

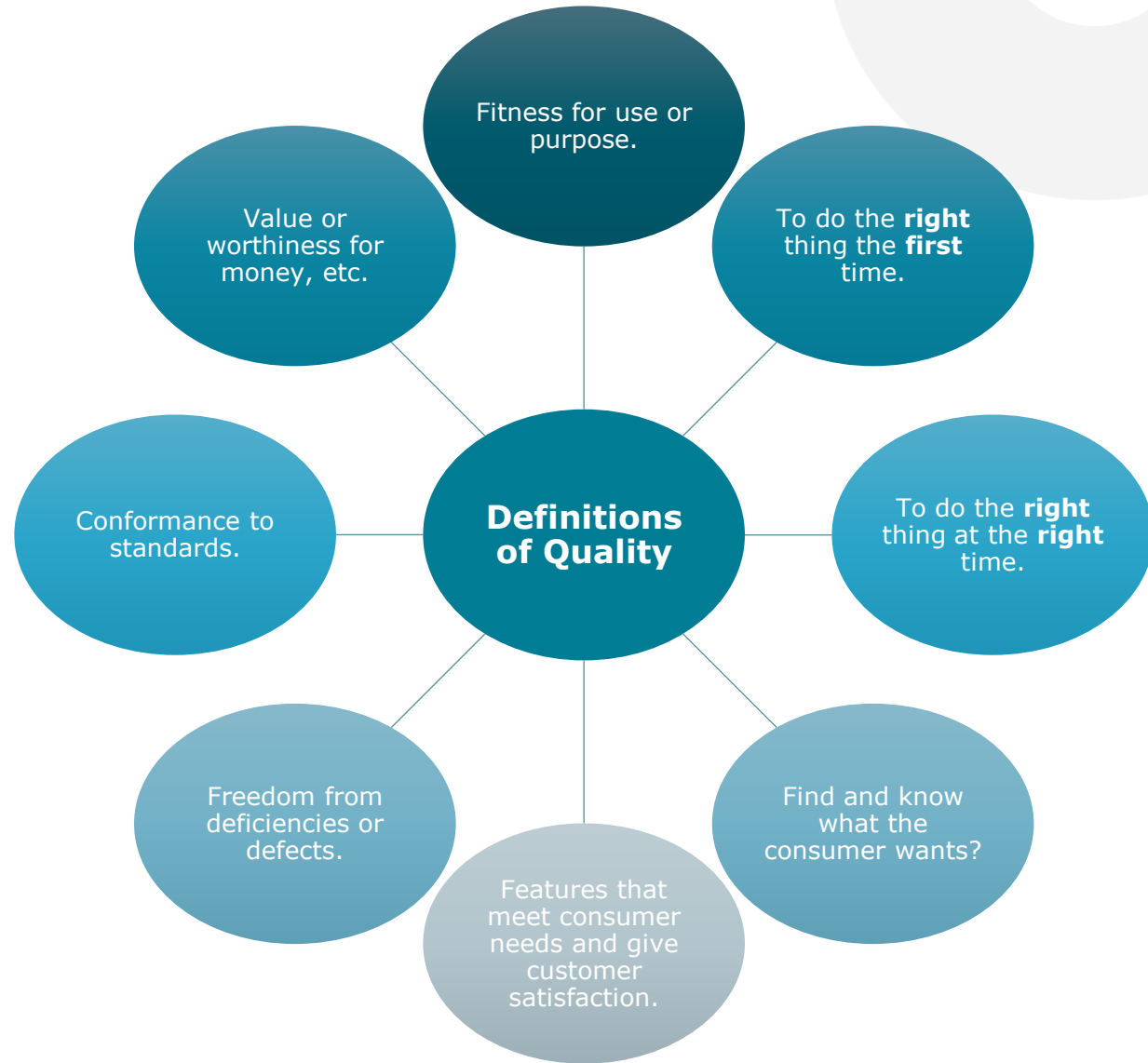
Quality System Essentials 101

Prepared by Accreditation Services

College of Physicians & Surgeons of Alberta (CPSA)



Quality is...




To be successful, quality needs to be...

- Sustainable
- Reliable
- Maintainable
- Inherent to a culture, process and operation



Stages of quality



Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, focus on long-term success through customer satisfaction
Quality Cost Management	Measurement system for the economic aspects of the 'cost of quality'
Quality Management System (QMS)	Systemic, process-oriented approach to meeting quality objectives and delivering consistent, high quality and cost-effective services
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation

- Some facilities work successfully at QMS level while many are operating at or below the stage of quality assurance

QC vs QA vs QMS

Quality Control (QC)	Quality Assurance (QA)	Quality Management System (QMS)
<ul style="list-style-type: none">• Testing the output• Method/procedure control• Method/procedure accuracy• Batch-related and time-limited	<ul style="list-style-type: none">• Defining outcomes and the process to get there• QA \neq QC• Process control• QA is bigger than QC	<ul style="list-style-type: none">• Plan, act, measure, review• Quality System Essentials (QSE) and the Path of Workflow• QC is in QSE Process Management• QA is in QSE Assessments• QMS is bigger than QC and QA and encompasses them

QC vs QA vs QMS

- QA is the series of pre-planned activities/processes that ensure examination/service results meet quality standards
 - It is a **proactive approach** that includes actual written standards operating procedures, checklists and documented activities staff are expected and required to perform
 - Concerning equipment, QA includes written “how to” processes for performing Calibration, QC and maintenance, as well as expected intervals, outcomes and steps to take if there are errors
- QC is the actions staff take to verify the quality of examination results as defined by the QA process and procedures
 - It is a **reactive process** in which corrective action must be performed in response to errors. An examination/test cannot be performed and finalized if the error isn't corrected
 - Concerning equipment, reactive approach includes running daily QC on a point of care device (i.e. glucose meter) to ensure it is in the specified range, documenting results and performing corrective action if not within range

What is a QMS?

- Set of essential building blocks needed for a facility's work operations to fulfill stated quality objectives through a **process-oriented approach**
- Provides means to direct and control the organization regarding quality
- Applies a core set of quality system essentials, basic to any organization, to all operations in any health care service's path of workflow
 - The organization's path of workflow includes the operational aspects that define how a particular product or service is delivered
 - Facility commitment to continual quality improvement will instill confidence in service being delivered to clients
- Facility can reduce potentially harmful errors by understanding and documenting processes, training staff to perform processes competently, and identifying and improving problematic processes

Quality Management principles



QMS implementation

- Implementation of the QMS model greatly enhances:
 - Ability to reduce or eliminate error
 - Likelihood of meeting customer expectations
 - Operational effectiveness and efficiency
 - Potential for successful accreditation assessments
 - Sustainable attainment of quality objectives
- Leadership commitment to building QMS establishes:
 - Platform for continuous improvement
 - Further progress toward overall total quality management



The Quality System Essentials (QSEs)

- Foundational building blocks
- Function effectively to support organization's path of workflow
- Some organizations modify these and combine several of the elements (i.e., Organization and Personnel often grouped together)
- If a QSE is missing or not well-implemented, problems will occur in pre-examination, examination, post-examination activities
 - I.e., Lack of process for installation, calibration and maintenance of equipment will result in problems in the examination phase

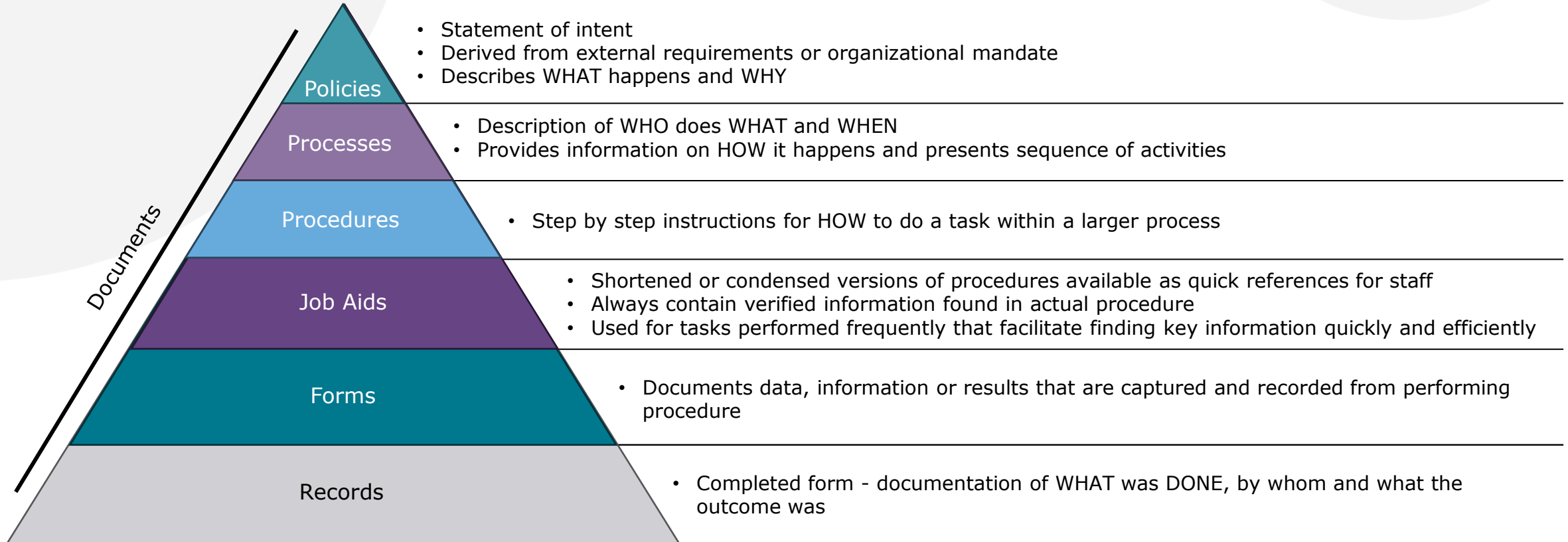
The 12 Quality System Essentials (QSEs)



Documentation of QMS/QSEs

- To fulfill requirement for QMS, the policies, processes and procedures (PPP) for the QSEs need to be documented
- This documentation clearly outlines the organization's intention for and implementation of related activities in each QSE
- The PPP tell staff how to perform tasks, expectations and responsibilities as well as troubleshooting issues that might arise
- There are four types of documents in a QMS:
 - Policies
 - Processes
 - Procedures
 - Forms
- Organizations need to organize, creating and maintaining necessary processes and procedures for implementing QSEs so staff understand how the organization functions within its commitment to quality
- Breakdowns can result in errors that can cause harm to patients and the organization's reputation

Document and record hierarchy



Adapted from the World Health Organization's *Supplement to the Laboratory Quality Management System Training Toolkit*, Module 16 – Documents and Records. Quality Manual version 2013; pg. 31. http://www.who.int/irh/training/laboratory_quality/Quality_Manual_template.doc.

QSE: Organization

Describes the key leadership responsibilities integral to an organization's success in achieving and maintaining a systematic approach to quality and meeting regulatory, accreditation, customer and internal requirements:

- Commitment to quality and good professional practice
 - Quality policy
- Organizational structure to ensure quality
 - Quality personnel
- Effective implementation of the QMS
 - Quality policies, processes, procedures
- Allocation of resources
- Planning for quality
 - Goals and objectives
- Management review
- Quality Report
- Communication

QSE: Customer focus

Describes the organization's identification of its customers and their expectations, the need to design work to meet those expectations and any applicable requirements:

- Identifying customers and their expectations
 - Internal vs. external
- Organization's capability to meet customer expectations
 - Communication
- Measuring customer and user satisfaction
 - Data collection and analysis of feedback
- Recording and managing of complaints
 - Reporting, investigation and follow-up



QSE: Facilities & safety

Provides information about the organization's physical environment and the maintenance and safety programs needed to support it:

- Facility design and modification
 - Space allocation, design, access, use, maintenance
- Safety Programs
 - Hazards, training, communication, prevention, occupational health, waste management, emergency management



QSE: Personnel

Obtaining and retaining an adequate number of qualified, well-trained and competent staff to perform and manage the activities of the organization:

- Job qualifications
 - Job descriptions
- Orientation of new personnel to organization
 - Orientation program
- Management of personnel training
 - Training process and records
- Assessment of competence
 - Competency assessment program
- Continuing education and professional development
- Performance evaluation
- End of employment
- Personnel files
 - Maintenance of personnel records

QSE: Purchasing & inventory

Describes agreements that the organization has with entities to which it provides services, and entities from which it obtains products and services to ensure that specified requirements for critical supplies are consistently met:

- Selection based on ability to meet requirements
- Purchase of materials or services
- Agreements, approved supplier lists, and use of referral services
 - Supplier, contractor and consultant evaluation
- Inspection and verification of received materials
- Storage and handling of materials
- Inventory management system
- Identification and tracing of critical materials and services

QSE: Equipment

Describes selection and installation of equipment, equipment maintenance and calibration, documentation of equipment-related problems and record maintenance to ensure that equipment performs for its intended use:

- Selection qualification and acquisition
- Equipment qualifications
 - Identification, installation, operational and performance qualification process
- Calibration program
- Maintenance programs
- Decommission and final disposition
 - Equipment files and records
- Master file

QSE: Process management

Describes processes, directly and indirectly, related to the organization's path of workflow to optimize both effectiveness in meeting requirements and efficiency in use of costly human and other resources:

- Analysis, design and documentation of the organization's essential work activities
 - Processes and procedures
- Process validation and/or verification
- Process control
 - Quality control, quality indicators, statistical techniques
- Change management

QSE: Documents & Records

Describes the creation, management and retention of the policy, process and procedure documents for the QSEs and path of workflow for the creation, management and retention of the records generated from performing the activities in the QMS:

- Document management system
 - Document identification, control, review, approval and change process
- Record management system
 - Creation, review, storage, changes, access, retention, disposal



QSE: Information management

Provides guidance for managing the information generated and entered into a record keeping system and disseminated electronically or otherwise to users or other computer systems:

- Planning for information needs
- Confidentiality of information
- Security for data access
 - Access levels, breaches, electronic access issues
- Integrity of data transfers and transmissions
- Provision for information availability during computer downtime
 - Downtime and notification processes

QSE: Nonconforming event management

Describes processes for detecting and documenting nonconformances, managing products and services that do not meet specified requirements, classifying nonconformances for analysis and correcting the problems they represent:

- Nonconforming event management program
 - [Linked to risk management program](#)
- Investigation of nonconforming events
- Nonconforming events related to manufacturer's products
 - [Recalls](#)
- Classification, analysis and trending the data and information collected
- Management review of nonconforming events
- Process improvements

QSE: Assessments

Describes the use of external and internal monitoring and assessments to verify that processes meet requirements and determine how well those processes are functioning:

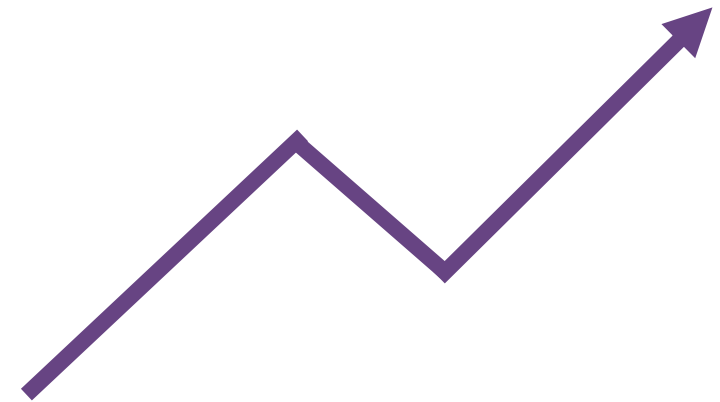
- External assessment
 - Accreditation Assessments, Proficiency Testing (laboratory tests)
- Internal assessments
 - Internal audit program, quality indicators, performance comparison, periodic reporting to service management (hand hygiene audit, turn around times, peer review)



QSE: Continual improvement

Describes mechanisms for identifying opportunities for improvement and use of a defined strategy for continual improvement (CI):

- Participation in quality improvement activities at an organization level
 - Record participation in QI activities
- Use of a defined strategy for CI
 - Opportunities for improvement, corrective action (reactive), preventive action (proactive); strategy for CQI, evaluation of effectiveness of CI activities



“Quality management is needed because nothing is simple anymore, if indeed it ever was.”

Philip Crosby

Resources

- <https://asq.org/quality-resources/quality-management-system>
- <https://www.iso.org/standard/62085.html>
- <https://www.iso.org/standard/76677.html>
- <https://clsi.org/standards/products/quality-management-systems/documents/qms01/>
- [https://www.cap.org/laboratory-improvement/accreditation/cap-15189-accreditation-program/quality-management-education-resources-\(qmed\)](https://www.cap.org/laboratory-improvement/accreditation/cap-15189-accreditation-program/quality-management-education-resources-(qmed))