

Conformity assessment schemes

If the regulator chooses to use a conformity approach to compliance and develop a scheme the following commentary will be useful.

This commentary is structured in the following way:

- voluntary and regulatory schemes;
- scheme ownership;
- scheme types; and
- design.

Voluntary and regulatory schemes

Conformity assessment schemes can be set up as voluntary 'self-regulation' or commercial marketing purposes such as to improve market perception for a group of suppliers, to share assessment facilities by a group of purchasers or to respond to market needs by a third party assessment organization.

In each of these cases there is no legal requirement for suppliers or purchasers to use the scheme, although there can be strong market and peer pressure to do so. Regulators may even interact with specific sectors to rely on such schemes as a method of allowing industry to regulate itself as an alternative to formal regulation.

On the other hand, regulators can find it useful to introduce specific conformity assessment approaches to enable compliance with legal requirements. The regulator will consider the dangers to workers, consumers, the environment and the economy posed by deficient goods, services or processes. The measures which they adopt will need to be proportional to the risks involved, with statutory inspection or certification schemes being introduced where the risks are highest.

Scheme ownership

Where conformity assessment schemes are used by regulators, it is important to confirm who the scheme owner and who takes responsibility for the scheme's design, administration and maintenance. Some examples of scheme owners are:

- an organization such as a regulatory body or a trade association might develop a scheme and either undertake the determination and decision activities themselves, or allow for one or more conformity assessment bodies to operate it. In that case the organization would be the scheme owner and would take responsibility for the operation of the scheme, probably through a contract or other formal agreement with the conformity assessment bodies it recognises; or
- a manufacturing organization could set up a conformity assessment scheme for its products, including testing, inspection and auditing, leading to the issuing of declarations of conformity;
- a scheme could be developed by a conformity assessment body (e.g. a certification body) for sole use of its clients, in which case the conformity assessment body takes on full responsibility for the design, application, management and maintenance of the scheme;
- a group of conformity assessment bodies, perhaps in different countries, might together set up a certification scheme. In that case it would be necessary for the bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating bodies.

If it was found necessary to operate several schemes which used the same rules, procedures and management, the scheme owner could set up a conformity assessment system under which the different schemes could operate without the need for replicating the management structure for each scheme. In that case the scheme owner would become the system owner and be responsible for the management of the system and the schemes operating within it.

Scheme types

Schemes should be developed in accordance with [ISO/IEC 17067:2013](#), *Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes*.

Scheme design

In the scheme the following matters should be addressed (in some cases these matters are simply the result from the steps outlined in this lesson):

- identification of the purpose and scope of the scheme;
- identification of the relevant characteristics of the selected 'object of conformity';
- the specified requirements that the 'object of conformity' must meet, including requirements related to sampling and utilising a management system to ensure the provision of a consistent 'object of conformity';
- creation, control and maintenance of adequate documentation for the operation, maintenance and improvement of the scheme, including the conformity assessment rules and operating procedures for the determination activities that are required under the scheme (e.g. auditing, examination, evaluation, inspection or testing). The rules should cover at least the following aspects:
 - identification of sources of information;
 - collecting the information (sampling and verifying);
 - evidence (records, interviews);
 - evaluate the evidence against criteria;
 - review findings and conclusions; and
 - report of the findings;
- the calibration of the equipment, and measurement traceability requirements and permissible levels of measurement uncertainty;
- who can carry out the determination activities, and what specified requirements they should meet (e.g. testing laboratories may be required to meet the requirements of ISO/IEC 17025, inspection bodies ISO/IEC 17020 and product certification bodies ISO/IEC 17065);
- whether organisations carrying out determination activities need to be accredited or be a member of a peer assessment group;
- if the scheme requires that that conformity assessment bodies are accredited, to what extent must the accreditation body fulfil ISO/IEC 17011 and be a member of a mutual recognition arrangement between accreditation bodies;
- the information to be supplied to the conformity assessment body an applicant;
- the degree to which conformity assessment results prior to any application can be considered during assessment;
- the content of any report (e.g. test report or inspection report), or a statement of conformity (e.g. a supplier declaration of conformity or certificate);
- conditions under which a client may use the statement of conformity or marks of conformity;
- where marks of conformity are used, confirmation of the ownership, use and control of the marks (see also [ISO/IEC 17030:2003](#), *Conformity assessment - General requirements for third-party marks of conformity* and [ISO/IEC Guide 23:1982](#), *Methods of indicating conformity with standards for third-party certification systems*);

- the resources required for the operation of the scheme, including impartiality and competence of the personnel (internal and external), the evaluation resources, and the use of subcontractors. Conformity assessment relies upon technically competent people that have the relevant experience and sector expertise. Therefore there is a need to establish requirements for qualifying the competence: education background, experience, training and ongoing competence monitoring of assessors/auditors/staff/peer evaluators and all persons included in the compliance process;
- how the results of the determination (evaluation) and surveillance stages are to be reported and used by the conformity assessment body and the scheme owner;
- how non-conformities with the specified requirements are to be dealt with and resolved;
- what are the surveillance procedures of the scheme;
- content, conditions and responsibility for publication of the directory of approved 'objects of conformity';
- the need for, and content of, contracts, e.g. between scheme owner, conformity assessment body, and the client;
- general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending and withdrawing approval, such as requirements for discontinuation of advertising and return of certification documents and any other action if the certification is suspended, withdrawn or terminated (see also [ISO Guide 27:1983](#), *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*);
- the extent to which appeals against decisions within the scheme and complaints are dealt with and reported;
- the way in which the clients' complaints records are to be verified if such verification is part of the scheme;
- the way in which the clients make reference to the scheme in their publicity material;
- retention of records by scheme owner and conformity assessment bodies.