

Session 5 – Functional approach to conformity assessment



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What is the functional approach (Definitions)

What is the functional approach

The functional approach is the sequence of stages or the macro process to be followed when performing conformity assessment and which is defined by the CASCO toolbox

The functional approach

The functional approach is the basis for all types conformity assessment. It is composed of the following:

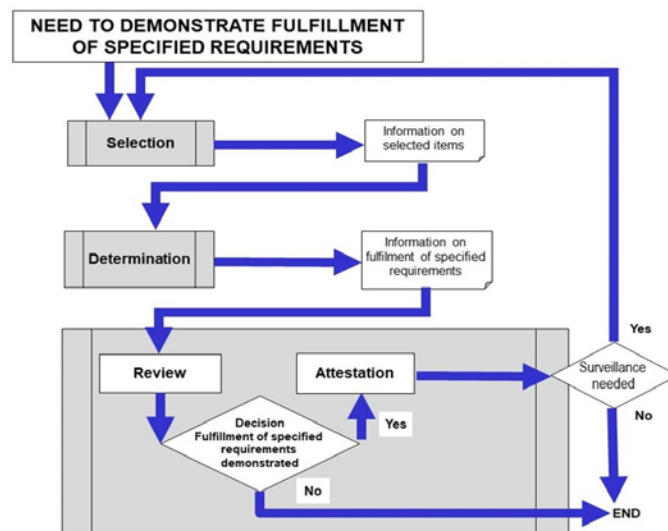
- Selection
- Determination
- Review, decision and attestation; and
- Surveillance, when required

The functional approach is set out in ISO/IEC 17000 (annex) and is described in the next slides.



The different stages in the functional approach

Functional approach



Conformity assessment is done using the functional approach

Functional approach is a combination of 3 main functions

1. Selection

2. Determination

3. Review and attestation

Surveillance, when required

The functional approach is set out in ISO/IEC 17000 and is described in the next slides.

All types of conformity assessment is done according to the functional approach. You need to go through each stage



Selection

- Decide or choose appropriate standards or specifications to which conformity will be assessed.
- Decide on how sampling of the product or service is to be done to get a representative sample.
- Select the actual samples to be assessed.
- Prepare and plan activities in order to collect all necessary information for the determination stage.



Determination

- All activities undertaken to obtain information regarding the fulfillment of specified requirements by the objects of conformity assessment, e.g. product, service, system.
- Examples of determination activities are testing, auditing, inspecting, validation and verification and peer assessment.
- The output of determination is the input to the review, decision and attestation stage.



Determination – Testing

Most common form of conformity assessment.

- Can be used in conjunction with other types of conformity assessment
- Tested against a specified set of criteria.
- Can be used to make decisions on performance of a product, process or service.



Determination – Inspection

Can include

- Visual examination of physical items.
- Measurement or testing of physical items.
- Examination of specification documents such as design drawings.
- Comparison of the findings with specification documents or with generally accepted good practices in the field.
- Reporting on the results of the inspection.



Determination – Auditing

- Audit criteria are the reference against which conformity is determined and are contained in policies, procedures or requirements, established by the organization being audited and considered as meeting its needs, including the implementation of managements system standards (MSS).
- Audit evidence is made up of records, statement of facts and other information related to the criteria and is verifiable.



Determination – Validation & verification

Based on the validation/verification plan which includes among others the following:

- scope and objectives of the validation/verification
- specified requirements as example those in validation/verification programmes

Determination involves

- collecting sufficient and objective evidence on original data/information, its traceability through the data/information management process, any further analysis and calculation.
- identifying misstatements and consideration of their materiality.
- assessing conformity with specified requirements, taking into account the validation/verification programme, see above.

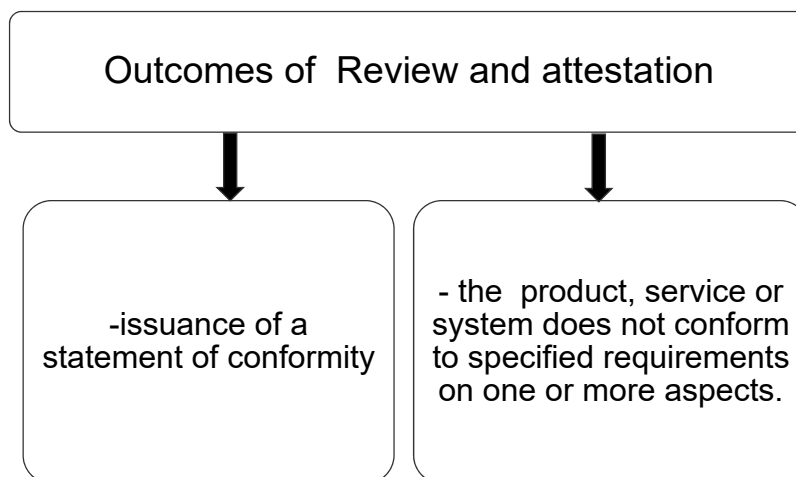


Review, decision and attestation

- Review is the final stage of checking before taking the decision as to whether or not the object of conformity assessment e.g. product, service and system has been reliably demonstrated to fulfil the specified requirements.
- Attestation results in a “statement of conformity”.
- “Statement of conformity” is a generic expression used to include all means of communicating that fulfilment of specified requirements has been demonstrated.
- For claims, a “Statement of conformity” can include non fulfilment of specified requirements.



Functional Approach - Review and attestation



Statement of conformity

Declaration of conformity

- Term used when issued by the manufacturer or supplier of the product (1st party) or the customer or purchaser of the product (2nd party).
- When a supplier self declares he conforms, this is referred to a Suppliers Declaration of Conformity (SDoC).
- This form differentiates it from statements of conformity issued by a third and independent party, “certificates”.

Certificate of conformity

- A statement of conformity issued by a third party is referred to as a certificate of conformity.
- Its content varies according to what is being certified.



Marks of conformity

- Marks are frequently used to indicate conformity to requirements e.g. on products.
- The owner of the mark can be a supplier, scheme owner, certification body or regulator.
- Ownership and conditions for use of the mark must be clearly stated.
- Marks should not mislead the consumer.
- Marks should be used within the terms of the license agreement.



Surveillance

- In many cases conformity assessment ends after review, decision and attestation.
- However, there are situations where there is a need to provide ongoing assurance of conformity.
- The term used to describe this is **surveillance**.



Surveillance

A systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.



Identification of CA activities in relation to the oven

Action	Conformity Assessment Activity
Design the oven	Decide on oven technical specification and testing procedures, sampling procedures etc.
Manufacture the oven on a on-going basis	Testing a sample of ovens from production line (testing) on an on-oing basis
Oven meets the technical specifications or technical standard.	Quality management system (QMS) in place in the factory (certification of QMS)
Place ovens in a storage facility to wait for distribution to the outlets	Inspect samples of the ovens placed in storage prior to distribution to make sure no damage and still safe
Distribute the ovens to shops	Take samples from the shop to ensure it meets specification the regulator may do this



Identification of Conformity Assessment activities in relation to the oven

Action	Conformity Assessment Activity
Design the oven	Selection g procedures,
Manufacture the oven on a on-going basis	Testing a sample of ovens from production is
Oven meets the technical standard.	Determination Quality management system (QMS) in place in (S)
Place ovens in a storage facility to wait for distribution to the	Review/Decision and attestation Inspect samples of the ovens placed in storage
	Determination/Review/Decision and attestation e no damage and
Distribute the oven	Market surveillance ensure it meets do this



Group Activity #3



Group Activity #3

Discuss in Groups (15-20 minutes)

Using the functional approach (see slide 8) choose one of the following conformity assessment activities and explain how each of the elements of the functional approach can be applied:

- testing/calibrating an item
- certifying a product or process
- certifying a management system



Thank you

