

## Glossary and acronyms

### Key quality terms and definitions Alphabetical Order

#### • A

**Accreditation** Procedure by which an authoritative body gives formal recognition that a body or person is competent to care out specific tasks. Reference:ISO 15189.

**Accreditation (and Certification) Bodies** An organization or agency with the authorized right and authority to inspect a facility, and provide written evidence of its compliance (Certification) and competence (Accreditation) with a standard.

**Accident** An undesirable or unfortunate event that occurs unintentionally.

**Accuracy** The closeness of a measurement to its true value.

**AFNOR** Association Française de Normalisation. AFNOR is the French Standardization Agency (national standards-setting organization).

**Analytical Phase** See Examination.

**Audit** Systematic, independent, and documented process for gathering evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

#### • B

**Benchmark** A point of reference or a criterion of quality. A benchmark is intended to serve the user as a guide for measuring optimum performance or to suggest solutions to problems or deficiencies. It implies the best practice.

**Bias** The difference between the average value of all measurements and the reference value.  
A numerical value used to measure accuracy.

**Biohazard** An infectious agent, or part thereof, that presents a real or potential risk to the well-being of man, animals or plants. It can occur directly through infection or indirectly through the disruption of the environment.

**Biological Safety Cabinet (BSC)** is an enclosure in which entry and exhaust air is filtered through a High Efficiency Particulate Air (HEPA) filter to remove any particle from potential aerosols, used to contain a biological hazard, protecting the operator and the environment. Depending on the class of the safety cabinet, it may or may not protect the actual biohazard itself from contamination.

**Biological Safety Level 1 (BSL1)** A laboratory that works with agents not known to cause disease in healthy adults; standard microbiological practices apply; no special safety equipment required; sinks required.

**Biological Safety Level 2 (BSL2)** A laboratory that works with agents associated with human disease; standard microbiological practices apply plus limited access, biohazard signs, sharps

precautions, and biosafety manual required; biological safety cabinet used for aerosol/splash generating operations; laboratory coats, gloves, face protection required; contaminated waste is autoclaved. An appropriate ventilation system should be in place.

**Biological Safety Level 3 (BSL3)** A laboratory that works with indigenous/exotic agents which may have serious or lethal consequences and with potential for aerosol transmission; BSL2 practices plus controlled access; decontamination of all waste and lab clothing before laundering; determination of baseline serums; BSC used for all sample manipulations; respiratory protection used as needed; physical separation from access corridors; double-door access; negative airflow into laboratory; The ventilation system must ensure removal of particulates by filtering entry/exhaust air through HEPA filters.

**Biological Safety Level 4 (BSL4)** A laboratory that works with dangerous/exotic agents of life threatening nature or unknown risk of transmission; BSL3 practices plus clothing change before entering laboratory; shower required for exit; all materials are decontaminated on exit; positive pressure personnel suit required for entry; separated/isolated building; dedicated air supply/exhaust with HEPA filters, and decontamination systems.

**Biosafety** The active, assertive, evidence-based process that laboratorians use to prevent microbial contamination, infection, or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public, and the environment.

**Brainstorming** A group decision-making technique designed to generate a large number of creative ideas through an interactive process. Brainstorming is used to generate alternative ideas to be considered in making decisions.

## • C

**Calibrators** Solutions with a specified defined concentration that are used to set or calibrate an instrument, kit, or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument.

**Certification** Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Reference: ISO/IEC 17000:2004.

**Certification arrangements** Certification requirements for a particular category of people who will go through the same certification procedure and standard application (ISO 17024:2003 standard).

**Certification (and Accreditation) Bodies** An organization or agency with the authorized right and authority to inspect a facility, and provide written evidence of its compliance (Certification) and competence (Accreditation) with a standard.

**Checklist** A list used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.

**CLIA** In the USA, the Centers for Medicare & Medicaid Services (CMS) regulates all medical laboratory testing (except research) performed on humans through the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The CLIA regulations provide standards to assure consistent, accurate, and reliable laboratory test results. CMS issues Certificates of Waiver and

**Certificates of Compliance.** Certificates of Accreditation are issued to laboratories by accrediting organizations with deemed status under CLIA.

**CLSI Clinical and Laboratory Standards Institute.** US-based institute that uses consensus process in developing standards.

**Coefficient of Variation (CV)** The standard deviation (SD) expressed as a percentage of the mean.

**Competence** Demonstrated ability to apply knowledge skills.

**Compliance** An affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. Meets both the text and the spirit of a requirement

**Confidentiality** Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure.

**Confirmatory test** A highly specific test designed to confirm the results of an earlier (screening) test. For example, a Western blot, an immunofluorescence assay (IFA), or an RNA might be used as a confirmatory test for HIV testing. The person is considered HIV-positive only if the confirmatory test result is positive.

**Conformité Européenne Mark (CE Mark)** Conformity European Union mark. The European Union created the CE Mark to regulate the goods sold within its borders. The mark represents a manufacturer's declaration products comply with the EU's New Approach Directives. These directives apply to any country that sells products within the EU.

**Consensus** Agreement between delegations representing all the stakeholders concerned-suppliers, users, government regulators and other interest groups. Consensus is not a numeric or majority determination. Consensus represents general agreement in the absence of strong and compelling objection.

**Continual/Continuous Improvement** The cornerstone of quality management systems, allows the laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing client satisfaction surveys. A recurring activity to increase the ability to fulfill requirements: Plan, Do, Check, Act.

**Continuous Quality Improvement (CQI)** A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve the objective of customer satisfaction.

**Controls** Substances that contain an established amount of the substance being tested – the analyte. Controls are tested at the same time and in the same way as patient samples.

**Control Chart** A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either control limit.

**Controlled Documentation** A system for maintaining and ensuring the proper use of time or version sensitive documents.

**Correction** Action to eliminate a detected nonconformity.

**Customer** Organization or person that receives a product or service from a supplier organization.

**Customer Satisfaction** Customer's perception of the degree to which the customer's requirements have been fulfilled. It can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

- **D**

**Deming Cycle for Continuous Improvement** A visualization of the CQI process usually consisting of four points - Plan, Do, Check, Act - linked by quarter circles. The cycle was first developed by Dr. Walter A. Shewhart but was popularized in Japan in the 1950 by Dr. W. Edwards Deming.

**Deming's 14 Principles** The foundation of Deming's philosophy. The points are a blend of leadership, management theory, and statistical concepts that highlight the responsibilities of management while enhancing the capacities of employees.

**Document** Information and its supporting medium; digital or physical. ISO identifies five types of documents: specifications, quality manuals, quality plans, records, and procedure documents. See Normative and Standard documents.

**Documentation** Written material defining the process to be followed.

- **E**

**EA** European national accreditation bodies have joined to form the European Accreditation (EA) to achieve uniformity of accreditation throughout Europe as well as internationally working in partnership with the International Laboratory Accreditation Cooperation.

**Error** A deviation from truth, accuracy or correctness; a mistake; a failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

**Event** An occurrence of some importance and frequently having an antecedent cause.

**Examination** 1. Activities and steps related to performing laboratory examinations. 2. A set of operations having the object of determining the value or characteristics of a property to describe these processes. 3. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing. Also referred to as Analytical phase. See Pre- and Post-examination.

**External Quality Assessment (EQA)** A system for objectively checking the laboratory's performance using an external agency or facility.

- **F**

**14 Points** W. Edwards Deming's 14 management practices to help companies increase their quality and productivity.

**False negative** A negative test result for a person who is actually infected.

**False positive** A positive test result for a person who is actually not infected.

**Flowchart** A graphical representation of the flow of a process. A useful way to examine how various steps in a process relate to each other, to define the boundaries of the process, to identify customer/supplier relationships in a process, to verify or form the appropriate team, to create common understanding of the process flow, to determine the current "best method" of performing the process, and to identify redundancy, unnecessary complexity and inefficiency in a process.

**FMEA Method (FMECA)** Failure Mode and Effect (and Criticality) Analysis. A tool of risk assessment and failure analysis for use in risk management and product liability control. The systematic method of identifying and preventing service, process or product failures before they occur.

**Form** A paper or electronic document on which information or results are captured; once completed becomes a record.

- **G**

**Gantt Chart** A very useful tool for visually representing the proposed time line: it shows tasks to be done, with times of beginning and completion.

**Gap / GAP Analysis** Planning tool used to compare present/current state with future desired state. Basis for development of action plans to address high priority gaps. See Spider Diagram.

- **H**

**Histogram** A graphic summary of variation in a set of data. The pictorial nature of the histogram lets people see patterns that are difficult to detect in a simple table of numbers.

- **I**

**IATA** International Air Transport Association.

**IEC** International Engineering Consortium A partnership between academia and industry providing quality continuing education, research, publications, and service programs for the international information industry.

**ILAC** International Laboratory Accreditation Cooperation. See EA.

**ILAC-G13:2000** Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes.

**Incident** An individual occurrence of brief duration or secondary importance.

**Incident Reporting** is the barometer of risk in an organization and all health service quality initiatives stress its importance. See Adverse Incident.

**Incremental Improvement** Improvements that are implemented on a continual basis.

**Indicators** Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations.

**Infrastructure** Buildings, workspaces, equipment, hardware, software, utilities, and support services such as transportation and communication.

**Informative Statement** Information with a document that is informational only; often it is in the form of a ‘note’. Information may be explanatory, or cautionary, or provide an example.

**Inspection** Activities such as measuring, examining, testing, gauging one or more characteristics of a product or service, and comparing these with specified requirements to determine conformity.

**Internal Audits** Internal quality audits are audits carried-out by the laboratory personnel who examine the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

**ISO** International Organization for Standardization.

**ISO Standards** A set of international standards providing guidance for quality in manufacturing and service industries; developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system. The standards, initially published in 1987, are not specific to any particular industry, product or service; broad applicability, many kinds of organizations can use.

**ISO 9001:2000 Standard** The most important and internationally recognized series of standards for Quality Management are referred to as the ISO 9000 series. The most recent iteration was written in 2000, and thus is referred to as ISO 9000:2000. A series of policy statements.

**ISO 15189:2007** Standard for medical laboratories. A series of policy statements.

- **J**

**Joint Committee for the Accreditation of Healthcare Organizations (JCAHO)** JCAHO sets standards for, evaluates and accredits nearly 18,000 healthcare organizations and programs in the United States.

- **K**

**Kaizen** Taken from the Japanese words kai and zen, where kai means change and zen means good. The popular meaning is continual improvement of all areas of a company not just quality. (Small, continuous improvements, often using the PDCA cycle.)

- **L**

**Laboratory Director** Person(s) with responsibility for, and authority over, a laboratory.

**Laboratory Manager** Person(s) who manage the activities of a laboratory headed by a laboratory director.

**Laboratorian** Person who works in a laboratory and trained to perform laboratory procedures.

**Lean** A system of methods that emphasize identifying and eliminating all non-value-adding activities. (Tools include, S5: sort, set, shine, standardize, sustain and CANDO: clearing up,

arranging, neatness, discipline, and ongoing improvement). An English phrase coined to summarize Japanese manufacturing techniques (specifically, the Toyota Production System).

**Licensure** Granting of ability to practice provided most often by a local governmental agency, usually based on demonstrated knowledge, training and skills. (Wikipedia 2007). Generally when laboratory licensure is used, it is a legal requirement for operation.

- **M**

**Management** Coordinated activities to direct and control an organization.

**Management Review** Evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried-out by the organization's top managers and are done on a regular basis.

**Material safety data sheet (MSDS)** Form containing data regarding the properties of a particular (chemical) substance intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner, and includes information such as physical data, storage, disposal, protective equipment, and spill handling procedures. The exact format of an MSDS can vary from source to source within a country depending on how specific is the national requirement. (Wikipedia 2007).

**Metrics** A measurement for standard of quality for comparing different items or time periods. You can't improve what you can't measure. Decision makers examine the outcomes of various measured processes and strategies and track the results to guide the company and provide feedback.

- **N**

**NCCLS** National Committee for Clinical Laboratory Standards (former name for CLSI) .

**Non-conformity** Failure to fulfill the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).

**Normative document** A document that provides rules, guidelines or characteristics for activities or their results. It covers such documents as standards, technical specifications, codes of practice and regulations.

**Normative statement** Information within a document that is a required and essential part of the standard. Includes the word “shall”.

- **O**

**Occurrence** An event, accident or circumstance that happened without intent, volition, or plan.

**Occurrence Management** A central part of continual improvement; it is the process by which errors, or near errors (also called near misses) are identified and handled.

**Organization** Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

**Organizational Charts** Defines the working structure for the organization; Organizes jobs along lines of authority; Defines reporting structure and span of control; Defines authority to make decisions and accountability for results; Works together with job descriptions to define the working structure of the organization.

**Organizational Structure** The pattern of responsibilities, authorities, and relationships that control how people perform their functions and govern how they interact with one another.

- **P**

**Pareto Chart** A graphical tool for ranking causes from most significant to least significant. It is based on the Pareto principle, which was first defined by J. M. Juran in 1950. The principle, named after 19th century economist Vilfredo Pareto, suggests most effects come from relatively few causes; that is, 80% of the effects come from 20% of the possible causes. The Pareto chart is one of the "seven tools of quality."

**Path of Workflow** (clinical laboratory) Sequential processes in preexamination, examination, and postexamination clinical laboratory activities that transform a physician's order into laboratory information.

**PDCA** Plan, Do, Check, Act (Quality improvement tool). A checklist of the four stages which you must go through to get from `problem-faced' to `problem solved'. See Deming Cycle.

**Policy** An overarching plan (direction) for achieving an organization's goals.

**Post-examination** (also Postanalytical Phase) Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples for the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

**Precision** The amount of variation in a series of repeated measurements. The less variation a set of measurements has, the more precise it is. See Quantitative examination.

**Pre-examination** (also Preanalytical Phase) Steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

**Preventive Action** Plan steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

**Problem Solving** The act of defining a problem; determining the cause of the problem; identifying, prioritizing and selecting alternatives for a solution; and implementing a solution.

**Process** The use of resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out.

**Process Approach** A management strategy used by managers to control the processes that make up their Quality Management Systems, the interaction between these processes.

**Process Control** Concerns monitoring all operations of the laboratory.

**Process Improvement** A systematic and periodic approach to improving laboratory quality, and the inputs and outputs that glue these processes together. It means that they manage by focusing on processes.

**Product** Result of a process. (May be services, software, hardware or processed materials, or a combination thereof).

**Proficiency Testing** ISO guide: 43 (EA-2/03) [1], proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel. See EQA. CLSI definition: “A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory’s results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others”.

**Project** Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.

- **Q**

**Q9000 Series** Refers to ANSI/ISO/ASQ Q9000 series of standards, which is the verbatim American adoption of the 2000 edition of the ISO 9000 series standards.

**Qualitative examinations** Measure the presence or absence of a substance, or evaluate cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as “positive” or “negative”; “reactive” or “non-reactive”; “normal” or “abnormal”; and “growth” or “no growth”.

**Quality** Degree to which a set of inherent characteristics fulfills requirements.

**Quality Assurance** A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.

**Quality Audit** (also Quality Assessment, or Conformity Assessment) A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Quality Control** A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining “control” materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.

**Quality Improvement** Part of quality management focused on increasing the ability to fulfill quality requirements.

**Quality Indicator** Established measures used to determine how well an organization meets needs and operational and performance expectations.

**Quality Management** Coordinated activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement. See Quality System Essentials.

**Quality Management Standards** (such as ISO 9001:2000 and ISO 15189:2007) are a series of policy statements. Required statements include the term “shall”. Full compliance with the standard requires that all “shall” statements are implemented. Were the laboratory to be inspected to ensure compliance with the standard, the auditor or inspector would expect to see evidence that each required “shall” policy was being met. “Shall” statements are often supplemented by notes or comments that often contain examples or statements using the term “should”. These statements are intended to give guidance on what would be considered as reasonable activities, content, or structure to demonstrate that the “shall” statement is being followed. The organization is not required to meet all the comments, suggestions or recommendations included within these notes or commentary.

**Quality Management System** Management system to direct and control an organization with regard to quality.

**Quality Manual** Document specifying the quality management system of an organization.

**Quality Partnerships** Collective group of independent stakeholders essential for laboratory quality.

**Quality Plan** Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

**Quality Policy** Overall intentions and direction of an organization related to quality as formally expressed by top management.

**Quality Record** Objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.

**Quality Surveillance** A set of activities whose purpose is to monitor an entity and review its records to prove that quality requirements are being met.

**Quality System** The defined organizational structure, responsibilities, processes, procedures and resources for implementing and coordinating the Quality Assurance and **Quality System**

**Audit** A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

**Quality System Essentials (QSE)** The necessary infrastructure or foundational building blocks in any organization that need to be in place and functioning effectively in order to support the organization’s work operations so that they proceed smoothly. See Quality Management.

**Quality System Review** A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and/or new objectives resulting from changing circumstances.

**Quality Tools** The diagrams, charts, techniques, and methods that, step by step, accomplish the work of quality improvement.

**Quantification** A process for calculating how much is required of any particular item supplies for a given period of time.

**Quantitative examinations** measure the quantity of an analyte present in the sample, and measurements need to be accurate and precise. The measurement produces a numeric value as an end-point, expressed in a particular unit of measurement.

## • R

**Record** Document stating results achieved or providing evidence of activities performed.

**Records** Information captured on worksheets, forms, and charts.

**Registrar Accreditation Board (RAB)** A board that evaluates the competency and reliability of registrars (organizations that assess and register companies to the appropriate ISO 9000 series standards and to the ISO 14000 environmental management standard). RAB provides ISO course provider accreditation.

**Referral Laboratory** External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure, or for testing not performed in the originating laboratory.

**Regulation** Any standard that is mandated by a governmental agency or authoritative body.

**Requirement** A need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, and product requirements.

**Risk** The combination of severity of harm and probability of occurrence of that harm.

**Risk Analysis** The systematic use of available information to identify hazards and estimate the risk.

**Risk Assessment** Identifying potential failure modes, determining severity of consequences, identifying existing controls, determining probabilities of occurrence and detection, and evaluating risks to identify essential control points.

**Risk Management** The identification, analysis and economic control of those risks which can threaten the assets or earnings of an enterprise.

**Root Cause** That which has the most impact on the problem being tackled.

**Root Cause Analysis** A tool designed to help identify not only what and how an event occurred, but also why it happened.

## • S

**Safety** Those processes implemented to protect laboratory workers, visitors, the public, and environment.

**Sample** (also Specimen) One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production.

**Scorecard** A scorecard is an evaluation device, usually in the form of a questionnaire, that specifies the criteria customers will use to rate your business performance in satisfying their requirements.

**Semi-quantitative Examinations** Results of these tests are expressed as an estimate of how much of the measured substance is present.

**Six Sigma** A quality process that measures defects in parts per million; stands for Six Standard Deviations (Sigma is the Greek letter “s” used to represent standard deviation in statistics) from mean. Six Sigma methodology provides the techniques and tools to improve the capability and reduce the defects in any process by constantly reviewing and re-tuning the process. To achieve this, Six Sigma uses a methodology known as DMAIC.

**Spaghetti Diagram** Lean process improvement tool. Line drawings representing a starting point or current "as is" process and a "to be" process.

**Specimen** (see Sample)

**Spider Diagram** A visual report card for the performance of a number of indicators on a single chart. Also known as a "radar chart" and a "gap analysis" tool, this diagram makes visible the gaps between the current and desired performance.

**Standard document** A document established by consensus, and approved by a recognized body, that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

**Standards vocabulary**

**Horizontal standards** are said to be very broad, but not deep or specific on many points. Horizontal standards tend most commonly to set down principles or systems such as quality management systems.

**Vertical standards** are often referred to as technical standards on a specific subject. They do not tend to cover a broad range of subjects or topics, but provide a large amount of specific detail.

**Normative statements** In international standards statements the described required action include the term “shall”. In less formal standards the word “must” or “required” may be used. Normative standards may be found in the body of the document or may be within an annex.

**Informative statements** In all standards, statements that clarify, or give examples, or give caution are usually included. Such statements are intended to provide information only and are not required to be enacted.

**STAT** short for *statim*, the Latin word for immediately; in the laboratory it indicates an emergency or urgent procedure requiring rapid turn around reporting of patient results.

**Statistical Tools** Methods and techniques used to generate, analyze, interpret, and present data.

**Supplier** Organization or person that provides a product or service.

**Survey** The act of examining a process or of questioning a selected sample of individuals to obtain data about a process, product or service.

• **T**

**TDG** Transportation of Dangerous Goods.

**Team** A group of individuals organized to work together to accomplish a specific objective.

**Test** Determination of one or more characteristics according to a procedure.

**Time to Result** Length of time that a sample's first result may be issued orally (e.g. telephoned) or written (e.g. faxed) to the ordering physician. Compare to Turn Around Time.

**Total Quality Management** Any management system that addresses all areas of an organization, emphasizes customer satisfaction, and uses continuous improvement methods and tools.

**Traceability** Ability to trace the history, application or location of that which is under consideration.

**Task** A specific, definable activity to perform an assigned piece of work, often finished within a certain time.

**Tree Diagram** A tool to expand a proposed change from a general idea to a specific series of concepts or actions. Used to systematically map out in increasing detail the full range of paths and tasks that need to be accomplished to achieve a primary goal and related sub-goals.

**Turn Around Time** Length of time that a sample's final result may be issued to the ordering physician. Compare to Time to Result.

- **U**

**Universal Precautions** An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other blood-borne pathogens.

- **V**

**Validation** Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

**Verification** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

**Verification of conformity** Confirmation by examination of evidence.

**Vision** An overarching statement of the way an organization wants to be; an ideal state of being at a future point.

- **W**

**Waste** Any activity that consumes resources and produces no added value to the product or service a customer receives.

**WHMIS** Workplace Hazardous Materials Information System.

**Work Environment** All the factors that influence work; these include social, cultural, psychological, physical, and environmental conditions. The term work environment includes

lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices as well as reward and recognition programs. All of these things influence how work is performed.

**World-class Quality** A term used to indicate a standard of excellence: best of the best.

- **Z**

**Zero Defects** A performance standard and methodology developed by Philip B. Crosby that states if people commit themselves to watching details and avoiding errors, they can move closer to the goal of zero.

## **Key quality management system acronyms Alphabetical List**

- **A**

**ABSA American Biological Safety Association**

**AFB acid-fast bacilli**

**AFNOR Association Francaise de Normalisation / French Standardization Agency  
France**

**ANSI American National Standards Institute**

**ASQ American Society for Quality**

- **B**

**BLQS Bureau of Laboratory Quality Standards, Thailand**

**BSC Biological Safety Cabinet**

**BSI British Standards Institute**

**BSL Biological Safety Level**

**BSI British Standards Institute**

**BNQ Bureau de Normalisation du Québec, Canada**

- **C**

**CAP College of American Pathologists (USA)**

**CDC Centers for Disease Control and Prevention (USA)**

**CE Mark Conformité Européenne Mark**

**CEN European Committee for Standardization (Brussels)**

**CLIA Clinical Laboratory Improvement Amendments of 1988 (USA)**

**CLSI Clinical and Laboratory Standards Institute (Wayne, Pennsylvania, USA)**

**CLSI GP26-A3 Application of a Quality Management System Model for Laboratory Services (Quality document)**

**CLSI HS1 A Quality Management System Model for Health Care (Quality document).**

**CMPT Clinical Microbiology Proficiency Testing Program, Vancouver, British Columbia, Canada**

**CMS Centers for Medicare and Medicaid Services (USA)**

**COLA Commission on Laboratory Accreditation (USA)**

**CQI Continuous Quality Improvement**

**CSA Canadian Standards Association**

**CV Coefficient of variation**

- **D**

**DGAC Dangerous Goods Advisory Council**

**DNA deoxyribonucleic acid**

- **E**

**EA European Accreditation**

**EBSA European Biological Safety Association**

**EDTA ethylenediaminetetraacetic acid**

**EIA Enzyme Immunoassay**

**ELISA Enzyme-Linked Immunosorbent Assay**

**EQA External Quality Assessment**

- **F**

**FMEA Method (FMECA) Failure Mode and Effect (and Criticality) Analysis**

- **G**

**GBEA Guideline for Good Analysis Performance (France)**

**GOARN Global Outbreak Assistance and Response Network**

- **H**

**HEPA High Efficiency Particulate Air filter**

**HIV human immunodeficiency virus**

- **I**

**IATA International Air Transport Association**

**ICAO International Civil Aviation Organization**

**IEC International Engineering Consortium**

**IHR International Health Regulations**

**ILAC International Laboratory Accreditation Cooperation**

**ILAC-G13:2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes**

**ISO International Organization for Standardization**

**ISO 9000 International standards for quality. Fundamentals and vocabulary document**

**ISO 9001:2000 Standard: Quality management systems-Requirements**

**ISO 15189:2003 ISO Standard for Medical laboratories — Particular requirements for quality and competence.**

**ISO/IEC Guide 43 Proficiency testing by inter-laboratory comparisons**

**ISR International Sanitary Regulations**

## REFERENCES

- **J**
  - JCAHO Joint Committee for the Accreditation of Healthcare Organizations**
- **L**
  - LIMS Laboratory Information Management System**
  - LQM Laboratory Quality Management**
- **M**
  - MSDS Material safety data sheet**
- **N**
  - NCCLS National Committee for Clinical Laboratory Standards (former name of CLSI)**
- **P**
  - PDCA Plan, Do, Check, Act (Quality improvement tool)**
  - PCR polymerase chain reaction**
  - PDSA Plan, Do, Study, Act (Quality improvement tool)**
  - PFMEA Process Failure Mode and Effects Analysis**
  - PHEIC Public Health Emergency of International Concern**
  - POLQM Program Office for Laboratory Quality Management (Vancouver, Canada)**
  - PT Proficiency Testing**
  - PTS Proficiency Testing Schemes**
- **Q**
  - QA Quality Assurance**
  - QC Quality Control**

**QM Quality Management**

**QMPLS Quality Management Program–Laboratory Services (Toronto, Canada)**

**QMS Quality Management System**

**QSE Quality System Essentials**

- **R**

**RAB Registrar Accreditation Board**

**RNA ribonucleic acid**

- **S**

**SCC Standards Council of Canada**

**SD Standard deviation**

**SDOs (Standards Development Organizations) Organizations that are dedicated to the task of developing and communicating laboratory standards**

**SI Units Modernized metric system, called SI from the French name le Systeme international d'unités**

**SIPOC chart/ diagram Suppliers, Inputs, Process, Outputs, Customers**

**SIPOCR chart/ diagram Suppliers, Inputs, Process, Outputs, Customers Requirements of the Customers**

**SPC Statistical Process Control**

**SWOT Analysis Strengths, Weaknesses, Opportunities, Threats**

- **T**

**TDG Transportation of Dangerous Goods**

**TDGR Transportation of Dangerous Goods Regulations**

**TQM Total Quality Management**

**TAT Turn Around Time**

- **U**

## REFERENCES

- **V**

**VBM Value Based Management**

- **W**

**WHA World Health Assembly**

**WHMIS Workplace Hazardous Materials Information System**

**WHO World Health Organization**