

Conformity assessment bodies – Testing and calibration laboratories

Testing

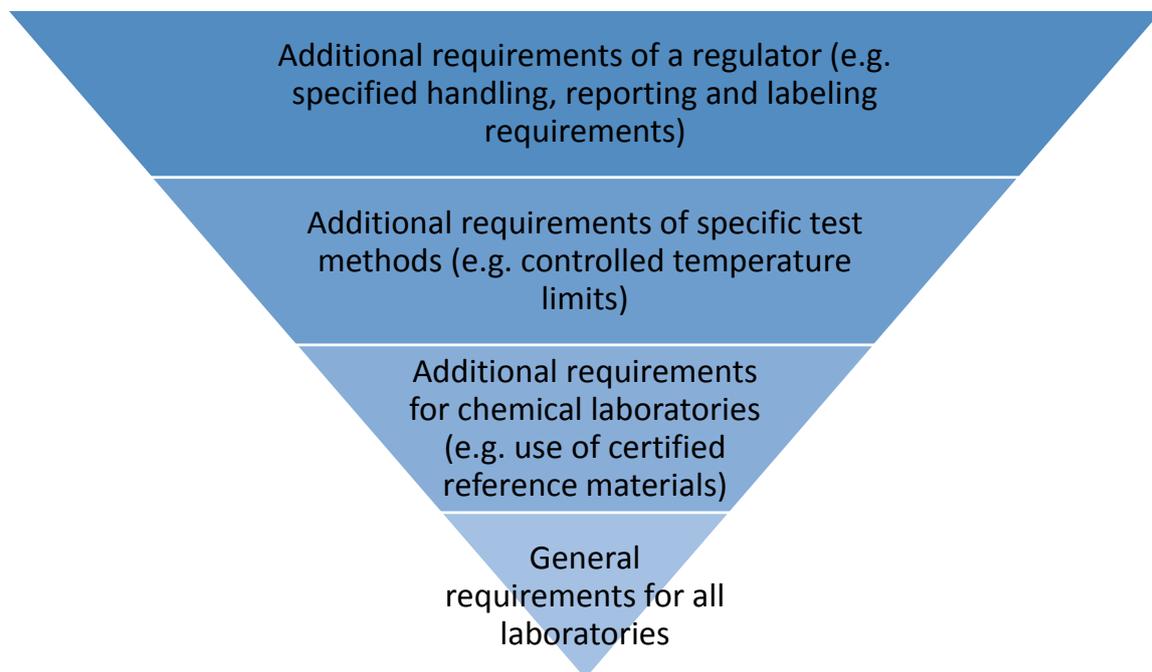
The recognised International Standard for testing laboratories is ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*.

For example, medical laboratories have had to develop supplementary criteria for medical sub-disciplines (such as biochemistry, microbiology etc). In fact in this instance a separate standard for medical laboratories ISO 15189 has been produced, but it remains compatible with ISO/IEC 17025.

It is important for the laboratory to specify the scope of its testing work so that it can be confident that it has the people, equipment and facilities to carry out the work competently. In many cases, the laboratory will use standardised test methods and it is useful for the scope to be specified by reference to the standards. In this way, clients of the laboratory will be confident of its capability to perform the tests which they require.

When the laboratory seeks accreditation, the accreditation body will not only assess compliance with the general standard and any field-specific supplements, but also their compliance with the technical requirements of specific standard test methods for which the laboratory is recognised. In some cases this will also include specific requirements of regulators.

There thus becomes a hierarchy of criteria which laboratories may need to satisfy as shown in the following example of a chemical laboratory:



The management systems and technical requirements of sector specific standards such as ISO 15189 for medical laboratories are compatible and cover similar issues. However, the language of ISO 15189 is more aligned to terminology used in clinical testing and includes some specific needs of such laboratories. The content of the management systems requirements of both standards is

aligned with the principles in ISO 9001, but again the language has been tailored to the needs of laboratories.

Inter-laboratory comparison testing and proficiency testing

Testing laboratories may need to become involved in inter-laboratory comparison testing and in particular with proficiency testing. Inter-laboratory comparison testing may be used for a number of purposes including:

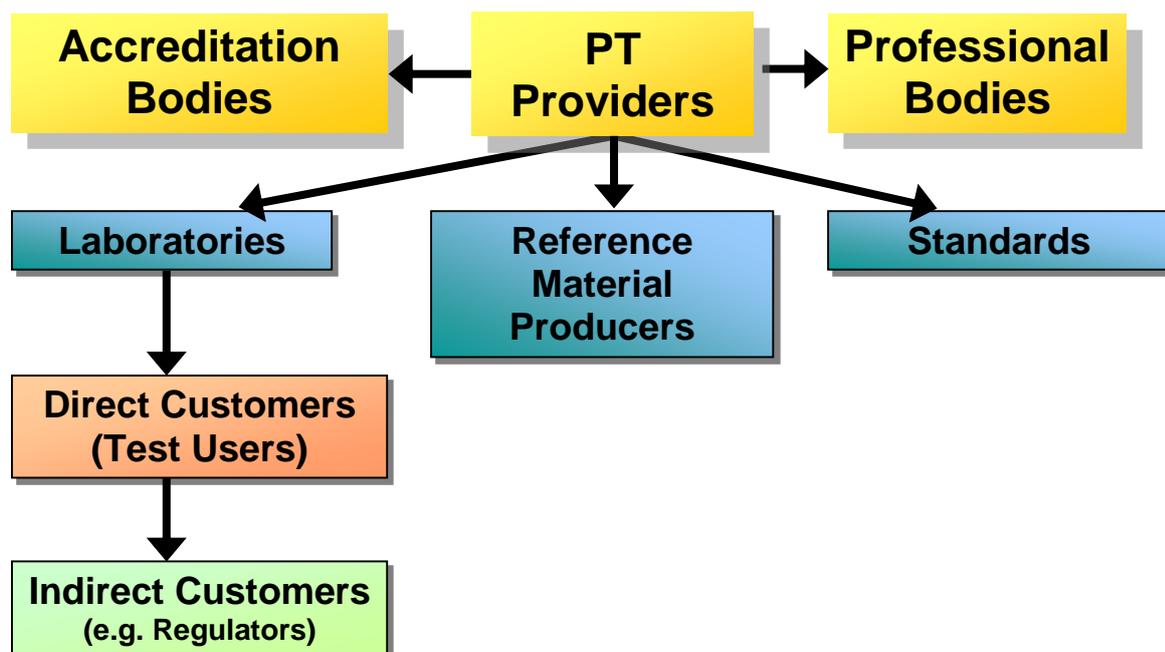
- Establishing the effectiveness and comparability of new test or measurement methods and similarly to monitor established methods;
- Identifying the reasons for differences in the results obtained by different laboratories;
- Determining the performance of individual laboratories for specific tests or measurements and to monitor laboratories' continuing performance.

Proficiency testing is the use of inter-laboratory comparison testing for the last of these items but it can also provide information for other purposes including those listed above.

The relevant International Standard for proficiency testing is [ISO/IEC 17043:2010](#), *Conformity assessment -- General requirements for proficiency testing*.

Proficiency testing can be a powerful tool for the laboratories. Successful performance can be a major risk management tool, while any poor performance arising from their participation can be the catalyst to investigate the causes and take appropriate corrective action. Because competent proficiency testing is so critical to the confidence which accreditation bodies need in their recognition of the competence of testing and calibration laboratories, a number of accreditation bodies are now actively involved in accrediting proficiency testing providers.

Many proficiency tests also benefit other stakeholders, as the results of the inter-laboratory tests might also be used in determining values for certified reference materials; in improving standard test methods; in re-assuring clients of laboratories, including regulators; and as an educational tool for professional bodies. The figure below shows some of the stakeholders in proficiency testing.



Drivers and benefits for testing and calibration

Examining first the drivers and benefits for calibration, it is critical to acknowledge that testing depends on the support of competent calibration. If test equipment is not appropriately calibrated, the results it generates will not be reliable. (Poor data leads to poor decisions based on that data). Some calibrations will not require a high level of expertise, and many calibrations may be performed routinely by testing laboratories for their own needs. In these circumstances the calibration can be considered a routine operation of the laboratory, rather than a conformity assessment activity. However, where special measurement expertise is required, laboratories usually need to use the services of competent calibration services.

The drivers and benefits for laboratories in using these services include the access they provide to traceability of measurement to International Standards and information on the measurement uncertainty of the devices and equipment calibrated for them. If a testing laboratory wishes to comply with standards such as ISO/IEC 17025, they need to have both measurement traceability and appropriate determination of the measurement uncertainty of their own tests. So, the fundamental benefit and driver for such laboratories in using competent calibration services, is that calibration underpins most laboratory activities.

However, calibration is also a foundation for confidence in manufacturing, telecommunications, construction, defence, aviation, meteorology, mining, health services, general commerce and many other facets of life where decisions are based on measurement. Where the measurements concerned, or the decisions based on those measurements, are critical, it is essential that those performing the measurements and calibrations are competent to do so.

In some cases the calibrations may be performed by the organizations themselves. In other cases the use of specialized, independent calibration services may be needed. For the most accurate measurements needed in a country, they are usually provided by a national measurement institute.

The primary drivers and benefits for testing are similar to those for calibration. Many decisions in society require the availability of data and information which can only be obtained through testing. Testing is therefore an essential feature of daily life. The primary drivers and benefits for testing depend on the criticality of the decisions being made. Judgment on the costs of testing and the levels of expertise needed for their conduct will vary depending on individual circumstances. Some testing may only need to be indicative, while other tests may require highly-developed expertise. The degree of benefits derived from testing will thus depend on the needs of individual users, as will the levels of risk taken in choosing appropriate testing services.