



Writing Standards and Conformity Assessment

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Until recently the rules for standards writing laid out in the ISO/IEC Directives, and adopted by Standards Australia, prohibited the inclusion of conformity assessment aspects in standards for products, processes or services, with the exception of testing provisions. Initiatives at the international level have included allowing the inclusion of additional requirements associated with testing such as sampling, and permitting committees to now specify additional conformity assessment requirements for products, processes or services, provided that these are in a separate standard.

This article seeks to clarify the issue of what is and is not appropriate in terms of the inclusion of conformity assessment requirements in standards. Conformity assessment is explained in AS ISO/IEC 17000:2005, Conformity assessment – Vocabulary and general principles, with conformity assessment itself being defined as *demonstration that specified requirements relating to a product, process, system, person or body are fulfilled*.

As readers know Standards Australia produces and maintains thousands of standards, a vast majority of which contain specified requirements for products or services. Generally speaking there are three sets of requirements that might be specified in standards:

- (1) product (or service) requirements that relate directly to the product;
- (2) product conformity requirements that set out agreed method for confirming a product is meeting the product requirements (e.g. test methods); and
- (3) conformity assessment requirements that stipulate the procedures, rules and actors in how product conformity should be undertaken.

Most standards writing committees focus on the first two sets of requirements i.e. specified requirements for the product itself, and in some cases the requirements for product conformity. When a committee identifies a need to specify conformity assessment requirements, these may only be included in a standard which is separate from the product standard and are subject to some limiting conditions.

Specific requirements for the product include dimensions, allowable tolerances and minimum performance expectations. For many years standards writing committees have been encouraged to write these types of requirements in performance based terms so as not to inadvertently 'freeze' the current state of technology as the only way to make the product.

Product conformity requirements are limited to testing methods and associated sampling. These are prescribed procedures for use in determining if the product complies with the requirements of the standard. Developing product conformity requirements is important to ensure that any subsequent claims of product conformity have been based on standardised procedures. Sometimes there may be several product conformity requirements or test methods developed for a single product standard, each addressing a specific characteristics of the product. In writing product conformity requirements, committees should consider whether specialized input is

needed from experts familiar with testing practices, or other forms of assessment that might be relevant.

As per international practice¹ and Standards Australia's own Standardisation Guides, it is appropriate for standards development committees to develop product requirements and requirements for product conformity.

Contemporary understanding is that it is the market or a regulatory body on behalf of the public interest that may prescribe what forms of conformity assessment are acceptable and by whom they should be carried out. Generally this should not be the role of a standards development committee producing what are fundamentally voluntary national standards.

Conformity assessment ranges from first party 'supplier's declarations of conformity' through to independent third party conformity assessment such as product certification. Except in exceptional circumstances, it would not be appropriate for a committee to develop a product standard and associated test methods, and then state that the only accepted form of conformity assessment to comply with the product standard is through the use of a supplier's declaration of conformity; or alternatively a third party product certificate.

As one example, a manufacturer or service provider wants to supply their product or service to the market. They seek out the relevant product (or service) standard and establish their product on that basis. They then seek to test the product's conformity against the parameters included in the standard i.e. product conformity. To do this they use the relevant test methods or other assessment requirements. They may choose to do this in-house, using their own in-house test laboratory or internal audit regime. The results of this exercise may give the manufacturer or service provider the confidence to then self-declare to the market that their product or service conforms to the relevant standard. However if the product standard, or the product conformity requirements, state that only independent testing facilities are permissible, and that the final judgement must be through a third-party product certifier, then the manufacturer will not be able to self-declare and still comply with the standard. In this instance the standards development committee have skewed the market in favour of third party conformity assessment (i.e. certification) at the expense of the acceptability of first-party conformity assessment (i.e. self-declaration). Having this possible effect on the market is generally understood as *not* being the role of a standards development committee.

In summary, standards development committees should write their product (process, service) standards in a way that is neutral as to the type of any subsequent conformity assessment. The standards requirements must be clear and precise enough to allow subsequent conformity assessment to be achieved through either a first party (self-declaration); a second party (e.g. the purchaser undertakes the conformity assessment of the products being supplied by the supplier); or an independent third-party (e.g. a certification body).

ISO and IEC have produced a guidance standard on how to best write standards so their subsequent use as the basis for conformity assessment can be optimized. The standards is ISO/IEC 17007:2009, *Conformity assessment - Guidance for drafting normative documents suitable for use for conformity assessment*, and this will be cross-referenced in future editions of the relevant Standards Australia Standardisation Guides.

As indicated earlier, standards development committees can indeed write conformity assessment requirements as long as they do so in a *separate* document, and do *not* link adherence to this separate document as a prerequisite for a product to comply with the requirements of the main product standard. Before undertaking development of such a separate standard a committee should satisfy itself that the product, process or service that is the subject of the principal standard is (1) not subject to regulation (in such cases the regulator will specify the relevant

¹ See the ISO/IEC Directives, Part 2.

conformity assessment requirements); (2) could impose a significant adverse risk if it fails to comply fully with the requirements of the principal standard; and (3) there is an established market need for the conformity assessment standard.

If the need for specific conformity assessment requirements for a product is supported, it may be appropriate for the committee responsible for the product standard to develop the specific conformity assessment regime or scheme. However, this exercise should not be embarked upon lightly, and will require expertise in conformity assessment in addition to expertise on the product or service.

Any such development would need to be considered on a case by case basis.

There is guidance on the development and operation of conformity assessment schemes in the form of Standards Australia's adoption of ISO/IEC documents on conformity assessment (e.g. HB 18.67-2005 (ISO/IEC Guide 67, *Conformity assessment - Fundamentals of product certification*) and HB 18.28-2005, (*ISO/IEC Guide 28, Conformity assessment - Guidance on a third-party certification system for products*)).