



Main changes in ISO/IEC DIS 17025

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- Initialed in February 2015
- Published ISO/IEC DIS 17025 in December 2016
- Plan to publish ISO/IEC FDIS 17025 in Autumn 2017

Structure of ISO/IEC DIS 17025

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Annex A (informative) Traceability

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Reference

Main changes

- The statement of “relationship with ISO 9001”
 - It deletes the “relationship with ISO 9001” statement in the Introduction and Clause 1.6.
 - Only keep the sentence “Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001”
 - Fully considered the requirements of the ISO/IEC 9001:2015, especially for the management requirements

Main changes

- The statement of “relationship with ISO 9001”
 - In the Annex B, it was explained the relationship of 17025 and 9001
 - Keep the sentence “Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate to the competence of the laboratory to produce technically valid data and results” in Annex B

Main changes

- Simplify the Scope
 - Delete “1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this International Standard”
 - Delete the description of first-, second- and third-party, but only make it clear that this International Standard is applicable to all organizations performing testing and/or calibrations, regardless of the number of personnel

Main changes

- Simplify the Scope
 - Delete “This International Standard is not indented to be used as the basis for certification of laboratory”(1.4)
 - Delete “1.3 The notes given provide clarification of the text.....”
 - Delete the explanation of 1.2 “such as sampling and the design/development of new methods, the requirements of those clauses do not apply”

Main changes

- Normative reference
 - Only keep the VIM (according to the ISO new requirement, all the referenced ISO standards will all put into the Bibliography)

Main changes

- Added Terms and definitions
 - There is no terms in the ISO/IEC 17025:2005
 - In the ISO/IEC DIS it has added the terms
 - Impartiality
 - Compliant
 - Inter-laboratory comparison test
 - Proficiency test
 - Laboratory (Laboratory activity)
 - Decision rule

Main changes

- Impartiality and confidentiality requirement
 - In the ISO/IEC 17025:2005, the requirements of impartiality and confidentiality are principal and simple
 - In the ISO/IEC DIS 17025:
 - 4.1 Impartiality
 - 4.2 Confidentiality

Main changes

- Structure requirement
 - The structure requirements are mainly from Clause 4.1 in ISO/IEC 17025:2005
 - Cancel the title “Quality management” and “Quality Manager” (only emphasize the their position’s functions, no matter what the titles they have)
 - Add “The laboratory shall make any laboratory activity documental that apply to this Standard”
 - Delete the “appoint deputies for key managerial personnel” (not a mandatory requirement)
 - Move the supervision requirement of personnel to Clause 6.2 Personnel

Main changes

- Personnel requirement (simplified and combined)
 - Delete the description of the supervision to the under training personnel
 - Not use the word “employed by or under contract to the laboratory” (as in may have different understanding in different countries)
 - Delete the note 1 and note 2 of 5.2.1 in ISO/IEC 17025:2005
 - Simplified the training requirements, it only requires the laboratory clearly specifies the training requirements of each position that will affect the results, and keep the records. It deletes some detailed requirements, such as training procedure, training plan and evaluation of the effectiveness of the training.

Main changes

- Personnel requirement (simplified and combined)
 - Delete the 5.2.4 note of ISO/IEC 17025:2005 Job description (the job description will be defined by the laboratory according to its own situation)

Main changes

- Accommodation and environmental conditions
 - There is no significance difference, but with more refined language, and states clearly the regular evaluation of the accommodation control measures.
 - Delete the housekeeping requirements

Main changes

- Equipment requirement
 - There is no significance difference, but made the necessary simplification.
 - Main changes:
 - Make it more clear that the equipment does not include measurement instrument, but also software, reference materials, reference data, consumable materials and other support device.
 - Use the work “Verification” instead of “Check/calibration” before use.
 - Delete the authorization of using the equipment (as it has been stated in Clause 6.2)

Main changes

- Equipment requirement
 - Main changes:
 - Make it clear to review the calibration plan, and do any necessary adjustment if necessary
 - It only requires the calibration mark and be identified the calibration status or valid period
 - In the equipment record, it delete the manual from manufacturer (as this is an external document, not a record)
 - In the equipment record, it add the requirements of reference materials (record of date, results, document, acceptable criteria, valid period)

Main changes

- Equipment requirement
 - Main changes:
 - Delete the 5.5.4 of ISO/IEC 17025:2005 (as this has been required in 6.4.9b)
 - Intermediate checks apply to all the equipments (not only for the calibrated equipments)
 - Delete the 5.5.9 of ISO/IEC 17025:2005 (in 6.4.2 of DIS, has been covered)
 - Add the selection requirements of reference materials

Main changes

- Measurement traceability requirement
 - Simplify the content, and the put the explanation into the Annex A
 - It does not require separately for the testing and calibration laboratory, but emphasize the traceability of the results
 - Delete 5.6.1 of ISO/IEC 17025:2005 the requirement of equipment calibration and calibration plan (as it has been covered in Clause 6.4)

Main changes

- Measurement traceability requirement
 - For the 5.6.2.1.2 of ISO/IEC 17025:2005
“.....establishing traceability to appropriate measurement standards.....”, it make give more clear description of measurement standards that shall be acceptable by authorized organization, and give an example of authorization organization.

Main changes

- Purchasing services and supplies
 - Combine the Clause 4.6 and Clause 4.5 of ISO/IEC 17025:2005 into one Clause, and some content of Clause 4.5 moved into Review of requests, tenders and contracts
 - There are two parts, one is for supporting the laboratory operation, one is for providing to customers directly (subcontracting)
 - Except the evaluation to the suppliers, it also requires to monitor and re-evaluate, and take necessary measures according to the monitoring and re-evaluation results.

Main changes

- Review of requests, tenders and contracts
 - In the DIS version, this covers the Clause 4.4, 4.5 and 4.7 of ISO/IEC 17025:2005
 - New add content
 - The deviation requested by the customers shall not affect the integrity of laboratory or integrity of the results
 - If the customer requires to give evaluation to the results, it should define clearly on the reference standard and decision rule.

Main changes

- Testing methods and method validation
 - Generally the same as the Clause 4.4 of ISO/IEC 17025:2005
 - Main changes:
 - Modification method development plan shall be approved and authorized
 - Specify the contents to be included in the method validation record
 - Delete the recommendation on contents to be included in the testing or calibration method

Main changes

- Sampling
 - Main changes:
 - Sampling record shall include date, and time as necessary, and relevant data of the sample, for example: identification number, quantity and name
 - Delete the customer's deviation requirements from the sampling procedure

Main changes

- Handling of test and calibration items
 - Added: when custom knows the sample has deviations from the specified conditions, and insists to conduct the test or calibration, the laboratory shall state the disclaimer in the test report, and indicate that the results may be affected.

Main changes

- Technical record
 - Considered that there are more and more laboratories use the automatic equipments and information management system, it may be flexible for the data amendment. It is not to do the “crossed out”, but to keep the original data or observations, and show the alterations and signed or initialed by the person making the correction

Main changes

- Evaluation of uncertainty
 - It does not need to have the procedure of evaluation of uncertainty, but requires to evaluate the measurement uncertainty
 - It is added the notes for the evaluations
 - The DIS version firstly proposes the uncertainty evaluation for sampling

Main changes

- Assuring of quality of test and calibration results
 - Non significant change
 - Expressed by internal quality control and external quality control
 - For internal quality control, it adds some measurement: the function check of the equipment, intermediate check of equipment, review of the testing data, comparison test inside of the laboratory, blind sample test, etc.
 - For external quality control, it emphasizes the programme and evaluation

Main changes

- Reporting the results
 - All the reports shall be recorded as technical records
 - It makes clear that laboratory shall take the responsibility of all information in the report or certificate, except those information provided by the customer. The information provided by the customer shall be identified clearly, and if those information may affect the test results, it should make a disclaimer in the test report

Main changes

- Reporting the results
 - The language changing regarding the test report content:
 - Use contact information instead of customer address
 - When this is very important to the validness or application of results, except the receiving sample date, it may also need to include the sampling date
 - It does not need to give the title/position of authorized signatory, but it requires to identify the signatory clearly
 - Add the issuing date of the test report

Main changes

- Reporting the results
 - For the sampling report, it requests to include the uncertainty information
 - Delete “when a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory”
 - It requests the laboratory to consider the risk of Declaration of Conformity, it shall make it documental of decision rule.

Main changes

- Reporting the results
 - The opinions and interpretations shall be based on the results.
 - For the amended report, it shall state the amendment information
 - Delete the electronic transmission requirement in Clause 5.10.7 of ISO/IEC 17025:2015
 - Delete the test report format requirement in Clause 5.10.8 of ISO/IEC 17025:2015

Main changes

- Complaints
 - Significant changes in Complaints
 - It gives clear requirements on each step from deal with the complaint, evaluate the complaints, decisions of complaints and inform the Complainant
 - Based on ISO/CASCO

Main changes

- Control of nonconforming testing and/or calibration work
 - Almost the same as the Clause 4.9 of ISO/IEC 17025:2005

Main changes

- Data control
 - Comprehensive requirements
 - Most are from ISO 15189:2012

Main changes

- Management requirement
 - Most are from ISO 9001:2015
 - Give two ways: one is A (the laboratory does not establish ISO 9001 management system), another is B (the laboratory has established ISO 9001 management system)
 - Add Clause 8.5, introduce the risk and opportunity management requirement
 - Delete the detailed contents included in distribution of controlled documents, amendment of documents, and document identification

Main changes

- Management requirement
 - Delete the preventive actions, and incorporate it into the improvement
 - Delete the recommended internal audit period, and more the requirements of training and qualification of internal auditor to Personnel requirement.
 - Delete “the internal audit programme shall address all elements of the management system, including the testing and/or calibration activities”

Main changes

- Management requirement
 - Delete “it is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management”
 - Delete the requirement of auditor shall be independent of activities to be audited
 - Delete the additional audit
 - Delete the recommendation of management review period
 - Give detailed requirements to the output of management review

Main changes

- Management requirement
 - There are no substantive changes for corrective actions and improvement, but there are some changes on the expressions.

Thank you!





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