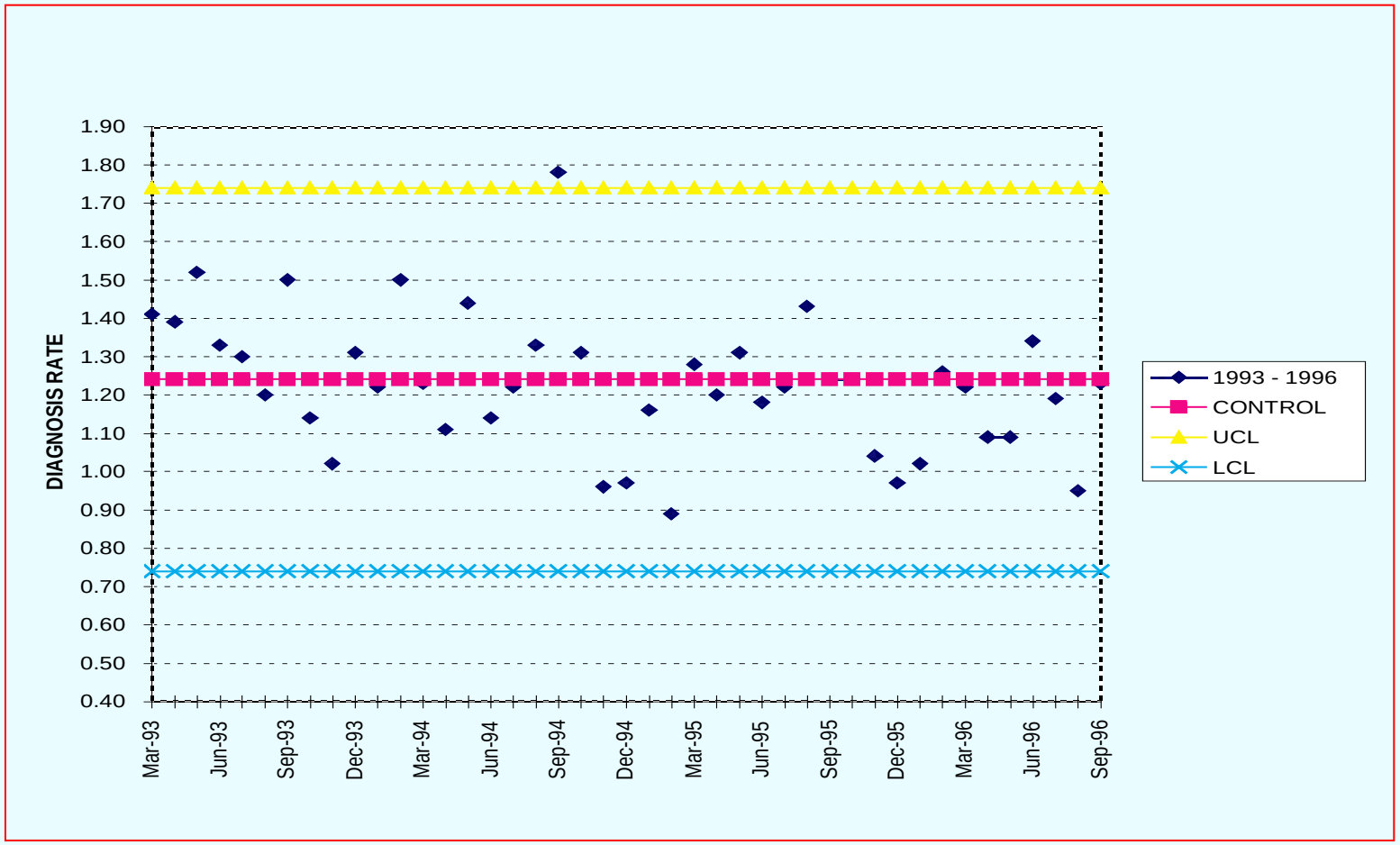
- ***Planning identifies indicators, criteria and standards***
- ***Doing is the process of implementing a QA plan monitor***
- ***Checking is comparing outcomes with expected standards***
- ***Acting is taking steps to correct the problem***

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*

CONTROL CHARTS



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

ORGANIZATION

- *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*

ISO 15189 Technical Requirements (continued)

- *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*

References

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