Quality Management

Action Plan – The result of root cause analysis or other quality management process that:
1) addresses system and process deficiencies with specific improvement strategies and
2) monitors outcome measures to determine whether deficiencies have been corrected.

Document – CLSI defines a document as any recorded item of a factual or informative nature, either paper or electronic. Examples of documents are: policies, processes, procedures, or forms.

Document Control/Management - The management system is concerned with keeping policies and procedures current and reviewed annually by the lab director or designee, ensuring personnel have read all policies/procedures relevant to their job activities, ensuring all policies/procedures have been initially approved/signed by the lab director and or designee, and assure discontinued policies/procedures are kept in a separate file for a minimum of 2 years after date of discontinuation (5 years for Transfusion Medicine).

Plan – Do – Study – Act: a rapid, simple method of quality improvement proposed by Shewhart, which involves the design of a change to improve a process ("Plan"), implementation of the change on a test basis ("Do"), evaluation of the impact of the change on process variation and bias ("Study"), and if the change is successful, implementation on an ongoing basis(Act").

Quality Assurance: A system of quality control activities that promote the quality of higher-level processes and functions. These higher-level processes are typically composed of multiple steps, each of which may fail and each of which are individually subject to quality control. QA is best applied to all steps in the laboratory test cycle, including integrity of the test ordering process and collection process, analyses, and the reporting of results, as well as to other important variables that impact quality, such as the training of laboratory personnel.

Quality Control: Activities that ensure that specific processes and basic functions meet acceptable parameters. Quality control may be applied to an analytical instrument, a centrifuge or water bath, or specimen labeling. Intrinsic to quality control are the development of standards of acceptable performance, a system for measuring performance, and rejection (or remediation) of product that does not meet acceptable standards. Quality control is an integral component of quality assurance.

Quality Improvement: An effort to improve the quality of product beyond its current state. Quality may be improved by a properly designed and implemented quality assurance program. Quality may also be improved by redesigning a process – eliminating unnecessary steps or reworking operations that have a high risk of failure.

Quality Management: The application of quality management systems to an operation. Different approaches to managing quality all involve the application of one or more quality management systems.

Quality Management System: The process through which an organization exerts control over quality of its product and operations, meeting a customer's quality requirements and complying with applicable regulations.

Quality System Essentials: In the Clinical Laboratory Standards Institute (CLSI) formulation, quality system essentials (QSEs) are necessary elements of a quality management system. An example of a QSE might be adequate policies, processes and procedures for acquiring and maintaining equipment. QSEs are controls or quality laboratory practices that CLSI considers essential. QSEs are: Organization, Process Improvement, Process Control, Occurrence Management, Assessment – External & Internal, Documents & Records, Personnel, Customer Service, Information Management, Equipment, Facilities & Safety, and Purchasing & inventory.

Risk Assessment – The identification and analysis of risks that cause an organization not to meet its objectives. Risk assessment also forms a basis for determining how risks should be managed.

Statistical Process Control – The use of statistical methods to monitor and ultimately control the quality of a process.

Total Quality Management (TQM) – Practical philosophy of excellence. TQM concerns itself with how to best organize a business to apply statistical process control to quality and productivity.

CAP Checklist Standards

Phase I – *Do not seriously affect the quality of patient care* or significantly endanger the welfare of a laboratory worker. If a laboratory is cited with a Phase I deficiency, correction and a written response to the CAP are required, but supportive documentation of deficiency correction is not required. A Phase I requirement may also be a new checklist question, which in subsequent checklist editions may be changed to a Phase II.

Phase II – *May seriously affect the quality of patient care* or the health and safety of hospital or laboratory personnel. All Phase II deficiencies must be corrected before accreditation is granted by the Commission on Laboratory Accreditation (CLA). Correction requires both a plan of action and supporting documentation that the plan has been implemented.