

Changes to ISO/IEC 17025

The following is a listing of the changes to the requirements of **ISO/IEC 17025:General requirements for the competence of testing and calibration laboratories**, from the 1999 version to the 2005 version. These changes will be reflected in the forthcoming revision of **NIST Handbook 150: NVLAP Procedures and General Requirements**. General changes and changes for clarity and conformance typically will not require much action by laboratories and/or assessors. Specific changes will require some action by the laboratories and/or assessors.

Italics are used to indicate a change.

General changes

The terms “quality system” and “laboratory management system” have been changed to *management system*.

Note 1 has been added to subclause 1.4 (1.1.2 of NIST Handbook 150) of the Scope and states: “*The term ‘management system’ in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory.*”

The term “client” has been changed to *customer*, all forms, all occurrences.

The term “nonconformances” has been changed to *nonconformities*.

Subclause 1.4 (1.1.2 of NIST Handbook 150) of the Scope now states: “This International Standard is for use by laboratories in developing their management system *for quality*, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. *This International Standard is not intended to be used as the basis for certification of laboratories.*”

Note 2 has been added and states: “*Certification of a management system is sometimes also called registration.*”

Subclause 1.6 (1.1.5 of NIST Handbook 150) of the Scope now states: “If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality *management system* for their testing and calibration activities that also meets the *principles* of ISO 9001. Annex A provides nominal cross-references between this International Standard and ISO 9001. This International Standard covers technical competence requirements that are not covered by ISO 9001.”

Changes for the sake of clarity and conformance

4.1.5 a [The laboratory shall] have managerial and technical personnel who, *irrespective of other responsibilities*, have the authority and resources needed to carry out their duties, *including the implementation, maintenance and improvement of the management system*, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

4.2.2 The laboratory’s management system policies *related to quality, including a quality policy statement*, shall be defined in a quality manual (however named). The overall objectives shall be

established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

4.2.2 c [It shall include at least the following :] *the purpose of the management system related to quality;*

4.7.1 The laboratory shall *be willing to cooperate with* customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. *When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.*

Specific changes (numbered to correspond to NIST Handbook 150 Checklist:2005)

4.1.5 k [The laboratory shall:] *ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.* (new clause)

4.1.6 *Top management shall ensure that the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.* (new clause)

4.2.2 e [It [the quality policy statement] shall include at least the following]: *the laboratory management's commitment to comply with this handbook and to continually improve the effectiveness of the management system.*

4.2.3 *Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.* (new clause)

4.2.4 *Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.* (new clause)

4.2.7 *Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.* (new clause)

4.7.2 *The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.* (new clause)

4.10 *Improvement. The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.* (new clause)

4.12.1 b *When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.*

4.15.1 j [The [management] review shall take account of:] *recommendations for improvement*; (new clause)

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. *The effectiveness of the training actions taken shall be evaluated.*

5.9.2 *Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.* (new clause)