

## *chapter one*

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# *Vocabulary of food quality assurance*

### *1.1 Introduction*

This chapter introduces the vocabulary of food quality assurance. The terms and phrases defined and explained here are the common vocabulary of food quality and food safety. Knowing and understanding the vocabulary and technical language of a field is essential for any area of study.

The international recognition of systems for food safety and for quality management has resulted in the need to adopt terminology that can be interpreted in a uniform and consistent manner. The systems for food safety and for quality management that have been adopted by international organizations such as the Codex Alimentarius Commission and the International Organization for Standardization (ISO) have been based on fundamental principles developed by recognized experts or recognized scientific or professional organizations. As a result, there is now standardized vocabulary in the field of food quality assurance.

When the ISO revised the international quality management system standards in 2000, a section of the ISO 9000:2000 standard was devoted to vocabulary. The definitions in the ISO 9000:2000 standard are the most current and widely accepted definitions. In the area of food safety, the Codex Alimentarius Commission has defined terms used in the internationally recognized hazard analysis critical control point (HACCP) system. These definitions are the most widely accepted internationally and are similar to — and in many cases, identical to — the definitions of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

The role of the various organizations in promoting the use of a consistent vocabulary in systems for food quality and food safety is recognized in this chapter. In general, the definitions and explanations given are those of the ISO, the American Society for Quality (ASQ), the Codex Alimentarius Commission and NACMCF. The definitions and explanations of terms and phrases as they are stated by these four organizations are provided here in alphabetical order, with permission.

## 1.2 Definitions and explanation of terms\*

**Acceptable quality level (AQL)** In a continuing series of lots, a quality level that, for the purpose of sampling inspection, is the limit of satisfactory process average (QP, 2002).

The AQL is used in acceptance sampling of product lots. It can also be expressed as the maximum percent defective that can be considered satisfactory for the average of the process that is producing several lots of a product.

**Acceptance sampling** Procedure by which a decision to accept or reject a lot is based on the results of inspection of samples (ASQ, 1998).

**American Society for Quality (ASQ)** A professional, not-for-profit association that develops, promotes, and applies quality-related information and technology for the private sector, government, and academia (QP, 2002).

ASQ is the largest professional association for practitioners in the quality field. Its activities include offering the following certification programs to quality professionals: Certified Mechanical Engineer, Certified Quality Auditor (CQA), Certified Quality Auditor (CQA)-Biomedical, Certified Quality Auditor (CQA)-Hazard Analysis Critical Control Point (HACCP), Certified Quality Engineer (CQE), Certified Quality Improvement Associate (CQIA), Certified Quality Manager (CQM), Certified Quality Technician (CQT), Certified Reliability Engineer (CRE), Certified Six Sigma Black Belt (CSSBB), Certified Software Quality Engineer (CSQE).

**Assignable cause** Those observations of a process measurement that are not randomly caused (ASQ, 1998). A name for the source of variation in a process that is not due to chance and, therefore, can be identified and eliminated. Also called *special cause* (QP, 2002).

Assignable causes can be identified by use of control charts.

**Attributes (method of)** A measurement of quality consisting of noting the presence (or absence) of some characteristic or attribute in each of the units in a group under consideration, and counting how many units do (or do not) possess the quality attribute or how many such events occur in the unit, group, or area (ASQ, 1998). See also: *variables*.

\* Source: "Quality Glossary." ASQ *Quality Progress*, July 2002, Pages 49-61. Reprinted with permission. Source: ASQ Food, Drug, and Cosmetic Division. 1998. *Food Processing Industry Quality System Guidelines*. Milwaukee, WI: ASQ Quality Press. Reprinted with permission. From the Food and Agriculture Organization of the United Nations, Codex Alimentarius, 1997 *Basic Texts on Food Hygiene*, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Program, Rome. From ISO 9000: 2000 *International Standard*, 2nd ed., 2002-12-15, *Quality management systems — fundamentals and vocabulary*. ISO, Geneva. From *J. Food Prot.*, 61, 9, 1998, 1246-1259.

**Audit** Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000:2000).

Common types of audits in the food industry are audits of quality management systems, audits of good manufacturing practices (GMP audits), and audits of the hazard analysis critical control point system (HACCP audit). GMP audits and HACCP audits are food safety audits and are frequently conducted in food companies by government regulatory agencies. Internal audits are commonly carried out within a food company for the benefit of the company. Internal audits are first-party audits. External audits are also common in the food industry. An external audit conducted in a food company by a customer, or on behalf of the customer, for the benefit of the customer is a second-party audit. An external audit carried out by an organization that is independent of both the company and the customer is a third-party audit. A registration audit is a third-party audit carried out for the purpose of registering the company to a recognized standard, such as the ISO 9001:2000 quality management system standard.

**Auditee** Organization being audited (ISO 9000:2000).

For an internal audit, the auditee is commonly a department, section, or sector that is being audited. For an external audit, the auditee is the company that is being audited.

**Auditor** A person with the competence to conduct an audit (ISO 9000:2000). For an internal audit, the auditor is appointed by the company's management. For an external audit, the auditor is appointed by the organization responsible for conducting the audit. For all types of audits, an auditor must have the necessary qualifications to conduct the audit. The person who performs an audit of a process must not be involved in the activities of the process; this ensures that the audit is an independent process.

**Audit client** Organization or person requesting an audit (ISO 9000:2000). For example, in the case of a second-party audit of an organization, done by someone on behalf of a customer, the audit client is the customer.

**Audit conclusion** Outcome of an audit provided by an audit team after consideration of the audit objectives and all audit findings (ISO 9000:2000).

The audit conclusions are contained in the audit report after the completion of an audit. In general, when there is more than one person on the audit team, the lead auditor on the audit team is responsible for providing the audit conclusions.

**Audit criteria** Set of policies, procedures, or requirements used as a reference (ISO 9000:2000).

**Audit evidence** Records, statements of fact, or other verifiable information relevant to the audit criteria (ISO 9000:2000).

Audit evidence is obtained by an auditor during an audit by examination of records, from the observation of activities, and from information obtained during interviews of personnel responsible for activities.

**Audit findings** Results of the evaluation of the collected audit evidence against audit criteria (ISO 9000:2000).

After gathering the audit evidence during the course of an audit, an auditor carries out an objective evaluation of the evidence in relation to the audit criteria to arrive at the audit findings.

**Audit program** Set of one or more audits planned for a specific time frame and directed toward a specific purpose (ISO 9000:2000).

**Audit team** One or more auditors conducting an audit (ISO 9000:2000).

An audit team should have a lead auditor who has overall responsibility for the audit.

**Batch** See: *lot*.

**Benchmarking** An improvement process in which a company measures its performance against that of best-in-class companies, determines how those companies achieved their performance levels, and uses the information to improve its own performance. The subjects that can be benchmarked include strategies, operations, processes, and procedures (QP, 2002).

**Best practice** A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as “best” by other peer organizations (QP, 2002).

**Blemish** An imperfection severe enough to be noticed but that should not cause any real impairment with respect to intended normal or reasonably foreseeable use (QP, 2002). See also: *defect*, *imperfection*, and *non-conformity*.

**Body of knowledge (BOK)** The prescribed aggregation of knowledge in a particular area an individual is expected to have mastered to be considered or be certified as a practitioner (QP, 2002).

**Breakthrough improvement** A dynamic, decisive movement to a new, higher level of performance (QP, 2002).

**Calibration** Correcting a measuring device to agree with a standard (ASQ, 1998). The comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or system of a

known accuracy to detect any variation from the required performance specification (QP, 2002).

**Capability** Ability of an organization, system, or process to realize a product that will fulfil the requirements for that product (ISO 9000:2000). See also: *process capability*.

**Cause-and-effect diagram** Used for analyzing process dispersion, it illustrates the main causes and subcauses leading to an effect (symptom). It was developed by Kaoru Ishikawa and is also referred to as the *Ishikawa diagram* and the *fishbone diagram* because of its shape. It is one of the seven tools of quality (QP, 2002).

**Characteristic** Distinguishing feature (ISO 9000:2000). A property that helps to differentiate among items of a given sample or population (ASQ, 1998). The factors, elements, or measures that define and differentiate a process, function, product, service, or other entity (QP, 2002). See also: *quality characteristic*.

For food products, some common quality characteristics are safety, suitability, appearance, color, taste, texture, and composition.

**Chart** A tool for organizing, summarizing and depicting data in graphic form (QP, 2002).

**Check sheet** A form for recording data from a process or product; may be used as a first step of a processor product quality analysis (ASQ, 1998). It is a simple data recording device custom designed by the user to allow ready interpretation of the data recorded. It is one of the seven tools of quality (QP, 2002).

**Checklist** A tool used to ensure that all important steps or actions in an operation have been taken. A checklist contains items that are important or relevant to an issue or situation (QP, 2002).

Checklists are commonly used by auditors as a tool to obtain objective evidence during audits.

**Cleaning** The removal of soil, food residue, dirt, grease, or other objectionable matter (Codex Alimentarius, 1997).

**Codex Alimentarius** Set of internationally recognized food standards developed by the Codex Alimentarius Commission.

**Codex Alimentarius Commission** A joint, subsidiary body of the Food and Agricultural Organization (FAO) of the United Nations and the World Health Organization (WHO). The Codex Alimentarius Commission was established in 1962 for the purpose of developing, promoting, and harmonizing standards for food in order to facilitate international trade. Membership on the Commission is open to all member nations and associate members of the FAO and

WHO. The Codex Alimentarius Commission has developed numerous internationally recognized food standards as well as an internationally recognized HACCP system.

**Common cause(s)** Attributes or variables of a process that are the result of random variations inherent in the process (ASQ, 1998). Causes of variation that are inherent in a process over time. They affect every outcome of the process and everyone working in the process (QP, 2002).

Common causes are also referred to as chance causes. See also: *assignable cause* and *special causes*.

**Company culture** A system of values, beliefs and behaviors inherent in a company. To optimize business performance, top management must define and create the necessary culture (QP, 2002).

**Competence** Demonstrated ability to apply knowledge and skills (ISO 9000:2000).

**Compliance** The state of an organization that meets prescribed specifications, contract terms, regulations, or standards (QP, 2002). See also: *conformance* and *conformity*.

**Concession** Permission to use or release a product that does not conform to specified requirements (ISO 9000:2000). See also: *deviation permit*. A customer can grant a concession to an organization for the acceptance of a product that has been made but which does not conform to the product requirements; the concession is granted before use or release of the nonconforming product.

**Conformance** An affirmative indication or judgement that a product has met the requirements of a relevant specification, contract, or regulation (QP, 2002). See also: *compliance* and *conformity*.

The terms *conformity* and *conformance* are often used interchangeably. In the ISO 9000:2000 standards, *conformity* is used in preference to *conformance*.

**Conformity** Fulfillment of an requirement (ISO 9000:2000). See also *compliance* and *conformance*.

Conformity can be associated with a product, a process, or a system.

**Consumer** The external customer to whom a product or service is ultimately delivered. Also called end user (QP, 2002). See also: *customer*.

**Consumer's risk** The probability that an unacceptable lot will be accepted under a specified sampling plan (ASQ, 1998). Pertains to sampling and the potential risk that bad product will be accepted and shipped to the consumer (QP, 2002).

**Contaminant** Any biological or chemical agent, foreign matter, or other substances not intentionally added to food, which may compromise food safety or food suitability (Codex Alimentarius, 1997).

**Contamination** The introduction or occurrence of a contaminant in food or food environment (Codex Alimentarius, 1997). See also: *cross-contamination*.

**Continual improvement** Recurring activity to increase the ability to fulfill requirements (ISO 9000:2000). Continual improvement is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "Continual improvement of the organization's overall performance should be a permanent objective of the organization."

**Continuous improvement (CI)** Sometimes called continual improvement. The ongoing improvement of products, services, or processes through incremental and breakthrough improvements (QP, 2002). See also: *continual improvement*.

**Control** (Verb) To take all necessary actions to ensure and maintain compliance with the criteria established in the HACCP plan. (Noun) The state wherein correct procedures are being followed and criteria are being met (Codex Alimentarius, 1997). To manage the conditions of an operation to maintain compliance with established criteria. The state in which correct procedures are being followed and criteria are being met (NACMCF, 1997). Commonly used in other phrases, including *process control*, *quality control*, *control chart*, *control point*, *critical control point*, and *control measure*.

**Control chart** Usually a graph of groups or individuals of a process parameter sampled at regular intervals and plotted on a format that includes statistical process limits (ASQ, 1998). 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. It is one of the seven tools of quality (QP, 2002). Control charts are commonly used in statistical process control. There are several types of control charts; the most commonly used are the control chart for variables and the control chart for attributes.

**Control limits** Statistically calculated extreme values of a process or product, outside of which a process is considered to be out of statistical control; not to be confused with specification limits, tolerance limits, or critical limits (ASQ, 1998). The natural boundaries of a process within specified confidence levels, expressed as the upper control limit (UCL) and the lower control limit (LCL) (QP, 2002). See also: *control chart*, *upper control limit* and *lower control limit*.



**Control measure** Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex Alimentarius, 1997). Any action or activity that can be used to prevent, eliminate or reduce a significant hazard (NACMCF, 1997).

Control measures are identified to control food safety hazards during the development of a HACCP plan.

**Control point** Any step at which biological, chemical or physical factors can be controlled (NACMCF, 1997; ASQ, 1998). See also: *critical control point*.

**Correction** Action to eliminate a detected nonconformity (ISO 9000:2000). See also: *corrective action*.

For a product with a detected nonconformity, the correction can be to rework the product so that it conforms to the requirements.

**Corrective action** Action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000:2000). Any action to be taken when the results of monitoring at the CCP indicate a loss of control (Codex Alimentarius, 1997). Procedures followed when a deviation occurs (NACMCF, 1997). The implementation of solutions resulting in the reduction or elimination of an identified problem (QP, 2002). See also: *correction* and *preventive action*.

**Critical control point (CCP)** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Codex Alimentarius, 1997; NACMCF, 1997). The processing factors whose loss of control would result in an unacceptable food safety risk (ASQ, 1998). See also: *control point*.

**Critical control point (CCP) decision tree** A sequence of questions to assist in determining whether a control point is a CCP (NACMCF, 1997). CCP decision trees have been developed by the NACMCF and by Codex Alimentarius.

**Critical limit** A criterion that separates acceptability from unacceptability (Codex Alimentarius, 1997). A maximum or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level, the occurrence of a food safety hazard (NACMCF, 1997).

**Criterion** A requirement on which a judgment or decision can be made (NACMCF, 1997).

**Critical processes** Processes that present serious potential dangers to human life, health, and the environment or that risk the loss of very large sums of money or a great number of customers (QP, 2002).



**Cross-contamination** The transfer of contaminant from one food to another; common means of cross-contamination include personnel, utensils and equipment.

**Customer** Organization or person that receives a product (ISO 9000:2000). See also: *internal customer and external customer*.

A customer can be a consumer, a client, an end-user, a retailer, a beneficiary, or a purchaser. A customer can be internal or external to an organization.

**Customer focus** One of the eight quality management principles recognized by ISO 9000:2000, states: "Organizations depend on their customers and, therefore, should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations."

**Customer satisfaction** Customer's perception of the degree to which the customer's requirements have been fulfilled (ISO 9000:2000).

**Data** A set of collected facts. There are two basic kinds of numerical data: measured or variable data and counted or attribute data (QP, 2002).

**Defect** Nonfulfillment of a requirement related to an intended or specified use (ISO 9000:2000). A departure of a quality characteristic from its intended level or state that occurs with a severity sufficient to an associated product or service not to satisfy intended normal, or reasonably foreseeable, usage requirements (ASQ, 1998). A product's or service's nonfulfillment of an intended requirement or reasonable expectation of use, including safety considerations. There are four classes of defects: class one, very serious, leads directly to severe injury or catastrophic economic loss; class two, serious, leads directly to significant injury or significant economic loss; class three, major, is related to major problems with respect to intended normal or reasonably foreseeable use; class four, minor, is related to minor problems with respect to intended normal or reasonably foreseeable use (QP, 1992). See also: *nonconformity*.

**Defective** A unit of product containing at least one defect or having several imperfections that in combination cause the unit not to satisfy normal or reasonably foreseeable usage requirements (ASQ, 1998). A defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under characterization (QP, 2002).

**Deming cycle** See: *plan-do-check-act cycle*.

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

1. Create constancy of purpose for improving products and services.

2. Adopt the new philosophy.
3. Cease dependence on inspection to achieve quality.
4. End the practice of awarding business on price alone; instead, minimize total cost by working with a single supplier.
5. Improve constantly and forever every process for planning, production and service.
6. Institute training on the job.
7. Adopt and institute leadership.
8. Drive out fear.
9. Break down barriers between staff areas.
10. Eliminate slogans, exhortations and targets for the workforce.
11. Eliminate numerical quotas for the workforce and numerical goals for management.
12. Remove barriers that rob people of pride of workmanship, and eliminate the annual rating or merit system.
13. Institute a vigorous program of education and self-improvement for everyone.
14. Put everybody in the company to work to accomplish the transformation (QP, 2002).

**Dependability** Collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance (ISO 9000:2000).

**Design and development** Set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system (ISO 9000:2002).

**Deviation** Failure to meet a critical limit (Codex Alimentarius, 1997; NAC-MCF, 1997). See also *nonconformity*.

The term deviation is used in the HACCP vocabulary; it represents a situation where there is a failure to meet a critical limit that has been established as a requirement at a process step that is a CCP.

**Deviation permit** Permission to depart from the originally specified requirements of a product prior to realization (ISO 9000:2000). See also *concession*.

A deviation permit from a customer allows an organization to realize a product without having to meet the customer's specified requirements. Generally, a deviation permit applies to a specified quantity of product or a specified period of time, and is for a specific use of the product.

**Disinfection** The reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or food suitability (Codex Alimentarius, 1997).

**Document** Information and its supporting medium (ISO 9000:2000). See also *record*.

The types of documents that are part of a quality management system include specifications, records, documented procedures, work instructions, drawings, reports, standards, quality manuals, and quality plans. The supporting medium for documents includes paper, photograph, and magnetic, electronic or optical computer disc.

**Effectiveness** Extent to which planned activities are realized and planned results achieved (ISO 9000:2002). The state of having produced a decided upon or desired effect (QP, 2002). See also: *efficiency*.

**Efficiency** Relationship between the result achieved and the resources used (ISO 9000:2002). The ratio of the output to the total input in a process (QP, 2002). See also: *effectiveness*.

**Employee involvement** A practice within an organization whereby employees regularly participate in making decisions on how their work areas operate, including making suggestions for improvement, planning, goal setting, and monitoring performance (QP, 2002). See also: *involvement of people*.

**Empowerment** A condition whereby employees have the authority to make decisions and take action in their work areas without prior approval (QP, 2002).

**Establishment** Any building or area in which food is handled and the surroundings are under the control of the same management (Codex Alimentarius, 1997).

**Expectations (customer)** Customer perceptions about how an organization's products and services will meet the customer's specific needs and requirements (QP, 2002).

**External customer** A person or organization that receives a product, service or information but is not part of the organization supplying the product (QP, 2002). See also: *customer* and *internal customer*.

**External failure** Nonconformance identified by the external customers (QP, 2002). See also: *internal failure*.

**Factual approach to decision making** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "Effective decisions are based on the analysis of data and information."

**Fishbone diagram** See: *cause-and-effect diagram*.

**Flowchart** A graphical representation of the steps in a process, which is drawn in order to better understand the process. It is one of the seven tools of quality (QP, 2002). See also: *flow diagram*.

**Flow diagram** A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item (Codex Alimentarius, 1997). A pictorial representation of a process indicating each of the branches and main steps in order of performance (ASQ, 1998). See also: *flowchart*.

The preparation of a process flow diagram is one of the steps in the development of an HACCP plan for a food item.

**Food handler** Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements (Codex Alimentarius, 1997).

**Food hygiene** All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain (Codex Alimentarius, 1997).

**Food safety** The assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use (Codex Alimentarius, 1997).

**Food suitability** Assurance that food is acceptable for human consumption according to its intended use (Codex Alimentarius, 1997).

**Go/no-go** State of a unit or product. Two parameters are possible: go (conforms to specifications) and no-go (does not conform to specifications) (QP, 2002).

**Grade** Category or rank given to different quality requirements for products, processes, or systems having the same functional use (ISO 9000:2000).

**Hazard** A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect (Codex Alimentarius, 1997). A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (NACMCF, 1997).

**Hazard analysis** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and, therefore, should be addressed in the HACCP plan (Codex Alimentarius, 1997). The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan (NACMCF, 1997).

**Hazard analysis critical control point (HACCP)** A system that identifies, evaluates, and controls hazards that are significant for food safety (Codex Alimentarius, 1997). A systematic approach to the identification, evaluation, and control of food safety hazards (NACMCF, 1997).

HACCP, which is recognized for its science-based approach, consists of a set of seven principles that have been adopted internationally through the work of the Codex Alimentarius Commission.

**HACCP plan** A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration (Codex Alimentarius, 1977). The written document that is based on the principles of HACCP and that delineates the procedures to be followed (NACMCF, 1997).

An HACCP plan is obtained after an HACCP team has carried out the activities required by the seven principles of HACCP.

**HACCP system** The result of the implementation of the HACCP plan (NACMCF, 1997).

**HACCP team** The group of people responsible for developing, implementing, and maintaining the HACCP system (NACMCF, 1997).

**Histogram** A bar chart representing a frequency distribution of a process variable or product characteristic (ASQ, 1998). A graphic summary of variation in a set of data. It is one of seven tools of quality (QP, 2002).

**Imperfection** A quality characteristic's departure from its intended level or state without any association to conformance to specification requirements on usability of a product or service (QP, 2002). See also: *blemish*, *nonconformity* and *defect*.

**Improvement** The positive effect of a process change effort (QP, 2002). See also: *breakthrough improvement* and *incremental improvement*.

**In-control process** A process in which the statistical measure being evaluated is in a state of statistical control; in other words, the variations among the observed sampling results can be attributed to a constant system of chance causes (QP, 2002). See also: *out-of-control process*.

**Incremental improvement** Improvements that are implemented on a continual basis (QP, 2002). See also: *breakthrough improvement*.

**Information** Meaningful data (ISO 9000:2000). See also: *data*.

**Infrastructure** System of facilities, equipment, and services needed for the operation of an organization (ISO 9000:2000).

**Inputs** The products, services, materials, and so forth obtained from suppliers and used to produce the outputs delivered to customers (QP, 2002). See also: *outputs*.

**Inspection** Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing, or gauging (ISO 9000:2000). The process of measuring, examining, testing, gauging, or otherwise comparing the unit with the applicable requirements (ASQ, 1998). Measuring, examining, testing and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic (QP, 2002).

**Inspection (100%)** Inspection of all the units in a lot or batch (QP, 2002).

**Inspection lot** A collection of similar units or a specific quantity of similar material offered for inspection and acceptance at one time (QP, 2002).

**Interested party** Person or a group having an interest in the performance or success of an organization (ISO 9000:2000).

The interested parties of an organization include the organization's customers, suppliers, owners, partners, bankers, people in the organization, or anyone who may have an interest in some aspect of the organization's performance.

**Internal customer** The recipient (person or department) within an organization of an output from another person or department in the organization (QP, 2002). See also: *external customer*.

**Internal failure** A product failure that occurs before the product is delivered to external customers (QP, 2002). See also: *external failure*.

**International Organization for Standardization (ISO)** A network of national standards institutes from 140 countries working in partnership with international organizations, governments, industry, business, and consumer representatives to develop and publish international standards (QP, 2002). A worldwide federation of national standard bodies which are referred to as ISO member bodies (ISO 9000:2000).

**Involvement of people** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit."

**ISO 9000 family of standards** A coherent set of four quality management system standards facilitating mutual understanding in national and international trade (ISO 9000:2000).

The standards have been developed by the International Organization for Standardization to assist all types and sizes of organizations to implement and operate effective quality management systems. ISO 9000:2000 Quality management systems — Fundamentals and vocabulary describes fundamentals of quality management systems and specifies and defines the terminology used in these systems. ISO 9001:2000 Quality management systems — Requirements specify the requirements for the quality management system of an organization that needs to demonstrate its ability to provide products that meet customer and regulatory requirements, and aims to enhance customer satisfaction. ISO 9004:2000 Quality management systems — Guidelines for performance improvements provides guidelines that address the effectiveness and efficiency of quality management systems to improve organizational performance and the satisfaction of customers and other parties. ISO 19011:2002 provides guidance on auditing quality management systems and environmental management systems.

**Just-in-time (JIT) manufacturing** An optimal material requirement planning system for a manufacturing process in which there is little or no manufacturing material inventory on hand at the manufacturing site and little or no incoming inspection (QP, 2002).

**Just-in-time training** The provision of training only when it is needed to all but eliminate the loss of knowledge and skill caused by a lag between training and use (QP, 2002).

**Kaizen** A Japanese term that means gradual, unending improvement by doing little things better and setting and achieving increasingly higher standards (QP, 2002).

**Leadership** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: “Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization’s objectives.” An essential part of a quality improvement effort. Organization leaders must establish a vision, communicate that vision to those in the organization, and provide the tools and knowledge necessary to accomplish the vision (QP, 2002).

**Lot** A definite quantity of product or material accumulated under conditions that are considered uniform for sampling purposes (ASQ, 1998). A defined quantity of product accumulated under conditions considered uniform for sampling purposes (QP, 2002).

**Lot (batch)** A definite quantity of some product manufactured under conditions of production that are considered uniform (QP, 2002).



**Lower control limit (LCL)** Control limit for points below the central line in a control chart (QP, 2002). See also: *upper control limit*.

**Malcolm Baldrige National Quality Award (MBNQA)** An award established by the U.S. Congress in 1987 to raise awareness of quality management and recognize U.S. companies that have implemented successful quality management systems. The awards program is managed by the National Institute of Standards and Technology (NIST) and administered by the American Society for Quality (QP, 2002).

The Malcolm Baldrige National Quality Award is considered an excellence model and the criteria are referred to as the Baldrige Criteria for Performance Excellence; the seven categories of criteria are: leadership, strategic planning, customer and market focus, information and analysis, human resource focus, process management, and results. See also: *quality management principles*.

**Management** Coordinated activities to direct and control an organization (ISO 9000:2000). See also: *top management* and *quality management*.

**Management review** A periodic meeting of management at which it reviews the status and effectiveness of the organization's quality management system (QP, 2002).

**Management system** System to establish policy and objectives and to achieve those objectives (ISO 9000:2000). See also "quality management system."

There are several types of management systems; these include quality management systems, environmental management systems, financial management systems, and occupational health and safety systems. Quality management systems are covered by the ISO 9000:2000 standards.

**Measurement** The act or process of quantitatively comparing results with requirements (QP, 2002).

**Measurement process** Set of operations to determine the value of a quantity (ISO 9000:2000). See also: *inspection* and *test*.

**Measuring equipment** Measuring instrument, software, measurement standard, reference material, or auxiliary apparatus or combination thereof necessary to realize a measurement process (ISO 9000:2000).

**Monitor** The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (Codex Alimentarius, 1997). To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification (NACMCF, 1997).

**Mutually beneficial supplier relationships** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value."

**National Institute of Standards and Technology (NIST)** An agency of the U.S. Department of Commerce that develops and promotes measurements, standards, and technology. NIST manages the Malcolm Baldrige National Quality Award (QP, 2002).

**Nonconformity** Nonfulfillment of a requirement (ISO 9000:2000). A departure of a quality characteristic from its intended level or state that occurs with severity sufficient to cause associated product or service to meet a specification requirement (ASQ, 1998). The nonfulfillment of a specified requirement (QP, 2002). See also: *blemish*, *defect*, and *imperfection*.

**Objective evidence** Data supporting the existence or verity of something (ISO 9000:2000).

**Operating characteristic (OC) curve** A plot showing, for a given sample plan, the probability of accepting a lot, as a function of the lot quality (ASQ, 1998).

**Organization** Group of people and facilities with an arrangement of responsibilities, authorities, and relationships (ISO 9000:2000).

**Organizational structure** Arrangement of responsibilities, authorities, and relationships between people (ISO 9000:2000).

**Out-of-control process** A process in which the statistical measure being evaluated is not in a state of statistical control. In other words, the variations among the observed sampling results cannot be attributed to a constant system of chance causes but to assignable or special causes (QP, 2002). See also: *in-process control*.

**Outputs** Products, materials, services, or information provided to customers from a process (QP, 2002).

**Pareto chart** A bar chart or graph of the frequency of product or process measurements. The bars are plotted in order of frequency. The graph may be expressed in numbers or cumulative percentages (ASQ, 1998). 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 nineteenth-century economist Vilfredo Pareto, suggests that most effects come from relatively few causes; that is, 80% of the effects come from 20% of the possible causes. It is one of the seven tools of quality (QP, 2002).

**Pest control** Suppression of pests, usually by chemical, physical or environmental means, to a level at which few are still existing (ASQ, 1998).

**Plan-do-check-act (PDCA) cycle** A four-step process for quality improvement, which is sometimes referred to as the Shewhart cycle and sometimes as the Deming cycle. In the first step (plan), a plan to effect improvement is developed. In the second step (do), the plan is carried out. In the third step (check), the effects of the plan are observed. In the last step (act), the results are studied to determine what was learned and can be predicted. Also called the plan-do-study-act (PDSA) cycle (QP, 1992).

The ISO 9001:2000 standard proposes that the methodology of the PDCA cycle can be applied to all processes in an organization's quality management system, as follows: plan – establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies; do – implement the processes; check – monitor and measure processes and product against policies, objectives, and requirements for the product and report the results; act – take actions to continually improve process performance.

**Prerequisite programs** Procedures, including good manufacturing practices that address operational conditions providing the foundation for the HACCP system (NACMCF, 1997).

Prerequisite programs must be developed and implemented before an effective HACCP system can be implemented. The NACMCF provides the following examples of common prerequisite programs: facilities, supplier control, specifications, production equipment, cleaning and sanitation, personal hygiene, training, chemical control, receiving, storage and shipping, traceability and recall, pest control. These topics are covered in the Codex General Principles of Food Hygiene under the following categories: design and facilities, control of operation, maintenance and sanitation, personal hygiene, transportation, product information and consumer awareness, and training.

**Preventive action** Action taken to eliminate the cause of a potential non-conformity or other undesirable potential situation (ISO 9000:2000). See also: *corrective action*.

**Procedure** Specified way to carry out an activity or a process (ISO 9000:2000). The steps in a process and how these steps are to be performed for the process to fulfill customers' requirements (QP, 2002).

**Process** Set of interrelated or interacting activities which transforms inputs into outputs (ISO 9000:2000). A set of interrelated work activities

characterized by a set of specific inputs and value-added tasks that make up a procedure for a set of specific outputs (QP, 2002).

**Process approach** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "A desired result is achieved more efficiently when activities and related resources are managed as a process." The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes (ISO 9000:2000). See also *process management*.

**Process capability** The limits within which a tool or process operates, based upon minimum variability as governed by the prevailing circumstances (ASQ, 1998). A statistical measure of the inherent process variability for a given characteristic (QP, 2002).

**Process capability index** The value of the tolerance specified for the characteristic divided by the process capability (QP, 2002).

**Process control** The methodology for keeping a process within boundaries; minimizing the variation of a process (QP, 2002).

**Process improvement** The application of the plan-do-check-act (PDCA) cycle philosophy to a process to produce improvement and better meet the needs and expectations of customers (QP, 2002).

**Process management** The pertinent techniques and tools applied to a process to implement and improve process effectiveness, hold the gains and ensure process integrity in fulfilling customer requirements (QP, 2002).

**Process map** A type of flowchart depicting the steps in a process, with identification of responsibility for each step and the key measure (QP, 2002).

**Process owner** The person who coordinates the various functions and work activities at all levels of a process, has the authority or ability to make changes in the process as required and manages the entire process to ensure performance effectiveness (QP, 2002).

**Producer's risk** The probability that an acceptable lot of product will be rejected under a specified sampling plan (ASQ, 1998). See also: *consumer's risk*.

**Product** Result of a process (ISO 9000:2000).

The ISO 9000 standard recognizes four generic product categories: services, software, hardware, and processed materials. Food products are examples of processed materials, while food service is an example of a service.

**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 (ISO 9000:2000).

**Qualification process** Process to demonstrate the ability to fulfil specified requirements (ISO 9000:2000).

**Quality** Degree to which a set of inherent characteristics fulfils requirements (ISO 9000:2000). The totality of characteristics of a product or service that bear on its ability to satisfy stated and implied needs (ASQ, 1998).

**Quality assurance (QA)** Part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000:2000). All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs (ASQ, 1998). All the planned and systematic activities implemented within a quality system that can be demonstrated to provide confidence a product or service will fulfill requirements for quality (QP, 2002). See also: *quality control*.

**Quality audit** See: *audit*.

**Quality characteristic** Inherent characteristic of a product, process or system related to a requirement (ISO 9000:2000). See also: *characteristic*.

**Quality control (QC)** Part of quality management focused on fulfilling quality requirements (ISO 9000:2000). The operational techniques and activities that sustain a quality of product or service that will satisfy given needs; also the use of such techniques and activities. (ASQ, 1998) The operational techniques and activities used to fulfill requirements for quality (QP, 2002). See also: *quality assurance*.

**Quality improvement** Part of quality management focused on increasing the ability to fulfill quality requirements (ISO 9000:2000). See also: *continual improvement*.

**Quality management** Coordinated activities to direct and control an organization with regard to quality (ISO 9000:2000). The totality of functions involved in the determination and achievement of quality (ASQ, 1998). See also: *total quality management*.

**Quality management principles** The ISO 9000:2000 standard identifies eight quality management principles that can be used by an organization's top management in order to lead the organization toward improved performance. These principles are: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, mutually beneficial supplier relationships.

**Quality management system** Management system to direct and control an organization with regard to quality (ISO 9000:2000). A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management (QP, 2002).

**Quality manual** Document specifying the quality management system of an organization (ISO 9000:2000).

**Quality objective** Something sought, or aimed for, related to quality (ISO 9000:2000).

**Quality plan** Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process, or contract (ISO 9000:2000) A document or set of documents that describe the standards, quality practices, resources and processes pertinent to a specific product, service or project (QP, 2002).

**Quality planning** Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives (ISO 9000:2000).

**Quality policy** Overall intentions and direction of an organization related to quality as formally expressed by top management (ISO 9000:2000). An organization's general statement of its beliefs about quality, how quality will come about, and what is expected to result (QP, 2002).

**Random cause** A cause of variation due to chance and not assignable to any factor (QP, 2002).

**Record** Document stating results achieved or providing evidence of activities performed (ISO 9000:2000).

**Regrade** Alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones (ISO 9000:2000).

**Release** Permission to proceed to the next stage of a process (ISO 9000:2000).

**Reliability** The ability of an item to perform a required function under stated conditions for a standard period of time (ASQ, 1998). The probability of a product performing its intended function under stated conditions without failure for a given period of time (QP, 2002).

**Repair** Action taken on a nonconforming product to make it acceptable for the intended use (ISO 9000:2000). See also: *rework*.

**Requirement** Need or expectation that is stated, generally implied or obligatory (ISO 9000:2000). Examples include product requirements,

customer requirements, and quality management system requirements.

**Review** Activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter to achieve established objectives (ISO 9000:2000).

**Rework** Action on a nonconforming product to make it conform to the requirements (ISO 9000:2000).

**Scatter diagram** A graph relating two process variables. Useful for investigating the relationship (if any) between these variables. It is one of the seven tools of quality (ASQ, 1998). A graphical technique to analyze the relationship between two variables (QP, 2002).

**Scrap** Action taken on a nonconforming product to preclude its originally intended use (ISO 9000:2000).

**Severity** The seriousness of a hazard's effect(s) (NACMCF, 1997).

**Seven tools of quality** Tools that help organizations understand their processes in order to improve them. The tools are: cause-and-effect diagram, check sheet, control chart, flowchart, histogram, Pareto chart, and scatter diagram (QP, 2002).

**Shewhart cycle** See: *plan-do-check-act cycle*.

**Six Sigma** A methodology that provides businesses with the tools to improve the capability of their business processes. This increase in performance and decrease in process variation leads to defect reduction and improvement in profits, employee morale, and product quality (QP, 2002).

**Six Sigma quality** A term generally used to indicate that a process is well controlled (i.e., six sigma from the centerline in a control chart) (QP, 2002).

**Special causes** Causes of variation that arise because of special circumstances. They are not an inherent part of a process. Special causes are also referred to as assignable causes (QP, 2002). See also: *common causes*.

**Specification** Document stating requirements (ISO 9000:2000) A document that states the requirements to which a given product or service must conform (QP, 2002).

**Statistical process control (SPC)** The application of statistical techniques to control a process (QP, 2002). See also: *statistical quality control*.

**Statistical quality control (SQC)** The application of statistical techniques to control quality, includes statistical process control (QP, 2002).



- Step** A point, procedure, operation, or stage in the food chain including raw materials, from primary production to final consumption (Codex Alimentarius, 1997). A point, procedure, operation, or stage in the food system from primary production to final consumption (NACMCF, 1997).
- Supplier** Organization or person that provides a product (ISO 9000:2000). An organization that provides a product or service to the customer (ASQ, 1998). A source of materials, service, or information input provided to a process (QP, 2002).
- Supply chain** The series of suppliers relating to a given process (QP, 2002).
- Surveillance** Monitoring or observation to verify whether an item or activity conforms to specified requirements (ASQ, 1998). The continual monitoring of a process; a type of periodic assessment or audit conducted to determine whether a process continues to perform to a predetermined standard (QP, 2002).
- System** Set of interrelated or interacting elements (ISO 9000:2000). A group of interdependent processes and people that together perform a common mission (QP, 2002).
- System approach to management** This is one of the eight quality management principles recognized by ISO 9000:2000. This principle states: "Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives."
- Technical expert (audit)** Person who provides specific knowledge or expertise on the subject to be audited (ISO 9000:2000).
- Test** Determination of one or more characteristics according to a procedure (ISO 9000:2000).
- Testing** A means of determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operating actions and conditions (ASQ, 1998).
- Top management** Person or group of people who directs and controls an organization at the highest level (ISO 9000:2000).
- Total quality control (TQC)** A system that integrates quality development, maintenance and improvement of the parts of an organization. It helps a company to economically manufacture its product and deliver its services (QP, 2002).
- Total quality management (TQM)** A term initially coined by the U.S. Naval Air Systems Command to describe its Japanese-style management approach to quality improvement. TQM is a management approach to long-term success through customer satisfaction. It is based on

the participation of all members of an organization in improving processes, products, services, and the culture in which they work. The methods for implementing this approach are found in the teachings of such quality leaders as Philip B. Crosby, W. Edwards Deming, Armand V. Feigenbaum, Kaoru Ishikawa, and Joseph M. Juran (QP, 2002).

**Traceability** Ability to trace the history, application or location of that which is under consideration (ISO 9000:2000). The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification (ASQ, 1998).

**Upper control limit (UCL)** Control limit for points above the central line in a control chart (QP, 2002). See also: *lower control limit*.

**Validation** Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (ISO 9000:2000). Obtaining evidence that the elements of the HACCP plan are effective (Codex Alimentarius, 1997). That element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards (NACMCF, 1997). The act of confirming that a product or service meets the requirements for which it is intended (QP, 2002). See also: *verification*.

**Value added** The parts of the process that add worth from the perspective of the external customer (QP, 2000).

**Variables (method of)** Measurement of quality consisting of measuring and recording the numerical magnitude of a quality characteristic for each of the units in the group under consideration (ASQ, 1998).

**Verification** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. (ISO 9000:2000). The application of methods, procedures, tests, and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Codex Alimentarius, 1997). Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan (NACMCF, 1997). The act of determining whether products and services conform to specific requirements (QP, 2002).

**World-class quality** A term used to indicate a standard of excellence: best of the best (QP, 2002).

**Work environment** Set of conditions under which work is performed (ISO 9000:2000).

In food processing, control of the work environment is required as good manufacturing practice and as part of the prerequisite programs of HACCP.

**Zero defects** A performance standard developed by Philip Crosby (QP, 2002).

### 1.3 *Recognized experts in the quality field*

The evolution of quality management principles and practices has resulted from the pioneering work of several recognized experts during the last century and particularly since the 1950s. Among the experts whose contributions are particularly well recognized are:

**Philip Crosby** introduced the zero defects concept. He has authored several books in the field of quality management (QP, 2002).

**W. Edwards Deming** developed the 14 points referred to as the 14 quality management practices to help companies increase their quality and productivity. He has authored several books in the field of quality management and is also recognized for his expertise in statistical quality control (QP, 2002).

**Harold F. Dodge** is recognized for his work with acceptance sampling and standardized inspection procedures. He has contributed to the development of several acceptance sampling concepts, including consumer's risk, producer's risk and average outgoing quality level. Together with Harry G. Romig, he developed the Dodge-Romig sampling tables (QP, 2002).

**Armand, V. Feigenbaum**, the author of *Total Quality Control*, is recognized for being the first to propose the concept (QP, 2002).

**Eugene L. Grant** introduced statistical quality control concepts to improve manufacturing production. He has authored and co-authored several books (QP, 2002).

**Kaoru Ishikawa** is recognized for the development of the cause-and-effect diagram which is also known as the Ishikawa diagram. He is regarded as a pioneer in quality control activities in Japan and has authored several books in the field of quality control and quality management (QP, 2002).

**Joseph M. Juran** is recognized for his contributions to the quality management; he has authored or co-authored several books on various topics in the field of quality management (QP, 2002).

**Harry G. Romig** was the first to develop the sampling plans using variable data and the concept of average outgoing quality limit. Together with Harold F. Dodge, he developed the Dodge-Romig sampling tables (QP, 2002).

**Walter A. Shewhart** is recognized for his pioneering work in bringing together the disciplines of statistics, engineering, and economics. This work is the subject of his book *Economic Control of Quality of Manufactured Product*. He has authored books on statistical quality control and is best known for creating the control chart (QP, 2002).

**Genichi Taguchi** developed methodology to improve quality and reduce costs, this is referred to as the Taguchi methods. He also developed the concept of quality loss function (QP, 2002).

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