

## Conformity assessment - Functional approach

The functional approach consists of four main stages where the output from one stage serves as the input to the next:

- 1) selection;
- 2) determination;
- 3) review and attestation; and
- 4) surveillance (not in all cases).

### Selection

Selection involves planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function. Selection activities vary widely in number and complexity.

Selection includes:

- identification of the product, process, service, management system, person or organization that must demonstrate its fulfilment of the specified requirements (i.e. the object of conformity assessment);
- confirmation to what extent sampling of the 'object of conformity' is necessary and on what basis should samples be collected (e.g. application of statistical sampling techniques);
- confirmation of the specified requirements that the object of conformity must fulfil;
- choosing the most appropriate conformity assessment techniques for the subsequent determination activities; and
- stipulating the information required to be presented in order for determination activities to be undertaken.

### Determination

Determination activities are the conformity assessment techniques used to develop information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample.

Examples of these techniques include:

- auditing of systems and records relating to the object of assessment;
- evaluation of qualities of the object of assessment;
- examination of specifications and drawings for the object of assessment, or the competence of a person when a person is the object of assessment;
- inspection of physical features of the object of the assessment; or
- testing to determine specified characteristics of the object of assessment.

### Resolution of non-conformities

One possible outcome from determination activities is a finding that the object does not conform to the specified requirements in one or more respects. Alternatively it could be the case that the evidence of conformity is incomplete and one or more of the specified requirements has been overlooked. In either case the finding is normally returned to the person or organization responsible for the object (e.g. the manufacturer or, for a 2nd or 3rd party situation, the supplier). Discussion of

the determination results is permissible so that the person or organization responsible can understand the cause of the non-conformity.

### Report

Normally at the completion of a determination activity the evidence of conformity is contained in a report, sometimes referred to as a technical file, which includes:

- a definitive identification of the object which has been assessed;
- a statement of the requirements to which conformity has been assessed;
- details of the determination activities which have been carried out, such that it would be possible to repeat the activities in the same manner if it was necessary to verify the evidence;
- details of the resources used, including people, measuring instruments and other evaluation tools, to provide traceability of the results; and
- the results of the activities in sufficient detail for a person not involved in the activities to verify conformity (or non-conformity) with the specified requirements.

The report is passed to the person or body responsible for review and attestation and should be made available to the person or organization for which the work has been done.

### Review and Attestation

Review constitutes the final stage of checking before taking the decision as to whether it has been adequately demonstrated that the object of conformity fulfils the specified requirements. The decision is the attestation which results in a statement of conformity being issued.

Review and attestation normally include the following activities:

- reviewing the evidence collected from the determination function as to the conformity of the object with the specified requirements;
- making a decision on whether the object does or does not demonstrate conformity with the specified requirements;
- issuing a statement of conformity; and
- in some cases placing a mark of conformity on conforming products

### Statement of conformity

A statement of conformity which can take a number of forms as described below. Whichever form it takes, the statement should provide unequivocal identification of the object and of the specified requirements with which it has been found to conform. The statement may be on paper or in some other retrievable means such as photographic or digital media.

### Declaration of conformity

A statement of conformity issued by a first party, e.g. the supplier of a product, or a second party, e.g. the purchaser, is known as a declaration of conformity. This practice has been adopted to differentiate these statements from those issued by a third party body, which are known as certificates.

ISO/IEC 17050 provides information on the content of a supplier's declaration of conformity. A declaration by a second party could take a similar form.

## Certificate of conformity

A statement of conformity issued by an impartial and independent third party is often referred to as a certificate of conformity. However the term used and the specific content can vary according to the object being assessed and the nature of the specified requirements.

## Mark of conformity

Statements of conformity may be associated with placing marks of conformity on a product.

Examples include:

- the first party's (supplier's) own trade mark;
- a second party mark of quality or branding;
- a third party certification mark controlled by a scheme owner or certification body;
- marks of regulatory compliance such as the European Union's CE mark.

## Surveillance

Conformity assessment can end when attestation is performed, but where there is a need to provide continuing assurance of conformity, surveillance can be used. Surveillance is defined as a systematic iteration of conformity assessment activities as a basis for maintaining the ongoing validity of the statement of conformity.

Surveillance activities can include:

- carrying out determination activities at the point of production or in the supply chain to the marketplace;
- carrying out determination activities in the marketplace;
- carrying out determination activities at the place of use;
- reviewing the outcome from the determination activities;
- referring back to the determination stage to resolve non-conformities;
- drawing up and issuing confirmation of continued conformity; and
- initiating remedial and preventive action in the case of non-conformities.

Surveillance is a particular form of post attestation activity. It could be conducted by the supplier in the form of customer surveys or periodic inspection of installed products, perhaps as part of a servicing contract.

Surveillance is also carried out in some certification schemes, where samples of certified products are taken from the marketplace and subjected to inspection or testing to determine whether they conform to the specified requirements.

In many countries the regulatory authorities have a responsibility for protecting consumers and enforcing the health and safety regulations by carrying out market surveillance. This kind of work can be carried out on a routine basis but the economic constraints usually lead to a targeted surveillance, either concentrating on the highest areas of risk or responding to reports of non-conforming products. ISO have published [\*A guide to good practice - Principles and practices in product regulation and market surveillance\*](#).

Whether the surveillance is carried out by the supplier, a certification body or market surveillance is carried out by the regulatory authority, it needs to be done in a systematic way with comprehensive and accessible records. There should also be a systematic follow up so that any adverse effects can

be corrected, if possible, and can be prevented from happening in the future. Measures can include remedial action and product recall.

In today's global economy, it is advantageous for regulatory authorities in different countries to share market surveillance information, so that lessons learned from an incident in one country can be used in others to prevent defective items from reaching the market or to take them out of use before they cause damage.

Examples of this include rapid alert systems developed and used by groups of regulators such as the:

- [EU Rapid Alert System for Food and Feed](#) (RASFF) used by European Union Member States;
- [ASEAN RASFF](#) used by members of the Association of South-East Asian Nations (ASEAN);
- [EU Rapid Alert System for Non-Food Consumer Products](#) (RAPEX) system used by European Member States to notify marketing or use of products posing a serious risk to the health and safety of consumers.

For more information on the function approach see ISO/IEC 17000:2004, *Conformity assessment -- Vocabulary and general principles*.