ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

新版ISO/IEC 17025标准的新变化

Contents

ISO/IEC 17025由来

- 1977检测实验室基本技术要求----ILAC

- ISO导则25:1978《实验室技术能力评审指南》（第一版）

- ISO/IEC导则25:1982《检测实验室基本技术要求》（第二版）
  ISO 9000: 1987 《质量管理和质量保证》
  EN 45001:1989《检测实验室运作的一般准则》

- ISO/IEC导则25:1990《校准和检测实验室能力的基本要求》（第三版）
  GB/T 15481-1995《校准和检测实验室能力的基本要求》

  ISO 9000:1994《质量管理和质量保证》
- ISO/IEC 17025:1999《检测和校准实验室能力的基本要求》（第一版）
  GB/T 15481-2000《检测和校准实验室能力的基本要求》

  ISO 9000: 2000 《质量管理体系要求》
- ISO/IEC 17025:2005《检测和校准实验室能力的基本要求》（第二版）
  GB/T 27025-2008《校准和检测实验室能力的基本要求》

  ISO 9001: 2015《质量管理体系要求》
- ISO/IEC 17025:2017《检测和校准实验室能力的基本要求》（第三版）

Why has ISO/IEC 17025 been revised?

- The last version of ISO/IEC 17025 was published in 2005 and, since then, market conditions and technology have changed. The new version covers technical changes, vocabulary and developments in IT techniques. It also takes into consideration the latest version of ISO 9001.

- ISO/IEC 17025的最后一个版本是在2005出版的，从那时起，市场条件和技术发生了变化。新版本涵盖了技术变化、词汇和IT技术的发展。它还考虑到ISO 9001的最新版本。

ISO 9001: 2015主要变化

——采用基于风险的思维；
——更少的规定性要求；
——对成文信息的要求更加灵活；
——提高了服务行业的适用性；
——更加强调组织环境；
——增强对领导作用的要求；
——更加注重实现预期的过程结果以增强顾客满意。

修订过程
Revision process

CASCO Working Group 44

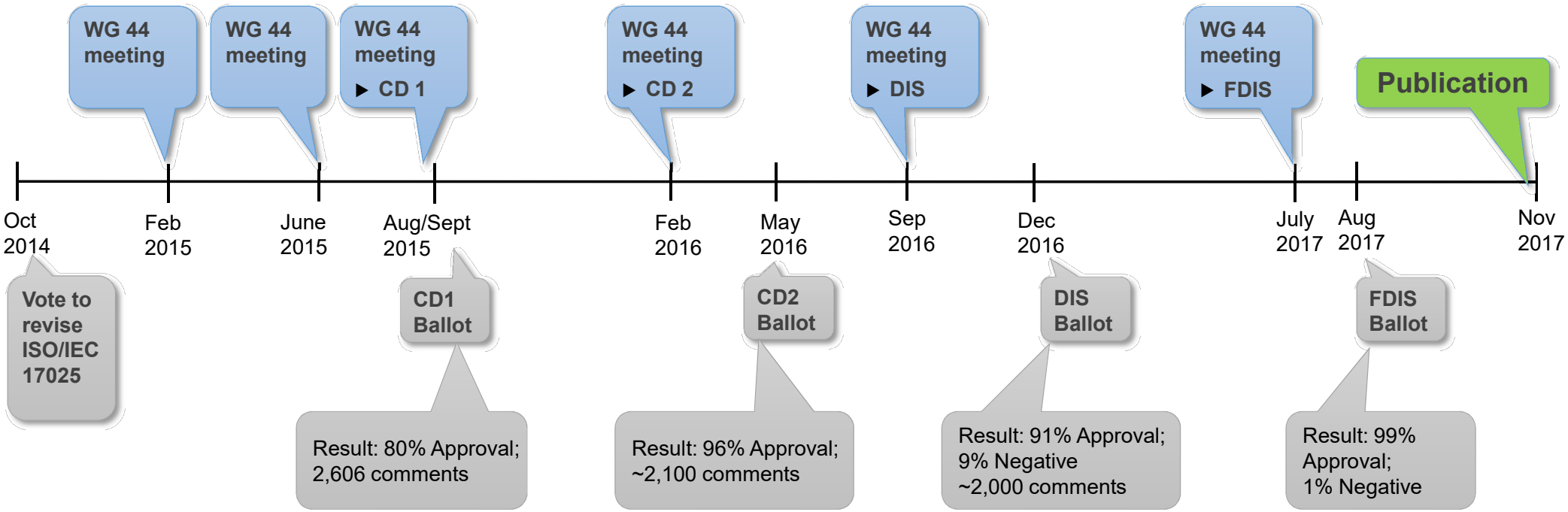
联合召集人 Co-Convenors	提名成员 Nominating Member:
Heribert Schorn	International Electrotechnical Commission (IEC)
Steve Sidney	South African Bureau of Standards
Warren Merkel	International Laboratory Accreditation Cooperation (ILAC)

~150 experts

- 129 Committee members 委员会成员
- 21 Liaison members 联络员

Fifth meeting of
Working Group 44
20-23 September 2016
ISO Headquarters, Geneva

修订时间表 Revision timeline



修订目标
Objectives of revision

修订目标 Objectives of revision

- 按照ISO/CASCO的要求，新版ISO/IEC 17025的结构框架必须满足“CASCO决议12/2002”的规定，相关表述必须满足CASCO内部文件QS-CAS-PROC/33《ISO/CASCO标准中的公共要素》的要求。

  与ISO 9001: 2015在管理要求上相协调。
- Align structure and content with other recently revised ISO standards
  - CASCO QS-CAS-PROC/33, Common elements in ISO/CASCO Standards
  - Other CASCO toolbox standards
  - ISO 9001:2015

修订目标 Objectives of revision

- 注重结果而非规定性要求，引入风险管理的要求，增加了对“判定规则”的要求；
- 更新语言以反映当前的实践和技术，采用新版术语标准，如 VIM；LIMS广泛使用，如电子采集数据和电子报告
- 尽可能保留2005版本的表述，简化主体内容，删除不必要的注和解释
- Focus on outcomes rather than prescriptive requirements
- Update language to reflect current practices and technologies
- Retain language from 2005 version whenever possible

主要变化
Main changes

主要变化Main changes

本标准所采用的基于风险的思路减少了一些具体的描述，并被以表现为基础提出的要求所取代；对于过程、程序、形成文件的信息和组织责任要求，比ISO/IEC 17025:2005更具有灵活性；重新定义实验室

From the Foreword of ISO/IEC 17025:2017:

- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- a definition of “laboratory” has been added.

主要变化Main changes

- 实验室的活动
  检测、校准、与后续检测或校准相关的抽样三种活动
- 不应包括持续从外部获得的实验室活动
- Scope of the standard: laboratory activities
  - Testing, calibration, sampling associated with subsequent testing or calibration
- Defined range of activities for laboratory
  - Excludes externally provided laboratory activities on an ongoing basis

主要变化Main changes

- 强调公正性，而不在意是否独立
- 过程导向
- 信息技术：考虑电子文档的风险、数据完整性、机密性、软件验证
- 计量溯源性
- 符合性声明的判定规则（通过/失败）
- Emphasis on “Impartiality” vs. “Independence”
- Process orientation
- Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents
- Metrological traceability
- Decision Rules for statements of conformity (pass/fail)

变化细节
Detailed review of changes and updates

New structure

1.范围 Scope

2.规范性引用文件 Normative references

3.术语和定义 Terms and definitions

4.通用要求 General requirements

5.结构要求 Structural requirements

6.资源要求 Resource requirements

7.过程要求 Process requirements

8.管理要求 Management requirements

附录A 计量溯源性 Annex A Metrological traceability

附录B 管理体系方式 Annex B Management system

1 范围Scope

本标准规定了实验室能力、公正性以及一致运作的通用要求。

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

本标准适用于所有从事实验室活动的组织，不论其人员数量多少。

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

实验室的客户、法定管理机构、采用同行评审的组织和制度、认可机构及其他机构使用本准则确认或承认实验室能力。

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

3术语和定义 Terms and definitions

[new or modified]

3.3实验室间比对 interlaboratory comparison

按照预先规定的条件，由两个或多个实验室对相同或类似的物品进行测量或检测的组织、实施和评价。

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3术语和定义 Terms and definitions

[new or modified]

3.4实验室内比对 **intralaboratory comparison**

按照预先规定的条件，在同一实验室（3.6）内部对相同或类似的物品进行测量或检测的组织、实施和评价。

organization, performance and evaluation of measurements or tests on the same or similar items, within the same laboratory (3.6), in accordance with predetermined conditions

[New, based on ISO/IEC 17043:2010 definition for “interlaboratory comparison”, which is included as 3.3 in ISO/IEC 17025:2017]

3术语和定义 Terms and definitions

[new or modified]

3.5能力验证 proficiency testing

利用实验室间比对，按照预先制定的准则评价参加者的能力。

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

3术语和定义 Terms and definitions

[new or modified]

3.6实验室 laboratory

从事下列一个或多个活动的机构body that performs one or more of the following activities:

—检测testing；

—校准calibration；

—与后续检测或校准相关的抽样sampling, associated with subsequent calibration or testing

注1：在本标准中，“实验室活动”指上述三种活动。

Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.

3术语和定义 Terms and definitions

[new or modified]

3.7判定规则decision rule

当声明与规定要求的符合性时，描述如何考虑测量不确定度的规则。

a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

4通用要求
General requirements

4.1公正性 Impartiality

- 相关表述必须满足CASCO内部文件QS-CAS-PROC/33《ISO/CASCO标准中的公共要素》的要求
- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- 实验室应持续识别影响公正性的风险。 如果识别出公正性风险，实验室应能够证明如何消除或最大程度减小这种风险。
- New/changed requirements:
  - Identifying and risks to impartiality on an on-going basis
  - Addressing risks to impartiality

4.2保密性 Confidentiality

- 相关表述必须满足CASCO内部文件QS-CAS-PROC/33《ISO/CASCO标准中的公共要素》的要求
- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- 强调客户意识；更关注可能影响保密性的特殊情况
- New/changed requirements:
  - Stronger emphasis on customer awareness
  - More detail regarding specific cases where confidentiality could be affected

5结构要求
Structural requirements

5结构要求Structural requirements

- 不再区分技术管理层和质量主管，保持相同的基本功能
- Removed terms “technical management” and “quality manager”
  - Retained same essential functions
- 实验室应以文件形式明确规定检测或校准活动的范围，实验室声明符合本标准的实验室活动不应包括持续从外部获得的实验室活动。
- Introduced requirement for laboratory to identify range of laboratory activities for which it conforms with ISO/IEC 17025
  - Restricts claims of conformity to the defined range
  - Excludes externally provided laboratory activities on an on-going basis

5结构要求Structural requirements

- 5.5 c)将程序形成文件的程度以确保实验室活动实施的一致性和结果有效性为原则。

  requires laboratory to “document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.”

  - Revised standard consistently uses term “procedure” when the intent is for laboratory to maintain documentation
  - The extend of detail in that documentation is up to the laboratory, subject to the conditions in 5.5 c)

6资源要求
Resource requirements

6.1总则General

实验室应获得管理和实施实验室活动所需的人员、设施、设备、系统及支持服务。

“The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities.”

- 使用“可用”一词表示修订中的一种方法，较少关注资源的状态或所有权，更多地关注这些资源的相关要求。
- Use of the term “available” indicates an approach in the revision to focus less on the status or ownership of resources and more on the relevant requirements for those resources
- Examples:
  - 6.2.1 refers to all personnel, internal or external
    [vs. 2005 version requiring personnel be employed by or under contract]
  - 6.4.1 requires laboratory to have access to equipment
  - [vs. 2005 version requiring laboratory be furnished with all items]

6.2人员 Personnel

- 修订中对术语和要求进行了更新和重组。ISO/IEC 17025:2017中对于人员的要求进行了适当的简化，删除了对人员培训的具体要求，不再区分在培员工、长期雇佣人员或签约人员，删除了对特定领域人员资格以及“意见或解释”人员的注释，以管理层取代“最高管理者”，不再区分技术管理层和质量主管，取消“指定关键管理人员的代理人”，删除了对工作描述中应包含内容的注释。
- Terminology and requirements have been updated and reorganized in the revision
- Otherwise, no significant changes to this clause compared to the 2005 version

6.3设施和环境条件 Facilities and environmental conditions

- 修订中对术语和要求进行了更新和重组，内容没有显著变化。
- ISO/IEC Terminology and requirements have been updated and reorganized in the revision
- Otherwise, no significant changes to this clause compared to the 2005 version

6.4设备Equipment

6.4.1 实验室应获得正确开展实验室活动所需的并能影响结果的设备(包括但不限于：测量仪器、软件、测量标准、标准物质、参考数据、试剂、消耗品或辅助装置)。

The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

- Description of items considered as equipment is more inclusive than in 2005 version
- Notes provide more information regarding reference materials

6.4设备Equipment

- 6.4.6在下列2种情况下，测量设备应进行校准： identifies two criteria that determine when calibration of equipment is requirement
  - 测量准确度或测量不确定度影响报告结果的有效性；和（或）

    the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
  - 为建立所报告结果的计量溯源性，要求对设备进行校准

    calibration of the equipment is required to establish the metrological traceability of the reported result.
- These criteria apply for all laboratory activities
  [2005 version had different requirements for calibration and testing]
- Metrological traceability addressed in a separate clause (6.5)
  [2005 version included calibration in the traceability clause]

6.5计量溯源性
Metrological traceability

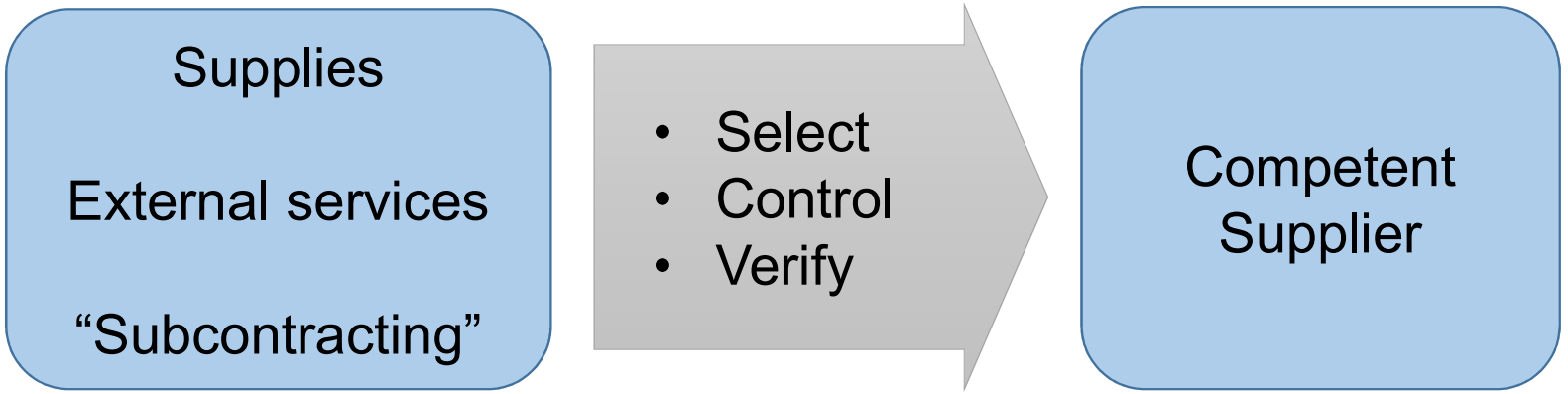
ISO/IEC 17025:2017用VIM第3版中的“计量溯源性”术语取代“测量溯源性”。

ISO/IEC 17025:2017从结果的计量溯源性角度提出要求，并且不再区分检测和校准活动，描述方式更为科学和严谨。

- Terminology and requirements have been updated in the revision to reflect current practice in traceability
- Reduced the number of Notes compared to 2005 version
- Additional explanatory information included in Annex A

6.6外部提供的产品和服务Externally provided products and services

- 将ISO/IEC 17025:2005中的4.5“检测和校准的分包”与4.6 “服务和供应品的采购”合并成一个条款
- Combines 4.5 Subcontracting and 4.6 Purchasing services and supplies from 2005 version
- In all cases, have requirements and controls
- Focuses on communication with customer



7过程要求
Process requirements

7.1要求、标书和合同的评审 Review of requests, tenders and contracts

- 7.1.3在合同评审时应做出与规范或标准符合性的声明
- 7.1.4客户要求的偏离不应影响实验室的诚信或结果的有效性。

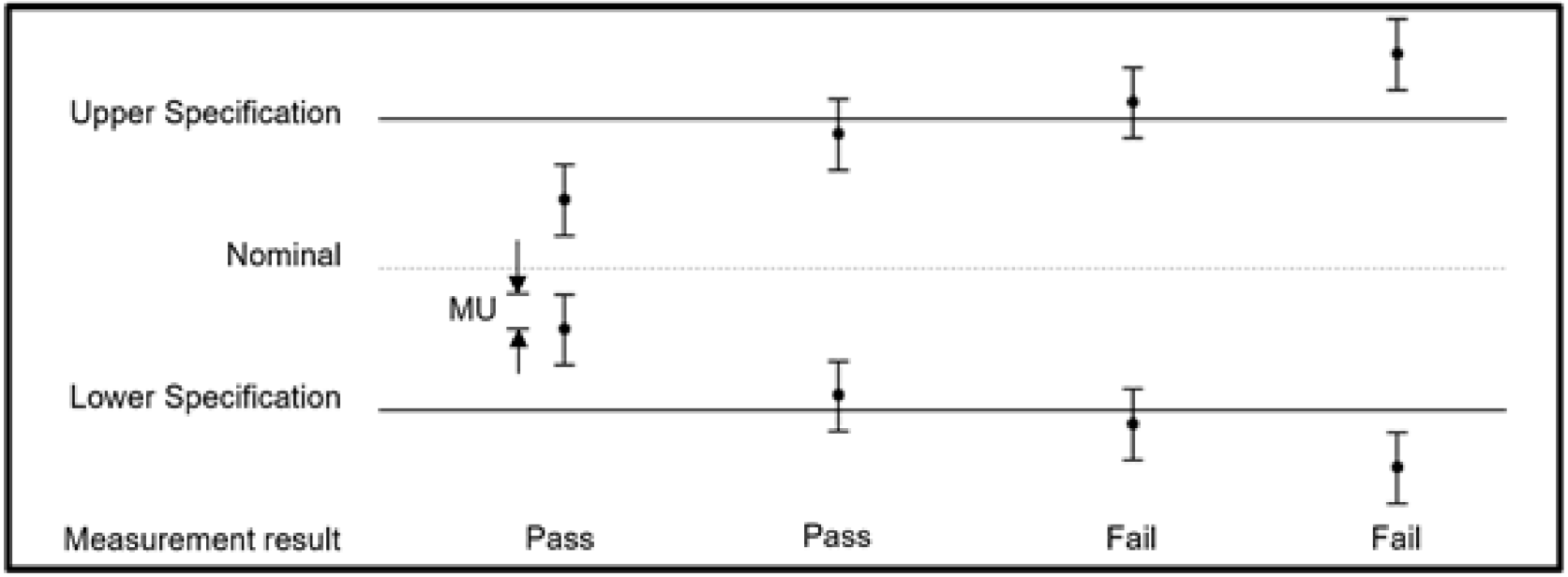
New/updated requirements

- 7.1.3 requires statements of conformity and associated decision rules be addressed during contract review
- 7.1.4 states that deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results

判定规则

- 本标准对“判定规则”的要求，也就是实验室在做与规范的符合性判断时，如何考虑测量不确定度，特别是结果的区间跨越了规定的限值，实验室如何做出“合格”或“不合格”的判断。在合同评审阶段，实验室应将使用的决定规则与客户沟通，并在合同中予以明确。在结果的报告中应指明所使用的决定规则，以便报告或证书的任何使用方了解实验室做出符合性结论时如何考虑测量不确定度的，使结果更加科学和透明。此条款对于实验室做出符合性声明提出了更严格的要求，可以料想这也是实验室在实施新版标准时遇到的难题，需要更多的研究和准备。

判定规则



MU = 95% expanded measurement uncertainty

合同评审 → 应用 → 报告

判定规则

- 增加了对“判定规则”的要求，也就是实验室在做与规范的符合性判断时，应该考虑测量不确定度，特别是某些检测结果的跨越了限值（超出限值）。
- 实验室做出“合格”或“不合格”的判断时，需要特别谨慎。

- 假设：
- (1)测量值：1.60 ppm
- (2)产品的限值（上限）：1.50 ppm
- PASS or Fail ??

判定规则

- 如果考虑测量不确定度：0.20 ppm :
- PASS: 1.60 -0.20=1.40 ppm
- Fail:　1.60+0.20=1.80ppm

实验室下什么结论？
结论【实验室不可能做出：不符合规范的判定】
但是，如果置信水平可以低于95%时，则有可能得出：不符合规范的声明。

报告符合性声明案例

样品: 玉米

检测标准：SN/T 2158 进出口食品中毒死蜱残留量检测方法

检测结果

报告中表述（仅供参考）

测试项目	CAS NO.	结果	判定
毒死蜱	2921-88-2	0.02 mg/kg	符合

测试项目	CAS NO.	结果	符合标准	使用判定规则	判定
毒死蜱	2921-88-2	0.02 mg/kg	GB 2763-2016 食品安全国家标准 食品中农药最大残留限量 4.90.4 最大残留限量：应符合表 90 的规定。 0.05mg/kg	SH-WI-001 检测结果判定规则	符合

7.2方法的选择、验证和确认 Selection, verification and validation of methods

- 修订中对术语和条款进行了更新和重组，内容没有显著变化。
- Terminology and organization of clause updated from 2005 version
- 7.2.1.1注：本标准所用“方法”可视为是ISO/IEC指南99定义的“测量程序”的同义词。
- Note after 7.2.1.1 clarifies that “method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99.

7.3抽样 Sampling

- 实验室的定义（3.6）阐明了抽样活动是与后续检测或校准相关的。
- Definition of laboratory (3.6) clarifies that the sampling activity is associated with subsequent testing or calibration
- Otherwise, no significant changes to this clause compared to the 2005 version

7.4检测或校准物品的处置Handling of test or calibration items

- 7.4.3 includes a new requirement:

  当客户知道偏离了规定条件仍要求进行检测或校准时，实验室应在报告中做出免责声明，说明偏离可能影响结果。

  “When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.”

- Otherwise, no significant changes to this clause compared to the 2005 version

7.5技术记录 Technical records

- 技术记录作为过程要求条款；管理体系记录见条款8，其他内容没有显著变化。
- Technical records placed in this clause as process requirements
- Other types of records (e.g., management system records) addressed in Clause 8
- Otherwise, no significant changes to this clause compared to the 2005 version

7.6测量不确定度的评定 Evaluation of measurement uncertainty

- 7.6.1实验室应识别测量不确定度的贡献。requires all laboratories to identify contributions to measurement uncertainty
- 7.6.2开展校准的实验室，包括校准自己的设备，应评定所有校准的测量不确定度。requires evaluation of measurement uncertainty for all calibrations, including those a laboratory performs on its own equipment (i.e. “in-house” calibrations)
- 7.6.3开展检测的实验室应评定测量不确定度。includes essentially the same requirements for evaluation of uncertainty for testing as the 2005 version
- Note 2 applies to all laboratories, and clarifies that a laboratory is not required to calculate a unique uncertainty every time a test or calibration is performed provided the stated conditions are met

7.7 确保结果的有效性 Ensuring the validity of results

- 分为内部监控和外部实验室比对。Clause separates requirements for monitoring done within the laboratory (7.7.1) and those involving comparison with other laboratories (7.7.2)
- 记录结果数据的方式应便于发现其发展趋势，如可行，应采用统计技术审查结果。Data from internal activities (7.7.1) required to be recorded such that trends can be detected and, where practicable, statistical techniques applied
- 实验室应对监控进行策划和审查，并用于控制和（如适用）改进实验室活动。Both required to be planned and reviewed, analyzed, used to control and (if applicable) improve laboratory activities
- 如果发现监控活动数据分析结果超出预定的准则时，应采取适当措施。Action required when results of analysis of data found to be outside pre-defined criteria

7.8报告结果Reporting of results

- New/updated requirements
  - 7.8.2.2当客户提供的信息可能影响结果的有效性时，报告中应有免责声明。addresses data provided by a customer, including a disclaimer when those data can affect validity of results
  - 7.8.5报告抽样reporting sampling
  - 7.8.6报告符合性声明 reporting statements of conformity

7.9投诉 Complaints

- 采用CASCO表述方式 Language taken from CASCO Procedure document(consistent with other conformity assessment standards)
- New/updated requirements
- 7.9.2利益相关方有要求时，应可获得对投诉处理过程的说明。requires a description of the complaints handling process be available to any interested party upon request
- 7.9.6与投诉人沟通的结果应由与所涉及的实验室活动无关的人员做出，或审查和批准。requires the outcomes to be communicated to the complainant be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question

7.10不符合工作 Nonconforming work

- 内容没有显著变化。
- No significant changes to this clause compared to the 2005 version

7.11数据控制和信息管理 Control of data and information management

- 2005版中5.4.7结合目前的实际进行了扩展和更新。Extends and updates 5.4.7 in the 2005 version to address current laboratory practice
- 7.11.2Note 1本准则中“实验室信息管理系统”包括计算机化和非计算机化系统中的数据和信息管理。clarifies that use of the term “laboratory information management system(s)” in this document includes both computerized and non-computerized systems
- 7.11.4当实验室信息管理系统在异地或外部供应商进行管理和维护，实验室应确保系统的供应商或运营商符合本标准的所有适用要求。requires laboratory to ensure that off-site or external providers of information management comply with applicable requirements of ISO/IEC 17025

8管理体系要求
Management system requirements

8.1方式 Options

- 提供了两种不同的选项（A或B）来建立管理系统。The revision now provides two distinct options (A or B) for establishing a management system
  - Option A: 实验室的管理体系至少应满足第8.2至第8.9条的要求。 As a minimum the management system of the laboratory shall address the requirements in clauses 8.2 to 8.9
  - Option B: 实验室按照 ISO9001 的要求建立并保持管理体系。Establish and maintain a management system in accordance with the requirements of ISO 9001
- 实验室持续满足本标准条款4至7要求并且保证实验室结果的质量。Both options require that the management system is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 clauses 4 to 7 and assuring the quality of the laboratory results.
- 实验室只需要符合其中的一个方式。Laboratories need only conform to one of the options (not both)

8.1 Options

8.1.2方式 A Option A

实验室管理体系至少应包括下列内容：

As a minimum the management system of the laboratory shall address the following:

Similar to 2005 version

- 管理体系文件（ management system documentation (see 8.2)
- 管理体系文件的控制control of management system documents (see 8.3)
- 记录控制control of records (see 8.4)

Aligned with ISO 9001:2015

- 应对风险和机遇的措施actions to address risks and opportunities (see 8.5) **New**
- 改进improvement (see 8.6)
- 纠正措施corrective action (see 8.7)
- 内部审核 internal audits (see 8.8)
- 管理评审management review (see 8.9)

8.5应对风险和机遇的措施Actions to address risks and opportunities

- 本标准中使用基于风险的思维 Revision incorporates “risked-based thinking”
- 标准引言和8.5.2注中包含2个要点 Introduction and Note after 8.5.2 include two important points:
  - 并未要求运用正式的风险管理方法或形成文件的风险管理过程。There is no requirement for formal methods for risk management or a documented risk management process
  - 实验室负责决定处理哪些风险和机会。The laboratory is responsible for deciding which risks and opportunities need to be addressed

内部审核要点

审核什么？

- 检测、校准活动
- 17025相关要求

审核依据？

- 检测或校准方法
- 17025和相关认可要求
- 体系文件

审核员资格？

- 被审核检测和校准活动专业背景
- 熟悉审核依据
- 审核技巧

8.9管理评审（方式A）
Management reviews (Option A)

- 8.9.2 实验室应记录管理评审的输入，并包括以下相关信息：
- The inputs to management review shall be recorded and shall include information related to the following:

a) 与实验室相关内外部因素的变化；

- changes in internal and external issues that are relevant to the laboratory;

b) 目标实现；fulfilment of objectives

c) 政策和程序的适宜性； suitability of policies and procedures

d) 以往管理评审的措施状况；

- status of actions from previous management reviews

e) 近期内部审核的结果； outcome of recent internal audits;

f) 纠正措施； corrective actions;

g) 由外部机构进行的评审； assessments by external bodies

8.9管理评审（方式A）
Management reviews (Option A)

h) 工作量和工作类型的变化或实验室活动范围的变化；

- changes in the volume and type of the work or in the range of laboratory activities;

i) 客户和员工的反馈； customer and personnel feedback;

j) 投诉； complaints;

k) 实施改进的有效性； effectiveness of any implemented improvements

l) 资源的充分性； adequacy of resources;

m) 风险识别的结果； results of risk identification

n) 保证结果有效性的输出；

- outcomes of the assurance of the validity of results; and

o) 其他相关因素，如监控活动和培训。

- other relevant factors, such as monitoring activities and training.

8.9管理评审（方式A）
Management reviews (Option A)

- **8.9.3 管理评审的输出应至少记录与下列事项有关的决定和措施：**
- The outputs from the management review shall record all decisions and actions related to at least:
  - **a) 管理体系及其过程的有效性；**
  - the effectiveness of the management system and its processes;
  - **b) 履行本标准要求的实验室活动的改进；**
  - improvement of the laboratory activities related to the fulfilment of the requirements of this document;
  - **c) 提供所需的资源；**
  - provision of required resources ;
  - **d) 变更的需求。**
  - any need for change.

检测或校准流程

- 对检测或校准过程控制

样品
/抽样

样品处理

设施/环境

质量控制

人员

测试方法

设备/溯源

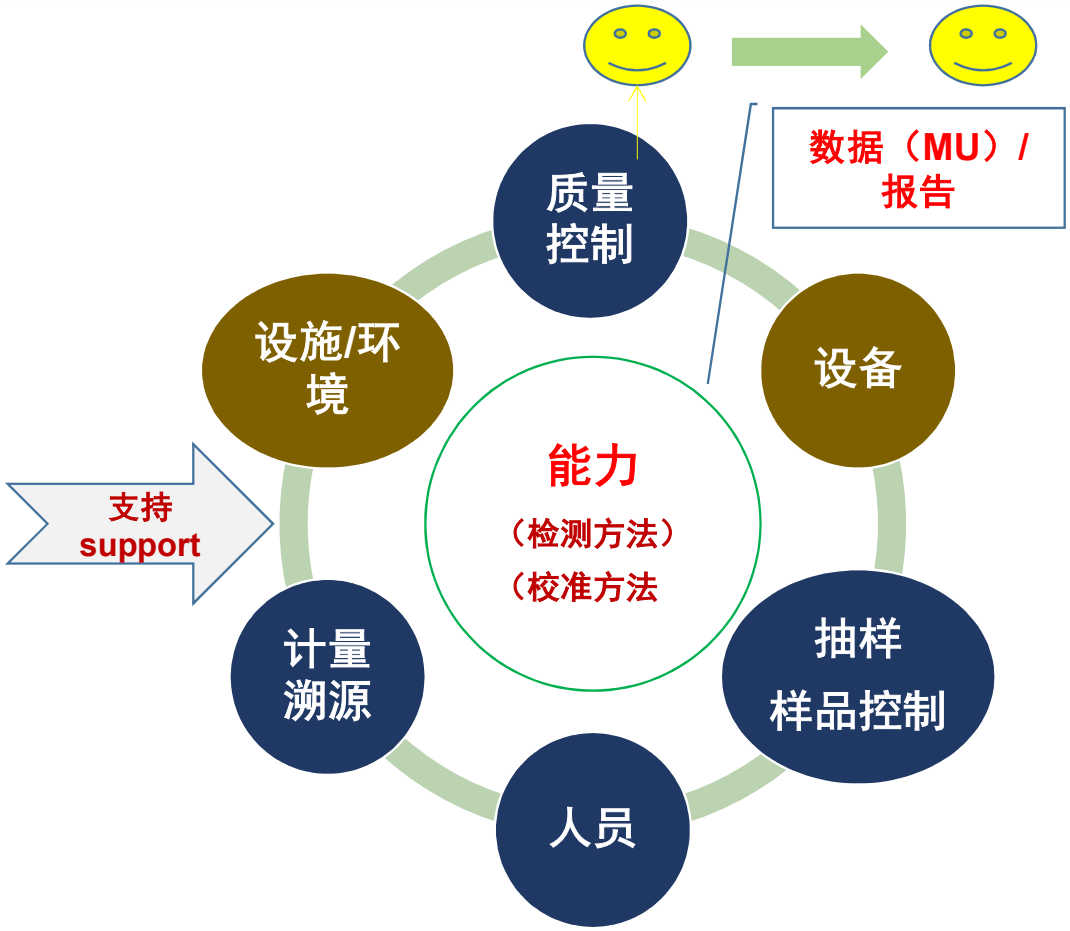
数据（MU）
报告/证书

对ISO/IEC 17025:2017要素的理解

质量管理体系

- 法律地位
- 公正性
- 保密性
- 合同
- 外部产品和服务
- 文件
- 记录
- 改进
- 不符合工作
- 纠正措施
- 风险分析
- 投诉
- 数据控制、信息管理
- 内审
- 管评

•••



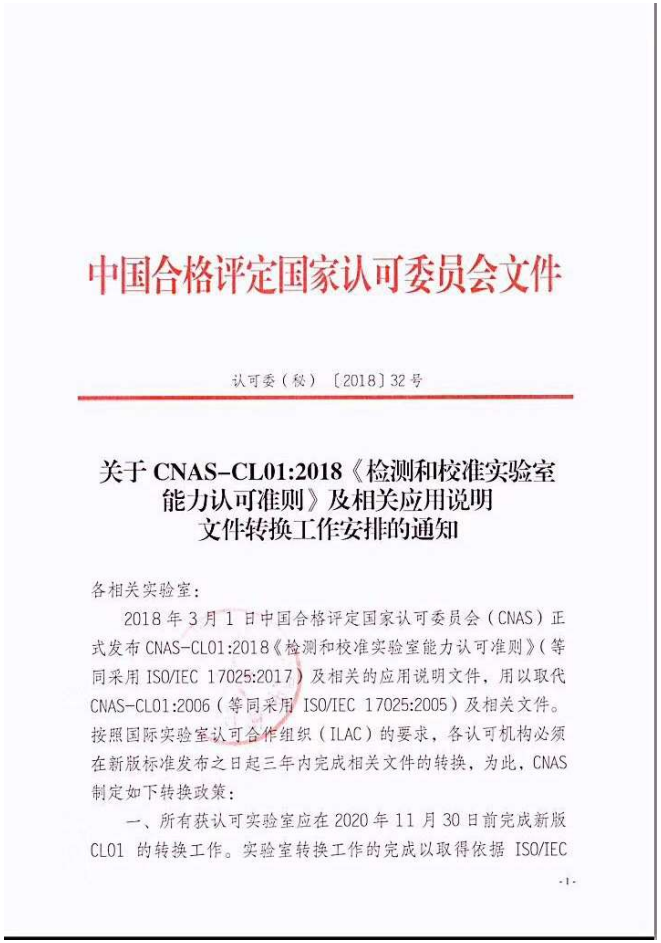
ISO/IEC 17025:2017标准回顾

- 文件的要素增加（由原来25个要素，增加到29个要素）；
- 文件要求更加灵活，实验室自由度更大，但不降低要求；
- 主要变化：
  1. 结构框架进行了调整；
  2. 将与ISO 9001关系的声明，放入附录A中；
  3. 引入风险管理的要求；
  4. 将“服务和供应品的采购”与“分包”合并；
  5. 增加了对“判定规则”的要求；
  6. 明确实验室应作出免责声明的情况；
  7. 对公正性和保密性要求进一步细化；
  8. 对投诉的处理过程给出明确要求；
  9. 报告和证书要求的变化；
  10. 内审和管理评审要求的变化。

ILAC的过渡转换政策

根据国际实验室认可合作组织（ILAC）的决议，新版ISO/IEC 17025的过渡转换期为自发布之日起三年。过渡期后，ILAC互认协议将不接受以ISO/IEC 17025:2005认可的实验室。

CNAS新版标准转换政策



中国合格评定国家认可委员会文件

认可委（秘）〔2018〕32号

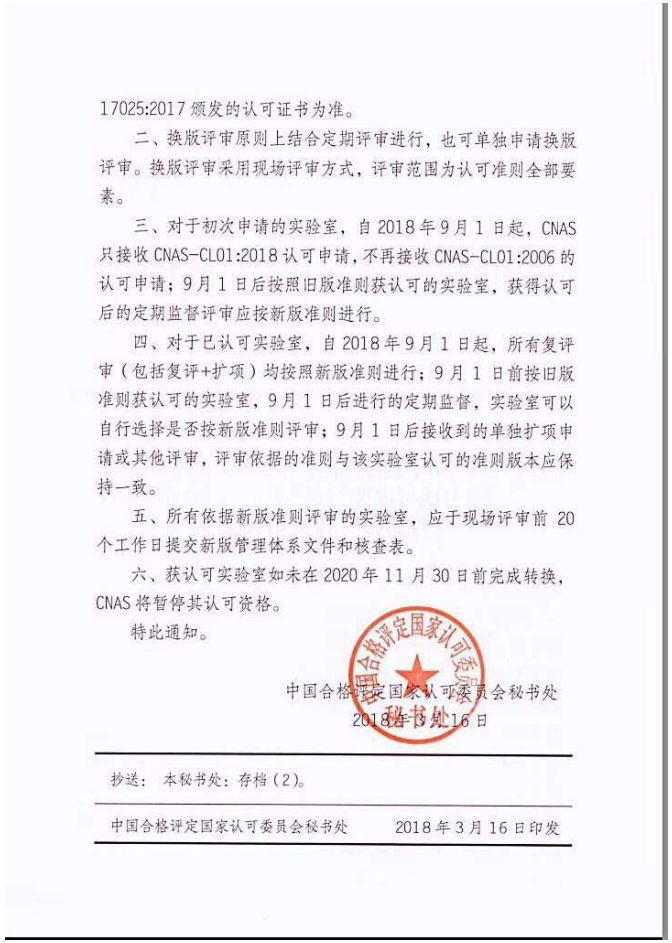
关于 CNAS-CL01:2018《检测和校准实验室能力认可准则》及相关应用说明文件转换工作安排的通知

各相关实验室：

2018 年 3 月 1 日中国合格评定国家认可委员会（CNAS）正式发布 CNAS-CL01:2018《检测和校准实验室能力认可准则》（等同采用 ISO/IEC 17025:2017）及相关的应用说明文件，用以取代 CNAS-CL01:2006（等同采用 ISO/IEC 17025:2005）及相关文件。按照国际实验室认可合作组织（ILAC）的要求，各认可机构必须在新版标准发布之日起三年内完成相关文件的转换，为此，CNAS 制定如下转换政策：

一、所有获认可实验室应在 2020 年 11 月 30 日前完成新版 CL01 的转换工作。实验室转换工作的完成以取得依据 ISO/IEC

-1-



17025:2017 颁发的认可证书为准。

二、换版评审原则上结合定期评审进行，也可单独申请换版评审。换版评审采用现场评审方式，评审范围为认可准则全部要素。

三、对于初次申请的实验室，自 2018 年 9 月 1 日起，CNAS 只接收 CNAS-CL01:2018 认可申请，不再接收 CNAS-CL01:2006 的认可申请；9 月 1 日后按照旧版准则获认可的实验室，获得认可后的定期监督评审应按新版准则进行。

四、对于已认可实验室，自 2018 年 9 月 1 日起，所有复评审（包括复评+扩项）均按照新版准则进行；9 月 1 日前按旧版准则获认可的实验室，9 月 1 日后进行的定期监督，实验室可以自行选择是否按新版准则评审；9 月 1 日后接收到的单独扩项申请或其他评审，评审依据的准则与该实验室认可的准则版本应保持一致。

五、所有依据新版准则评审的实验室，应于现场评审前 20 个工作日提交新版管理体系文件和核查表。

六、获认可实验室如未在 2020 年 11 月 30 日前完成转换，CNAS 将暂停其认可资格。

特此通知。

中国合格评定国家认可委员会秘书处

2018 年 3 月 16 日

抄送：本秘书处：存档（2）。

中国合格评定国家认可委员会秘书处　　2018 年 3 月 16 日印发

如何向新版标准过渡Actions of transfer to new standard

- 培训（可以是内部培训）
- 文件审核，识别差异
  - 补丁式或手册全新修改都可以接受
  - 评审时关注是否覆盖即可
  - SOP相对稳定，程序文件略修改
- 明确修改的文件清单、责任人、时限
- 审核或附加审核

考虑资质认定的要求

关注要点

- 切记：
  - 有些变动，并不一定需要实验室修改文件
  - 新版标准变得灵活，实验室依据按旧版运作，不应是不符合
    - 质量主管
    - 技术负责人
    - 内审周期
    - 代理人
    - 良好内务等等等

重点关注：
新要求如何覆盖，如何满足

感谢CNAS张明霞处长在微信群中提供的ISO发布的ISO/IEC 17025新旧版本差异对照ppt原文。

Thank you

For questions contact: gqyan@vip.sina.com

For additional resources visit the ISO page dedicated to ISO/IEC 17025,

or visit the CNAS page: www.cnas.org.cn; or visit the page: www.gqyan.com