

A black and white photograph showing a person from behind, walking away on a wide, paved path made of rectangular cobblestones. The path leads towards a distant horizon under a clear sky.

Using ISO/CASCO standards in regulations

ONLINE CONTENT STRUCTURE

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INTRODUCTION

The purpose of this online platform is twofold:

- introduce the basics of conformity assessment and the ISO/CASCO toolbox; and
- explain how conformity assessment can be used by regulators.

Conformity assessment is the term given to techniques and activities that ensure a product, process, service, management system, person or organisation fulfils specified requirements.

Since the 1970s the ISO policy committee on conformity assessment (ISO/CASCO) has published a series of International Standards and Guides that contain internationally agreed provisions for conformity assessment. These International Standards and Guides are revised and republished on a regular basis and are known collectively as the 'ISO/CASCO toolbox'.

Conformity assessment can be used in societies on a voluntary or regulatory (mandatory) basis. Every day conformity assessment impacts our lives from the time we wake up, when we turn on an electric switch, when we buy and consume our food, when we travel, when we are at work or play, when we answer the phone, when we use a health service, when we are enjoying the outdoors, when we turn on the television, when we relax in the evening and even when we are sleeping. Conformity assessment gives all of us confidence and certainty about the environment in which we live.

Conformity assessment can be used by regulators to help them implement public policy objectives. It can be used as a regulatory tool to confirm compliance and take corrective actions. When designed and used appropriately, mandatory conformity assessment requirements can enable efficient market operation and access, and protect health, safety and the environment.

This online support is split into several main sections, each with specific topics. Users of this tool can easily navigate the material via the links provided at their own pace. Some topics have links to relevant standards and other documents containing more detail, or further sources of information.

UNDERSTANDING CONFORMITY ASSESSMENT

BASIC CONCEPTS

What is conformity assessment?

Conformity assessment is the term given to techniques and activities that ensure a product, process, service, management system, person or organisation fulfils specified requirements.

Examples of these techniques and activities include assessment, auditing, calibration, evaluation, examination, inspection, and testing which can result in a supplier's declaration of conformity, certification or accreditation.

Specific requirements for a product, process, service, management system, person or organisation are found in normative documents such as regulations, standards and codes of practice.

The [International Organization for Standardization](#) (ISO) and the [International Electrotechnical Commission](#) (IEC) have published joint International Standards and Guides on conformity assessment. These International Standards and Guides are the internationally accepted basis for conformity assessment and are used by many regulators around the world.

Regulations and conformity assessment

Regulations feature in most economies and most have some direct or indirect interaction with both standards and conformity assessment.

Often regulations require compliance with a national, regional or international standard, technical specification or code of practice. Some regulations may only specify parts of standards, such as those aspects affecting safety and might not cover product performance or quality aspects.

Regulations can include requirements for how compliance is to be demonstrated and communicated (for example, regulations may require testing of a product by a recognised testing laboratory and the subsequent marking of those products if they have fulfilled the requirements).

By relying on conformity assessment in accordance with International Standards, regulators and the market can be assured that claims of conformance in relation to the products, processes, services, management systems, persons or organisations are well-founded and legitimate.

Conformity assessment in accordance with International Standards assists in avoiding regulation that may add unnecessary costs to the economy and reduce competitiveness of domestic production, and that may be substantially different to those in other economies which can lead to technical barriers to trade.

Functional approach to conformity assessment

A basic concept underpinning all conformity assessment is the functional approach. The functional approach can be used as a good starting point when developing conformity assessment frameworks to support regulations.

The functional approach consists of four main functions:

- 1) **Selection** involves planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function.
- 2) **Determination** activities are used to develop information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample.
- 3) **Review and attestation** are the final stages of the process. Review is the activity 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 (e.g. a certificate and/or mark of conformity) being issued.
- 4) **Surveillance** can be used where there is a need to provide continuing assurance of conformity, although conformity assessment can end when attestation is performed. Surveillance is defined as a systematic iteration of conformity assessment activities as a basis for maintaining the ongoing validity of the statement of conformity.

Each function involves certain activities which are described in Figure 1, the output from one function being the input to the next. Figure 1 provides an illustration of the functional approach.

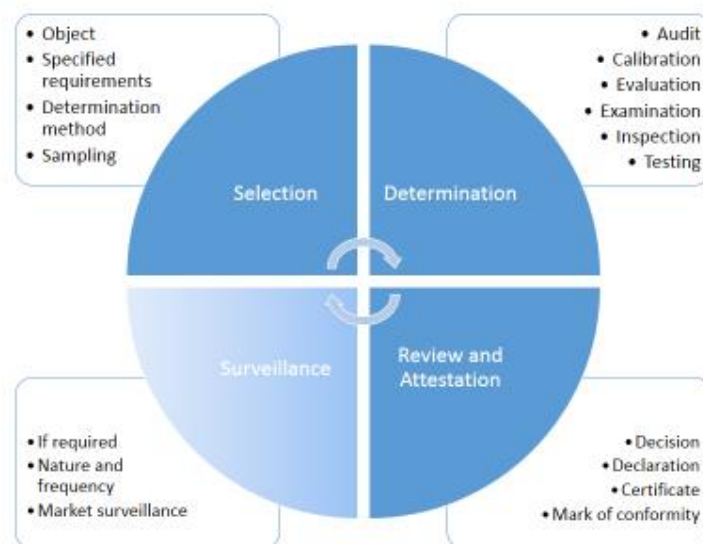


Figure 1 Functional approach to conformity assessment

For more information on the functional approach see **Annex 1: Conformity assessment - Functional approach** and [ISO/IEC 17000:2004](#), *Conformity assessment - Vocabulary and general principles*.

CONFORMITY ASSESSMENT TECHNIQUES AND SCHEMES

The main conformity assessment techniques and their most common applications **can** be described as follows:

Assessment	of an organisation's technical competence;
Auditing	of a management system within an organisation;
Evaluation	of a product, process or service's fulfilment of specified requirements that are set out in a defined conformity assessment scheme;
Examination	of a person's competence;
Inspection	of an installation or of a product or service in use;
Testing	of a product characteristic.

In some instances, one conformity assessment technique may encompass another, e.g. an inspection can include a test technique, or a product evaluation may take into account a test report or an inspection report. How these conformity assessment techniques are used and interrelated is often prescribed in a specific mandatory or voluntary conformity assessment schemes.

These schemes are further detailed in **Annex 2: Conformity assessment – Certification schemes**.

Assessment

Assessment applies to the process of determining whether an organisation fulfils requirements related to its technical competence. An example is the assessment of conformity assessment bodies (e.g. laboratories, inspection bodies and certification bodies) to ensure that the results that they produce can be relied upon. Assessments are carried out during accreditation and peer assessment.

The following International Standards set out requirements for how assessments are undertaken:

- [ISO/IEC 17011:2004](#), *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*; and
- [ISO/IEC 17040:2005](#), *Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies*.

More information is provided in **Annex 3: Conformity assessment techniques – Accreditation**.

Auditing

An audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audit criteria are contained in policies, procedures and requirements adopted by an organization and may include applicable laws and regulations, policies, procedures, standards, management system requirements (e.g. ISO 9001 *Quality management systems – Requirements* or ISO 14001, *Environmental management systems – Requirements with guidance for use*), contractual requirements or industry/business sector codes of conduct. Audit criteria are used as a reference against which conformity is determined.

Audit evidence comprises of records, statements of fact or other information relevant to the audit criteria which are verifiable. Audit evidence may be qualitative or quantitative.

[ISO 19011:2011](#), *Guidelines for auditing management systems*, is the comprehensive standard for auditing. [ISO/IEC 17021:2011](#), *Conformity assessment - Requirements for bodies providing audit and certification of management systems*, augments this guidance when the auditing being performed is undertaken by an independent third-party certification/registration body.

More information on auditing is provided in **Annex 4: Conformity assessment techniques – Auditing**.

Inspection

Inspection is a form of conformity assessment which has a long history. Some inspection activities are closely aligned with testing activities; others may be closely associated with certification activities (and particularly product certification); while other inspection is a stand-alone activity without any relation to testing or certification. One of the key aspects of inspection is that the determination of conformity with specific requirements is made on the basis of professional judgement of the inspection bodies' personnel. This underlines the fact that the competence of inspection bodies is highly dependent on the knowledge, experience and interpretive skills of the inspection bodies' personnel.

Inspection as a conformity assessment technique 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 the requirements of specification documents or with generally accepted good practice in the field; and
- drawing up a report on the results of the inspection.

The requirements for inspection bodies are specified in ISO/IEC 17020:2012, *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*.

Evaluation

Evaluation is the process of gathering evidence about whether a product, process or service meets specified requirements. It is also sometimes used in the context of person certification.

Evaluation includes the 'selection' and 'determination' functions described in the functional approach, including:

- confirming the specific products, process or services to be evaluated;
- confirming the specific requirements that those products, process or services must fulfil;
- sampling the specified products, process or service;
- applying one or more determination techniques such as testing, inspection and auditing, and also other activities such as studying the design drawings and specifications to ascertain whether the features required to meet the specified requirements are adequately defined;
- collating the evidence from the above techniques prior to a decision on overall conformity being made.

Examination

Examination is one of the terms used almost interchangeably to cover a number of techniques, but it is used in a more specific way when referring to methods for certifying the competence of a person.

In this context, the relevant International Standard is [ISO/IEC 17024:2012](#), *Conformity assessment - General requirements for bodies operating certification of persons*. Examination is defined as a mechanism that measures a candidate's competence by one or more means, such as written, oral, practical and observational, as defined in the certification scheme.

Examinations need to be planned and structured in a manner which ensures that all specified requirements are objectively and systematically verified, with sufficient documented evidence produced to confirm the competence of the candidate.

Testing

Testing, measurement and calibration are the most prevalent conformity assessment techniques used. [ISO/IEC 17000:2004](#) defines testing as:

“(...) determination of one or more characteristics of an object of conformity assessment, according to a procedure”

A procedure is defined as a specified way to carry out an activity or a process. A note to the definition of testing states that testing typically applies to materials, products or processes.

In the case of testing used for conformity assessment, the characteristics will be included in the ‘specified requirements’ which form the focus of the testing.

Testing applies in public health and safety, commerce, manufacturing, construction, environmental monitoring, transport, agriculture, quarantine, forensic sciences, meteorology, telecommunications, mining, forestry, defence, professional services and trade.

[ISO/IEC 17025:2005](#), *General requirements for the competence of testing and calibration laboratories*, specifies the requirements for testing and calibration laboratories. Included in its requirements are all of the elements essential to the conduct of testing for conformity assessment:

- competent people;
- validated test methods which are repeatable and reproducible;
- properly maintained and calibrated equipment;
- measurements which are traceable to the SI standard units of measurement;
- sampling and handling of test items; and
- correct reporting and interpretation of testing results.

Further details on testing can be found in **Annex 5: Conformity assessment bodies – Testing and calibration laboratories**.

CLAIMS OF CONFORMITY

After the application of one or more conformity assessment techniques to generate evidence of fulfilment of requirements, a claim of conformity can be made. Claims of conformity can be made about the product, process, service, management system, person or organisational body - that is about the **object** of the conformity assessment.

Claims of conformity can be made by the:

- **first party (1st party)** – the person or organization that provides the object and which is responsible for that object's fulfilment of specified requirements (e.g. a manufacturer);
- **second party (2nd party)** – a person or organization that has a user interest in the object (e.g. a retail chain that is purchasing the product for subsequent sale);
- **third party (3rd party)** – a person or body that is independent of the person or organization that provides the object, and of user interests in the object (e.g. an independent and impartial testing laboratory or certification body).

First-party claims of conformity - Supplier's declaration of conformity

Many products on the world's markets have manufacturers or supplier's declarations of conformity. In some instances these are simply statements or personal guarantees that may make the products more attractive to prospective purchases. Such claims may or may not be based on objective evidence associated with one or more conformity assessment techniques.

ISO and IEC have a recognised International Standard for making first party claims of conformity. This standard is in two parts as follows:

- [ISO/IEC 17050-1:2004](#), *Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements*; and
- [ISO/IEC 17050-2:2004](#), *Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation*.

Under these International Standards self-declarations of conformity:

- a) are based on results of an appropriate conformity assessment techniques;
- b) provide enough information for the recipient of the declaration to understand what is conformity assessment claim is being made, including:
 - unique identification;
 - name and address of the issuer;
 - identification of the *object of conformity* (e.g. the product, process, service, management system etc.);
 - statement of conformity;
 - complete and clear list of the specified requirements (e.g. standards) as well as selected options (if relevant);
 - data and place of issue of the declaration;
 - signature or equivalent of the authorized person;
 - any limitations (e.g. geographical);
- c) the issuer has procedures in place to ensure continued conformity; and
- d) the issuer maintains a 'technical file' for each declaration that contains:
 - description of the *object of conformity* (product, process, services etc.);

- design documentation;
- conformity assessment results, including:
 - methods used (auditing, audit procedures, batch testing, design review, verification and validation, sampling plan, test methods, type testing) and reasons for their selection;
 - results;
 - evaluation of the results, including deviations and concessions; and
 - identification and competence records of people and organisations involved in producing and reviewing conformity assessment results.

Second-party claims of conformity

Second party claims of conformity are often made through supplier and retail chains where the purchaser of the object undertakes some form of conformity assessment to check that the object meets the specified requirements. In this regard any combination of the main conformity assessment techniques can be used. The second party then makes a claim about the products that they have purchased.

Apart from the various International Standards about conformity assessment techniques and how to develop conformity assessment schemes in general, ISO and IEC do not have any specific standard or guide about second party conformity assessment.

Third party claims of conformity - Certification

Third party claims of conformity are made by organisations that are independent of the person or organization that provides the object, and of user interests in the object. Examples of third parties include independent and impartial testing laboratories, inspection bodies or certification bodies. Third-party statements of conformity are defined as **certification**.

ISO/IEC have developed a number of International Standards and Guides related to third-party conformity assessment as follows.

Guidance on product certification schemes

- [ISO/IEC 17067:2013](#), *Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes*
- [ISO/IEC Guide 28:2004](#), *Conformity assessment - Guidance on a third-party certification system for products*
- [ISO/IEC Guide 53:2005](#), *Conformity assessment - Guidance on the use of an organization's quality management system in product certification*

Certification requirements

- [ISO/IEC 17021:2011](#), *Conformity assessment - Requirements for bodies providing audit and certification of management systems*
- [ISO/IEC 17024:2012](#), *Conformity assessment - General requirements for bodies operating certification of persons*
- [ISO/IEC 17065:2012](#), *Conformity assessment - Requirements for bodies certifying products, processes and services*

Who carries responsibility for claims of conformity?

The question of who should carry out the conformity assessment is a crucial one when it comes to putting theory into practice. One of the basic principles of conformity assessment is that the organization which owns the object of assessment or places it on the market has the primary responsibility for its conformity with the stated requirements.

To illustrate the principle of primary responsibility, the supplier of a product will have a contractual and a legal duty to the user that the product will perform its declared function and that it will not endanger the health or safety of the user. Even if the supplier obtains a certificate from an independent body stating that the product conforms to the relevant specification, if anything goes wrong, the supplier remains responsible.

Although the independent body might incur some degree of liability, particularly if it had been negligent in performing the conformity assessment, that would not absolve the supplier from the primary responsibility. Of course, misuse by the end user, particularly a failure to read instructions or carry out proper maintenance, could absolve the supplier from liability for subsequent damage and its consequences.

Marks of conformity

Statements of conformity may be associated with placing marks of conformity on a product. However, it should be appreciated that test reports, audit evidence, examination, inspection or evaluation results are snapshots in time, and can be issued to report a failure. A certificate/mark of conformity can only be issued where conformance has been confirmed and certifies the ability of performing a certain function through a certain period of time, which is generally pre-defined.

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 a certification body;
- marks of regulatory compliance such as the European Union's CE mark.

Frequently, the use of a mark of conformity is controlled through a registration or licence issued by the owner of the mark or by an organization operating on behalf of the owner such as a certification body. The licence spells out the conditions under which the licensee can use the mark, such as the restriction to use it only on products which the supplier has verified as conforming to the certified product type. Policing of the use of marks of conformity is vital for the interests of the owner and licensing body, since products bearing their mark are often produced under a system in which only occasional samples of product are verified by the licensing body.

Advice on marks of conformity is contained in the following ISO/IEC conformity assessment publications:

- [ISO/IEC Guide 23:1982](#), *Methods of indicating conformity with standards for third-party certification systems*;
- [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*; and
- [ISO/IEC 17030:2003](#), *Conformity assessment - General requirements for third-party marks of conformity*.

Marks must be distinctive and their ownership and conditions of use should be clearly stated. In particular the use of a mark should not be misleading to purchasers and users of the products. For example, a supplier which has a certified management system conforming to ISO 9001 must not place the certification body's mark on its products, since that would imply that the body had actually certified the products and not just the management system.

CONFORMITY ASSESSMENT BODIES

There are different types of conformity assessment bodies (CABs) that can undertake conformity assessment techniques and activities. They can come in any organisational form and ownership, and can be commercial in focus or not-for-profit entities. They can be government agencies, national standards bodies, trade associations, consumer organisations, or private or publically owned companies.

Conformity assessment bodies range from multibillion dollar multinational companies that undertake all types of conformity assessment activity (e.g. testing, inspection and certification), to CABs offering national services within one specific country, or small localised entities that work in a specific sector and region. In most cases CABs can act as first, second or third party that is making the claim of conformity.

	International Standard	First party	Second party	Third party
Testing laboratories	ISO/IEC 17025	✓	✓	✓
Inspection bodies	ISO/IEC 17020	✓	✓	✓
Certification body for persons	ISO/IEC 17024			✓
Certification body for products, process and services	ISO/IEC 17065			✓
Certification body for management systems	ISO/IEC 17021			✓

The structure of the above International Standards is similar in that they contain both technical and organisational requirements. The structure is often divided as follows:

- **general requirements** – e.g. legal and contractual matters;
- **structural requirements** – e.g. specific organisational structures that must be in place;
- **resource requirements** – competency, equipment and work environment requirements, and subcontracting/outsourcing requirements;
- **records and information requirements** – e.g. evidence and records retention, confidentiality and public accessibility;
- **process requirements** – requirements for the specific conformity assessment activity; and
- **management system requirements** – requirements for the internal management of the CAB to ensure it is managing its overall fulfilment the relevant International Standard.

The above International Standards contain requirements associated with topics that are common, to a greater or lesser extent, across all conformity assessment activities, such as:

- impartiality
- confidentiality
- complaints and appeals
- public disclosure; and
- use of management systems by CABs

Where bodies act in a third party capacity, an important feature is that they have to act in an impartial way so that the results of their work can be objective and maintain the highest degree of confidence.

Provision of conformity assessment activities by CABs are generally on the basis of a fee for service which may or may not reflect a return on investment or profit. Many countries have a competitive market amongst CABs for the provision of conformity assessment activities. However in some countries and markets a monopoly is given to one or more government recognised conformity assessment bodies by statute, regulations or through procurement practices.

Testing laboratories

The relevant International Standard for testing laboratories is [ISO/IEC 17025:2005](#), *General requirements for the competence of testing and calibration laboratories*. Testing laboratories covered by this standard can be owned and operated by government, or industry bodies, or be separate organisations.

This International Standard for laboratory operation and management contains management system and technical requirements. The management system requirements are common to all laboratories. However there is a need to apply the technical requirements taking into account the specific field of testing being carried out. An informative Annex in the International Standard provides guidelines for applying ISO/IEC 17025 for specific fields of testing.

For further information see Annex 5: Conformity assessment bodies – Testing and calibration laboratories.

Inspection bodies

The relevant International Standards for inspection bodies is [ISO/IEC 17020:2012](#), *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*. Inspection bodies covered by this standard can be owned and operated by government, or industry bodies, or be separate organisations.

ISO/IEC 17020 identified three types of inspection body:

- **Type A** Inspection Bodies - these bodies provide third-party services and are expected to be independent of the other parties involved;
- **Type B** Inspection Bodies - provide first-party services to their parent body only; and
- **Type C** Inspection Bodies - first-party inspection bodies which may also provide inspection services to other organizations.

The requirements contained in the standard apply to all types of inspection body, except for special requirements in an Annex that related to the specific type of inspection body being referred to.

The general requirements include:

- general requirements, including impartiality and independence and confidentiality;
- structural requirements, including administrative requirements and organizational management;
- resource requirements, including personnel, facilities and equipment, subcontracting
- process requirements, including inspection methods and procedures, handling inspection items and samples, inspection records, inspection reports and inspection certificates, complaints and appeals; and
- management system requirements.

Certification bodies

Certification bodies are always third-party impartial conformity assessment bodies that can certify product, process or services, management systems or persons. They can be owned and operated by government, industry bodies, or be separate organizations and have all a set of relevant international standards in place.

Product, process or service certification bodies

The relevant International Standards for product, process or service certification bodies is [ISO/IEC 17065:2012](#), *Conformity assessment - Requirements for bodies certifying products, processes and services*. It sets out the following requirements:

- **general requirements**, including legal and contractual matters, management of impartiality, liability and financing, non-discriminatory conditions, confidentiality and publicly available information;
- **structural requirements**, including organizational structure and top management and a mechanism for safeguarding impartiality;
- **resource requirements**, including certification body personnel, resources for evaluation activities and outsourcing;
- **process requirements**, including application, application review, evaluation, review, certification decision, certification documentation, directory of certified products, surveillance, changes affecting certification, termination, reduction, suspension or withdrawal of certification, records, and complaints and appeals; and
- **management system requirements**.

One of the critical things about product, process or service certification is that it must take place in the context of a certification scheme. The certification scheme sets out the following parameters:

- product, process or service to be certified;
- the specified requirements (e.g. standards) that the product, process or service must fulfil;
- sampling criteria for the certification if required;
- types and combinations of conformity assessment techniques (e.g. audit, inspection or test) that will be used to evaluate the product, process or service;
- the process to be followed for the evaluation, review and decision;
- the mark of conformity and its control;
- activities that must be undertaken during surveillance, if any.

[ISO/IEC 17067:2013](#), *Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes* and [ISO/IEC 17026](#), *Conformity assessment - Example of a product certification scheme*, contain guidance on how to establish and manage certification schemes for products, processes and services.

Management system certification bodies

The relevant International Standards for management system certification bodies is [ISO/IEC 17021:2011](#), *Conformity assessment - Requirements for bodies providing audit and certification of management systems*. It sets out the following requirements:

- **general requirements**, including legal and contractual matters, management of impartiality, and liability and financing;
- **structural requirements**, including organizational structure and top management, and committee for safeguarding impartiality;

- **resource requirements**, including competence of management and personnel, personnel involved in the certification activities, use of individual external auditors and external technical experts; personnel records and outsourcing;
- **information requirements**, including publicly accessible information, certification documents, directory of certified clients, reference to certification and use of marks, confidentiality and information exchange between a certification body and its clients;
- **process requirements**, including initial audit and certification, surveillance activities, recertification, special audits, suspending, withdrawing or reducing the scope of certification, appeals, complaints and records of applicants and clients; and
- **management system requirements**.

Specific requirements in ISO/IEC 17021 focus on the relationship of providing consultancy services and any subsequent independent certification activities, and also the understanding that competent auditors are needed for specific technical areas. There are a series of parts to the main ISO/IEC 17021 standard that deal with auditor competence for different types of management system, e.g. quality management systems auditors, environmental management system auditors etc.

Person certification bodies

The relevant International Standards for person certification bodies is [ISO/IEC 17024:2012](#), *Conformity assessment - General requirements for bodies operating certification of persons*. It sets out the following requirements :

- **general requirements**, including legal matters, responsibility for decision on certification, management of impartiality, and finance and liability;
- **structural requirements**, including management and organization structure, and structure of the certification body in relation to training;
- **resource requirements**, including general personnel requirements, personnel involved in the certification activities, outsourcing and other resources;
- **records and information requirements**, including records of applicants, candidates and certified persons, public information, confidentiality and security;
- **certification scheme requirements**;
- **process requirements**, including application process, assessment process, examination process, decision on certification, suspending, withdrawing or reducing the scope of certification, recertification process, use of certificates, logos and marks, appeals against decisions on certification and complaints; and
- **management system requirements**.

Unlike the other types of certification requirements standards, ISO/IEC 17024 sets requirements for the certification scheme. Another critical issue addressed is the relationship between providing training services and any subsequent independent certification of that person.

RECOGNITION OF CONFORMITY ASSESSMENT BODIES AND THEIR RESULTS

There are several ways in which the competence and impartiality of conformity assessment bodies (CABs) can be recognised, including government recognition, accreditation and peer assessment. Government recognition, accreditation and peer assessment normally utilise specified requirements set out in the following documents as a basis for recognition:

- relevant laws or regulations;
- conformity assessment schemes;
- the relevant International Standards for the type of conformity assessment body; and
- supplementary documents related to the specific technical area being covered.

Relevant International Standards for each type of conformity assessment body as a basis for recognition are as follows:

Type of conformity assessment body (CAB)	Relevant International Standard
Testing or calibration laboratory or facility	ISO/IEC 17025:2005 , <i>General requirements for the competence of testing and calibration laboratories</i>
Inspection body	ISO/IEC 17020:2012 , <i>Conformity assessment - Requirements for the operation of various types of bodies performing inspection</i>
Certification body for products, process and services	ISO/IEC 17065:2012 , <i>Conformity assessment - Requirements for bodies certifying products, processes and services</i>
Certification body for management systems	ISO/IEC 17021:2011 , <i>Conformity assessment - Requirements for bodies providing audit and certification of management systems</i>
Certification body for person certification	ISO/IEC 17024:2012 , <i>Conformity assessment - General requirements for bodies operating certification of persons</i>

Government recognition

Governments can recognise CABs in the following ways:

- administrative recognition, where no consideration of technical competence is required; or
- technical recognition, where consideration of technical competence is required.

Consideration of technical competence should be based on the relevant International Standards, and the persons making the assessment of the CAB should be competent in the relevant International Standard and technical area. Recognition may take the form of a license to operate, admission to an approved list of CABs or a pre-qualification list of suppliers.

Where there is an urgent need for a conformity assessment approach to be set up, the regulatory authorities could decide to directly assess and appoint bodies. However, the basis of the assessment might not be clear and it could be difficult for the bodies and their certificates to gain recognition in other countries.

Accreditation

Accreditation is a specific conformity assessment activity involving the independent third-party assessment of CABs with specified requirements. The specified requirements normally include relevant International Standards. Accreditation generally involves the use of auditing techniques by assessment teams including experts in the organizational aspects such as management systems and also in the technical activities of the body. For example, for a testing laboratory the team would include one or more experts in the types of measurement and testing being carried out.

Accreditation is carried out by accreditation bodies, in accordance with the requirements set out in [ISO/IEC 17011:2004](#), *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*.

ISO/IEC 17011 sets out the following requirements for accreditation bodies and the process of accreditation:

- **accreditation body requirements**, including legal responsibility, structure, impartiality, confidentiality, liability and financing and accreditation activity;
- **management requirements**, including requirements for the management system of the accreditation body, document control, records, nonconformities and corrective actions, preventive actions, internal audits, management reviews and complaints;
- **human resource requirements**, including personnel associated with the accreditation body, personnel involved in the accreditation process, monitoring and personnel records;
- **accreditation process requirements**, including accreditation criteria and information, application for accreditation, resource review, subcontracting the assessment, preparation for assessment, document and record review, on-site assessment, analysis of findings and assessment report, decision-making and granting accreditation, appeals, reassessment and surveillance, extending accreditation, suspending, withdrawing or reducing accreditation, records on CABs, and proficiency testing and other comparisons for laboratories;
- **requirements for responsibilities of the accreditation body and the CAB**, including obligations of the CAB, obligations of the accreditation body and reference to accreditation and use of symbols.

Relationship between IAF, ILAC and ISO/CASCO documents

Accreditation bodies around the world have formed several international organisations of which they are the members. These bodies include the [International Accreditation Forum](#) (IAF), which focuses on issues related to consistent accreditation of certification bodies; and the [International Laboratory Accreditation Cooperation](#) (ILAC), which focuses on issues related to consistent accreditation of laboratories and inspection bodies.

IAF and ILAC produce documents which help their members provide consistent interpretation and application of the relevant International Standards on conformity assessment. This builds confidence that accredited conformity assessment activities in one country can be deemed to be equivalent to accredited conformity assessment activities undertaken in another country, and hence countries can mutually recognise each other conformity assessment results (e.g. test reports, inspection reports and certificates).

IAF and ILAC have produced a series of brochures on the benefits and use of accreditation by regulators. These include:

- IAF How does Accredited Certification benefit Regulators (2012);
- IAF The IAF Multilateral Recognition Arrangement (MLA) (2012);
- ILAC Factsheet – Specifying accreditation in Regulation;
- ILAC How does accredited inspection benefit government and regulators? (2012);
- ILAC How does accredited inspection benefit government and regulators? (2012);
- ILAC How do I gain confidence in an Inspection Body? (2012);
- ILAC Why use an Accredited Inspection Body? (2012); and
- ILAC Why use an Accredited Laboratory? (2012).

Peer assessment

Peer assessment, also known as peer evaluation, is a conformity assessment activity used to ascertain the conformity of a person or organization with a set of specified requirements for membership of a group which the person or body wishes to join. The assessment is carried out by other members of the group, in other words the peers of the applicant. The specified requirements normally include relevant International Standards.

In conformity assessment, the process of peer assessment is specified in [ISO/IEC 17040:2005](#), *Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies*. As noted in the title of this International Standard, peer assessment can take place amongst groups of conformity assessment bodies, or amongst groups of accreditation bodies.

Examples of peer assessment groups are:

- product certification bodies that are members of the IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE CB Scheme);
- System for Certification to Standards Relating to Equipment for use in Explosive Atmospheres (IECEx);
- Quality Assessment System for Electronic Components (the IECQ);
- management system certification bodies that are members of the IQNet certification network;
- accreditation bodies that are signatories to the Multilateral Agreement (MLA) of the International Accreditation Forum (IAF), or the Mutual Recognition Agreement (MRA) of the International Laboratory Accreditation Cooperation (ILAC).

ISO/IEC 17040:2005 contains requirements for peer assessment including:

- **structural requirements;**
- **human resource requirements**, including qualifications and selection, and languages and translation;
- **information and documentation;**
- **peer assessment process requirements**, including application for peer assessment or an extension of scope, review and acceptance of the application, preparation for the peer assessment process, appointment of peer assessment team, documentation review, on-site assessment, analysis of findings, peer assessment report, review of the peer assessment report, peer assessment in support of continuing membership of agreement group, and notification of changes;
- **confidentiality requirements;** and
- **complaints handling requirements.**

The International Standard also provided guidance on financial aspects, assessment techniques for use by peer assessment teams and information to be included in the peer assessment report.

Peer assessment practice is based on:

- competent assessors, drawn from members of the group;
- clearly specified membership criteria decided by the group;
- a methodical assessment of the candidate organization's conformity with the criteria; and
- a report of the findings with sufficient information for the group to decide on the candidate organization's suitability for membership.

The group will decide upon whether there is a need for periodic auditing and re-assessment of the members of the group. If so, the relevant parts of the process will be undertaken. The members of peer assessment agreement groups are generally all expert in the particular technical areas covered by the agreement and so provide a high level of technical competence for the peer assessment. On the other hand, the bodies could be in competition with each other and might not be totally impartial. The peer assessment scheme needs to be well-managed in order to maintain its effectiveness in inspiring confidence in the work of its members.

One aspect of peer assessment in a multilateral arrangement is to ensure that the assessment teams are drawn from across the membership and do not involve assessors from two different members assessing each other's organizations.

Important examples of peer assessment arrangements are the conformity assessment systems that are run by IEC: the IECEE (System of Conformity Assessment Schemes for Electrotechnical Equipment and Components), the IECEx (System for Certification to Standards Relating to Equipment for use in Explosive Atmospheres), the IECQ (Quality Assessment System for Electronic Components) and the IECRE (System for Certification to Standards relating to Equipment for use in Renewable Energy Applications):

- IECEE covers safety and performance for a wide variety of equipment and components used in homes, offices, workshops, healthcare facilities and more (www.iecee.org);
- IECEx covers the highly specialized field of explosion protection associated with the use of equipment in areas where flammable gases, liquids and combustible dusts may be present (www.iecex.org);
- IECQ ensures the safety and reliability of electronic components used in the IT industry, avionics, and more (www.iecq.org);
- IECRE covers certification to standards relating to equipment for use in Renewable Energy applications. (www.iecre.org).

Several thousand testing laboratories participate in these systems and more than 1 million valid certificates have been issued to date by certification bodies holding membership with them. Each member of these systems automatically accepts the conformity certificates and reports of all the other System members.

Mutual recognition of conformity assessment results

The results of conformity assessment bodies, such as test reports, inspection reports and certificates can be recognised in other jurisdictions and by other bodies if there is confidence that the results have been generated in an appropriate way.

This is often confirmed through mutual recognition agreements or arrangements (MRAs) on acceptance of conformity assessment results, especially in the context of international trade and facilitating market access of goods and services. The MRAs normally include reciprocal assessment of each other's facilities and competence so as to provide confidence in the conformity assessment results.

[ISO/IEC Guide 68:2002](#), *Arrangements for the recognition and acceptance of conformity assessment results* contains guidance for MRAs. The Guide provides information on the elements of an agreement and advice on setting up an agreement group, stressing the importance of using internationally agreed criteria such as those in the ISO/CASCO toolbox. It mentions peer assessment and accreditation as methods for establishing the basis for confidence in the results produced by the members of the group. The Guide also advises that these two techniques can be used in a complementary way as, for example, where accreditation can provide assurance on the organization and management systems of the members while peer assessment can concentrate on the technical aspects.

USING CONFORMITY ASSESSMENT IN REGULATORY PRACTICE – BENEFITS AND KEY CONSIDERATIONS

Benefits of using the ISO/CASCO toolbox

Regulators in many sectors specify the use of conformity assessment by referring to relevant International Standards and Guides, known as the [ISO/CASCO toolbox](#). Most of them are developed and published jointly by the [International Organization for Standardization](#) (ISO) and the [International Electrotechnical Commission](#) (IEC). They have a broad geographical reach because the experts that have contributed to their development are nominated by many national standards bodies around the world. Those experts also come from a range of stakeholders and perspectives, including regulators, industry, consumer groups, scheme owners, standards officers, testing laboratories, inspection bodies, certification bodies and accreditation bodies. This combination of broad geographical reach and development with a multi-stakeholder environment mean the ISO/CASCO toolbox is widely supported and used. Using the ISO/CASCO toolbox benefits many stakeholders.

For regulators, it provides a tool for managing compliance and providing an objective and defensible means to implement public policy and enforce national health, safety and environmental legislation. The ISO/CASCO toolbox provides a means for organisations to take responsibility for their own compliance, and can reduce costs for governments when regulatory schemes utilise recognised private sector conformity assessment providers.

For manufacturers, wholesalers, retailers and service providers, they can make sure that their products and services meet specified requirements and deliver on customer expectations. Assessing their products and services in accordance with the ISO/CASCO toolbox helps them to meet the current best practice and avoid the financial costs and reputational damage of product failure in the market, including subsequent activities such as product recalls, product returns and destruction of unsuitable product;

Consumers also derive benefit from the ISO/CASCO toolbox because it provides them with a basis for selecting products or services in the market, including matters such as quality, price, safety, reliability, compatibility, interoperability, efficiency and effectiveness, and even the colour of a product. Consumers may have more confidence in products or services that are supported by a formal mark or certificate of conformity that attests to quality, safety or other desirable characteristics.

And finally for **traders, importers** and **exporters** the ISO/CASCO toolbox are the recognised International Standards and Guides for conformity assessment procedures under the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement). Application of the ISO/CASCO toolbox can be a basis for mutually accepting trading partners' products and services, and avoiding unnecessary barriers to trade.

Key considerations for using conformity assessment in regulatory practice

There are a number of key considerations that should be kept in mind when using conformity assessment in regulatory practice. These key considerations include:

- a. good regulatory practice;

- b. functional approach to conformity assessment;
- c. identifying regulated products and requirements;
- d. conformity assessment scheme design and ownership;
- e. investment and costs of conformity assessment options;
- f. conformity assessment and competition;
- g. risk management;
- h. access to competent resources;
- i. surveillance activities;
- j. suggested steps for musing conformity assessment in regulations.

Some of these considerations are interrelated and can be applied more than once during the development of regulation that uses conformity assessment. For example, risk management can be used when:

- identifying the characteristics of products that should be subject to conformity assessment;
- deciding what conformity assessment techniques (e.g. audit, test, inspection) to apply; and
- confirming the frequency and nature of the surveillance activities.

a. Good regulatory practice

Good regulatory practice includes consideration of a number of compliance options. One of these options is to use conformity assessment as prescribed in the ISO/CASCO toolbox.

Good regulatory practice obligations from the **World Trade Organization (WTO)** agreements that include conformity assessment comprise:

- [WTO Agreement on Technical Barriers to Trade](#) (TBT Agreement);
- [WTO Agreement on Agreement on Sanitary and Phytosanitary Measures](#) (SPS Agreement);
- [WTO Agreement on Trade in Services](#) (Services Agreement);
- [WTO Agreement on Preshipment Inspection](#) (Preshipment Inspection Agreement); and
- [WTO Agreement on Trade Facilitations](#) (Trade Facilitation Agreement).

Examples of **pluri-lateral and regional statements** on good regulatory practice that include standards and conformity assessment are:

- [OECD Recommendation of the Council on Regulatory Policy and Governance](#) (2012);
- UNECE A Common Regulatory Language for Trade and Development (2009);
- PTB/ITC Technical regulations - Recommendations for their elaboration and enforcement (2009);
- [UNECE International Model for Technical Harmonization Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards](#) (2001);
- [APEC Information Notes On Good Practice For Technical Regulation](#) (2000);
- [UNECE Risk Management in Regulatory Frameworks: Towards a Better Management of Risks](#) (2012)

Other examples of **global and regional bodies** that have used standards to achieve policy goals and showing evidence of these good practices are:

- [North American Free Trade Agreement](#) (NAFTA) - High Level Regulatory Cooperation Council (HLRCC), use standards which helps:
 - making regulations more compatible;
 - improve the analysis of regulations;

- increase regulatory transparency;
- increase technical cooperation; and
- European Union’s use of standards and conformity assessment systems in the **New and Global Approach** and the New Legislative Approach that enables operation of EU’s single market.
- The [UNECE Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere](#) that aims at promoting free trade of these products. It is built on international standards which form the backbone of the common regulatory requirements, while the use of the IEC Conformity Assessment System IECEx provides the presumption of conformity with the said requirements.

Examples of **national statements and codes** on good regulatory practice include:

- Australian Government [Best Practice Regulation Handbook](#) (2013);
- A Guide to using NATA Accreditation in Legislation, Regulation and Specification (2009);
- The Brazilian Guide on Good Regulatory Practices;
- Standards Systems – A Guide to Canadian Regulators (2004);
- United Kingdom - Standards and accreditation - Tools for delivering better regulation;
- United States [National Technology Transfer and Advancement Act](#) (1995) and Office of Management and Budget (OMB) Circular A-119, [Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities](#); and
- United Kingdom [Regulators’ Compliance Code – Statutory Code of Practice for Regulators](#) (2007)
- [The EU Blue Guide](#) (2014)

Regulators may require the use of conformity assessment either through:

- direct reference to the relevant International Standard or Guide in the regulation; or
- through developing a conformity assessment scheme or referencing an existing one.

Examples of direct references and use of conformity assessment schemes are provided in the last section with Examples.

In some cases use of conformity assessment in regulatory practice may need to be included in a Regulatory Impact Analysis (RIA) or Regulatory Impact Statement (RIS). RIAs/RISs are formal justification and cost benefit studies required in some countries prior to the proposed regulation being accepted.

One common aspect of good regulatory practice when it applies to using conformity assessment to ensure the conformity assessment approach is commensurate with the risk or level of market failure that is trying to be managed.

The European Commission uses the ‘principle of proportionality’ in the selection of conformity assessment options. Its [Guide to the implementation of directives based on the New Approach and the Global Approach](#) states *“In setting the range of possible [conformity assessment] modules, directives take into consideration, according to the principle of proportionality in particular, such issues as the type of products, the nature of the risks involved, the economic infrastructures of the given sector (such as the existence or non-existence of third parties)... and “The principle of proportionality also requires that the directives should not include unnecessary procedures, which are too onerous relative to the objectives, in particular as laid down in the essential requirements.”* (page 31).

The UNECE [Risk Management in Regulatory Frameworks: Towards a Better Management of Risks](#) (2012) provides a comprehensive guide to using standards and in a way that is proportionate to risks. It provides examples of how certification options may add costs and delays in reaching global markets, with potential impact on business competitiveness.

Figure 2 illustrates a possible range of options for use of conformity assessment in regulation.

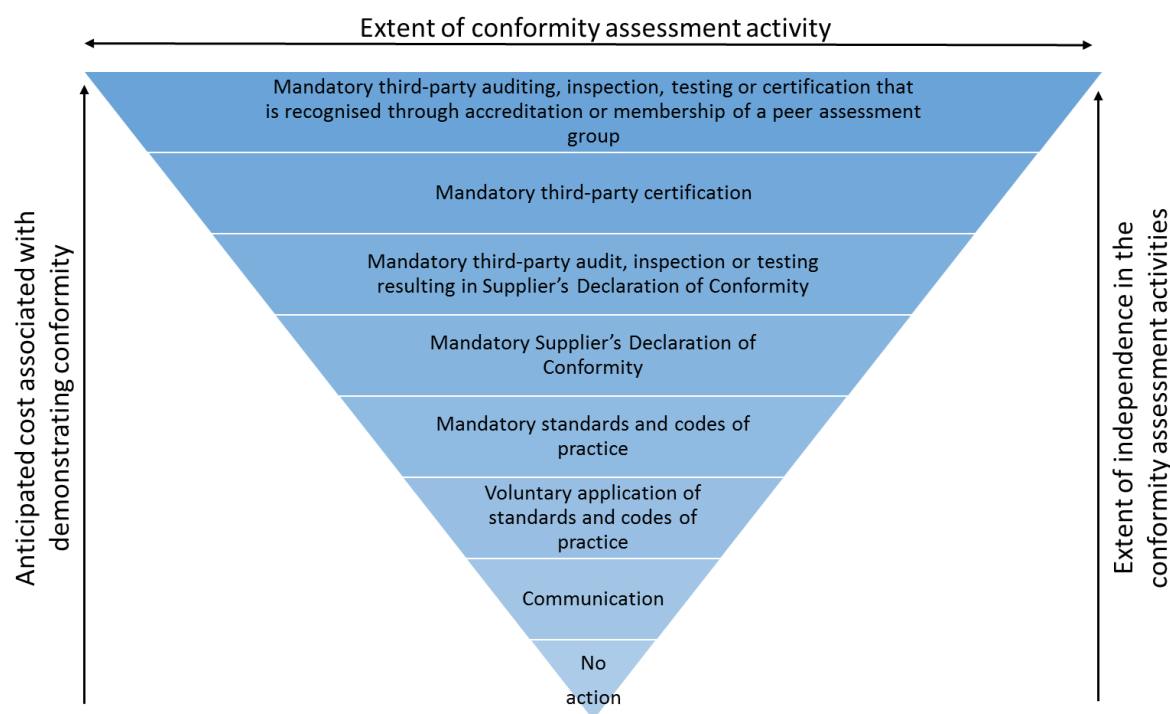


Figure 2 Options for use of conformity assessment in regulation

Regulators may consider which option best meets their needs by taking into account the:

- nature of the risks involved;
- extent or complexity of the conformity assessment required;
- ability to practically access the selected conformity assessment option at the domestic level;
- anticipated costs of each conformity assessment option (both in terms of administrative burden, price and time involved);
- degree of independence the regulator expects in terms of providing conformity assessment results and statements of conformity;
- level of market and political acceptance of the proposed option.

b. Functional approach to conformity assessment

In using conformity assessment in regulatory practice it may be helpful to structure the policy development and discussion about the design of the conformity assessment options around the functional approach which provides for:

- selection;
- determination;
- review and attestation;
- surveillance.

c. Identifying controlled products and requirements

It is appropriate to have a clear justification why the regulator considers an *object of conformity* (e.g. product, process, service, management system, person, or organisation) needs to be regulated. In helping to identify the *object of conformity* and the characteristics of particular concern it is useful to consider:

- empirical evidence such as reported instances of failure of the object and the subsequent consequences;
- injury, hospital admission rates, morbidity statistics, crime and police statistics;
- demographics, including populations most at risk (e.g. children or the elderly);
- prevalence of the object in the market; and
- sources of supply, distribution channels etc.

In many countries, lists of controlled products with mandatory standards and conformity assessment activities (e.g. mandatory certification) exist. In some cases these lists of controlled products are outdated or may simply be duplicated from other countries without due consideration as to whether the same issues actually occur in the country of adoption. Lists of controlled products should be regularly reviewed and updated to reflect contemporary risks and market concerns.

Once the *object of conformity* and its characteristics of most concern are identified, specified requirements can be stated for that *object of conformity* in regulations, standards, codes of practice, technical specifications etc.). In some cases specified requirements may need to be developed or adopted. Specified requirements should be written in clear and unambiguous language. Guidance on how to write specified requirements is provided in [ISO/IEC 17007:2009](#), *Conformity assessment - Guidance for drafting normative documents suitable for use for conformity assessment*.

d. Conformity assessment scheme design and ownership

Regulators can develop and mandate the use of conformity assessment schemes.

As part of the ISO/CASCO toolbox, ISO and IEC have produced [ISO/IEC 17067:2013](#), *Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes*, and ISO/IEC 17026, *Conformity assessment - Example of a product certification scheme*.

While these International Standards contain guidance in relation to schemes for certifying products, process and services, their content can be applied in the case of other 'objects of conformity' such as management systems, persons and organizations, and also for conformity assessment schemes that rely on first- and second-party claims of conformity.

If regulators choose to develop and mandate a scheme they must decide whether they will take the role of scheme owner, or simply mandate the use of an existing scheme. There are certain responsibilities for being a scheme owner, including developing, managing and maintaining the scheme, and determining who is to carry out the conformity assessment activities.

More details can be found in **Annex 2: Conformity assessment schemes**.

e. Investment and cost associated with conformity assessment

When deciding on the appropriate conformity assessment approach for a particular situation, it helps to be aware of the amount of investment and cost associated with each alternative approach.

As with most compliance options in regulation, resources must be committed to undertaking conformity assessment. Whether these commitments are considered to be 'costs of compliance' or 'an investment' in achieving company or public policy outcomes is a matter of perspective.

There is always an investment or cost associated with carrying out self-assessment but as soon as another party becomes involved it is necessary to take account of what additional costs might be incurred and by whom.

If the purchaser of a product decides to carry out their **own assessment**, they will generally have to bear the costs of undertaking their own conformity assessment (e.g. employing or outsourcing their testing activities, auditors and inspectors).

If an **independent body** is contracted to carry out conformity assessment, the body will need to recover its costs from whoever it is working for. In the case of product certification, it is usually the supplier who will engage and pay the certification body. The conformity assessment body's costs will not only relate to the assessors involved in the assessment work but also all of the expenditure incurred in running its business, a proportion of which will be charged to each certification customer.

Thus the decision to establish a conformity assessment scheme can add to the costs incurred in the supply of the certified products. Similarly, a decision to require conformity assessment bodies to be accredited will add a further layer of expenditure to cover the operation of the accreditation.

In addition to the direct costs of conformity assessment, there are other factors which have financial implications particularly for suppliers of certified products.

The involvement of a third party can lead to delays in producing and delivering products if there is a significant time lag between the application for certification and the receipt of the certificate of conformity. With the ever-accelerating pace of product and market development, such delays can lead to lost opportunities to sell products and can even have an adverse effect on the reputation of the supplier. The financial consequences can be serious and measures need to be adopted to minimize them, such as fully understanding the specified requirements and maintaining good communications with the certification body from the outset.

In summary, the benefits of independent conformity assessment in terms of market acceptance and the avoidance of the consequences of product failures can outweigh the direct and indirect costs of the conformity assessment approaches, but such an outcome should be the result of a careful analysis of the risks, rather than being a matter of simply following the current fashion.

f. Conformity assessment and competition

Another important aspect to consider when designing a conformity assessment approach is whether to allow or encourage **competition between conformity assessment bodies**. The main benefits of competition are to provide choice for the suppliers and to prevent a single body from abusing a monopoly position. On the other hand, competing bodies might be tempted to cut corners in an effort to meet the needs of customers and care needs to be taken to prevent the standard of assessment

from falling. Accreditation or peer assessment can help to counteract the adverse effects of competition.

g. Taking into account risk

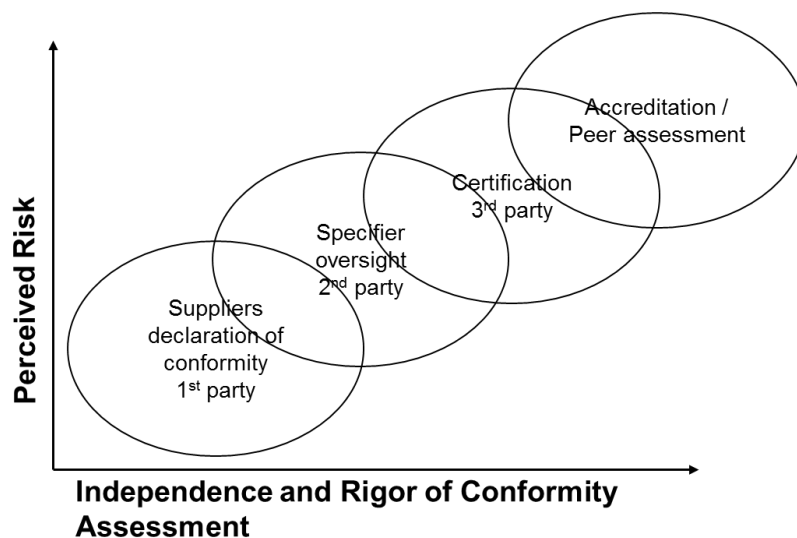
Some commentators suggest that when there is a **low risk** of an adverse effect being associated with failure of the *object of conformity* then the conformity assessment tool most appropriate can be to 'do nothing' or require a first party supplier's declaration of conformity (SDoC).

If SDoC is undertaken in accordance with ISO/IEC 17050 -1, 2, then it means the manufacturer/supplier has undertaken appropriate conformity assessment activities to support their SDoC and that a formal technical file exists for that *object of conformity*.

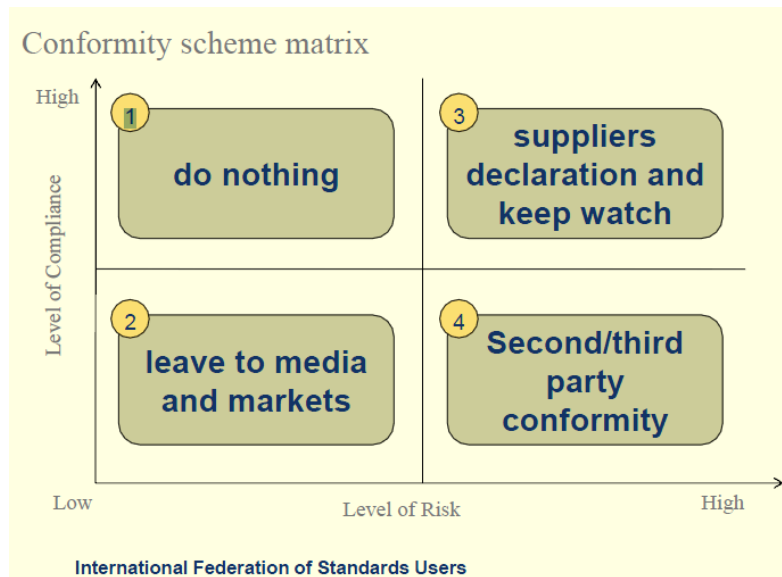
If failure of the *object of conformity* results in a **high risk** of an adverse effect then some commentators consider that involvement of a second or third party is necessary to independently assure the object complies with specified requirements. This can be achieved through certification.

As an added level of assurance conformity assessment results (e.g. test reports, inspection reports, certificates, etc.) can come from conformity assessment bodies (e.g. laboratories, inspection bodies, certification bodies) that are accredited and/or recognised through a peer assessment group.

The following figure illustrates this concept:



Another representation of this issue is the conformity scheme matrix developed by the International Federation of Standards Users (IFAN):



It should be noted that not all people support the above concept. Some proponents of SDoC argue that when SDoC is undertaken by a conscientious manufacturer/supplier can result in better conformity outcomes than independent third-party assessment. This is especially true if the manufacturer/supplier has invested in the own internal quality control activities, such as:

- maintaining a quality management system;
- ongoing production testing and inspection using competent in-house resources that may be accredited and/or participate in proficiency testing;
- undertaking internal audits;
- undertaking corrective and preventive actions; and
- seeking customer feedback and responding to complaints.

This is argued as being superior to the less frequent and often time-constrained external assessments by an independent third party conformity assessment bodies. In some cases SDoC use is based on mandatory third-party conformity results (e.g. the approach adopted for the CE marking system).

For more information see **Annex 6: Conformity assessment – Risk management**.

h. Access to competent resources

Competence is another consideration in using conformity assessment in regulation. Competence is defined as “*ability to apply knowledge and skills to achieve intended results*” ([ISO/IEC 17027:2014](#)).

Whether conformity assessment activities are being carried out by the supplier of the products, the purchaser or an independent body, there must be a clear understanding of the competence necessary for those performing the conformity assessment tasks.

Recognised general requirements for the competence of conformity assessment bodies are contained in various International Standards that make up the ISO/CASCO toolbox. Sometimes it is necessary to augment these general requirements with more specific requirements for the sector that is being covered, e.g. specific competencies for fields of testing. These more specific levels of competence can be stipulated by regulators as part of their regulations, or in association with requirements for accreditation or peer assessment.

Another important aspect in consideration of competence is access to competent resources. In many countries specialised competencies of conformity assessment bodies and people may not exist. In which case regulation needs to take this into account to specify alternative conformity assessment means, or allow time for competence and capacity to build up. This could be achieved through setting a transition period to allow for the establishment of public and/or private competence capacity, and to engage with donors and development agencies to establish in-country capability.

i. Surveillance activities

Surveillance can be considered in at least two ways:

- **market surveillance** activities that the regulator may undertake; and
- **surveillance** that may be undertaken that is associated with the conformity assessment activity.

In some case these two forms of surveillance can be combined into the one activity. It is the regulation and the associated conformity assessment scheme that defines what is required in terms of surveillance.

Market surveillance

Market surveillance by a regulator can be either pre-market, at-the-border, or post-market. It can involve sampling the *object of conformity* in the above situations and carrying out some form of conformity assessment activity to ensure specified requirements are fulfilled. In this regard inspection and testing are often used to demonstrate an object's conformity with specified requirements.

For some countries a form of pre-market surveillance especially for imports is pre-shipment verification of conformity (PVOC) which is carried out by an authorised agent of the regulator at the port of origin. Controlled goods that need to meet national standards are inspected and tested by these agents and if found to fulfil specified requirements a pre-shipment certificate of conformity is issued. This certificate then accompanies the shipment of those goods to the destination market and the shipment can be released at the port of arrival and onto the market once that certificate is authenticated. To ensure PVOC does not act as a technical barrier to trade, the specified requirements should also apply to the same goods that are produced domestically.

The advantage of PVOC is it allows the regulator to outsource the compliance checks associated with imported products, especially where there is a limited capacity to perform these checks within the destination country. It can also speed up delivery of compliant products onto the domestic market without holding up shipments at the border.

Conformity assessment surveillance

In conformity assessment activities, surveillance is the partial or full reiteration of the determination activities (e.g. audit, examination, evaluation, inspection or test) on a periodic basis to ensure ongoing production or service delivery continues to fulfil the specified requirements and to maintain the validity of the statement of conformity. Samples of the objects of conformity can be assessed either during production or once on the market, or both. Such surveillance is required when the conformity assessment activities result in a mark of conformity being used on the product on an ongoing basis.

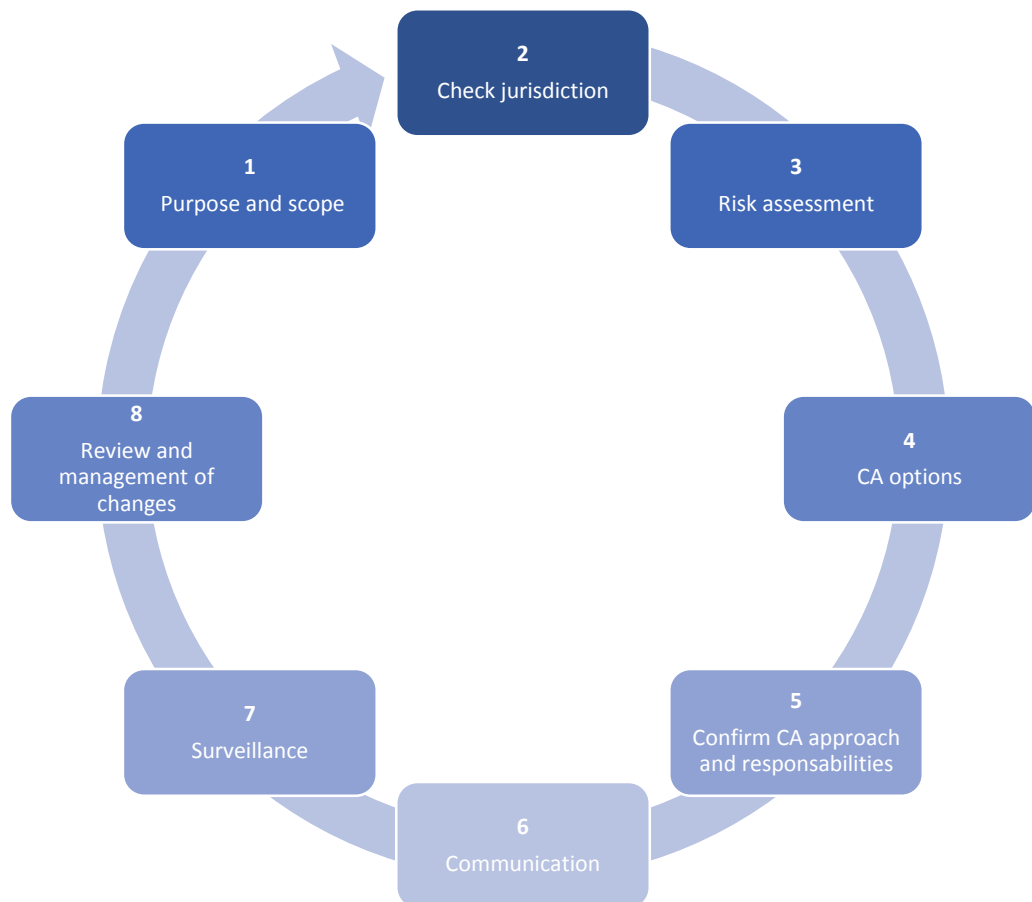
Where surveillance is required, good schemes will define the sampling criteria, determination techniques, and frequency at which surveillance must be undertaken. It is also good practice to

moderate sampling and frequency to take into account the level of risk being managed and the track records of the individual supplier.

Further information and examples can be found in [*A guide to Good Practice – Principles and Practices in Product Regulation and Market Surveillance*](#) published by ISO.

Suggested steps for using of conformity assessment in regulations

When considering the use of conformity assessment in regulations the following suggested steps can be used:



These steps are suggestions only, and the actual process used to consider and use conformity assessment in regulations will depend on the legal system in each country. In many countries a regulatory impact analysis (RIA) may be required to justify the selected option.

Step 1 Purpose and scope

The **purpose** for using conformity assessment to support regulation should be clear and be related to achievement of relevant public policy outcomes and the responsibilities of the regulator.

The **scope** of the use of the conformity assessment should:

- identify the *object of conformity* (e.g. the type of product, process, service, management system, person or organisation) being targeted through the regulation, and in particular what characteristics of that object that need to be controlled;
- the specified requirements that the object must fulfil; and
- identify the stakeholders that have the responsibility for complying with the regulations and demonstrating this compliance through adherence to conformity assessment requirements.

Step 2 Check jurisdiction

From the outset it is important to ensure the following points are fulfilled:

- The responsibilities and regulatory powers the regulator has and confirm that it has a **legal ability** to develop and mandate conformity assessment requirements as part of fulfilling its responsibilities.
- It is clear what **regulatory controls** apply to the object of conformity (e.g. product, process, service, management system, person or organisation), especially if different aspects of the same object are controlled by more than one regulator (e.g. an electrical consumer product that is controlled for electrical safety by one regulator, and energy efficiency by a different regulator). Duplication of conformity assessment requirements should be avoided.
- It is clear which regulators have control over the *object of conformity* at different stages of the object's 'life cycle' (e.g. at the point of raw material creation, processing, manufacture or fabrication, wholesaling, distribution (including both imports and domestic production), retailing, during the period the product is available for use, during the use of the object by the customer, through to end of life of the object). This is especially true for products that have complex supply chains, or are perishable, or have specific issues in terms of waste and disposal. It is important to know which regulators have jurisdiction at which stages in the life cycle so as to ensure critical stages are covered. It is also important to coordinate across regulators, if necessary.
- The limits of delegations of any regulatory powers are known and respected, and to avoid situations where conformity assessment activities take on too much responsibility on behalf of the regulator which is not in accordance with the law.
- The international obligations (e.g. WTO agreements) and regional commitments, especially for mandatory conformity assessment schemes that need to support and be integrated with any regional regulatory practice are known. In some regions regional mandatory conformity assessment exists for specific product types, e.g. the [Gulf Cooperation Council \(GCC\) Regulatory System for Control of Products](#), or the [New Legislative Framework](#) with its association regulations and directives of the European Union.

Step 3 Risk assessment

Having confirmed the scope (including the objects of conformity and specified requirements) in Step 1, a **risk assessment** should be undertaken to understand the nature of the risks that are trying to be managed through regulation and conformity assessment.

Step 4 Conformity assessment options

The use of conformity assessment represents only a part of the range of options that regulators may choose to facilitate compliance with their regulations. Practical access to the selected conformity assessment activity is critical if the use of conformity assessment is to be successful.

For example, it is of no benefit to require testing to be carried out in an accredited laboratory if those laboratories do not actually exist, or access to those laboratories is limited in some way (e.g. government laboratories that are prohibited from undertaking testing for private industry clients that require this testing to comply with regulations). In many countries access to appropriate conformity assessment services is enabled through provision of such activities by both, public and private sectors, some of which are multinational conformity assessment companies.

Based on the level of risk, the adequate determination methods are adequate. For example it could be a requirement for:

- self-declaration of conformity (SDoC) based on a test report from an accredited laboratory;
- product certification based on the testing of an initial product type (type-approval) which is then copied for all subsequent units of production without any further involvement of a third-party certifier;
- a production certification based on testing plus surveillance where a third party takes samples on an ongoing basis by the certification body from the market and testing or inspection to confirm the ongoing conformity.

Step 5 Confirm conformity assessment approach and responsibilities

If a mandatory conformity assessment option is selected, the regulator should develop an appropriate conformity assessment scheme.

Best practice in development of a scheme includes:

- engage a multi-party stakeholder's process;
- involve the sectors that will be required to comply with the regulations;
- provide a level of coverage that reflects domestic circumstances and priorities; and
- manage regulations and associated conformity assessment scheme with transparency and certainty.

Competence can be articulated through carrying out:

- a competence analysis to define the qualification criteria (the person certification standards of ISO/CASCO toolbox could provide you guidance on expected qualifications, work experience and levels of technical competence);
- a prescribed training system;
- qualification process including monitoring the performance; and
- then select the conformity assessment bodies, accreditation and peer assessment, and persons.

Once competence criteria are established, competence persons and organisations need to be appointed. A selection process will help to be consistent on implementing the defined competence criteria. This should also include considerations of independence, impartiality and confidentiality.

Step 6 Communication

A specific communication strategy should be established, implemented and maintained, once the conformity assessment scheme is ready for operation. This could include:

- a high profile launch event;
- distribution of information through various media channels including social networking;
- contact and seminars for those organisations and people that need to comply with the regulation or are involved in the associated conformity assessment activities;
- dedicated website for posting rules and updated scheme details;
- training courses etc.

Step 7 Surveillance

Irrespective of which form of surveillance (market surveillance or conformity assessment surveillance) it is good practice to take a risk management approach to what is selected for surveillance and the frequency of surveillance. Surveillance provisions should be flexible in order to allow for:

- periodic concentration on particular aspects on noncompliance that are especially prevalent and that have the highest risk of noncompliance;

- distinguishing between good and bad performers in terms of compliance, especially in terms of frequency of surveillance; and
- the ability to switch focus to novel or emerging risks of noncompliance.

Step 8 Review and management of changes

The regulator in their role as scheme owner should implement a process for reviewing the operation of the conformity assessment scheme on a periodic basis, taking into account feedback from stakeholders. The review should:

- consider whether the conformity assessment scheme is assisting in achieving the relevant public policy and legislative objectives;
- consider whether activities can be undertaken more costs effectively and efficiently; and
- identify aspects requiring improvement.

The regulator in their role as scheme owner should monitor and participate in the development of the standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the regulator should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the conformity assessment bodies, clients and, where necessary, other stakeholders.

USING CONFORMITY ASSESSMENT IN REGULATORY PRACTICE – EXAMPLES

ISO and IEC provides guidance on how to reference standards in regulations in their booklet on [Using and referencing ISO and IEC standards for technical regulations](#). The following are examples of referencing the International Standards and Guides contained in the ISO/CASCO toolbox in regulation, and using conformity assessment schemes in various regulated sectors.

Agriculture

Australia - Livestock Disease Control Regulations 2006

Regulation 37 Standards for testing

- (1) *For the purposes of section 16(3)(a) of the Act the prescribed standards for the testing, analysis and diagnostic examination of any sample or specimen for the purpose of determining whether it is infected with a disease are -*
 - (a) *the standards relevant to that disease in the Australian and New Zealand Standard Diagnostic Procedures as approved by the Primary Industries Standing Committee as amended and in force from time to time; and*
 - (b) *in any other case, the standards relevant to that disease in the Australian Standard Diagnostic Techniques for Animal Diseases as published by the Standing Committee on Agriculture and Resource Management in 1993 as amended and in force from time to time.*
- (2) *For the purposes of section 16(4) of the Act the prescribed standard of accreditation for the facilities and operational practices of veterinary diagnostic laboratories is accreditation in accordance with AS ISO/IEC 17025 —2005 General requirements for the competence of testing and calibration laboratories published 6 December 2005 as amended and in force from time to time.*

Dangerous goods and hazardous substances

New Zealand - Hazardous Substances (Compressed Gases) Regulations 2004

Part 6 - Labelling and marking, Marking of cylinders and fire extinguishers

Clause 39 Markings for cylinders and fire extinguishers

- (1) *A refillable cylinder and a fire extinguisher (whether refillable or not) must be marked with the following information:*
 - (a) *the register number of the cylinder design to which the cylinder or fire extinguisher was manufactured:*
 - (b) *the manufacturer's serial or batch number for the cylinder or fire extinguisher.*
- (2) *A refillable cylinder must be marked with the following information...*
- (3) *A fire extinguisher must be marked with a fire extinguisher registration number issued by a product certification body.*

Clause 23B Fire extinguisher registration number

- (1) *A low-pressure fire extinguisher must have a fire extinguisher registration number issued under subclause (2).*
- (2) *A product certification body may issue a fire extinguisher registration number for a low-pressure fire extinguisher if it is satisfied that the fire extinguisher—*
 - (a) *has been manufactured in accordance with this Part; and*
 - (b) *meets the quality assurance requirements specified in the fire extinguisher's design.*

Clause 3 Interpretations:

'product certification body' means a body accredited to ISO/IEC Guide 65 by a national or New Zealand joint accreditation agency operating to ISO/IEC 17011:2004.

Equipment Used in Environments with an Explosive Atmosphere

UNECE: Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere 2011

Part 4 - Common Regulatory Objectives, Recognition of conformity assessment bodies

Clause 33

The accreditation of conformity assessment bodies and test laboratories has to follow the applicable ISO/IEC International Standards (see appendix D.1). The accreditation body has to be member of International Laboratory Accreditation Cooperation/International Accreditation Forum (ILAC/IAF). One member of the assessor team needs competence in the field of explosion protection (see e.g. the list of approved IECEx Assessors).

Clause 34

Certificates have to be in line with ISO System No. 5 requirements of the applicable ISO/IEC Guide (see appendix D.2).

Clause 35

Certificates have to be in line with ISO System No. 5 requirements of the applicable ISO/IEC Guide (see appendix D.2).

US Coast Guards Regulations regarding electrical equipment installed in hazardous areas on foreign-flagged Mobile Offshore Drilling Units (MODUs)

They that have never operated, but intend to operate on the U.S. Outer Continental Shelf (OCS). They provide for acceptance on the market of IECEx-certified equipment (see: <http://www.gpo.gov/fdsys/pkg/FR-2012-12-03/html/2012-29138.htm>)

Public utilities

Singapore - Public Utilities (Water Supply) Regulations

Clause 5 Requirements for water fittings

(1) Every water fitting shall be —

- (a) of an appropriate quality and standard;
- (b) suitable for the circumstances in which it is used;
- (c) fit for the conveyance of potable water;
- (d) except in the case of exposed terminal fittings such as taps, resistant to dezincification if such fitting is made of brass; and
- (e) capable of withstanding a hydrostatic field test pressure of not less than 12 bars or an internal water pressure of not less than 1 1/2 times the maximum pressure to which the fitting is designed to be subjected in operation, whichever is the greater.

(2) For the purposes of paragraph (1)(a), a water fitting is of an appropriate quality and standard only if it conforms to —

- (a) such standard as the Board may stipulate from time to time for compliance, being —
- (b) an appropriate Singapore Standard;
- (c) an appropriate British Standard; or
- (d) some other standard which provides an equivalent or higher level of protection and performance; and
- (e) such other requirements as the Board may stipulate from time to time for compliance.

- (3) For the purposes of paragraph (2)(a), a water fitting shall be treated as conforming with a standard stipulated by the Board if it is certified or tested as complying with such standard by —
- (a) a product certification body or a testing laboratory accredited by the Singapore Accreditation Council or any of its Mutual Recognition Arrangement partners; or
 - (b) such other product certification body or testing laboratory as the Board may allow.
- (4) Any person who wishes to supply or install any water fitting for which no standard or requirement has been stipulated by the Board under paragraph (2) shall submit a request to the Board for the Board to stipulate the appropriate standard and requirement for that fitting for compliance.

Medical devices

Canada

A copy of the quality management system certificate certifying that: The quality management system under which the device is manufactured satisfies: National Standard of Canada **CAN/CSA-ISO 13485:03**, Medical devices — Quality management systems — Requirements for regulatory purposes.

Testing services

Mexico – Testing laboratory accreditation

A copy of the accreditation certificate that states: “The accreditation under which the laboratory was accredited satisfies: **NMX-EC-17025-IMNC-2006/ISO 17025:2005 — General requirements for the competence of testing and calibration laboratories**”-shall be presented.

The reference to the standard can also be included in a regulatory document.

Transport

United States - Code of Federal Regulations for Energy

The ANSI Standard MH5.1 (1971) “Basic requirements for cargo containers” and the **(ISO) 1496 (1978) “General cargo containers”**, have been approved for incorporation by reference by the Director of the Federal Register: A copy of each of these standards is available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland.

Health

Australia – Access to funding for medical testing

Pathology testing in Australia is carried out at both public and private laboratories. Partial reimbursement of the costs of medical testing is permitted under the universal public health insurance scheme in Australia (known as Medicare).

For reimbursement claims to be accepted, the pathology laboratory used must be an accredited pathology laboratory under the *Health Insurance Act 1973* (Cth) (HI Act). One of the conditions of gaining this status is the maintenance of an accreditation by the National Association of Testing authorities (NATA), the relevant national accreditation body in Australia.

NATA have a formal Memorandum of Understanding with the federal Department of Health and Ageing (DoHA) which endorses its accreditation role.

Medical testing (pathology) laboratories apply to NATA to be accredited in accordance with relevant guidelines issued by the National Pathology Accreditation Advisory Council (NPAAC) which reflect the requirements of [ISO 15189](#), *Medical laboratories - Requirements for quality and competence*. As a competent accreditation body NATA itself fulfils the requirements of [ISO/IEC 17011:2004](#), *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*.

Through this conformity assessment scheme the federal government of Australia control the quality of medical testing laboratories indirectly through controlling the access to funding. Access is only granted after the laboratories meet accreditation requirements and demonstrate their adherence to relevant standards. The federal Department of Health and Ageing (DoHA) do not directly accredit laboratories but instead rely upon the national technical accreditation system through NATA to achieve this outcome. This saves DoHA the direct expense of undertaking the accreditation service, and removes the Department from a conflict of interest that might be perceived if they were to accredit public health laboratories.

Building and construction

New Zealand – Accreditation of Building Consent Authorities

Building Consent Authorities

From 31 March 2009, only registered Building Consent Authorities (BCAs) may perform building consenting and inspection functions in terms of the Building Act 2004. The Act provides for Territorial Authorities and private organizations to apply for registration. Also, local government authorities will need to be registered to carry out building control work on dams.

Accreditation Criteria

The Department of Building and Housing has published standards and criteria for accrediting Building Consent Authorities under the Building (Accreditation of Building Consent Authorities) Regulations 2006. IANZ undertakes the assessments of Building Consent Authorities against these standards and criteria for registration by the Department of Building and Housing.

There are 19 regulations, of which applicants are expected to meet 11 of the standards and criteria by 31 March 2009. The most important are that a Building Consent Authority must have:

- appropriate policies, systems and procedures in writing record how it ensures that it implements effective policies, procedures and systems;
- it must record the key decisions it makes, the reasons for them, and the outcomes and actions of those decisions.

Assessment Criteria

To assist applicants, the Department of Building and Housing has published the Building Consent Authority Accreditation Preparation and Self-assessment Guide (published February 2007). The purpose of the guide is to:

- assist organisations that apply to become building consent authorities to prepare their policies, processes and procedures for accreditation assessment and ongoing compliance;

- assist organisations to assess how well existing policies, processes and procedures comply with the accreditation requirements;
- assist organisations to assess how well implemented their existing and new systems; and
- provide good-practice guidance that may be used (or adapted for use) by building consent authorities to demonstrate compliance with the accreditation standards.

This should be read in conjunction with the Department's Building Consent Authority Development Guides (published in 2006).

Accreditation Criteria

- General: [Building Consent Authority Accreditation – Procedures and Conditions \(P&C\) \(pdf\)](#)
- Specific: [Specific Criteria Building Consents Authorities \(BCA\)](#)

Toy safety

Brazil - Toy Safety Certification Scheme

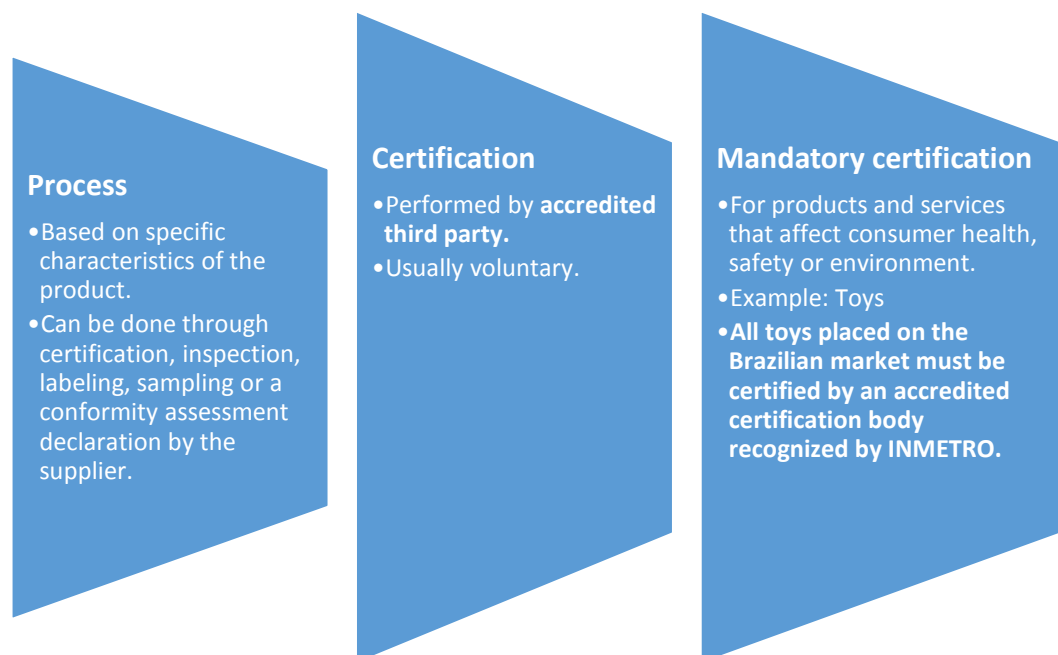
In Brazil the authority for technical regulations is represented at federal level by several agencies, depending of the area of competence. The regulations can be developed ex officio or upon request of a third party.

These regulations are generally based on International Standards, among which ISO standards. Even if the regulation is identical to the international regulation, potential impact of regulations needs to be notified this to the World Trade Organization (WTO). The National Institute of Metrology, Quality and Technology (**INMETRO**) is responsible for this. INMETRO is also responsible for conformity assessment bodies' accreditation. More information can be found in the [Guide to Brazil's Toy Compliance Requirements](#).

The choice of conformity assessment activity is based on specific characteristics of the product and can range from certification, inspection to declaration of conformity by the supplier. It is usually voluntary-based, but if the *object of conformity* affects consumers' health, safety or environment, conformity assessment should be performed by an accredited third party.

A good example of this process is the certification of toys' safety. All toys placed on the Brazilian market must be certified by an accredited certification body. The voluntary and mandatory certification scheme is described in Figure 4 below. It is adapted from the *Guide to Brazil's Toy Compliance Requirements*.

Figure 4. Conformity assessment bodies and voluntary and mandatory certification

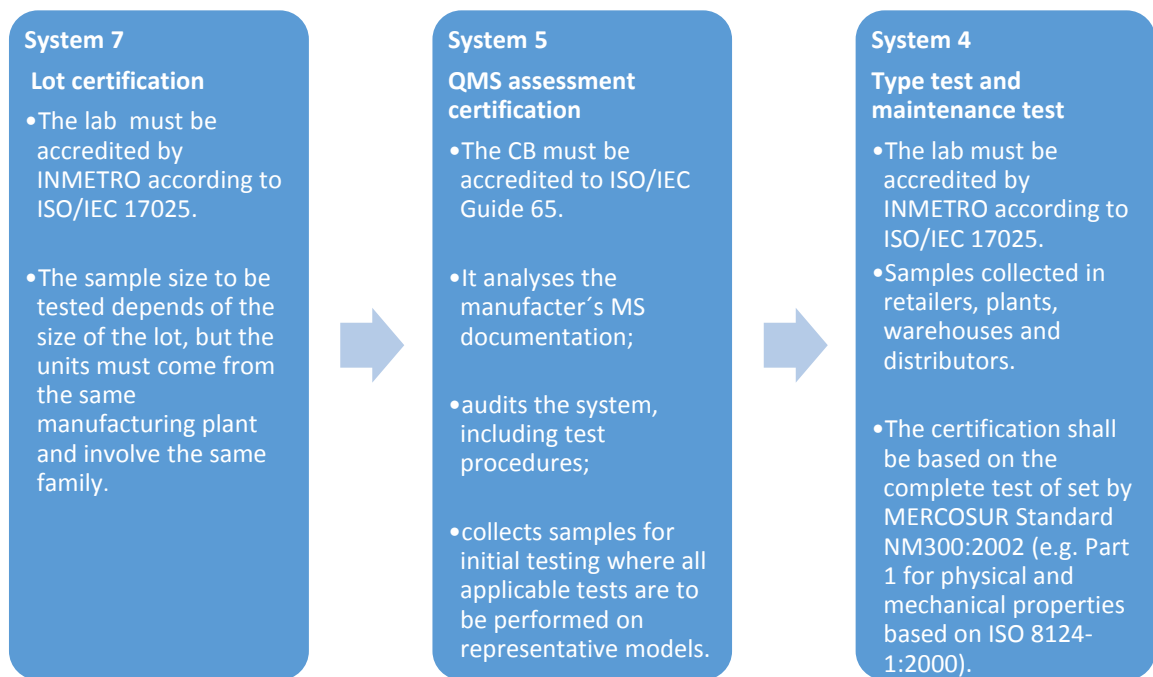


The toy safety certification process can use different certification systems that comprise specific technical regulations:

- MERCOSUR Standard on Toy Safety **NM300:2002**, Parts 1-6;
- **NM 300 - 1:2002**, Safety of Toys, Part 1: General, mechanical and physical properties, which are based on ISO 8124-1:2000;
- **NM 300 - 2:2002**, Safety of toys, Part 2: Flammability, with normative references to ISO 2431:1993;
- **NM 300-4:2002**, Safety of toys Part 4: Experimental sets for chemistry and related activities, with normative references to ISO 8317:1989- Child - resistant packaging;
- Additional requirements or methodologies such as the one to approve the Procedure for Certification of Toys and toxicological testing.

More information can be found on the ABNT website: www.abnt.org.br

Figure 5. The toy safety certification systems and related ISO standards



The toy safety certification also requests accredited certification bodies and laboratories, where the common elements of the systems request the compliance based at least on:

- **ISO/IEC 17025:2005**, General requirements for the competence of testing and calibration laboratories, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
- As an IAF/ILAC MLA signatory, INMETRO also shall request confident testing, where a mandatory rule for laboratories is the proficiency testing participation based on **ISO 17043:2010**, Conformity assessment - General requirements for proficiency testing. The standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes.
- **Guide ISO/IEC 65:1996**, General requirements for bodies operating product certification systems. This Guide has been replaced by: ISO/IEC 17065:2012 *Conformity assessment - Requirements for bodies certifying products, processes and services*. This new version has been fully revised with more and better terms and definitions, resources, and guidance. Christian Priller, Convenor of the ISO/CASCO working group that developed ISO/IEC 17065 standard says:

".....Product certification is perhaps the most visible type of certification because it is usually accompanied by a mark that is recognized and appreciated by regulators, consumers and other stakeholders. It is therefore crucial that we ensure the reliability of these claims. I am confident that the new ISO/IEC 17065 will increase trust and comparability of product certification around world." (ISO News, 3 October 2012).

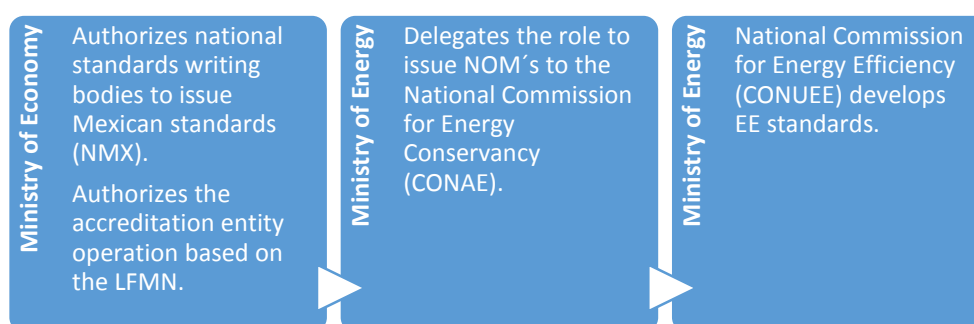
Mexico - Energy Efficiency (EE) products certification

Energy-Efficiency standards are procedures and regulations that prescribe the energy performance of manufactured products. A well designed EE standard can help reduce unnecessary electricity and fuel consumption by households and office equipment (e.g. electronic equipment, refrigerators, air conditioners and water heaters). It supports the portfolio of EE policies and climate change mitigation actions or programs.

Mexico implemented a policy that established a fund to facilitate the reduction of emissions in energy consumption by replacing incandescent light bulbs with compact fluorescent light bulbs and the project of energy-efficient refrigeration to reduce energy consumptions. This policy was supported by standards.

Mexico mandates for EE standards comes from the *Federal Law on Metrology and Standardization* ([LFMN](#) - Ley Federal sobre Metrología y Normalización), which established a list of specific and generic public and private organizations for implementing the Standards' Programme. The LFMN lists in Article 3 the responsible parties for developing voluntary (NMXs) and mandatory standards (NOMs). The **National Commission for Energy Efficiency (CONUEE)** is responsible for developing EE standards. It is a decentralized, administrative agency of the Secretary of Energy, with technical and operative autonomy to promote energy efficiency.

Figure 6. Public organizations in Mexico and EE standards



When a Ministry in Mexico issues technical regulations, this are mandatory, so all products, processes, methods, facilities, services or activities must comply with the Mexican Official Standards that are published in the Official Gazette (DOF). A detail current list of EE standards in Mexico can be find at link:

http://www.conuee.gob.mx/wb/CONAE/CONA_1002_nom_publicadas_vigen

To demonstrate compliance with mandatory standards, products such as refrigerators, air conditioners, laundry machines or water heaters shall be certified. The certification and related testing shall be performed by accredited third parties. Private organizations that participate in this EE conformity assessment system in Mexico are:

- **Testing laboratories:** independent or operated by manufacturers. When accredited to ISO/IEC 17025:2005: *General requirements for the competence of testing and*

calibration laboratories, the laboratory does the tests under NOMs requirements and issues the results' report.

- **Calibration laboratories:** accredited to ISO/IEC 17025:2005 give traceability to the measurement instruments of testing laboratories.
- **Certification bodies:** accredited to ISO/IEC 65:1996: *General requirements for bodies operating product certification systems* (new ISO/IEC 17065:2012) and approved by corresponding ministries to certify compliance with EE standards (NOMs). The certification bodies only recognize test reports of accredited laboratories.
- **Accreditation bodies:** ensures technical competence of certification bodies, testing laboratories and calibration bodies ([Mexican accreditation entity](#) - EMA). A competent accreditation body complies with the requirements of ISO/IEC 17011:2004 *Conformity assessment - General requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs)*.

Example of EE refrigerators:

- An accredited certification body confirms compliance with requirements of NOM-015-ENER-2012 – *Energy efficiency of refrigerators*;
- Limits, test methods and labelling by receiving a test report from an EMA accredited laboratory and technical documentation;
- EE labels are posted to identify the product.

Figure 7. EE labels for refrigerators in compliance with NOM-015-ENER-2012

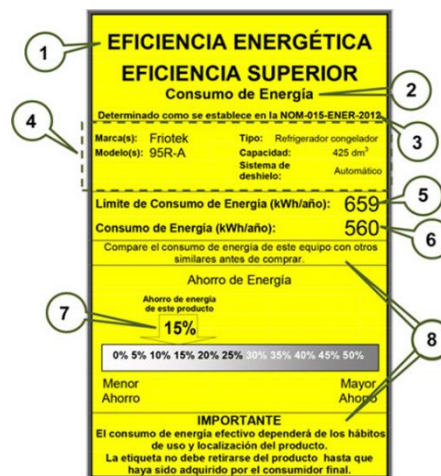


Figure 7 describes the label information:

- 1) The efficiency of the product
- 2) How much energy (top energy) would be consumed
- 3) The mandatory standard for EE refrigerators
- 4) Type, mark, model and capacity of the refrigerator
- 5) Energy limit (kWh/year)
- 6) Energy use (kWh/year)
- 7) Energy saving (%) in a range from 0% to 50%.
- 8) Notice inviting to the consumer to use EE products and how the label can help to compare the energy saving with other products

There are other systems that exist on the Mexican market, such as the **Electric Power Saving Trust Fund (FIDE)** label, a voluntary label that identifies energy-efficient products. It certifies that products meet specified standards and identifies them as FIDE certified energy-efficient products. FIDE also requires conformity assessment bodies to be accredited to issue its certificates.

FIDE label covers the products listed below and its targets to increase coverage to 7700 products across 85 companies¹ :

- Electric three phase induction motors
- Lamps, ballasts and luminaries
- Water pumps
- Commercial refrigerators
- TV sets and monitors
- Air conditioners

Regarding EE voluntary standards, Mexico also promotes the use of **ISO 50001** - Energy management systems, that supports organizations in all sectors to use energy more efficiently and improve environmental performance, through the development of an energy management system (EnMS). The Certification Bodies seeking accreditation on Energy Management Systems program shall comply with ISO/IEC 17021:2011: *Conformity assessment – Requirements for bodies providing audit and certification of management systems*.

¹ Companies as Samsung, Mabe and LG electronics Mexico are FIDE label users.

http://www.fide.org.mx/index.php?option=com_content&view=article&id=154%3Aelectrodomesticos&catid=67%3Aproductos&Itemid=234