## Glossary

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- **audit**

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

  - When two or more *management systems* are audited together, this is termed a combined audit.
  - When two or more auditing organizations cooperate to audit a single *auditee*, this is termed a joint audit.

- **audit (internal)**

  Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the *organization* itself for management review and other internal purposes, and may form the basis for an organization's declaration of *conformity*. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

- **audit (external)**

  External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as *customers*, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing certification/registration of conformity to ISO 9001 or ISO 14001.

- **audit client**

  *Organization* or person requesting an *audit*.

  - The audit client may be the *auditee* or any other *organization* that has the regulatory or contractual right to request an audit.

- **audit conclusion**

  Outcome of an *audit* provided by the *audit team* after consideration of the audit objectives and all *audit findings*.

- **audit criteria**

  Set of policies, *procedures* or *requirements*.

  - criteria are used as a reference against which *audit evidence* is compared.

- **audit evidence**

  *Records*, statements of fact or other *information* which are relevant to the *audit criteria* and verifiable.

  - Audit evidence can be qualitative or quantitative.

- **audit findings**

  Results of the evaluation of the collected *audit evidence* against *audit criteria*.

  - Audit findings can indicate either *conformity* or *non-conformity* with audit criteria or opportunities for improvement.

- **audit plan**

  Description of the activities and arrangements for an *audit*.

- **audit programme**

  Set of one or more *audits* planned for a specific time frame and directed towards a specific purpose.

- An audit programme includes all activities necessary for planning, organizing and conducting the audits.

- **audit scope**

  Extent and boundaries of an *audit*.

  - The audit scope generally includes a description of the physical locations, organizational units, activities and *processes*, as well as the time period covered.

- **audit team**

  One or more *auditors* conducting an *audit*, supported if needed by *technical experts*.

  - One auditor of the audit team is appointed as the audit team leader.
  - The audit team may include auditors-in-training.

- **auditee**

  *Organization* being audited.

- **auditor**

  Person with the demonstrated personal attributes and *competence* to conduct an *audit*.

  - The relevant personal attributes for an auditor are described in ISO 19011.

- **capability**

  Ability of an *organization*, *system* or *process* to realize a *product* that will fulfil the *requirements* for that product.

- **characteristic**

  Distinguishing feature.

  - A characteristic can be inherent or assigned.
  - A characteristic can be qualitative or quantitative.
  - There are various classes of characteristic, such as physical, sensory, behavioral, temporal, functional, etc.

- **competence**

  Demonstrated ability to apply knowledge and skills.

- **concession**

  Permission to use or release a *product* that does not conform to specified *requirements*.

  - A concession is generally limited to the delivery of a product that has nonconforming *characteristics* within specified limits for an agreed time or quantity of that product.

- **conformity**

  Fulfilment of a *requirement*.

- **continual improvement**

  Recurring activity to increase the ability to fulfil *requirements*.

  - The *process* of establishing objectives and finding opportunities for improvement is a continual process through the use of *audit findings* and *audit conclusions*, analysis of data, management *reviews* or other means and generally leads to *corrective action* or *preventive action*.

- **contract**

  Binding agreement.

- **correction**

  Action to eliminate a detected *nonconformity*.

  - A correction can be made in conjunction with a *corrective action*.
  - A correction can be, for example, *rework* or *re-grade*.

- **corrective action**

  Action to eliminate the cause of a detected *nonconformity* or other undesirable situation.

  - There can be more than one cause for a nonconformity.
  - Corrective action is taken to prevent recurrence whereas *preventive action* is taken to prevent occurrence.
  - There is a distinction between *correction* and corrective action.

- **customer**

  *Organization* or person that receives a *product*.

  - A customer can be internal or external to the organization.

- **customer satisfaction**

  Customer's perception of the degree to which the customer's *requirements* have been fulfilled.

  - Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

- Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

- **defects**

  Non-fulfilment of a *requirement* related to an intended or specified use.

  - The distinction between the concepts defect and *nonconformity* is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term "defect" should be used with extreme caution.

- **dependability**

  Collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance.

  - Dependability is used only for general descriptions in non-quantitative terms.

- **design and development**

  Set of *processes* that transforms *requirements* into specified *characteristics* or into the *specification* of a *product*, *process* or *system*.

  - The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.
  - A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).

- **deviation permit**

  Permission to depart from the originally specified *requirements* of a *product* prior to realization.

  - A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.

- **document**

  *Information* and its supporting medium.

  - The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.
  - A set of documents, for example specifications and records, is frequently called "documentation".

- **documented procedure**

  A procedure which is established, documented, implemented and maintained.

- **effectiveness**

  Extent to which planned activities are realized and planned results achieved.

- **efficiency**

  Relationship between the result achieved and the resources used.

- **grade**

  Category or rank given to different quality requirements for *products*, *processes* or *systems* having the same functional use.

- **information**

  Meaningful data.

- **infrastructure**

  Organization *system* of facilities, equipment and services needed for the operation of an *organization*.

- **inspection**

  Conformity evaluation by observation and judgment accompanied as appropriate by measurement or testing.

- **interested parties**

  Person or group having an interest in the performance or success of an *organization*.

- **management**

  Coordinated activities to direct and control an *organization*.

  - In English, the term "management" sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an organization. When "management" is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept "management" defined above.

- **management system**

  *System* to establish policy and objectives and to achieve those objectives.

  - A management system of an *organization* can include different management systems, such as a *quality management system*, a financial management system or an environmental management system.

- **measuring equipment**

  Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement process*.

- **measuring devices**

  Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process.

- **measurement**

  Set of interrelated and interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

- **measurement management system**

  Set of interrelated and interacting elements necessary to achieve *metrological confirmation* and continual control of *measurement processes*.

- **measurement process**

  Set of operations to determine the value of a quantity.

- **metrological characteristics**

  Distinguishing feature which can influence the results of measurement.

  - *Measuring equipment* usually has several metrological characteristics.
  - Metrological characteristics can be the subject of calibration.

- **metrological confirmation**

  Set of operations required to ensure that *measuring equipment* conforms to the *requirements* for its intended use.

  - Metrological confirmation generally includes calibration or *verification*, any necessary adjustment or *repair*, and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labeling.
  - Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.
  - The requirements for intended use include such considerations as range, resolution and maximum permissible errors.
  - Metrological requirements are usually distinct from, and are not specified in, product requirements.

- **metrological function**

  Function with administrative and technical responsibility for defining and implementing the *measurement management system*.

  - The word "defining" has the meaning of "specifying". It is not used in the terminological sense of "defining a concept" (in some languages, this distinction is not clear from the context alone).

- **nonconformities**

  Non-fulfilment of a *requirement*.

- **objective evidence**

  Data supporting the existence or verity of something.

  - Objective evidence may be obtained through observation, measurement, *test*, or other means.

- **organization**

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

  - The arrangement is generally orderly.
  - An organization can be public or private.

- **organizational structure**

  Arrangement of responsibilities, authorities and relationships between people.

  - The arrangement is generally orderly.
  - A formal expression of the organizational structure is often provided in a *quality manual* or a *quality plan* for a *project*.
  - The scope of an organizational structure can include relevant interfaces to external *organizations*.

- **precision**

  A measure of closeness of agreement between results.

- **preventive action**

  Action to eliminate the cause of a potential *nonconformity* or other undesirable potential situation.

  - There can be more than one cause for a potential nonconformity.
  - Preventive action is taken to prevent occurrence whereas *corrective action* is taken to prevent recurrence.

- **procedure**

  Specified way to carry out an activity or a *process*.

  - Procedures can be documented or not.
  - When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The *document* that contains a procedure can be called a "procedure document".

- **process**

  Set of interrelated or interacting activities which transforms inputs into outputs.

  - Inputs to a process are generally outputs of other processes.
  - Processes in an *organization* are generally planned and carried out under controlled conditions to add value.
  - A process where the *conformity* of the resulting *product* cannot be readily or economically verified is frequently referred to as a "special process".

- **products**

  Result of a *process*.

  - There are four generic product categories, as follows: Services, Software, Hardware and Processed materials.
  - Many products comprise elements belonging to different generic product categories.Whether the product is then

called service, software, hardware or processed material depends on the dominant element.
    - Service is the result of at least one activity necessarily performed at the interface between the *supplier* and *customer* and is generally intangible.

- **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.

    - An individual project can form part of a larger project structure.
    - In some projects the objectives are refined and the product *characteristics* defined progressively as the project proceeds.
    - The outcome of a project can be one or several units of *product*.

- **qualification process**

  *Process* to demonstrate the ability to fulfil specified *requirements*.

    - The term "qualified" is used to designate the corresponding status.
    - Qualification can concern persons, *products*, *processes* or *systems*.

- **quality**

  Degree to which a set of inherent *characteristics* fulfils *requirements*.

- **quality assurance**

  Part of *quality management* focused on providing confidence that quality requirements will be fulfilled.

- **quality characteristic**

  Inherent *characteristic* of a *product*, *process* or *system* related to a *requirement*.

  - Inherent means existing in something, especially as a permanent characteristic.
  - A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.

- **quality control**

  Part of *quality management* focused on fulfilling quality requirements.

- **quality improvement**

  Part of *quality management* focused on increasing the ability to fulfil quality requirements.

  - The requirements can be related to any aspect such as *effectiveness*, *efficiency* or *traceability*.

- **quality management**

  Coordinated activities to direct and control an *organization* with regard to *quality*.

  - Direction and control with regard to quality generally includes establishment of the *quality policy* and *quality objectives*, *quality planning*, *quality control*, *quality assurance* and *quality improvement*.

- **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 manuals can vary in detail and format to suit the size and complexity of an individual organization.

- **quality objectives**

  Something sought, or aimed for, related to *quality*.

  - Quality objectives are generally based on the organization's *quality policy*.
  - Quality objectives are generally specified for relevant functions and levels in the *organization*.

- **quality plan**

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

  - These procedures generally include those referring to quality management processes and to product realization processes.
  - A quality plan often makes reference to parts of the *quality manual* or to procedure documents.
  - A quality plan is generally one of the results of *quality planning*.

- **quality planning**

  Part of *quality management* focused on setting *quality objectives* and specifying necessary operational *processes* and related resources to fulfil the quality objectives.

  - Establishing *quality plans* can be part of quality planning.

- **quality policy**

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

  - Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of *quality objectives*.

- **re-grade**

  Alteration of the *grade* of a nonconforming *product* in order to make it conform to *requirements* differing from the original ones.

- **records**

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

  - Records can be used, for example, to document *traceability* and to provide evidence of *verification*, *preventive action* and *corrective action*.

- **release**

  Permission to proceed to the next stage of a *process*.

  - In English, in the context of computer software, the term "release" is frequently used to refer to a version of the software itself.

- **repair**

  Action on a nonconforming *product* to make it acceptable for the intended use.

  - Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance.
  - Unlike *rework*, repair can affect or change parts of the nonconforming product.

- **requirement**

  Need or expectation that is stated, generally implied or obligatory.

  - expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted.

- **review**

  Activity undertaken to determine the suitability, adequacy and *effectiveness* of the subject matter to achieve established objectives.

  - Review can also include the determination of *efficiency*.

- **rework**

  Action on a nonconforming product to make it conform to the requirements.

- **scraps**

  Action on a nonconforming *product* to preclude its originally intended use.

  - In a nonconforming service situation, use is precluded by discontinuing the service.

- **specification**

  *Document* stating *requirements*.

  - A specification can be related to activities (e.g. procedure document, process specification and test specification), or *products* (e.g. product specification, performance specification and drawing).

- **supplier**

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

  - A supplier can be internal or external to the organization.
  - In a contractual situation, a supplier is sometimes called "contractor".

- **system**

  Set of interrelated or interacting elements.

- **technical expert**

  Person who provides specific knowledge or expertise to the *audit team*.

  - Specific knowledge or expertise relates to the *organization*, the *process* or activity to be audited, or language or culture.
  - A technical expert does not act as an *auditor* in the audit team.

- **test**

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

- **traceability**

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

  - When considering *product*, traceability can relate to the origin of materials and parts, the processing history, and the distribution and location of the product after delivery.
  - In the field of tests and calibrations, traceability is understood as the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.

- **trueness**

  A measure of closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value.

- **top management**

  Person or group of people who directs and controls an *organization* at the highest level.

- **uncertainty**

  The parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

- **validation**

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

  - The term "validated" is used to designate the corresponding status.
  - The use conditions for validation can be real or simulated.

- **verification**

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

  - The term "verified" is used to designate the corresponding status.
  - Confirmation can comprise activities such as:
    - performing alternative calculations,
    - comparing a new design *specification* with a similar proven design specification,
    - undertaking *tests* and demonstrations reviewing documents prior to issue.

- **work environment**

  Set of conditions under which work is performed.

  - Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).