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| | QUALITY MANUAL | |
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BAI adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the BAI typically adopts the definitions provided in **ISO 9000:2005 Quality Management – Fundamentals and Vocabulary**. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

General Terminology

BAI – Bureau of Animal Industry

Document – written information used to describe how an activity is done

Record – captured evidence of an activity having been done

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty

Opportunity – Positive effect of uncertainty

Inspection Terminology

Inspection body - body that performs inspection; can be an organization, or part of an organization

Inspection system- rules, procedures, and management for carrying out inspection; can be operated at international, regional, national or sub-national level.


Impartiality - presence of objectivity; Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the inspection body. Other terms that are useful in conveying the element of impartiality are: independence, freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

Appeal - request by the provider of the item of inspection to the inspection body for reconsideration by that body of a decision it has made relating to that item

Complaint- expression of dissatisfaction, other than appeal, by any person or organization to an inspection body, relating to the activities of that body, where a response is expected.

NOTE Adapted from ISO/IEC 17000:2004.

The terms and definitions were copied from [ISO 9000:2005](#), Quality Management Systems – Fundamentals and Vocabulary.

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Benchmarking refers to the methodology used to search for best practices. Benchmarking can be applied to strategies, policies, operations, processes, products, and organizational structures. By finding and adopting best practices you can improve your organization's overall performance.

Characteristic refers to a distinctive feature or property of something. Characteristics can be inherent or assigned. 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.

Concession refers to a special approval that is granted to release a nonconforming product for use or delivery. Concessions are usually limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.

Conformity means to meet or comply with requirements. There are many types of requirements. There are quality requirements, customer requirements, product requirements, management requirements, legal requirements, and so on.

Continual improvement is a set of recurring activities that an organization carries out in order to enhance its ability to meet requirements. Continual improvements can be achieved by carrying out audits, self-assessments, management reviews, and benchmarking projects. Continual improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions.


Correction refers to any action that is taken to eliminate a nonconformity. However, corrections do not address causes. When applied to products, corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.

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 - A customer is anyone who receives products or services from a supplier organization. Customers can be people or organizations and can be either external or internal to the supplier organization. For example, a factory may supply products or services to another factory (customer) within the same organization. According to ISO 9000, examples of customers include clients, consumers, end-users, purchasers, retailers, and beneficiaries.

Customer satisfaction is a perception. It is 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.

Design and development is a process (or a set of processes). This process uses resources to transform requirements (inputs) into characteristics or specifications (outputs) for products, processes, and systems. You may treat design and development as different stages of a single integrated design and development

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process or you may treat design and development as two (or more) separate processes. You may also use the terms design and development interchangeably if they mean the same thing in your organization.

Design and development review is a set of activities whose purpose is to evaluate the suitability, adequacy, effectiveness, and sometimes the efficiency of a set of characteristics or specifications. Design and development review can be used to evaluate product, process, and system characteristics or specifications. In this context, an effective set of characteristics or specifications is one that has the potential to achieve planned results or realize planned activities.

Design and development validation is a process. This process uses objective evidence to confirm that products meet the requirements which define their intended use or application. Whenever specified requirements have been met, a validated status is achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment.

Design and development verification is a process. It uses objective evidence to confirm that design and development outputs meet design and development input requirements. Whenever specified input requirements have been met, a verified status is achieved.


Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are realized. Similarly, planned results are effective if these results are actually achieved.

Efficiency is a relationship between results achieved (outputs) and resources used (inputs). Efficiency can be enhanced by achieving more with the same or fewer resources. The efficiency of a process or system can be enhanced by achieving more or getting better results (outputs) with the same or fewer resources.

Infrastructure refers to the entire system of facilities, equipment, and services that an organization needs in order to function. According to ISO 9001, Part 6.3, the term infrastructure includes buildings and workspaces (including related utilities), process equipment (both hardware and software), support services (such as transportation and communications), and information systems.

Inspection use observation, measurement, testing and judgment to evaluate conformity. Inspection results are compared with specified requirements in order to establish whether conformity has been achieved. Product inspections compare product characteristics with product requirements in order to evaluate conformity.

Interested party is a person or group that has a stake in the success or performance of an organization. Interested parties may be directly affected by the organization or actively concerned about its performance. Interested parties can come from inside or outside of the organization. Examples of interested parties include customers, suppliers, owners, partners, employees, unions, bankers, or members of the general public. Interested parties are also referred to as stakeholders.

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Key performance indicator (KPI) is a metric or measure. KPIs are used to quantify and evaluate organizational success. They measure how much success you've had and how much progress you've made relative to the objectives you wish to achieve. KPIs are also used to set measurable objectives, evaluate progress, monitor trends, make improvements, and support decision making. KPIs should be quantifiable and appropriate and should collect information that is useful to your organization and relevant to the needs and expectations of interested parties.

Management refers to all the activities that are used to coordinate, direct, and control an organization. In this context, the term management does not refer to people. It refers to activities.

Management review - The overall purpose of a management review is to evaluate the suitability, adequacy, and effectiveness of an organization's quality management system, and to look for improvement opportunities. Management reviews are also used to identify and assess opportunities to change an organization's quality policy and quality objectives, to address resource needs, and to look for opportunities to improve its products.

Measuring equipment - In the context of this standard, measuring equipment includes all the things that are needed to carry out a measurement process. Accordingly, measuring equipment includes measuring instruments and apparatuses as well as all the associated software, standards, and reference materials.


Mission- According to ISO 9004, a mission statement explains why an organization exists. It defines its reason for being (its *raison d'être*).

Nonconforming product - When one or more characteristics of a product fail to meet specified requirements, it is referred to as a nonconforming product. When a product deviates from specified product requirements, it fails to conform. Nonconforming products must be identified and controlled to prevent unintended use or delivery.

Nonconformity refers to a failure to comply with requirements. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, product requirements, and legal requirements. Whenever your organization fails to meet one of these requirements, a nonconformity occurs. ISO 9001 lists quality management system requirements. When your organization deviates from these requirements, a nonconformity occurs.

Objective evidence is information that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or by using any other suitable method.

Organization's Environment - Your organization's environment includes all the internal and external factors and conditions that can affect how well you achieve your objectives and how you treat interested parties.

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Outsourced process is any process that is part of your organization's quality management system (QMS) but is performed by a party that is external to your organization.

According to ISO 9001, you must identify and control your outsourced processes, and you must ensure that each outsourced process is effective. You also need to figure out how to control the interaction between internal and outsourced processes.

A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs.

According to ISO/TC 176/SC 2/N526R, "the terms subcontract and outsource are interchangeable and have the same meaning".

Preventive actions are steps that are taken to remove the causes of potential nonconformities or potential situations that are undesirable.

The preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist. It tries to prevent occurrence by eliminating causes. Preventive actions address potential problems, ones that haven't yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

Procedure - is a way of carrying out a process or activity. According to ISO 9000, procedures may or may not be documented. However, in most cases, ISO 9001 expects you to document your procedures.


Documented procedures can be very general or very detailed, or anywhere in between. While a general procedure could take the form of a simple flow diagram, a detailed procedure could be a one-page form or it could be several pages of text.

A detailed procedure defines and controls the work that should be done and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which inputs should be used, and what outputs should be generated.

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 becomes the input for another process.

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

Process-based quality management system (QMS) - uses a process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes. Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS.

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Product is the output of a process. Products can be tangible or intangible. ISO 9000 lists four generic product categories: services, software, hardware, and processed materials. 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).

Service is always the result of an interaction between a service supplier and a customer and 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, service can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). Service can also involve the provision of an intangible thing to a customer (e.g. entertainment, transportation, or advice). While software is intangible, and includes things like approaches and procedures, hardware and processed materials are tangible and are often referred to as goods.

Product inspection is an activity that compares product characteristics with product requirements in order to evaluate conformity. More precisely, a product inspection compares one or more characteristics of a product with specified requirements in order to determine if the product meets these requirements. Product inspections use observation, measurement, testing and judgment to evaluate conformity.

Product realization refers to all the processes that are used to bring products into being. A product starts out as an idea. The idea is realized or actualized by following a set of product realization processes.

Quality - The quality of something can be determined by comparing a set of inherent characteristics with a set of requirements. If those inherent characteristics meet all requirements, high or excellent quality is achieved. If those characteristics do not meet all requirements, a low or poor level of quality is achieved. In short, the quality of something depends on a set of inherent characteristics and a set of requirements and how well the former complies with the latter.


Quality assurance (QA) is a set of activities intended to establish confidence that quality requirements will be met. QA is one part of quality management.

Quality characteristic is tied to a requirement and is an inherent feature or property of a product, process, or system. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. An inherent feature or property exists in something or is a permanent characteristic of something.

Quality control is a set of activities intended to ensure that quality requirements are actually being met. Quality control is one part of quality management.

Quality improvement refers to anything that enhances an organization's ability to meet quality requirements. Quality improvement is one part of quality management.

Quality management includes all the activities that organizations use to direct, control, and coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include quality planning, quality

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control, quality assurance, and quality improvement.

Quality management system (QMS) is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

Quality manual are the documents of an organization's quality management system (QMS). According to ISO 9001 section 4.2.2, your quality manual should contain the essential information for the implementation of the organization's QMS.

Quality planning involves setting quality objectives and then specifying the operational processes and resources that will be needed to achieve those objectives. Quality planning is one part of quality management.

Quality plan is a document that is used to specify the procedures and resources that will be needed to carry out a project, perform a process, realize a product, or manage a contract. Quality plans also specify who will do what and when.

Quality policy defines top management's commitment to quality. A quality policy statement should describe an organization's general quality orientation and clarify its basic intentions. Quality policies should be used to generate quality objectives and should serve as a general framework for action. Quality policies can be based on the ISO 9000 Quality Management Principles and should be consistent with the organization's other policies.


Quality objectives are quality oriented goal or something you aim for or try to achieve. Quality objectives are generally based on or derived from an organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.

Record is a type of document. Records provide evidence that activities have been performed or results have been achieved. They always document the past. Records can, for example, be used to show that traceability requirements are being met, that verification is being performed, and that preventive and corrective actions are being carried out.

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 quality requirements, customer requirements, management requirements, product requirements, and legal requirements.

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 of the review a suitable, adequate, effective, and efficient way of achieving your organization's objectives?

Self-assessment - According to ISO 9004, a self-assessment is a comprehensive and systematic review of an organization's overall maturity and is used to help achieve and sustain organizational success.

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Service - According to ISO 9000, a service is a type of product. Service is always the result of an activity or interaction between a service supplier and a customer and can take many forms.

Special process is any production or service delivery process that generates outputs that cannot be measured, monitored, or verified until it's too late. It's often too late because deficiencies may not be obvious until after the resulting products have been used or services have been delivered. In order to prevent output deficiencies, these special processes must be validated in order to prove that they can generate planned results.

Standard - A standard is a document. It is a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.

Strategy is a logically structured plan or method for achieving long term goals. According to ISO 9004, you need to develop a strategy and policies to ensure that your organization's mission, vision, and values are accepted and supported by interested parties.

Supplier is a person or an organization that provides products. Suppliers can be either internal or external to the organization. Internal suppliers provide products to people within their own organization while external suppliers provide products to other organizations. Examples of suppliers include organizations and people who produce, distribute, or sell products, provide services, or publish information.

Sustained success - According to ISO 9004 2009, an organization achieves sustained success when it meets its objectives and continues to do so over the long term. It further says that objectives can only be achieved if the organization consistently meets the needs and expectations of interested parties (stakeholders).


Systems approach - When managers use a systems approach, it means that they treat the interrelated processes that make up an organization as an integrated system and then they use this system to achieve its objectives. A system is a set of elements that are interrelated or interact with one another.

Top management - When ISO 9001 (and ISO 9004) uses the term top management it is referring to a person or a group of people at the highest level within an organization. It refers to the people who coordinate, direct, and control organizations.

Traceability is the ability to identify and trace the history, distribution, location, and application of products, parts, and materials. A traceability system records and follows the trail as products, parts, and materials come from suppliers and are processed and ultimately distributed as end products.

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 achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment.

Validation. Production and service provision processes must be validated whenever process outputs cannot be measured, monitored, or verified until after

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the product is in use or the service has been delivered (by then it's too late to do anything about output deficiencies and defects). In this case, validations use objective evidence to confirm that production and service provision processes are capable of producing planned results.

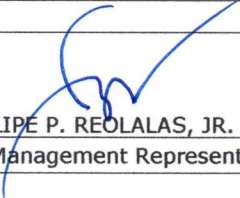

Values - According to ISO 9004, your values are the general principles and beliefs that are important to your organization.

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. In the context of this standard, the term verification is used in at least two different situations: design and development and purchasing. Design and development verifications use objective evidence to confirm that design and development outputs meet specified input requirements. Similarly, objective evidence must be used to verify or confirm that purchased products meet specified purchasing requirements.

Verification. There are many ways to verify that requirements have been met. For example, you could do tests, perform demonstrations, carryout alternative calculations, compare a new design specification with a proven design specification, or you could inspect documents before you issue them.

Vision - According to ISO 9004, an organization's vision describes what it wants to be and how it wants to be seen by interested parties.

Work environment refers to working conditions. It refers to all of the conditions and factors that influence work. In general, these include physical, social, psychological, and environmental conditions and factors. Work environment includes lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices as well as reward and recognition programs. All of these things influence work.

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