

# Plain English Process Definitions

## Audit

An **audit** is a systematic evidence gathering process. **Audits** must be independent. Evidence must be evaluated objectively to determine how well audit criteria are being met. There are three types of audits: first-party, second-party, and third-party. First-party audits are internal audits while second and third party audits are external audits.

Organizations use first party audits to audit themselves. First party audits are used to provide input for management review and for other internal purposes. They're also used to declare that an organization meets specified requirements (this is called a self-declaration).

Second party audits are external audits. They're usually done by customers or by others on their behalf. However, they can also be done by regulators or any other external party that has an interest in an organization. Third party audits are external audits as well. However, they're performed by independent organizations such as registrars (certification bodies) or regulators.

## Audit criteria

**Audit criteria** are used as a reference point and include policies, requirements, and other forms of documented information. They are compared against audit evidence to determine how well they are being met. Audit evidence is used to determine how well policies are being implemented and how well requirements are being followed.

## Audit evidence

**Audit evidence** includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, requirements, and other documented information.

## Audit findings

**Audit findings** result from a process that evaluates audit evidence and compares it against audit criteria. **Audit findings** can show that audit criteria are being met (conformity) or that they are not being met (nonconformity). They can also indicate areas for improvement opportunities.

## Audit program (programme)

An **audit program (or programme)** refers to a set of one or more audits that are planned and carried out within a specific time frame and are intended to operate as a special unit of operation.

## Characteristic

A **characteristic** is a distinctive feature or property of something. Characteristics can be inherent or assigned and can be qualitative or quantitative. An inherent characteristic exists in something or is a permanent feature of something while an assigned characteristic is a feature that is attributed or attached to something.

## Competence

**Competence** means being able to apply knowledge and skill to achieve intended results. **Being competent** means having the knowledge and skill that you need and knowing how to apply it. **Being competent** means that you're qualified to do the job.

## Conformity

**Conformity** is the "fulfillment of a requirement". To **conform** means to meet or comply with requirements and a requirement is a need, expectation, or obligation. There are many types of requirements including customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

## Context

An organization's **context** is its business environment. It includes all of the internal and external factors and conditions that affect its products and services, have an influence on its processes, and are relevant to its purpose and strategic direction.

An organization's **external context** includes all of the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment. An organization's **internal context** includes its values, culture, knowledge, and performance.

## Correction

A **correction** is any action that is taken to eliminate a nonconformity. However, corrections do not address root causes. When applied to products, corrections can include reworking products, reprocessing them, upgrading them, assigning them to a different use, or simply destroying them.

## Corrective action

**Corrective actions** are steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations don't happen again.

## Customer satisfaction

**Customer satisfaction** is a perception. It's also a question of degree. It can vary from high satisfaction to low satisfaction. If customers believe that you've met their requirements, they experience high satisfaction. If they believe that you've not met their requirements, they experience low satisfaction.

Since satisfaction is a perception, customers may not be satisfied even though you've met all contractual requirements. Just because you haven't received any complaints doesn't mean that customers are satisfied.

There are many ways to monitor and measure customer satisfaction. You can use customer satisfaction and opinion surveys; you can collect product quality data (post delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms, and analyze lost business opportunities.

## Defect

A **defect** is a type of nonconformity. It occurs when a product or service fails to meet specified or intended use requirements.

## Design and development

**Design and development** is a process (or a set of processes) that uses resources to transform general input requirements for an object into specific output requirements.

An **object** is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, tools, machines, technologies, techniques, and resources.

## Documented information

The term **documented information** refers to information that must be controlled and maintained and its supporting medium. Documented information can be in any format and on any medium and can come from any source.

**Documented information** includes information about the management system and related processes. It also includes all the information that organizations need to operate and all the information that they use to document the results that they achieve (aka records).

## Effectiveness

**Effectiveness** refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are actually carried out and planned results are effective if these results are actually achieved.

## Feedback

The term **feedback** is used to refer to a comment or an opinion expressed about a product or service or an interest expressed in a product or a service. It may also be used to refer to the customer complaints-handling process itself.

## Infrastructure

The term **infrastructure** refers to the entire system of facilities, equipment, and support services that organizations need in order to function.

## Interested party

An **interested party** is anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An **interested party** is a person, group, or organization that has an interest or a stake in a decision or activity.

## Management

The term **management** refers to all the activities that are used to coordinate, direct, and control an organization. These activities include developing policies, setting objectives, and establishing processes to achieve these objectives. In this context, the term management does not refer to people. Either you or your customer may decide.

## Management system

A **management system** is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

There are many types of **management systems**. Some of these include quality management systems, environmental management systems, financial management systems, information security management systems, business continuity management systems, emergency management systems, disaster management systems, food safety management systems, risk management systems, and occupational health and safety management systems.

The scope or focus of a **management system** could be restricted to a specific function or action of an organization or it could include or intersecting elements that organizations use to formulate policies across several organizations.

## Measurement

**Measurement** is a process that is used to determine a value. In most cases this value will be a quantity.

## Measuring equipment

**Measuring equipment** includes all the things needed to carry out a measurement process. Accordingly, measuring equipment includes instruments and apparatuses as well as all the associated software, standards, and reference materials.

## Monitoring

To **monitor** means to determine the status of an activity, process, or system at different stages or at different times. In order to determine status, you need to supervise and to continually check and critically observe the activity, process, or system that is being monitored.

## Nonconformity

**Nonconformity** is a nonfulfillment or failure to meet a requirement. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization or interested parties.

## Objective

An **objective** is a result you intend to achieve. Objectives can be strategic, tactical, or operational and can apply to an organization as a whole or to a system, process, project, product, or service. Objectives may also be referred to as targets, aims, goals, or intended outcomes.

## Objective audit evidence

**Objective audit evidence** is information that is verifiable and generally consists of records and other statements of fact that are relevant to the audit criteria being used.

## Objective evidence

**Objective evidence** is data that shows or proves that something exists or is true. **Objective evidence** can be collected by performing observations, measurements, tests, or using other suitable methods.

## Output

An **output** is the result of a process. **Outputs** can be either tangible or intangible. The output from one process is often the input for another process.

## Outsource

When an organization makes an arrangement with an outside organization to perform part of a function or process, it is referred to as **outsourcing**. To **outsource** means to ask an external organization to perform part of a function or process normally done inhouse.

## Performance

According to ISO, the term **performance** refers to a measurable result. It refers to the measurable results that activities, processes, products, services, systems and organizations are able to achieve. Whenever they **perform well** it means that acceptable results are being achieved and whenever they **perform poorly**, unacceptable results are achieved.

## Process

A **process** is a set of activities that are interrelated or that interact with one another. **Processes** use resources to transform inputs into outputs. Processes are interconnected because the output from one process often becomes the input for another process.

While processes usually transform inputs into outputs, this is not always the case. Sometimes inputs become outputs without transformation.

**Organizational processes** should be planned and carried out under controlled conditions. An effective process is one that realizes planned activities and achieves planned results.

## Process approach

The **process approach** is a management strategy. When managers use a process approach, it means that they manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.

## Product

A **product** is a tangible or intangible output that is the result of a process that does not include activities that are performed at the interface between the supplier (provider) and the customer.

**Products** can be tangible or intangible. According to a note to this definition, there are three generic product categories: hardware, processed materials, and software. Many products combine several of these categories. For example, an automobile (a product combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).

## Requirement

A **requirement** is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. A specified requirement is one that has been stated (in a document for example), whereas an implied requirement is a need, expectation, or obligation that is common practice or customary.

There are many types of requirements. Some of these include customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

## Review

A **review** is an activity. Its purpose is to figure out how well the thing being reviewed is capable of achieving established objectives. **Reviews** ask the following question: is the subject (or object) of the review a suitable, adequate, effective, and efficient way of achieving established objectives?

There are many kinds of reviews. Some of these include management reviews, design and development reviews, customer requirement reviews, nonconformity reviews, and peer reviews.

## Risk

According to ISO 31000, **risk** is the "effect of uncertainty on objectives" and an effect is a positive or negative deviation from what is expected. The following two paragraphs will explain what this means.

This definition recognizes that all of us operate in an uncertain world. Whenever we try to achieve something, there's always the chance that things will not go according to plan. Sometimes we get positive results and sometimes we get negative results and occasionally we get both. Because of this, we need to reduce uncertainty as much as possible.

**Uncertainty** (or lack of certainty) is a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding. In the context of risk management, uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete.

While this definition argues that risk can be positive as well as negative, a note acknowledges that "the term risk is sometimes used when there is only the possibility of negative consequences".

## Risk-based thinking

**Risk-based thinking** refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives. **Risk-based thinking** replaces what the old standards used to call preventive action.

## Service

A **service** is an intangible output and is the result of a process that includes at least one activity that is carried out at the interface between the supplier (provider) and the customer.

**Service provision** can take many forms. Service can be provided to support an organization's own products (e.g. warranty service or the serving of meals). Conversely, it can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). It can also involve the provision of an intangible thing to a customer (e.g. entertainment, ambulance, transportation, or advice).

## Special requirement

A **special requirement** is a requirement that may be especially difficult to achieve. Special requirements may be difficult to achieve because they force you to operate at the limit of your technical or process capability or at the limit of your industry's capability.

Since there is a risk that your organization may not be able to meet a special requirement, you're expected to include it in your operational risk management process. Either you or your customer may decide that a requirement is special. In order to figure out whether or not a requirement is special, consider the complexity and maturity of your product or process and your past experience.

## Supplier

A **supplier** is a person or an organization that provides products or services. **Suppliers** can be either internal or external to an organization. **Internal suppliers** provide products or services to people within their own organization while **external suppliers** provide products or services to other organizations.

## System

A **system** is defined as a set of interrelated or interacting elements. A **management system** is one type of system. It is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved.

## Traceability

**Traceability** is the ability to identify and trace the history, distribution, location, and application of products, parts, materials, and services. A traceability system records and follows the trail of products, parts, materials, and services from suppliers and providers to customers and ultimately distributed as final products and services.

## Validation

**Validation** is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment.

There are several ways to confirm that the requirements which define an intended use or application have been met. For example you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.

## Verification

**Verification** is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved.

There are many ways to verify that requirements have been met. For example you could inspect something, you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.

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