ISO/IEC 17025: 2017

条款阐释

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ISO/IEC 17025: 2017

检测和校准实验室能力的通用要求

General requirements for the competence of testing and calibration laboratories

标准结构

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标准结构

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附录B (资料性)实验室管理体系

Annex B (informative) Management system in a laboratory

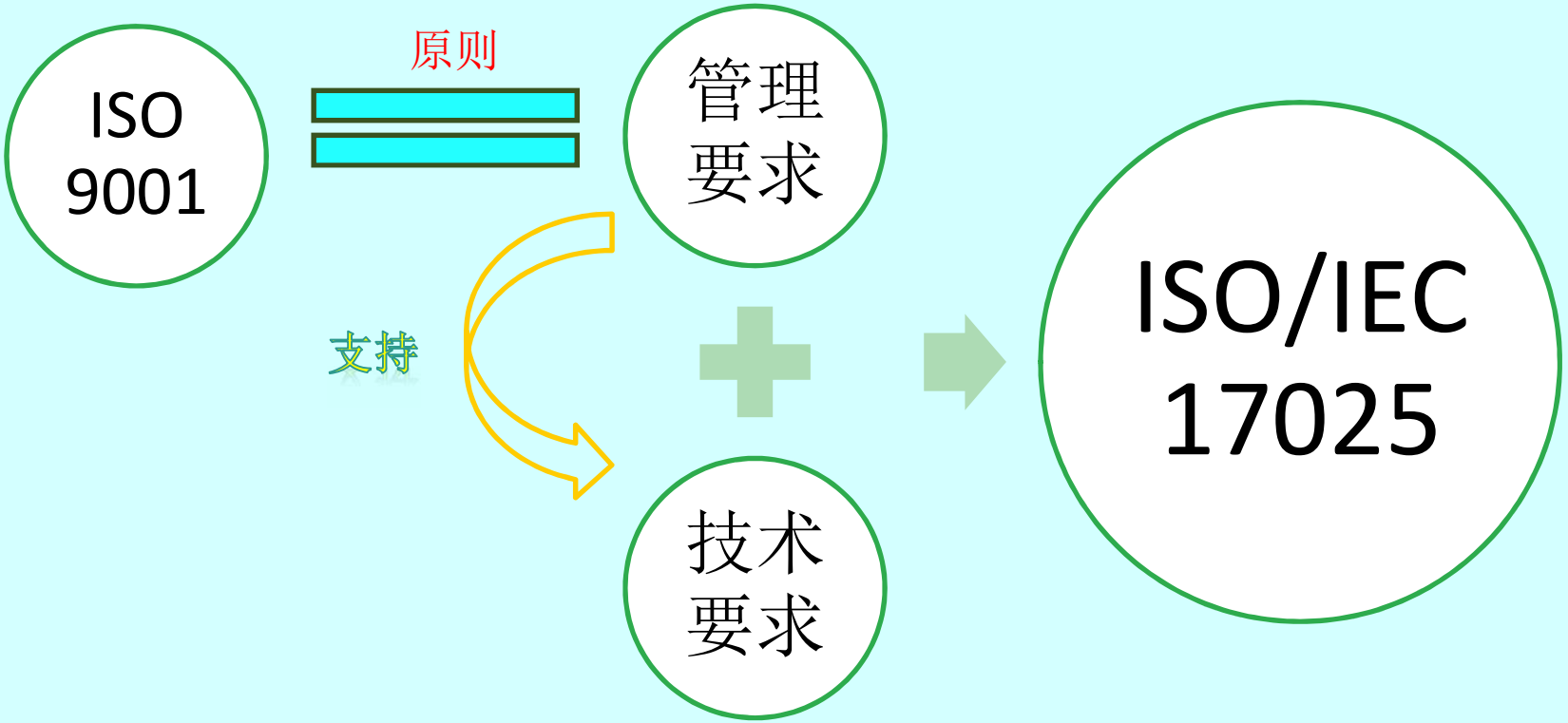
参考文件

Bibliography

前言forward

- 由于在本标准中使用基于风险的思维，因而一定程度上减少了规定性要求，并以基于表现（绩效、结果）的要求替代；
- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- 在过程、程序、成文信息和组织责任要求比前一版具有更大的灵活性；
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- 增加了“实验室”的定义（见3.6）
- a definition of “laboratory” has been added (see 3.6).

与ISO 9001关系

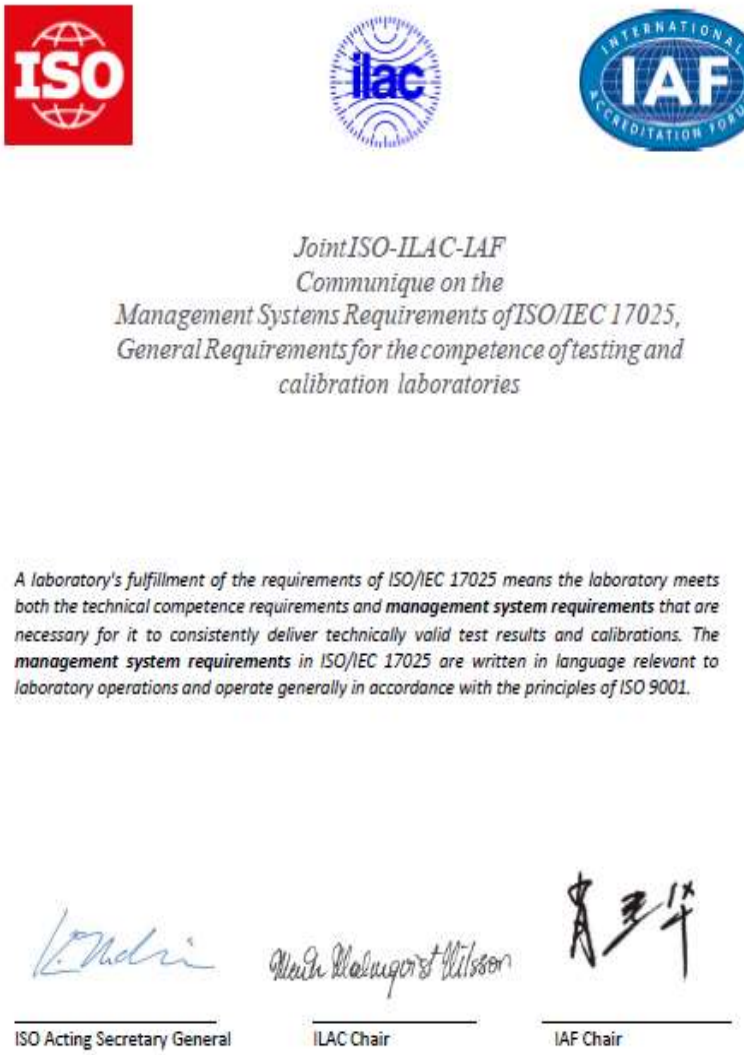


与ISO 9001:2015的关系
Relationship with ISO 9001: 2015

- 符合本标准的实验室也是基本按照ISO 9001的原则运作（前言）
- Laboratory conforming to this document will also operate generally in accordance with the principles of ISO 9001 （introduction)
- 实验室的管理体系仅符合ISO 9001并不能证明实验室具备出具技术有效的数据和结果的能力（附录B）
- Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the laboratory to produce technically valid data and results.

ISO-ILAC-IAF对于ISO/IEC 17025
管理体系要求的联合声明

- 实验室满足ISO/IEC 17025的要求意味着满足持续给出技术有效的检测和校准结果所需满足的技术能力要求和管理体系要求。
- ISO/IEC 17025中的管理体系要求的语言表述更贴近实验室运作来起草，并基本按ISO 9001原则运行。



Joint ISO-ILAC-IAF
Communique on the
Management Systems Requirements of ISO/IEC 17025,
General Requirements for the competence of testing and calibration laboratories

*A laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and **management system requirements** that are necessary for it to consistently deliver technically valid test results and calibrations. The **management system requirements** in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001.*

ISO Acting Secretary General　　ILAC Chair　　IAF Chair

April 2017

1.范围　Scope

- 本标准规定了实验室的能力、公正性和持续运作的通用要求。
- This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.
- 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.

实验室活动包括:检测、校准和与后续检测或校准相关的抽样。

1.范围　Scope

- 实验室客户、法定管理机构、使用同行评审的组织和制度、认可机构以及其他机构可使用本标准来确认或承认实验室的能力。
- 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.

1.范围　Scope

删除

- 1.1 这些检测和校准包括应用标准方法、非标准方法和实验室制定的方法进行的检测和校准。
- 1.2 包括诸如第一方、第二方和第三方实验室，以及将检测和/或校准作为检验和产品认证工作一部分的实验室。

1.范围　Scope

删除

- 1.2 当实验室不从事本标准所包括的一种或多种活动，例如抽样和新方法的设计（制定）时，可不采用本标准中相关条款的要求。
- 1.3 本标准中的注是对正文的说明、举例和指导。它们既不包含要求，也不构成本准则的主体部分。
- 1.4 本标准用于实验室建立质量、行政和技术运作的管理体系。本标准并不意图用作实验室认证的基础。
  - 注1：术语“管理体系”在本标准中是指控制实验室运作的质量、行政和技术体系。
  - 注2：管理体系的认证有时也称为注册。

1.范围　Scope

删除

- 1.5 本标准不包含实验室运作中应符合的法规和安全要求
- 1.6
- 注 1：为确保这些要求应用的一致性，或许有必要对本准则的某些要求进行说明或解释。
- 注 2：如果实验室希望其部分或全部检测和校准活动获得认可，应当选择一个依据ISO/IEC 17011 运作的认可机构。

2.规范性引用文件
Normative references

没变化

- ISO/IEC Guide 99，国际计量术语—基本和通用概念以及相关术语（VIM)
- ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
- ISO/IEC 17000，合格评定—术语和通用原则
- ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 术语和定义
Terms and definitions

- ISO/IEC指南99和ISO/IEC 17000中界定的以及下述术语和定义适用于本标准。[1)]
- For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.
- ISO和IEC维护的用于标准化的术语数据库地址如下：
- ISO and IEC maintain terminological databases for use in standardization at the following addresses:
- — ISO 在线浏览平台: http://www.iso.org/obp
  - ISO Online browsing platform: available at https:// www .iso .org/ obp
- — IEC 电子开放平台: http://www.electropedia.org/
  - IEC Electropedia: available at http:// www .electropedia .org/

3 术语和定义
Terms and definitions

- ISO/IEC 17025:2005

删除

- 注：ISO 9000 规定了与质量有关的通用定义，ISO/IEC 17000 则专门规定了与认证和实验室认可有关的定义。若ISO 9000 与ISO/IEC 17000 和VIM 中给出的定义有差异，优先使用ISO/IEC 17000 和VIM 中的定义。

3 术语和定义
Terms and definitions

- 3.1 公正性 Impartiality (ISO/IEC 17021-1:2015, 3.2)
  - 客观性的存在。
  - presence of objectivity
  - 注1：客观性意味着不存在或已解决利益冲突，不会对实验室（3.6）的活动产生不利影响。
  - Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).
  - 注2：其他可用于表示公正性的要素的术语有：无利益冲突、没有成见、没有偏见、中立、公平、思想开明、不偏不倚、不受他人影响、平衡。
  - Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.
  - [源自: ISO/IEC 17021-1:2015, 3.2，修改—在注1中以“实验室”代替“认证机构”,并在注2中删除了“独立性”。]

3 术语和定义
Terms and definitions

- 3.2投诉 **Complaints**（ISO 17000:2004, 6.5）
  - 新版为什么没有申诉？
  - 任何人员或组织向实验室（3.6）就其活动或结果表达不满意，并期望得到回复的行为。
  - [源自: ISO 17000:2004, 6.5 修改—删除了“除申诉外”，以“实验室就其活动或结果”代替“合格评定机构或认可机构就其活动”]

3 术语和定义
Terms and definitions

- 3.3 实验室间比对 Interlaboratory comparison
  - ISO/IEC 17043:2010, 3.4
  - 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.
- 3.4 实验室内比对 Intralaboratory comparison **[NEW]**
  - 按照预先规定的条件，在同一实验室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.

3 术语和定义
Terms and definitions

- 3.5 能力验证 **proficiency testing**（ISO/IEC 17043:2010, 3.7）
  - 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)

3 术语和定义
Terms and definitions

- 3.6 实验室 **laboratory** **[NEW]**
  - 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 testing or calibration
  - 注：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

- 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。
  - **rule that describes how measurement uncertainty is accounted for when stating conformity with a specified rquirement.**

定性分析？

3 术语和定义
Terms and definitions

- 3.8 验证 verification (VIM)【ISO/IEC 指南99:2007，2.44】
  - 提供客观证据证明给定项目满足规定要求。
  - provision of objective evidence that a given item fulfils specified requirements

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在新版标准中哪些条款用到了验证？

----方法验证
----设备验证
----投诉信息验证

- 例1：证实在测量取样量小至10mg时，对于相关量值和测量程序，给定标准物质的均匀性与其声称的一致。
- 例2：证实已达到测量系统的性能特性或法定要求。
- 例3：证实可满足目标测量不确定度。
- 注1：适用时，宜考虑测量不确定度。
- 注2：项目可以是，例如一个过程、测量程序、物质、化合物或测量系统。
- 注3：满足规定要求，如制造商的规范。
- 注4：在国际法制计量术语（VIML）中定义的验证，以及通常在合格评定中的验证，是指对测量系统的检查并加标记和（或）出具验证证书。在我国的法制计量领域，“验证”也称为“检定”。
- 注5：验证不宜与校准混淆。不是每个验证都是确认（3.9）。
- 注6：在化学中，验证实体身份或活性时，需要描述该实体或活性的结构或特性。
- [源自: ISO/IEC 指南99:2007，2.44]

3 术语和定义
Terms and definitions

- 3.9 确认 validation (VIM)【ISO/IEC 指南99:2007，2.45】
  - *verification* (3.8), where the specified requirements are adequate for an intended use
  - 对规定要求满足预期用途的验证（3.8）。

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在新版标准中哪些条款用到了确认？

----方法确认

----信息管理系统的确认

----投诉中用的“确认”==confirm, 不是validate

4.通用要求
General requirements

- 4.1 公正性 **Impartiality**
- 4.2 保密性 **Confidentiality**
- 规定语言：ISO/CASCO PROC/33 《ISO/CASCO标准中的通用要求》
- Mandatory wording: ISO/CASCO PROC/33 General requirements in ISO/CASCO standards

4.1 公正性 Impartiality 4.1.5b

- 4.1.1 实验室应公正地实施实验室活动，并从结构和管理上保证公正性
- Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.
- 4.1.2 实验室管理层应做出公正性承诺（新）
- The laboratory management shall be committed to impartiality.
- 4.1.3 实验室应对其活动的公正性负责，不允许商业、财务或其它方面的压力损害公正性
- The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality .

4.1.5.b) 有措施确保其管理层和员工不受任何对工作质量有不良影响的、来自内外部的不正当的商业、财务和其他方面的压力和影响；

4.1 公正性Impartiality

- 4.1.4 实验室应持续识别公正性的风险。这些风险应源于其活动、实验室各种关系或实验室人员关系。然而，这些关系并非一定会对实验室的公正性产生风险。（新） 4.1.5 d
- The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

4.1 公正性 Impartiality

- 注：危及实验室公正性的关系可能基于所有权、控制权、管理、人员、共享资源、财务、合同、市场营销（包括品牌）、支付销售佣金或其它引荐新客户的奖酬等。[新]
- NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1 公正性Impartiality

4.1.5 d

- 4.1.5 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
- If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 保密性
Confidentiality

4.1.5c

- 4.2.1 实验室应通过做出具有法律效力的承诺，对在实验室活动中获得或产生的信息承担管理责任。实验室应将其准备公开的信息事先通知客户。除非客户公开的信息，或实验室与客户有约定（例如：为回应投诉的目的），其他所有信息都被视为专属信息，应予保密。
- The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2 保密性Confidentiality

- 4.2.2 实验室依据法律要求或合同授权透露保密信息时，除法律禁止外，所提供的信息应通知到相关客户或个人。（新）
- When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2 保密性Confidentiality

- 4.2.3 从客户以外渠道（如投诉者、监管机构）获得有关客户的信息，应在客户和实验室间保密。除非信息的提供方同意，实验室不应告知客户信息的提供方（来源）。[新]
  - 可以选择通知或不通知实验室
- Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2 保密性Confidentiality

4.1.5 c

- 4.2.4 人员，包括委员会成员、合同方、外部机构人员或代表实验室的个人，应对实施实验室活动过程中获得或产生的所有信息保密，法律要求除外。
- Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

哪些合同方可能接触客户信息？
如LIMS系统开发程序员等

5 结构要求
Structural requirements

4.1

- 5.1 实验室应为法律实体，或法律实体中被明确界定的一部分，该实体为实验室活动承担法律责任。
- The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.
- ==========
- 注：在本标准中，政府实验室基于其政府地位被视为法律实体。
- NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5 结构要求
Structural requirements

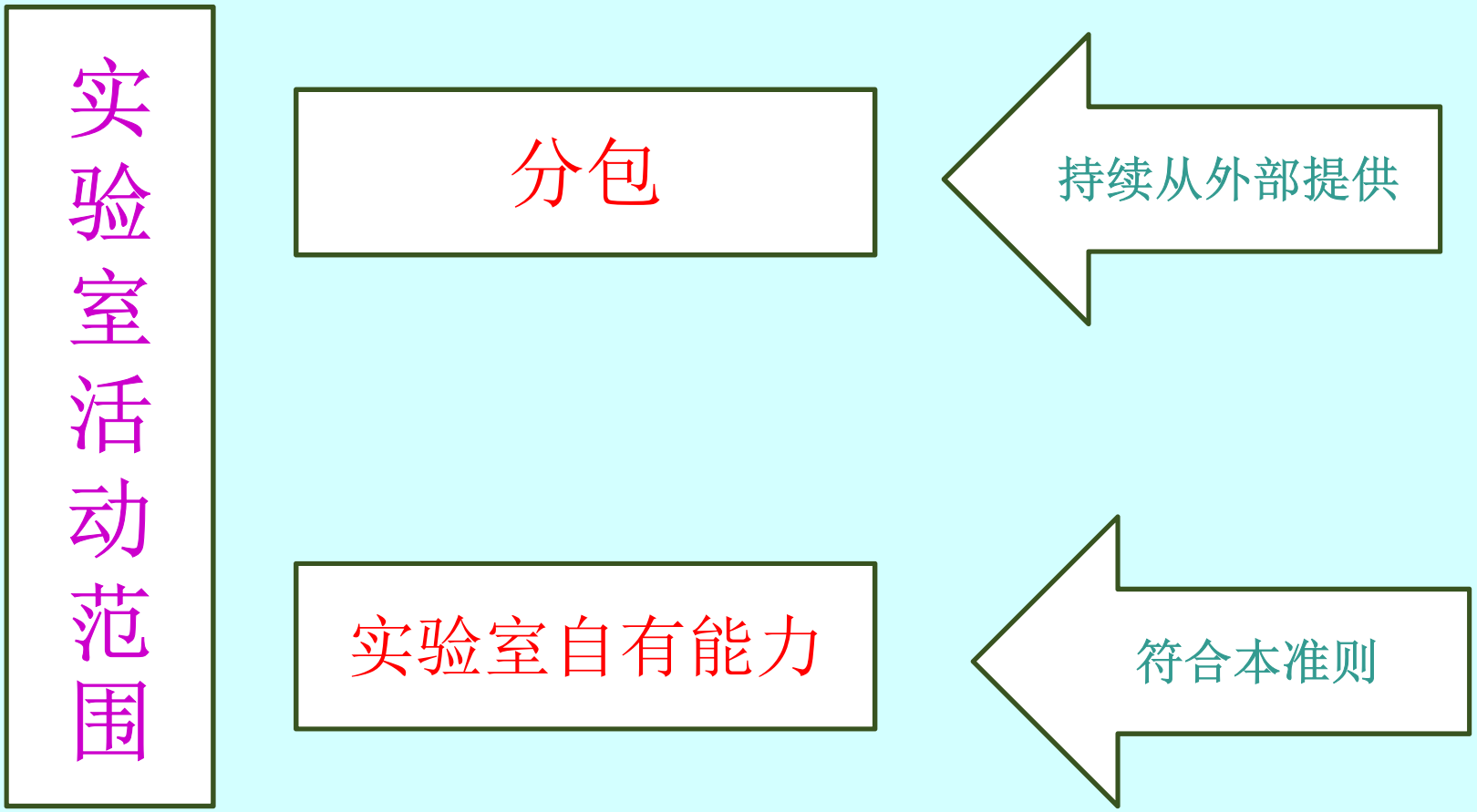
- 5.2 实验室应确定对实验室全权负责的管理层。
- The laboratory shall identify management that has overall responsibility for the laboratory.

不再使用“最高管理者”

5 结构要求Structural requirements

- 5.3 实验室应规定符合本标准的实验室活动范围并制定文件。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。[新]
- The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. (NEW)

实验室活动范围



5 结构要求Structural requirements

4.1.2/3

- 5.4 实验室应以满足本标准、实验室客户、法定管理机构和提供承认的组织要求的方式开展活动，这包括实验室在固定设施内、固定设施以外的地点，或在相关临时或移动设施内、客户的设施中实施的实验室活动。
- Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5 结构要求Structural requirements

4.1.5 e

- 5.5 实验室应 The laboratory shall: ：
  - a)确定实验室的组织和管理结构，其在母体组织中的位置，以及管理、技术运作和支持服务间的关系；
- define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

5 结构要求Structural requirements

4.1.5 f

- b)规定对实验室活动结果有影响的所有管理、操作或验证人员的职责、权力和相互关系;
- specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- c)将程序制定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。
- document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

4.2.1

5 结构要求Structural requirements

4.1.5 a

- 5.6 实验室人员应具有履行职责所需的权利和资源（不论其他职责），包括：
- The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:
  - a)实施、保持和改进管理体系；
  - implementation, maintenance and improvement of the management system;
  - b)识别与管理体系或实验室活动程序的偏离；
  - identification of deviations from the management system or from the procedures for performing laboratory activities;

5 结构要求Structural requirements

- c)采取预防或最大程度减少这类偏离的措施;
- initiation of actions to prevent or minimize such deviations; 4.1.5 a
- d)向实验室管理层报告管理体系运行状况和改进需求;
- reporting to laboratory management on the performance of the management system and any need for improvement; 4.1.5 i
- e)确保实验室活动的有效性。
- ensuring the effectiveness of laboratory activities. 4.1.5 h

不再使用：
- 管理人员和技术人员
- 质量主管
- 技术管理者

内容没有显著变化

删除：指定关键管理人员的代理人

5 结构要求Structural requirements

4.1.6
4.2.4

- 5.7 实验室管理层应确保
- Laboratory management shall ensure that：
  - a）针对管理体系有效性、满足客户和其他要求的重要性进行沟通。
  - communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
  - b）当策划和实施管理体系的变更时，保持管理体系的完整性；

4.2.7

  - the integrity of the management system is maintained when changes to the management system are planned and implemented.

6 资源要求Resource requirements

- 6.1 总则 **General**
- 6.2 人员 **Personnel**
- 6.3 设施和环境条件
  - **Facilities and environmental conditions**
- 6.4 设备 **Equipment**
- 6.5 计量溯源性 **Metrological traceability**
- 6.6 外部提供的产品和服务
  - **Externally provided products and services**

6.1 总则General

5.1.1

- 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 manage and perform its laboratory activities.

6.2 人员Personnel

5.2.1
5.2.3

- 6.2.1 所有可能影响实验室活动人员，无论是内部人员还是外部人员，应行为公正、有能力，并按照实验室管理体系要求工作。
- All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

人员包含：　　取消
- 在培人员
- 雇佣或签约人员

如何理解外部人员：
包括下列人员吗？
设备设施安装、调试、修理人员,软件安装维护人员、评审和内审人员,现场校准人员等

6.2 人员Personnel

5.2.1
5.2.2

- 6.2.2 实验室应将影响实验室活动结果的各职能的能力要求制定成文件，包括对教育、资格、培训、技术知识、技能和经验等要求。
- The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

简化培训要求，删除细节要求：
- 培训的政策和程序； 培训计划与任务适应；培训有效性评价

6.2 人员Personnel

5.2.1

- 6.2.3 实验室应确保人员具备其负责的实验室活动的能力，并能评价偏离的重要程度。
- The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

删除**5.2.1**中的注：

- 资格证书（法定的，标准包含的，客户指定）
- 意见和解释人员

6.2 人员Personnel

5.2.4

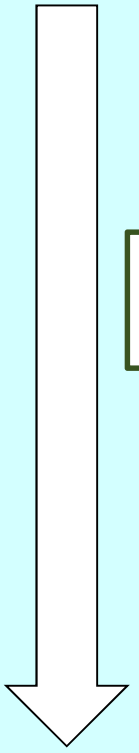
- 6.2.4 实验室管理层应与实验室人员就其职责、责任和权限进行沟通。
- The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

- 未使用“工作描述”一词
- 取消了对工作描述的注释（**5.2.4**注）

6.2 人员Personnel

5.2.5
5.2.2/3

- 6.2.5 实验室应有以下活动的程序和记录：
- The laboratory shall have procedure(s) and retain records for:
  - a) 确定能力要求(5.2.1)
  - determining the competence requirements
  - b) 人员选择
  - selection of personnel
  - c) 人员培训(5.2.2)
  - training of personnel
  - d) 人员监督(5.2.1)
  - supervision of personnel
  - e) 人员授权(5.2.5)
  - authorization of personnel
  - f) 人员能力监控(5.2.3)
  - monitoring of competence of personnel



人员管理流程

监督/监控

- 人员监督
  - 新人员，新授权之前，新项目运行
- 人员能力监控（授权以后）
  - 能力： 会且准，执行文件
  - 必须使用风险分析，建立监控方案
  - 技术复杂性、方法稳定性、人员经验、专业教育、客户现场、工作量、各种变动
  - 措施：
    - 现场见证，调阅记录，审核/批准报告，结合质控（盲样，内部质控结果，外部比对/PT）

6.2 人员Personnel

5.2.5

- 6.2.6 实验室应授权人员从事特定的实验室活动，包括但不限于：
- The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:
  - a) 开发、修改、验证和确认方法
  - development, modification, verification and validation of methods;

6.2 人员Personnel

- b) 分析结果，包括符合性声明或意见和解释
- analysis of results, including statements of conformity or opinions and interpretations;
- c) 报告、审查和批准结果
- report, review and authorization of results.

取消操作特定类型设备

如何授权？授权形式？
6.2.4是相关条款

6.3 设施和环境条件
Facilities and environmental conditions

5.3.1
5.3.2

- 6.3.1 设施和环境条件应适合于实验室活动，不应对结果有效性产生不利影响。
- The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results
- ==========
- 注：对结果有效性有不利影响的因素包括但不限于：微生物污染、灰尘、电磁干扰、辐射、湿度、供电、温度、声音和振动。
- NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3 设施和环境条件
Facilities and environmental conditions

- 6.3.2 应将从事实验室活动所必需的设施及环境条件要求制定成文件。
- The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented

5.3.1

6.3 设施和环境条件
Facilities and environmental conditions

5.3.2

- 6.3.3 当相关规范、方法或程序对环境条件有要求时，或环境条件影响结果的有效性时，实验室应监测、控制和记录环境条件。
- The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

环境条件的要求——来自标准，若标准无要求，可考虑专业通用标准要求（如洁净室、恒温恒湿区域环境条件规范要求等），或特殊的设备所要求的环境条件。
环境条件的记录——真实、客观、准确和可追溯，并与原始记录同条件、同时期保存，也是原始记录的一部分。

6.3 设施和环境条件
Facilities and environmental conditions

5.3.4/5.3.3

- 6.3.4 应实施、监控并定期评审控制设施的措施，包括但不限于：
- Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:
  - a)进入和使用影响实验室活动的区域
  - access to and use of areas affecting laboratory activities;
  - b)预防对实验室活动的污染、干扰或不利影响
  - prevention of contamination, interference or adverse influences on laboratory activities;
  - c)有效隔离不相容实验室活动区域
  - effective separation between areas with incompatible laboratory activities.

6.3 实验室设施和环境条件
Facilities and environmental conditions

5.3.1

- 6.3.5 当实验室在永久控制之外的地点或设施中从事实验室活动时，应确保满足本标准中有关设施及环境条件的要求。
- When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

删除 **delete**

- 应采取措施确保实验室的良好内务，必要时应制定专门的程序。
- Measures shall be taken to ensure good housekeeping in the laboratory.

  Special procedures shall be prepared where necessary.
- 当环境条件危及检则和（或）校准结果时，应停止检测和校准（6.3.1覆盖）

6.4 设备
Equipment

5.5.1

- 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)。[new]
- 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. [new]

6.4 设备
Equipment

- 注1 标准物质和有证标准物质有多种名称，包括标准样品、参考标准、校准标准、标准参考物质和质量控制物质。ISO 17034给出了标准物质生产者的其他信息。满足ISO 17034要求的标准物质生产者被认为是有能力的。满足ISO17034要求的标准物质生产者生产的标准物质会提供产品信息单/证书，除其他特性外至少包含规定特性的均匀性和稳定性，对于有证标准物质，信息中包含规定特性的标准值、相关的测量不确定度和计量溯源性。[new]

  NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability. [new]

6.4 设备
Equipment

new

- 注2： ISO指南33给出了标准物质选择和使用的指南。ISO指南80给出了内部制备质量控制物质的指南。
  - NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in house quality control materials.

6.4 设备Equipment

5.5.1

- 6.4.2 在实验室使用永久控制之外的设备时，应确保满足本标准对设备的要求
- When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

（客户的设备）

租借(租赁)设备本条控制？--No

6.4 设备Equipment

5.5.6

- 6.4.3 实验室应有处理、运输、储存、使用和按计划维护设备的程序，以确保其功能正常运行并防止污染或性能退化。
- The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4 设备Equipment

5.5.2

- 6.4.4在设备投入使用或重新投入使用前，实验室应验证其符合规定的要求。
- The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. back

设备投入使用——新设备安装调试完毕（可能与验证同时进行）
设备重新投入使用——故障设备修复后、设备搬迁移动后、设备脱离实验室控制后、设备校准返回后,实验室以外人员使用过的设备,长期停用的设备等
规定的要求——标准的要求、设备特性的要求、量值溯源的要求……
验证的手段——校准/检定、核查（检测、比对）等……
为了验证的有效实施，实验室应编制相应的文件，明确验证的步骤和验证结论的评价方法。----有相应的记录，标准本身没有要求一定形成文件，但总有些是意外的情况。必要时形成文件。评审时关注记录。

- **2005：*核查或校准 Check or calibrate***

6.4 设备 Equipment

5.5.2

- 6.4.5 用于测量的设备应能够达到所需的测量准确度和（或）测量不确定度，以提供有效的结果。
- The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4 设备Equipment

5.5.2

- 6.4.6 在下列情况下，测量设备应进行校准：
- Measuring equipment shall be calibrated when:
  - 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, and/or
  - 为建立所报告结果的计量溯源性，要求对设备进行校准 【new】
  - calibration of the equipment is required to establish the metrological traceability of the reported result. 【new】

6.4 设备
Equipment

- 注：影响报告结果有效性的设备类型可包括：
  - 用于直接测量被测量的设备，例如使用天平测量质量；
  - 用于修正被测量值的设备，例如温度测量；
  - 用于从多个量计算获得测量结果的设备
- NOTE Types of equipment having an effect on the validity of the reported results can include:
  - those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;
  - those used to make corrections to the measured value, e.g. temperature measurements;
  - those used to obtain a measurement result calculated from multiple quantities.

新

6.4 设备Equipment

5.5.2

- 6.4.7 实验室应制定校准方案，并进行复审和必要的调整，以保持对校准状态的信心。
- The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4 设备Equipment

5.5.8

- 6.4.8所有需要校准或具有规定有效期的设备应使用标签，编码或以其他方式标识，方便设备使用人能够迅速识别校准状态或有效期。
- All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

- 不再强调包括上次校准的日期、再校准或失效日期

6.4 设备Equipment

5.5.7

- 6.4.9如果设备有过载或处置不当、给出可疑结果、或已显示有缺陷或超出规定限度时，应停止使用。这些设备应予以隔离以防误用，或加贴标签或标记以清晰表明该设备已停用，直至经过验证表明能正常工作。实验室应核查缺陷或偏离规定要求的影响，并应启动对不符合工作管理程序（见7.10）。
- Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

6.4 设备Equipment

5.5.10

- 6.4.10 当需要利用期间核查以保持设备性能的信心时，应按程序进行核查。
- When intermediate checks are necessary to maintain confidence in the performance of the **equipment**, these checks shall be carried out according to a procedure.

2005:
当需要利用期间核查以保持设备校准状态的可信度时，应按照规定的程序进行
When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

期间核查

- 确定需要核查的设备，明确核查的方法
- a)设备检定、校准周期
- b)历次检定、校准结果；
- c)质量控制结果；
  - 连续质控对分析系统稳定性进行监控，不需要对使用的设备进行期间核查，化学分析中尤其如此；
  - 每次均校准的设备也不需要期间核查；
- d)设备使用频率
- e)设备维护情况；
- f)设备操作人员及环境的变化；
- g)设备使用范围的变化。

期间核查方法

- 关键的容易漂移的关键值
- 核查稳定性，因此不一定是等精度的
- 核查的周期

6.4 设备Equipment

5.5.11

- 6.4.11如果校准和标准物质数据中包含参考值或修正因子，实验室应确保该参考值和修正因子得到适当的更新和应用，以满足规定要求。
- When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4 设备Equipment

5.5.12

- 6.4.12实验室应有切实可行的措施，防止设备被意外调整而导致结果无效。
- The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4 设备Equipment

- 6.4.13应保存对实验室活动有影响的设备记录。记录应包括以下适用的内容：5.5.5
- Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:
  - a）设备的识别，包括软件和固件版本
  - the identity of equipment, including software and firmware version;
  - b）制造商名称、型式标识、系列号或其他唯一性标识；
  - the manufacturer's name, type identification, and serial number or other unique identification;
  - c）设备符合规定要求的验证证据；
  - evidence of verification that equipment conforms with specified requirements;
  - d）当前位置；
  - the current location;

5.5.4 用于检测和校准并对结果有重要影响的每一设备及其软件，如可能，均应加以唯一性标识。

6.4 设备Equipment

- e）校准日期、校准结果、设备调整、验收准则和下次校准的预定日期或校准周期；
- calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
  - 未强调校准证书？
- f）标准物质的文件、结果、验收准则、相关日期和有效期；
- documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity; [new]

6.4 设备Equipment

- g）与设备性能相关的维护计划和已进行的维护；
- the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
- h）设备的损坏、故障、改装或维修的详细信息。
- details of any damage, malfunction, modification to, or repair of, the equipment.

- 删除制造商说明书，作为外部文件控制 go
- **Delete manufacturer instruction, control as external document**

删除

- 5.5.3设备应由经过授权的人员操作。设备使用和维护的最新版说明书（包括设备制造商 提供的有关手册）应便于合适的实验室有关人员取用。
- Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

删除 delete

- 5.5.9 无论什么原因，若设备脱离了实验室的直接控制，实验室应确保该设备返回后，在使用前对其功能和校准状态进行核查并能显示满意结果。
- When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. go

6.5 计量溯源性
Metrological traceability

5.6.2.1.1

- 6.5.1为建立并保持测量结果的计量溯源性，实验室应通过形成文件的不间断的校准链将测量结果与适当参考标准相链接，其中每次校准对测量不确定度均有贡献。
- The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5 计量溯源性
Metrological traceability

- 注1：在ISO/IEC指南99中，计量溯源性定义为“测量结果的特性，结果可以通过形成文件的不间断的校准链与参考标准相关连，每次校准均会引入测量不确定度”
- NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”.
- 注2：关于计量溯源性的更多信息见附录A。
- NOTE 2 See Annex A for additional information on metrological traceability.

6.5 计量溯源性
Metrological traceability

5.6.2.1.1

- 6.5.2 实验室应通过以下方式确保测量结果可溯源到国际单位制（SI）：
- The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) :
  - a) 具备能力的实验室提供的校准；或
  - calibration provided by a competent laboratory; or

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  - 注1：满足本标准要求的实验室被视为是有能力的。
  - NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

6.5 计量溯源性
Metrological traceability

5.6.2.1.2

– **b)** 具备能力的标准物质生产者提供并声明计量溯源至**SI**的有证标准物质的标准值；

– **certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or**

==========

– 注2：满足ISO 17034要求的标准物质生产者被认为是有能力的；

– NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

6.5 计量溯源性
Metrological traceability

5.6.2.1.1

– **c) SI单位的直接复现，并通过直接或间接与国家或国际标准比对来保证。**
– **direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.**

==========

– 注3：SI手册给出了一些重要单位定义的实际复现详细信息。
– NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5 计量溯源性
Metrological traceability

5.6.2.1.2

- 6.5.3 技术上不可能计量溯源到SI单位时，实验室应证明可溯源至适当的参考标准，如：
- When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference such as:
  - a) 具备能力的生产者提供的有证标准物质的标准值
  - certified values of certified reference materials provided by a competent producer; or
  - b) 参考测量程序的结果、规定方法或描述清晰的协议标准，该标准的测量结果适宜预期用途，并通过适当比对予以保证。
  - results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

删除：可能时，要求参加适当的实验室间比对

6.5 计量溯源性
Metrological traceability

- 内容极大简化，不再区分检测或校准要求
  - 大量解释性内容放入附录A
- 从结果的溯源性来提出要求，而不是从校准的角度提出，校准只是实现计量溯源性的手段
- 与“设备”重复的要求予以删除---校准计划
- 删除5.6.3参考标准和标准物质---被设备覆盖

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

- 参照ISO 9001:2015，合并2005: 4.6与4.5
- 取消“分包”用词

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

- 6.6.1 实验室应确保影响实验室活动的外部供应品和服务的适用性，包括：
- The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:
  - a）用于实验室自身活动的产品和服务；
  - are intended for incorporation into the laboratory's own activities;
  - b）当实验室将部分或全部产品和服务直接提供给客户时；
  - are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider
  - c）用于支持实验室运作的产品或服务。
  - are used to support the operation of the laboratory.

4.6

4.5

new

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

- 注：产品可包括测量标准和设备、辅助设备、消耗材料和标准物质。服务可包括校准服务、抽样服务、检测服务、设施和设备维护服务，能力验证服务以及评审和审核服务。
- NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.
- 培训服务？

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

- 6.6.2实验室应有以下活动的程序和记录：
- The laboratory shall have a procedure and retain records for:
  - a）确定、审查和批准实验室对外部产品和服务的要求；（4.6.1/4.6.3/4.5.1）
  - defining, reviewing and approving the laboratory's requirements for externally provided products and services
  - b）确定对外部供应商的评价、选择、表现监控和重新评价准则；（4.6.3/4.6.4/4.5.1）
  - defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

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

- c）在使用外部提供的产品和服务前，或直接提供给客户之前，应确保符合实验室规定的要求，或适用时，满足本标准的相关要求；（4.5.4/4.5.1/5.6.2）
- ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d）根据对外部供应商的评价、监控和重新评价结果采取措施。（新）
- taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

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

- 6.6.3实验室应与外部供应商沟通以明确要求(4.6.3/4.5.1)
- The laboratory shall communicate its requirements to external providers for:
  - a）需提供的产品和服务;
  - the products and services to be provided;
  - b）验收准则;
  - the acceptance criteria;
  - c）能力，包括人员所具备的资格;
    - 校准服务，分包， PT？
  - competence, including any required qualification of personnel;
  - d）实验室或其客户拟在外部供应商的场所进行的活动。
  - activities that the laboratory, or its customer, intends to perform at the external provider's premises.
    - 分包？校准？

变化

- 实验室应保存检测和/或校准中使用的~~所有分包方的注册记录~~，并保存其工作符合本准则的证明记录
- The laboratory ~~shall maintain a register of all subcontractors that it uses for tests and/or calibrations a~~nd a record of the evidence of compliance with this International Standard for the work in question.

删除

- 4.6.4
- 实验室应保存这些评价的记录~~和获批准的供应商名单~~。
- The laboratory shall maintain records of these evaluations and list those approved.
- 4.6.1
  - 试剂和消耗材料存储（6.4.3覆盖）

7 过程要求
Process requirements

- 7.1 要求、标书和合同评审
- Review of requests, tenders and contracts
- 7.2 方法的选择、验证和确认
- Selection, verification and validation of methods
- 7.3 抽样 Sampling.
- 7.4 检测或校准物品的处置 Handling of test or calibration items
- 7.5 技术记录 Technical records
- 7.6 测量不确定度评定 Evaluation of measurement uncertainty
- 7.7 确保结果有效性 Ensuring the validity of results
- 7.8 结果报告 Reporting of results
- 7.9 投诉 Complaints
- 7.10 不符合工作 Nonconforming work
- 7.11 数据控制和信息管理 Control of data and information management

7.1 要求、标书和合同评审

Review of requests, tenders and contracts

- 7.1.1 实验室应有评审要求、标书和合同的程序，以确保（4.4.1）
- The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:
  - a) 明确规定要求，形成文件，并被理解；
  - the requirements are adequately defined, documented and understood;
  - b) 实验室有能力和资源满足这些要求
  - the laboratory has the capability and resources to meet the requirements;

2005: 4.4/4.5/5.4

7.1 要求、标书和合同评审

Review of requests, tenders and contracts

- c) 当使用外部提供者时，应满足6.6的要求，实验室应告知客户由外部提供者实施的实验室活动，并获得客户同意（4.5.2）
- where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

4.5.2实验室应将分包安排以书面形式通知客户，适当时应得到客户的准许，最好是书面的同意。
The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

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

- 注1：在下列情况下可能使用外部提供的实验室活动：
  - 实验室有开展活动的资源和能力，但由于不可预见的原因不能承担部分或全部活动；
  - 实验室没有开展活动的资源及能力。
- NOTE 1 It is recognized that externally provided laboratory activities can occur when:
  - the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;
  - the laboratory does not have the resources or competence to perform the activities.

4.5.1 正文

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

- d) 选择适当的方法或程序，并能满足客户的要求(4.4.1 c)
- the appropriate methods or procedures are selected and are capable of meeting the customers' requirements

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- 注2：对内部或例行客户，要求、标书和合同的评审可简化进行。
- NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

4.4.1 注 1：~~对要求、标书和合同的评审应当以可行和有效的方式进行，并考虑财务、法律和时间安排等方面的影响。~~对内部客户的要求、标书和合同的评审可以简化方式进行。

7.1 要求、标书和合同评审

Review of requests, tenders and contracts

- 7.1.2 当客户要求的方法不合适或是过时的，实验室应通知客户。
- The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

5.4.2

7.1 要求、标书和合同评审

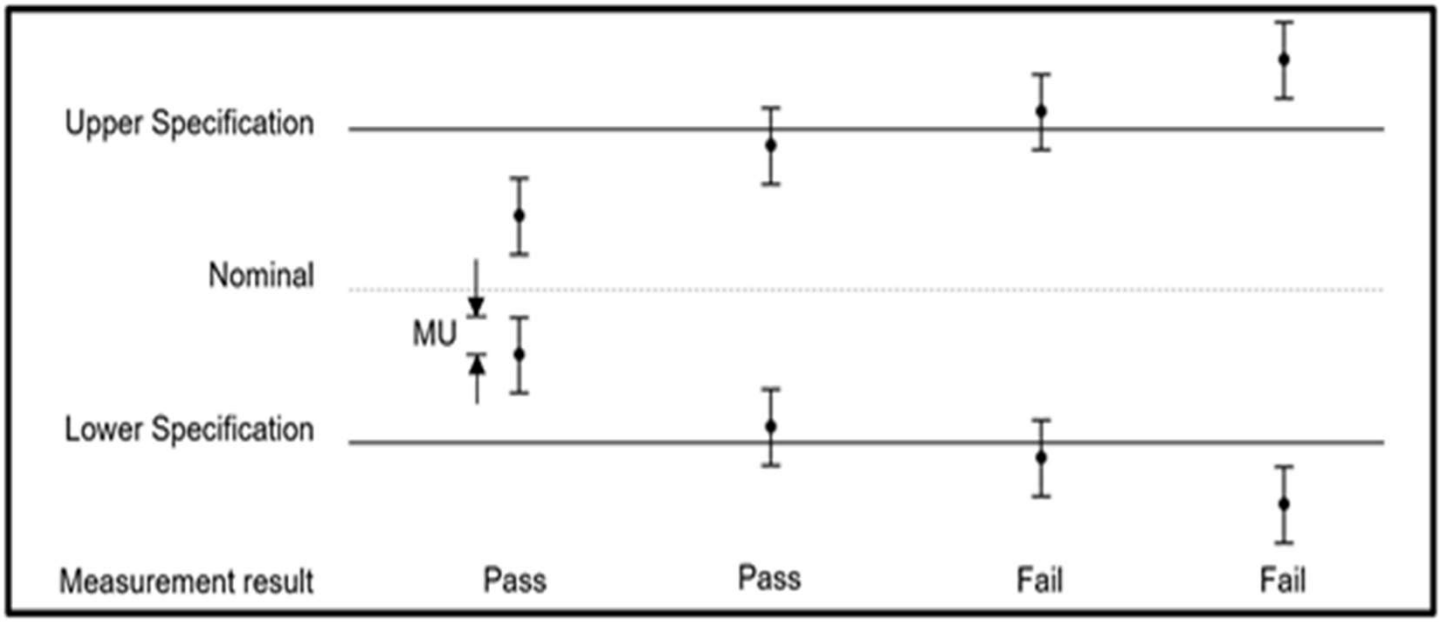
Review of requests, tenders and contracts

- 7.1.3 当客户要求针对检测或校准做出与规范或标准符合性的声明（如通过/未通过，在允许限内/超出允许限）时，应明确规定判定规则。选择的判定规则应与客户沟通并得到同意，除非规范或标准本身已包含判定规则。【新】
- When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. 【new】
- 注：符合性声明的指南见**ISO/IEC 98-4.**
- NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4. 【new】

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

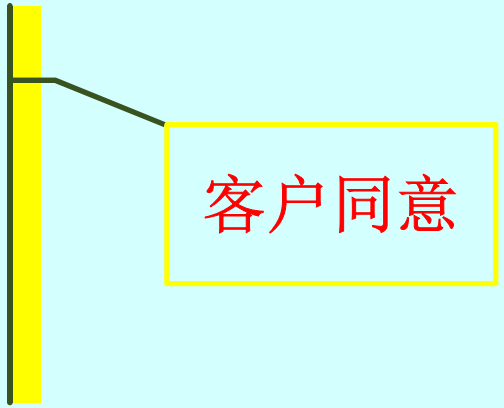


MU = 95% expanded measurement uncertainty

合同评审 → 应用 → 报告

判定规则

- 选择判定规则应考虑：
  - 定性分析不需要判定规则
  - 标准或规范中是否有判定规则？
  - 用途
    - 95%的不确定度？
    - 绝不不能超？
    - 绝对不允许假超限？
    - ……
  - 不考虑不确定度？



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。

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

4.4.1

- 7.1.4要求或标书与合同之间的任何差异，应在实验室活动开展前解决。每项合同应被实验室和客户双方接受。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】**
- Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer**. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.**

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

4.4.4

- 7.1.5 与合同的任何偏离应通知客户。
  - The customer shall be informed of any deviation from the contract.
- 7.1.6如果工作开始后修改合同，应重复进行合同评审，并将修改内容通知所有受影响的人员。

4.4.5

- If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

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

- 7.1.7 在澄清客户要求和允许客户监视其相关工作表现方面，实验室应与客户或其代表合作。 4.7.1
- The laboratory shall 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.

只能观摩客户委托的活动

~~4.7.1~~ ~~在确保其他客户机密的前提下，~~实验室应在明确客户要求、监视实验室中与工作相关操作方面积极与客户或其代表合作。

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

- 注：这种合作可包括：

4.7.1 note

- a) 允许适当进入实验室相关区域，以观察与该客户相关的实验室活动。
- b)客户出于验证目的所需的物品的准备、包装和发送。
- NOTE Such cooperation can include:
- a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;
- b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

4.7.1 注 2：客户非常重视与实验室保持技术方面的良好沟通并获得建议和指导，以及根据结果得出的意见和解释。实验室在整个工作过程中，应当与客户尤其是大宗业务的客户保持沟通。实验室应当将检测和/或校准过程中的任何延误或主要偏离通知客户。(删除）

7.1 要求、标书和合同评审

Review of requests, tenders and contracts

- 7.1.8 应保存评审记录，包括任何重大的变化。针对客户要求或实验室活动结果与客户的讨论也应作为记录予以保存。 4.4.2
- Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

删除 **delete**

- 4.5.3实验室应就分包方的工作对客户负责，由客户或法定管理机构指定的分包方除外。
- The laboratory is responsible to the customer for the subcontractor’s work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

删除

- 4.4.1
- 注 1：对要求、标书和合同的评审应当以可行和有效的方式进行，并考虑财务、法律和时间安排等方面的影响。
- 注 2：对实验室能力的评审，应当证实实验室具备了必要的物力、人力和信息资 源，且实验室人员对所从事的检测和/或校准具有必要的技能和专业技术。该评审也可包 括以前参加的实验室间比对或能力验证的结果和/或为确定测量不确定度、检出限、置信限等而使用的已知值样品或物品所做的试验性检测或校准计划的结果。
- 注 3：合同可以是为客户提供检测和/或校准服务的任何书面的或口头的协议。

删除

- 4.4.2注：对例行和其他简单任务的评审，由实验室中负责合同工作的人员注明日期并加 以标识（如签名缩写）即可。对于重复性的例行工作，如果客户要求不变，仅需在初期 调查阶段，或在与客户的总协议下对持续进行的例行工作合同批准时进行评审。对于新 的、复杂的或先进的检测和/或校准任务，则应当保存更为全面的记录。

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

- 7.2.1 方法的选择和验证 5.4.1
  - **Selection and verification of methods**
- 7.2.1.1实验室应使用适当的方法和程序开展实验室活动和（适当时）评定测量不确定度，以及使用统计技术进行数据分析。
  - The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

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

- 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[new]
- NOTE “Method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99. [new]

校准实验室将方法一般就称作测量程序。

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

5.4.1

- 7.2.1.2 所有方法、程序和支持文件应保持现行有效并易于人员取阅，例如与实验室活动相关的指导书、标准、手册和参考数据（见8.3）
- All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).

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

5.4.2

- 7.2.1.3实验室应确保使用最新有效的方法，除非该版本不合适或不可能使用。必要时，应补充方法使用细节，以确保应用的一致性。
- The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

旧方法是否可以认可？

7.2 方法选择、验证和确认

Selection, verification and validation of methods

5.4.1 note

- 注：如果国际、区域或国家标准，或其他公认的规范包含了如何实施实验室活动简明和充分的信息，并以可被实验室操作人员使用的方式书写，则不需要进行补充或改写为内部程序。对于方法中可选择的步骤，可能有必要制定补充文件或细则。
- NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

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

5.4.2

- 7.2.1.4当客户未指定所用的方法时，实验室应选择适当的方法并通知客户。推荐使用以国际标准、区域或国家标准发布的方法，或由知名技术组织或有关科技书籍或期刊中公布的方法，或设备制造商规定的方法，也可使用实验室开发或修改的方法。
- When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

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

5.4.2

- 7.2.1.5 实验室在引入方法前，应验证能够正确运用该方法，以确保能实现所需的方法性能。应保存验证记录。如果发布机构修订了方法，应在所需的程度上重新进行验证。
- The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

7.2 方法选择、验证和确认

Selection, verification and validation of methods

- 7.2.1.6当需要制定方法时，应予策划，并指定具有足够资源并具备能力的人员进行。在方法制定的过程中，应进行定期评审，以确认持续满足客户需求。开发计划的任何变更应得到批准和授权。（注上升为要求）
- When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

删除：计划应随方法制定的进度加以更新，以确保所有有关人员之间的有效沟通

5.4.3
5.4.5.3注2

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

5.4.1

- 7.2.1.7 实验室活动偏离了方法，应事先将该偏离形成文件、做技术判断、获得授权并被客户接受。
- Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

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- 注：客户接受偏离可以事先在合同中约定。[新]
- NOTE Customer acceptance of deviations can be agreed in advance in the contract. [new]

偏离是否可以事先知道？
偏离与更改方法有何区别

对方法的偏离

- 在标准征求意见的过程中，有的成员认为“与方法的偏离”和“对方法的改进”是一回事，需要进行方法确认，因此建议删除与方法偏离的有关条款。起草小组经过长时间的讨论确认，方法偏离是处理不能满足相关要求的一种特殊情况，是不得已而为之的情况，是负面的，因此此时需要做技术判断，获得批准才可发生。而方法改进是为使方法更有效而进行的一项积极的、正面的技术活动，为确保方法有效性而必须事先做好方法确认，这不是一种异外的情况。因此对两者的要求是不同的，应保留方法偏离的相关条款。

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

- 7.2.2 方法确认Validation of methods 5.4.5.2
- 7.2.2.1 实验室应对非标准方法、实验室制定的方法、超出预定范围使用的或其他修改的标准方法进行确认。确认应尽可能全面，以满足预定用途或应用领域的需求。
- The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

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

- 注1：确认可包括对抽样、检测或校准物品处置和运输程序的确认。
- NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

5.4.5.2
note 1

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

- 注2：可用以下一种或多种技术进行方法确认：

5.4.5.2
note 2

- NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:
- a) 使用参考标准或标准物质进行校准或评估偏倚和精密度；
  - calibration or evaluation of bias and precision using reference standards or reference materials;
- b) 对影响结果的因素做系统性评审；
  - systematic assessment of the factors influencing the result;

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

- c) 通过改变控制参数检验方法的稳健性：如恒温箱温度、加样体积等；[new]
  - testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
- d)与其他已确认的方法进行结果比对；
  - comparison of results achieved with other validated methods;
- e)实验室间比对
  - interlaboratory comparisons;
- f) 根据对方法理论原理的理解和抽样或检测方法的实践经验评定结果的测量不确定度。
  - evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

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

- 7.2.2.2 当修改已确认过的方法时，应确定这些修改的影响。当发现影响原有的确认时，应重新进行方法确认（原为注上升为要求）

5.4.5.2 note 3

- When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.
- 7.2.2.3当按使用目的对方法的性能特性进行确认时，应满足客户的需求，并符合规定要求。
- The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

5.4.5.3

7.2 方法选择、验证和确认

Selection, verification and validation of methods

5.4.5.3

- 注：方法性能特性包括但不限于：测量范围、准确度、结果的测量不确定度、检出限、定量限、方法的选择性、线性、重复性或复现性、抵御外部影响的稳健度或抵御来自样品或测试物基体干扰的交互灵敏度以及偏倚。（原在正文）
- NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

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

5.4.5.2

- 7.2.2.4 实验室应保存以下方法确认记录：
- The laboratory shall retain the following records of validation
  - a）使用的确认程序；
  - the validation procedure used;
  - b）规定的要求； [new]
  - specification of the requirements;
  - c）确定的方法性能特性； [new]
  - determination of the performance characteristics of the method;
  - d）获得的结果；
  - results obtained;
  - e）方法有效性声明,并详述与预期用途适宜性。
  - a statement on the validity of the method, detailing its fitness for the intended use.

方法偏离、验证、确认的区别

	方法偏离	方法验证（证实）	方法确认
对象	标准方法， 非标准方法	标准方法	非标准方法； 实验室自制方法； 扩大适用范围和扩充及修改的标准方法
目的	临时需要， 非常态	能正确使用标准方法	方法满足预期用途的特定要求
方法	文件规定、技术判断、授权和客户接受	人机料法环测 技术验证	五种方法
时机	偏离后回归到正常状态	投入使用前， 发生变更后	确认后使用

删除

- 5.4.4
- 注：对新的检测和/或校准方法，在进行检测和/或校准之前应当制定程序。程序中至少应该包含下列信息：
- a) 适当的标识；
- b) 范围；
- c) 被检测或校准物品类型的描述；
- d) 被测定的参数或量和范围；
- e) 仪器和设备，包括技术性能要求；
- f) 所需的参考标准和标准物质（参考物质）；
- g) 要求的环境条件和所需的稳定周期；
- h) 程序的描述，包括：
  - 物品的附加识别标志、处置、运输、存储和准备；
  - 工作开始前所进行的检查；
  - 检查设备工作是否正常，需要时，在每次使用之前对设备进行校准和调整；
  - 观察和结果的记录方法；
  - 需遵循的安全措施； i) 接受（或拒绝）的准则和/或要求；
- j) 需记录的数据以及分析和表达的方法；
- k) 不确定度或评定不确定度的程序。

删除 **delete**

- 5.4.5.1 确认是通过检查并提供客观证据，以证实某一特定预期用途的特定要求得到满足。
- **5.4.5.1** Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

删除 delete

- 5.4.5.3
- 注3：确认通常是成本、风险和技术可行性之间的一种平衡。许多情况下，由于缺 乏信息，数值（如：准确度、检出限、选择性、线性、重复性、复现性、稳健度和交互 灵敏度）的范围和不确定度只能以简化的方式给出。
- NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, electivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

7.3 抽样Sampling

5.7.1

- 7.3.1当实验室为后续检测或校准而对物质、材料或产品进行抽样时，应有抽样计划和方法。抽样方法应明确需要控制的因素，以确保随后检测或校准结果有效性。在抽样的地点应能够得到抽样计划和方法。只要合理，应根据适当的统计方法制定抽样计划。
- The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

7.3 抽样

5.7.1 注2

- **7.3.2 抽样方法应描述：**
- The sampling method shall describe:
- a) 样品或位置的选择
- the selection of samples or sites;
- b) 抽样计划
- the sampling plan;
- c) 从物质、材料或产品中取得样品的制备和处理，以作为随后检测或校准的物品
- preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.
- 注：实验室接收样品后，进一步处理要求见7.4的规定。
- NOTE When received into the laboratory, further handling can be required as specified in 7.4.

7.3 抽样

5.7.3

- 7.3.3实验室应将抽样数据作为检测或校准工作的一部分保留记录。这些记录应包括以下相关信息：
- The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:
  - a）所用的抽样方法；
  - reference to the sampling method used;
  - b）抽样日期和时间；
- date and time of sampling;
  - c）识别和描述样品的数据（如编号、数量和名称）；
- data to identify and describe the sample (e.g. number, amount, name);

7.3 抽样

- d）抽样人的识别；
- identification of the personnel performing sampling;
- e）所用设备的识别；
- identification of the equipment used;
- f) 环境或运输条件；
- environmental or transport conditions;
- g) 适当时，识别抽样位置图示或其他等效方式
- diagrams or other equivalent means to identify the sampling location when appropriate
- h) 与抽样方法和抽样计划的偏离或增减

5.7.2

- deviations, additions to or exclusions from the sampling method and sampling plan.

删除 delete

- 5.7.1
- 注1：抽样是取出物质、材料或产品的一部分作为其整体的代表性样品进行检测或 校准的一种规定程序。抽样也可能是由检测或校准该物质、材料或产品的相关规范要求的。某些情况下（如法庭科学分析），样品可能不具备代表性，而是由其可获性所决定。
- NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability.

7.4 检测和校准物品的处置

Handling of test or calibration items

5.8.1
5.8.4

- 7.4.1实验室应有检测或校准物品的运输、接收、处置、保护、存储、保留、清理或返还的程序，包括为保护检测或校准物品的完整性以及实验室与客户利益所需的所有规定。在处置、运输、保存/等候、制备或检测或校准过程中，应注意避免物品变质、污染、丢失或损坏。应遵守随物品提供的操作说明。
- The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.

5.8.4 当一个检测或校准物品或其一部分需要安全保护时，实验室应对存放和安全作出安排，以保护该物品或其有关部分的状态和完整性。

7.4 检测和校准物品的处置
Handling of test or calibration items

5.8.2

- 7.4.2 实验室应有清晰标识检测或校准物品的系统。实验室应在物品的保管期间保留该标识。标识系统应确保物品不会在实物上、记录或其他文件中混淆。适当时，标识系统应包含一个物品或一组物品的细分和物品的传递。
- The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

7.4 检测和校准物品的处置
Handling of test or calibration items 5.8.3

- 7.4.3 接收检测或校准物品时，应记录与规定条件的偏离。当对物品是否适合于检测或校准存有疑问，或当物品不符合所提供的描述时，实验室应在开始工作之前询问客户，以得到进一步的说明，并记录此次询问的结果。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。【new】
- Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. 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.

7.4 检测和校准物品的处置
Handling of test or calibration items

5.8.4

- 7.4.4如物品需要在规定环境条件下储存或调置，应保持、监控和记录这些环境条件。
- When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

5.8.4 当物品需要被存放或在规定的环境条件下养护时，应保持、监控和记录这些条件。

删除

- 5.8.4
- 注 1：在检测之后要重新投入使用的测试物，需特别注意确保物品的处置、检测或存储/等待过程中不被破坏或损伤。
- 注 2：应当向负责抽样和运输样品的人员提供抽样程序，及有关样品存储和运输的信 息，包括影响检测或校准结果的抽样因素的信息。
- 注 3：维护检测或校准样品安全的原由可能出自记录、安全或价值的原因，或是为了日后进行补充的检测和/或校准。

7.5 技术记录
Technical records

4.13.2.1
4.13.2.2

- 7.5.1实验室应确保每一项实验室活动的技术记录包含结果、报告和以便在可能时识别影响测量结果及其测量不确定度的因素的充足信息，并确保在尽可能接近原条件的情况下复现该实验室活动。技术记录应包括每项实验室活动和检查数据结果的日期和负责人。原始的观察结果、数据和计算应在观察到或获得时予以记录，并应按特定任务予以识别。
- The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

原始记录一定要签字吗？

7.5 技术记录

4.13.2.3

- 7.5.2实验室应确保技术记录的修改可以追溯到前一个版本或原始观察结果。应保存原始的以及修改后的数据和文件，包括更改的日期、标识更改的内容和负责更改的人员。
- The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

2005：出现错误-划改-正错写在旁边—改动人签名，
对电子记录同等措施，避免原始记录丢失或改动

删除

- 4.13.2.1
- 注 1：在某些领域，保留所有的原始观察记录也许是不可能或不实际的。
- 注 2：技术记录是进行检测和/或校准所得数据（见 5.4.7）和信息的累积，它们表明检测和/或校准是否达到了规定的质量或规定的过程参数。技术记录可包括表格、合同、工作单、工作手册、核查表、工作笔记、控制图、外部和内部的检测报告及校准证书、客户信函、文件和反馈。

7.6 测量不确定度评定
Evaluation of measurement uncertainty

5.4.6.3

- 7.6.1 实验室应识别测量不确定度的贡献。评定测量不确定度时，应采用适当的分析方法考虑所有显著贡献，包括来自抽样的贡献。
- Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

如果评定抽样引入的分量？

7.6 测量不确定度评估
Evaluation of 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。
- A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

5.4.6.1

- ==========
- 2005：5.4.6.1
- 校准实验室或进行自校准的检测实验室，对所有的校准和各种校准类型都应具有并应用评定测量不确定度的程序

7.6 测量不确定度评估
Evaluation of measurement uncertainty

- 7.6.3 开展检测的实验室应评定测量不确定度。当由于检测方法的原因难以严格评定测量不确定度时，实验室应基于对理论原理的了解或使用该方法的实践经验来进行评估。
- A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

5.4.6.2

7.6 测量不确定度评估
Evaluation of measurement uncertainty

- 注1：某些情况下，公认的检测方法对测量不确定度主要来源的值规定了限值，并规定了计算结果的表示方式，实验室只要遵守检测方法和报告说明，即满足7.6.3的要求。 5.4.6.2 注2
- NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

7.6 测量不确定度评估
Evaluation of measurement uncertainty

- 注2：对一特定方法，如果已确定并验证了结果的测量不确定度，实验室只要证明已识别的关键影响因素受控，就不需要对每个结果评定测量不确定度。【new】
- NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the dentified critical influencing factors are under control.
- 注3：更多信息参见ISO/IEC 指南98-3、ISO 21748和 ISO 5725系列标准。（5.4.6.3注3）
- NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

删除

- 5.4.6.2
- 注 1：测量不确定度评定所需的严密程度取决于某些因素，诸如：
  - 检测方法的要求；
  - 客户的要求；
  - 据以作出满足某规范决定的窄限。
- NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:
  - the requirements of the test method;
  - the requirements of the customer;
  - the existence of narrow limits on which decisions on conformity to a specification are based.

删除

- 5.4.6.3
- 注 1:不确定度的来源包括（但不限于）所用的参考标准和标准物质（参考物质）、方法和设备、环境条件、被检测或校准物品的性能和状态以及操作人员。
- 注 2: 在评定测量不确定度时，通常不考虑被检测和/或校准物品预计的长期性能。
- NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.
- NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when
- estimating the measurement uncertainty.

7.7 确保结果有效性
Ensuring the validity of results

5.9.1

- 7.7.1实验室应有监控结果有效性的程序。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。实验室应对监控进行策划和审查，监控应包括但不限于以下适当方式：
- The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

7.7 确保结果有效性
Ensuring the validity of results

- a) 使用标准物质或质量控制物质
  - use of reference materials or quality control materials;
- b) 使用其他已校准能够提供可溯源结果的仪器
  - use of alternative instrumentation that has been calibrated to provide traceable results;
- c) 测量和检测设备的功能核查--------6.4.10
  - functional check(s) of measuring and testing equipment;
- d) 适用时，使用核查或工作标准，并制作控制图
  - use of check or working standards with control charts, where applicable;
- e) 测量设备的期间核查 --------6.4.10
  - intermediate checks on measuring equipment;

7.7 确保结果有效性
Ensuring the validity of results

- f) 使用相同或不同方法进行重复检测或校准
  - replicate tests or calibrations using the same or different methods;
- g) 保存样品的重复检测或重复校准；
  - retesting or recalibration of retained items;
- h) 物品不同特性结果的相关性
  - correlation of results for different characteristics of an item;
- i) 审查报告的结果----------**7.8.1.1**
  - **review of reported results;**
- j) 实验室内比对
  - intralaboratory comparisons;
- k) 盲样测试
  - testing of blind sample(s).

7.7 确保结果有效性
Ensuring the validity of results

5.9.1 b

- 7.7.2可行和适当时，实验室应通过与其他实验室的结果比对来监控其表现。这种监控应进行策划和审查，包括但不限于以下措施：
- The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
  - a）参加能力验证；
  - participation in proficiency testing;
  - b）参加除能力验证之外的实验室间比对。
  - participation in interlaboratory comparisons other than proficiency testing.

7.7 确保结果有效性
Ensuring the validity of results

- 注：ISO / IEC 17043包含关于能力验证和能力验证提供者的附加信息。满足ISO / IEC 17043要求的能力测试提供者被认为是有能力的。
- NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

7.7 确保结果有效性
Ensuring the validity of results

5.9.2

- 7.7.3 应分析监控活动的数据，并用于控制和（如适用）改进实验室活动。如果发现监控活动数据分析结果超出预定的准则时，应采取适当措施防止报告不正确的结果。
- Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.8 报告结果
Reporting of results

5.10.1

- 7.8.1 总则 General
- 7.8.1.1 结果在发出前应审查和批准。

5.10.2.j) 检测报告或校准证书批准人的姓名、职务、签字或等效的标识；

- **7.8.1.2** 实验室通常以报告的形式提供结果（例如检测报告、校准证书或抽样报告），应准确、清晰、明确和客观地出具结果，并且应包括客户同意的、解释结果所必需的以及所用方法要求的全部信息。所有发出的报告应作为技术记录予以保存。 4.13.2.1
- The results shall be reviewed and authorized prior to release. The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

7.8 报告结果
Reporting of results

- 注1：在本文中，检测报告和校准证书有时称为检测证书和校准报告。 5.10.1注1
- NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.
- 注2：只要满足本标准的要求，报告可以硬拷贝或电子方式发布。 5.10.1注2
- NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8 报告结果
Reporting of results

5.10.1

- 7.8.1.3 经客户同意，可用简化的方式报告结果。如果未向客户报告7.8.2 至7.8.6 中所列的信息，客户应能方便地获得。
- When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8 报告结果
Reporting of results

- 7.8.2 报告的通用要求（检测、校准或抽样） 5.10.2
- Common requirements for reports (test, calibration or sampling)
- 7.8.2.1除非实验室有有效的理由，否则每份报告应至少包括下列信息，最大限度地减少误解或误用的可能性：
- Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:
- a) 标题（例如“检测报告”、“校准证书”或“抽样报告”）；
- a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”);
- b) 实验室的名称和地址；
- the name and address of the laboratory;

7.8 报告结果
Reporting of results

- c)开展实验室活动的地点，包括在客户设施、实验室固定设施以外的地点，或在相关的临时或移动设施内；
- the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- d) 将报告中所有部分标记为整体报告一部分的唯一性标识，以及表明报告结束的清晰标识；
- unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

7.8 报告结果
Reporting of results

- e) 客户的名称和联络信息；（不用地址）
- the name **and contact information** of the customer;
- f) 所用方法的识别；
- identification of the method used;
- g) 物品的描述、明确的标识以及必要时物品的状态（2005没有“必要时”）
- a description, unambiguous identification, and, when necessary, the condition of the item ;

7.8 报告结果
Reporting of results

- **h)**检测或校准物品的接收日期，以及对结果的有效性和应用至关重要的抽样日期；
- the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- **i)** 实验室活动的开展日期；
- the date(s) of performance of the laboratory activity;
- **j)** 报告的发布日期；
- the date of issue of the report;

7.8 报告结果
Reporting of results

- **k)** 如与结果的有效性或应用相关时，实验室或其他机构所用的抽样计划和抽样方法的说明；
- reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- **l)**结果仅与被检测、被校准或被抽物品有关的声明；
- a statement to the effect that the results relate only to the items tested, calibrated or sampled;

7.8 报告结果
Reporting of results

- **m)** 结果，适当时，带有测量单位；
- the results with, where appropriate, the units of measurement;
- **n)** 对方法补充、偏离或删减；（不仅仅针对检测报告）
- additions to, deviations, or exclusions from the method;
- 报告批准人的识别；（不要求：职务、签字或等效标识）
- identification of the person(s) authorizing the report;
- **o)** 当结果来自于外部提供者时，清晰标识（**5.10.6**）
- clear identification when results are from external providers.
- 注：在报告中声明“除全文复制外，未经实验室批准不得部分复制报告”可以确保报告不被部分摘用。5.10.2注2
- NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

删除delete

- 5.10.2 检测报告和校准证书
- 注1：检测报告和校准证书的硬拷贝应当有页码和总页数

7.8 报告结果
Reporting of results

- **7.8.2.2** 实验室对报告中的所有信息负责，由客户提供的信息除外。客户提供的数据应予明确标识。此外，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。当实验室不负责抽样阶段(如样品由客户提供)，应在报告中声明结果适用于收到的样品。【new】
- The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

5.10.2 k) 相关时，结果仅与被检测或被校准物品有关的声明。

7.8 报告结果
Reporting of results

5.10.3

- 7.8.3 检测报告的特定要求
- **Specific requirements for test reports**
- 7.8.3.1 除7.8.2所列要求之外，检测报告还应包含以下解释检测结果所必需的信息：
- **In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:**
  - a) 特定的检测条件信息，如环境条件；
  - information on specific test conditions, such as environmental conditions;
  - b) 相关时，与要求或规范的符合性声明（见7.8.6）；
  - where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

5.10.3a) 对检测方法的偏离、增添或删节，以及特定检测条件的信息，如环境条件；

7.8 报告结果
Reporting of results

- c) 适用时，带有被测量相同单位的测量不确定度或被测量的相对测量不确定度（如百分比）
- where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
  - 当与检测结果的有效性或应用有关时
  - it is relevant to the validity or application of the test results;
  - 客户有要求时
  - a customer's instruction so requires, or
  - 测量不确定度影响到与规范限量的符合性时
  - the measurement uncertainty affects conformity to a specification limit;

7.8 报告结果
Reporting of results

- d) 适用时，意见和解释（见7.8.7）；
  - where appropriate, opinions and interpretations (see 7.8.7);
- e) 特定方法、法定管理机构或客户要求的附加信息。
  - additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8 报告结果
Reporting of results

- **7.8.3.2** 当实验室负责抽样活动时，如果解释检测结果需要，检测报告应满足**7.8.5**条款的要求。
- Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

5.10.3.2 当需对检测结果作解释时，对含抽样结果在内的检测报告，除了5.10.2 和 5.10.3.1 所列的要求之外，还应包括下列内容：

7.8 报告结果
Reporting of results

5.10.4

- 7.8.4 校准证书的特定要求
- **Specific requirements for calibration certificates**
- 7.8.4.1 除7.8.2的要求外，校准证书应包含以下信息：
- In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:
  - **a)** 与被测量相同单位的测量不确定度或被测量的相对形式（如百分比）；
  - the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

2005：测量不确定度~~和（或）符合确定的计量规范或条款的声明~~

7.8 报告结果
Reporting of results

- 注：根据ISO/IEC 指南99，测量结果通常表示为一个被测量值，包括测量单位和测量不确定度。【new】
- NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

7.8 报告结果
Reporting of results

- **b)** 校准活动中对测量结果有影响的条件（如环境条件）；
- the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
- **c)** 测量如何计量溯源的声明（见附录**A**）；
- a statement identifying how the measurements are metrologically traceable (see Annex A);
- **d)** 如有，调整或修理前后的结果。
- the results before and after any adjustment or repair, if available;
- **e)** 相关时，与要求或规范的符合性声明 （见**7.8.6**）
- where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
- **f)** 适当时，意见和解释（见**7.8.7)**
- where appropriate, opinions and interpretations (see 7.8.7).

7.8 报告结果
Reporting of results

- 7.8.4.2当实验室负责抽样活动时，如果解释校准结果需要，校准证书应满足**7.8.5**条款的要求。**【new】**
- Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

2005版只在检测报告中提及抽样

校准会涉及抽样吗？

7.8 报告结果
Reporting of results

- 7.8.4.3校准证书或校准标签不应包含对校准周期的建议，除非已与客户达成协议。
- A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

5.10.4.4 校准证书（或校准标签）不应包含对校准时间间隔的建议，除非已与客户达成 协议　该要求可能被法规取代。（删除）

- This requirement may be superseded by legal regulations.

校准周期谁定？

删除

- 5.10.4.2 校准证书
- 当符合某规范的声明中略去了测量结果和相关的不确定度时，实验室应记录并保存这些结果，以备日后查阅。
- 作出符合性声明时，应考虑测量不确定度

7.8 报告结果
Reporting of results

5.10.3.2

- **7.8.5** 报告抽样—特定要求
- 如果实验室负责抽样，除**7.8.2**中的要求外，报告应包括以下解释结果所必需的信息：
- Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:
- **a)** 抽样日期；
- the date of sampling;
- **b)** 抽取的物品或物质的唯一性标识（适当时，包括制造商的名称、标示的型号或类型以及序列号）；
- unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);

原来包含在检测报告中

7.8 报告结果
Reporting of results

- **c)** 抽样位置，包括图示、草图或照片；
- the location of sampling, including any diagrams, sketches or photographs;
- **d)** 抽样计划和抽样方法；
- a reference to the sampling plan and sampling method;
- **e)** 抽样过程中影响结果解释的环境条件的详细信息；
- details of any environmental conditions during sampling that affect the interpretation of the results;
- **f)** 评定后续检测或校准的测量不确定度所需的信息。
- information required to evaluate measurement uncertainty for subsequent testing or calibration. 【new】

7.8 报告结果
Reporting of results

仅在校准证书中提及

- 7.8.6 报告符合性声明
- Reporting statements of conformity
- 7.8.6.1 当做出与规范或标准符合性声明时，实验室应考虑与所用判定规则相关的风险水平（如错误接受、错误拒绝以及统计假设），将所使用的判定规则制定成文件，并应用判定规则。
- When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

7.8 报告结果
Reporting of results

- 注：如果客户、法规或规范性文件规定了判定规则，无需进一步考虑风险等级了。
- NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8报告结果
Reporting of results

5.10.4.2

- 7.8.6.2 实验室在报告符合性声明时应清晰标识：
- The laboratory shall report on the statement of conformity, such that the statement clearly identifies:
  - a) 符合性声明适用于哪些结果；
  - a) to which results the statement of conformity applies;
  - b) 满足或不满足哪些规范、标准或其中的部分； 5.10.4.2
  - b) which specifications, standards or parts thereof are met or not met;
  - c) 使用判定规则（除非规范或标准中已包含）。
  - c) the decision rule applied (unless it is inherent in the requested specification or standard).

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

7.8 报告结果
Reporting of results

5.10.5

- 7.8.7 报告意见和解释
- Reporting opinions and interpretations
- **7.8.7.1**当表述意见和解释时，实验室应确保只有授权人员才能发布意见和解释。实验室应将意见和解释的依据制定成文件。
- When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

7.8 报告结果
Reporting of results

5.10.5注1

- 注：应注意区分意见和解释与ISO/IEC17020中的检查声明、ISO/IEC17065中的产品认证声明以及7.8.6中符合性声明的差异。
- NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

7.8 报告结果
Reporting of results

5.10.5

- 7.8.7.2 报告中的意见和解释应基于被检测或校准物品的结果，并清晰地予以标注。
- The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8 报告结果
Reporting of results

5.10.5注3

- 7.8.7.3 当以对话方式直接与客户沟通意见和解释时，应保留对话记录。(原来是注）
- When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

删除delete

- 5.10.5
- 注2：检测报告中包含的意见和解释可以包括（但不限于）下列内容：
  - 对结果符合（或不符合）要求的声明的意见；
  - 合同要求的履行；
  - 如何使用结果的建议；
  - 用于改进的指导。
- NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:
  - an opinion on the statement of compliance/noncompliance of the results with requirements;
  - fulfilment of contractual requirements;
  - recommendations on how to use the results;
  - guidance to be used for improvements.

7.8 结果报告
Reporting of results

5.10.9

- 7.8.8修改报告 **Amendments to reports**
- 7.8.8.1 当更改、修订或重新发布已发布的报告，应在报告中清晰标识修改的信息，适当时标注修改的原因。
- When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8 结果报告
Reporting of results

5.10.9

- 7.8.8.2修改已发布的报告时，应仅以追加文件或数据传输的形式，并包含以下声明：
  - “对序列号为……（或其他标识）报告的修改”，或其他等效的文字。

  修改应满足本标准的所有要求。
- Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording.
- Such amendments shall meet all the requirements of this document.

7.8 结果报告
Reporting of results

5.10.9

- 7.8.8.3当有必要发布全新的报告时，应给予唯一性标识，并注明所替代的原报告。
- When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

删除

- 5.10.6 从分包方获得的检测和校准结果
  - 分包方应以书面或电子方式报告结果。
  - 当校准工作被分包时，执行该工作的实验室应向分包给其工作的实验室出具校准证 书。
- **5.10.6 Testing and calibration results obtained from subcontractors**
  - The subcontractor shall report the results in writing or electronically.
  - When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

删除

- 5.10.7 结果的电子传送当用电话、电传、传真或其他电子或电磁方式传送检测或校准结果时，应满足本标准的要求（见 5.4.7）。
- **5.10.7 Electronic transmission of results**
- In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).

删除

- 5.10.8 报告和证书的格式 报告和证书的格式应设计为适用于所进行的各种检测或校准类型，并尽量减小产生 误解或误用的可能性。
- 注 1：应当注意检测报告或校准证书的编排，尤其是检测或校准数据的表达方式，并易于读者理解。
- 注 2：表头应当尽可能地标准化。
- **5.10.8 Format of reports and certificates**
- The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.
- NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.
- NOTE 2 The headings should be standardized as far as possible.

7.9 投诉
Complaint

4.8

- 7.9.1 实验室应有制订形成文件的过程来接收和评价投诉，并对投诉做出决定。
- The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

4.8 实验室应有政策和程序处理来自客户或其他方面的投诉。应保存所有投诉的记录以及实验室针对投诉所开展的调查和纠正措施的记录（见4.11）。

几乎都是新要求

7.9 投诉
Complaint

- 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文件。在接到投诉后，实验室应确认投诉是否与其负责的实验室活动相关，如相关，则应处理。实验室应对投诉处理过程中的所有决定负责。
- A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9 投诉
Complaint

- 7.9.3投诉处理过程应至少包括以下要素和方法：
- The process for handling complaints shall include at least the following elements and methods:
  - a) 对投诉的接收、确认、调查以及决定采取处理措施过程的说明；
  - description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
  - b) 跟踪并记录投诉，包括为解决投诉所采取的措施；
  - tracking and recording complaints, including actions undertaken to resolve them;
  - c) 确保采取适当的措施。
  - ensuring that any appropriate action is taken.

7.9 投诉
Complaint

- 7.9.4 接到投诉的实验室应负责收集并验证所有必要的信息，以便确认投诉是否有效。
- The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9 投诉
Complaint

- 7.9.5 只要可能，实验室应告知投诉人已收到投诉，并向其提供处理进程的报告和处理结果。
- Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9 投诉
Complaint

- **7.9.6** 与投诉人沟通的结果应由与所涉及的实验室活动问题无关的人员作出，或审查和批准。
- The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.
- 注：可由外部人员实施。
- NOTE This can be performed by external personnel.

小规模实验室

7.9 投诉
Complaint

- **7.9.7** 只要可能，实验室在投诉处理完成后应正式通知给投诉人。
- Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10不符合工作
Nonconforming work

4.9.1

- **7.10.1**当实验室活动或结果不符合自己的程序或与客户达成一致的要求时（例如，设备或环境条件超出规定限值，监测结果不能满足规定的准则），实验室应有程序予以实施。该程序应确保：
- The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

7.10不符合工作
Nonconforming work

- **a)** 确定不符合工作管理的职责和权力；
- the responsibilities and authorities for the management of nonconforming work are defined;
- **b)** 措施以实验室建立的风险等级为基础（包括必要时暂停或重复工作以及扣发报告）
- actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
- **c)** 评价不符合工作的严重性，包括分析对先前结果的影响；
- an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
- **d)** 对不符合工作的可接受性做出决定；
  - 删除立即纠正
- a decision is taken on the acceptability of the nonconforming work;
- **e)** 必要时，通知客户并取消工作；
- where necessary, the customer is notified and work is recalled;
- **f)** 规定批准恢复工作的职责；
- the responsibility for authorizing the resumption of work is define

7.10不符合工作
Nonconforming work

- **7.10.2** 实验室应记录不符合工作和**7.10.1**条款中**b)**至**f)**规定的措施。【**new**】
- The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).
- **7.10.3** 当评价表明不符合工作可能再次发生时，或对实验室的运行与其管理体系的符合性产生怀疑时，实验室应采取纠正措施。
- Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

4.9.2

7.11 数据控制和信息管理

Control of data and information management

- 7.11.1 实验室应能获得开展实验室活动所需的数据和信息。new
- The laboratory shall have access to the data and information needed to perform laboratory activities.

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

5.4.7.2

- 7.11.2 用于收集、处理、记录、报告、存储或检索数据的实验室信息管理系统在投入使用前应进行功能确认，包括实验室信息管理系统中界面的适当运行。当更改管理系统时，包括实验室软件配置或对商用现成软件的修改，在使用前应被授权、形成文件并确认。
- The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

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

- 注1：本文中“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。相比非计算机化的系统，有些要求更适用于计算机化的系统 new
- NOTE 1 In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.
- 注2：常用的商业软件在其设计的应用范围内使用可被视为已经过充分的确认。 5.4.7.2注
- NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

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

- **7.11.3** 实验室信息管理系统应：
- The laboratory information management system(s) shall:
  - **a)**防止未经授权的访问；
  - be protected from unauthorized access;
  - **b)**安全保护以防止篡改和丢失；
  - be safeguarded against tampering and loss;

5.4.7.2

4.13.1.4 实验室应有程序来保护和备份以电子形式存储的记录，并防止未经授权的侵入或修改。

•**5.4.7.2** b) 建立并实施数据保护的程序。这些程序应包括（但不限于）：数据输入或采集、数据存储、数据转移和数据处理的完整性和保密性；

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

- **c)**在符合提供商或实验室规定的环境中运行，或对于非计算机系统，提供保护人工记录和转录准确性的条件；**new**
- be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- **d)**以确保数据和信息的完整性的方式进行维护
- be maintained in a manner that ensures the integrity of the data and information;
- **e)**包括系统失效记录和适当的紧急措施及纠正措施。**new**
- include recording system failures and the appropriate immediate and corrective actions.

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

- **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。**new**
- When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11 数据控制和信息管理

Control of data and information management

- 7.11.5 实验室应确保员工易于获取与实验室信息管理系统有关的说明书、手册和参考数据。new
- The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

5.4.1 所有与实验室工作有关的指导书、标准、手册和参考资料应保持现行有效并易于员工取阅（见 4.3）。

- 7.11.6 应对计算和数据传输进行适当和系统地检查 5.4.7.1
- Calculations and data transfers shall be checked in an appropriate and systematic manner.

8. 管理体系要求
Management system requirements

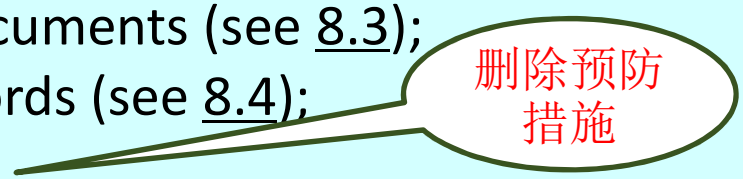
- 8.1 方式 Options
- 8.2 管理体系文件（方式A）
- Management system documentation (Option A)
- 8.3 管理体系文件控制（方式A）
- Control of management system documents (Option A).
- 8.4 记录控制（方式A）Control of records (Option A)
- 8.5 应对风险和机遇的措施（方式A）
- Actions to address risks and opportunities (Option A)
- 8.6 改进（方式A） Improvement (Option A).
- 8.7 纠正措施 （方式A）Corrective action (Option A)
- 8.8 内部审核（方式A） Internal audits (Option A)
- 8.9 管理评审（方式A） Management reviews (Option A)

8.1 方式 Options

- **8.1.1 总则 General** 4.2.1
- 实验室应建立、编制、实施和保持管理体系，该管理体系应能够支持和证明实验室持续满足本标准要求并且保证实验室结果的质量。除满足第**4**条款至第**7**条款的要求，实验室应按方式**A**或方式**B**实施管理体系。
- The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

8.1 方式

- 8.1.2 方式 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:
  - 管理体系文件（见8.2）
  - management system documentation (see 8.2);
  - 管理体系文件的控制（见8.3）
  - control of management system documents (see 8.3);
  - 记录控制（见8.4）control of records (see 8.4);
  - 应对风险和机遇的措施（见**8.5**）
  - actions to address risks and opportunities (see 8.5);
  - 改进（见8.6） improvement (see 8.6);
  - 纠正措施（见8.7） corrective actions (see 8.7);
  - 内部审核（见8.8） internal audits (see 8.8);
  - 管理评审（见8.9）management reviews (see 8.9).



8.1 方式

- 8.1.3 方式B
- Option B
- 实验室按照**ISO 9001**的要求建立并保持管理体系，并且能够支持和证明持续符合第**4**条款至第**7**条款要求的实验室，也至少满足了第**8.2**至第**8.9**条款中规定的管理体系要求。
- A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

8.2 管理体系文件

Management system documentation

- **8.2.1** 实验室管理者应建立、编制和保持符合本标准目的的政策和目标，且应确保该政策和目标在实验室组织的各级人员得到理解和执行。 4.2.2
- Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

4.2.1 实验室应建立、实施和保持与其活动范围相适应的管理体系；应将其政策、制度、计划、程序和指导书制订成文件，并达到确保实验室检测和/或校准结果质量所需的要求。体系文件应传达至有关人员，并被其理解、获取和执行。
4.2.2 实验室管理体系中与质量有关的政策，包括质量方针声明，应在质量手册（不论如 何称谓）中阐明。应制定总体目标并在管理评审时加以评审

8.2 管理体系文件
Management system documentation

- 8.2.2 政策和目标应体现实验室的能力、公正性和一致运作。new
- The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.
- 8.2.3 实验室管理者应提供建立和实施管理体系以及持续改进其有效性承诺的证据。
- Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. 4.2.3

4.2.3 最高管理者应提供建立和实施管理体系以及持续改进其有效性承诺的证据。

8.2 管理体系文件
Management system documentation

- 8.2.4 管理体系应包含、引用或链接满足本标准要求的所有文件、过程、系统和记录等。 4.2.5
- All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.
- 8.2.5 参与实验室活动的所有人员应可获得其职责适用的管理体系文件和相关信息。 4.2.1
- All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 管理体系文件的控制（方式A)

Control of management system documents (Option A)

- **8.3.1**实验室应控制与满足本标准要求有关的内部和外部文件。 4.3.1
- The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.
  - 注：本文中，“文件”可以是政策声明、程序、规范、制造商的说明书、校准表格、图表、教科书、张贴品、通知、备忘录、图纸或计划等。这些文件可承载在各种载体上，如硬拷贝或数码的。back
  - NOTE In this context, “document” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

4.3.1注1

8.3 管理体系文件的控制（方式A)

Control of management system documents (Option A)

- 8.3.2 实验室应确保： 4.3.2
- The laboratory shall ensure that:
  - a) 文件发布前由授权人员批准其充分性；
  - documents are approved for adequacy prior to issue by authorized personnel;
  - b) 定期评审文件，必要时更新；
  - documents are periodically reviewed, and updated as necessary;
  - c) 识别文件更改和当前修订状态；
  - changes and the current revision status of documents are identified;

8.3 管理体系文件的控制（方式A)

Control of management system documents (Option A)

- d) 在使用地点应获得适用文件的相应版本，必要时，其发放应受控。
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- e) 文件有唯一性标识；
- documents are uniquely identified;
- f) 防止作废文件的非预期使用，无论出于任何目的而保留的作废文件，应有适当的标识
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

- 取消标识应包括发布日期、修订标识、页码、总页数或表示文件结束的标记和发布机构
- 取消文件变更的要求，按要求控制

删除

- 4.3.2.1
- 应建立识别管理体系中文件当前的修订状态和分发的控制清单或等效的文件控制程序并使之易于获得，以防止使用无效和/或作废的文件。

删除

- **4.3.3** 文件变更
  - 4.3.3.1 除非另有特别指定，文件的变更应由原审查责任人进行审查和批准。被指定的人员应获得进行审查和批准所依据的有关背景资料。
  - 4.3.3.2 若可行，更改的或新的内容应在文件或适当的附件中标明。
  - 4.3.3.3 如果实验室的文件控制系统允许在文件再版之前对文件进行手写修改，则应确定修改的程序和权限。修改之处应有清晰的标注、签名缩写并注明日期。修订的文件应尽快地正式发布。
  - 4.3.3.4 应制订程序来描述如何更改和控制保存在计算机系统中的文件。

8.4记录的控制（方式A)
Control of records (Option A)

- 8.4.1 实验室应建立和保持清晰的记录以证明满足本标准的要求。 4.13.1
- The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

4.13.1.1 实验室应建立和保持识别、收集、索引、存取、存档、存放、维护和清理质量记录和技术记录的程序。质量记录应包括内部审核报告和管理评审报告以及纠正措施和预防措施的记录。

8.4记录的控制（方式A)
Control of records (Option A)

4.13.1

- **8.4.2**实验室应对记录的标识、存储、保护、备份、归档、检索、保存期和处置实施所需的控制。实验室记录保存期限应符合合同义务。记录的调阅应符合保密承诺，记录应易于获得。**new**
- The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.
- 注：对技术记录的其他要求见**7.5.**
- NOTE Additional requirements regarding technical records are given in 7.5.

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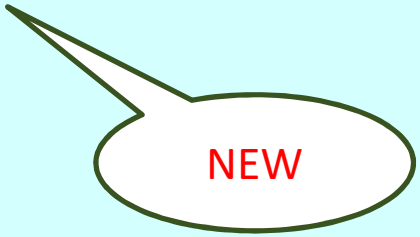
- 4.13.1.1
- 质量记录应包括内部审核报告和管理评审报告以及纠正措施和预防措施的记录。
- Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.
- 4.13.1.2
- 注：记录可存于任何媒体上，例如硬拷贝或电子媒体。
- NOTE Records may be in any media, such as hard copy or electronic media.

8.5应对风险和机遇的措施（方式A）

Actions to address risks and opportunities (Option A)

- 8.5.1 实验室应考虑实验室活动有关联的风险和机遇，以：
- The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
  - a) 确保管理体系实现其预期结果；
  - give assurance that the management system achieves its intended results;
  - b) 增强实现实验室目的和目标的机遇；
  - enhance opportunities to achieve the purpose and objectives of the laboratory;
  - c) 预防或减少实验室活动中的不利影响和可能的失败；
  - prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
  - d) 实现改进。
  - achieve improvement.



8.5应对风险和机遇的措施（方式A）

Actions to address risks and opportunities (Option A)

- 8.5.2 实验室应策划：
- The laboratory shall plan:

a) 应对这些风险和机遇的措施；

b) actions to address these risks and opportunities;

b) 如何：how to:

—在管理体系中整合并实施这些措施；

- integrate and implement the actions into its management system;

—评价这些措施的有效性

- evaluate the effectiveness of these actions.

8.5应对风险和机遇的措施（方式A）

Actions to address risks and opportunities (Option A)

- 注：虽然本标准规定组织应策划应对风险的措施，但并未要求运用正式的风险管理方法或将风险管理过程形成文件。实验室可决定是否采用超出本标准要求的更多风险管理方法，如：通过应用其它指南或标准。
- NOTE Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.
- back

8.5应对风险和机遇的措施（方式A）

Actions to address risks and opportunities (Option A)

- 8.5.3应对风险和机遇的措施应与其对于实验室结果有效性的潜在影响相适应。
- Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results

8.5应对风险和机遇的措施（方式A）

Actions to address risks and opportunities (Option A)

注1：应对风险的方式包括识别和规避威胁，为寻求机遇承担风险，消除风险源，改变风险的可能性或后果，分担风险，或在了解相关信息的基础上决定承担风险。

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

注2：机遇可能促使实验室扩展活动范围，赢得新客户，使用新技术和其他方式应对客户需求。

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6改进（模式A)
Improvement (Option A)

- **8.6.1** 实验室应识别和选择改进机会并采取必要的措施。 4.10
- The laboratory shall identify and select opportunities for improvement and implement any necessary actions.
  - 注：实验室可通过评审操作程序、实施政策、总体目标、审核结果、纠正措施、管理评审、人员建议、风险评估、数据分析和能力验证结果识别改进机会
  - NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

new

8.6改进（模式A)
Improvement (Option A)

- **8.6.2**实验室应向客户征求反馈，无论是正面还是负面的。应分析和利用这些反馈，以改进管理体系、实验室活动和客户服务。
- The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.
  - 注：反馈的类型示例包括：客户满意度调查、与客户的沟通记录和共同评审报告。
  - NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

4.7.2

8.7纠正措施（模式A)
Corrective actions (Option A)

4.11.1

- 8.7.1 发生不符合时，实验室应：
- When a nonconformity occurs, the laboratory shall:

a) 适用时，对不符合做出应对：

react to the nonconformity and, as applicable:

– 采取措施予以控制和纠正不符合；

– take action to control and correct it

– 处置后果；

– address the consequences

8.7纠正措施（模式A)
Corrective actions (Option A)

- b) 评价措施需求，以消除产生不符合的原因，避免其再次发生或者在其他场合发生：
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 评审和分析不符合；
  - reviewing and analysing the nonconformity
  - 确定不符合的原因；
  - determining the causes of the nonconformity
  - 确定是否存在或可能发生类似的不符合
  - determining if similar nonconformities exist, or could potentially occur。

8.7纠正措施（模式A)
Corrective actions (Option A)

c) 实施所需的措施；

– implement any action needed;

d) 评审所采取纠正措施的有效性；

– review the effectiveness of any corrective action taken;

e) 必要时，更新在策划期间确定的风险和机遇；

– update risks and opportunities determined during planning, if necessary;

f) 必要时，更改管理体系。

– make changes to the management system, if necessary.

8.7纠正措施（模式A)
Corrective actions (Option A)

- 8.7.2 纠正措施应与不符合所产生的影响相适应。
- Corrective actions shall be appropriate to the effects of the nonconformities encountered.
- 8.7.3 实验室应保留记录，作为下列事项的证据：
- The laboratory shall retain records as evidence of:

a）不符合的性质、产生原因和随后所采取的措施；

– the nature of the nonconformities, cause(s) and any subsequent actions taken;

b）纠正措施的结果

– the results of any corrective action.

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- 4.11.2
- 注：原因分析是纠正措施程序中最关键有时也是最困难的部分。根本原因通常并不明显，因此需要仔细分析产生问题的所有潜在原因。潜在原因可包括：客户要求、样品、样品规格、方法和程序、员工的技能和培训、消耗品、设备及其校准。
- NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

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- **4.11.5** 附加审核
- 当对不符合或偏离的识别引起对实验室符合其政策和程序，或符合本准则产生怀疑时，实验室应尽快依据4.14 条的规定对相关活动区域进行审核。
- 注：附加审核常在纠正措施实施后进行，以确定纠正措施的有效性。仅在识别出问题严重或对业务有危害时，才有必要进行附加审核。
- **4.11.5 Additional audits**
- Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure
- that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.
- NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness.
- An additional audit should be necessary only when a serious issue or risk to the business is identified.

8.8内部审核（方式A）
Internal audits (Option A)

- 8.8.1实验室应按照策划的时间间隔进行内部审核，以提供有关管理体系的下列信息：
- The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) 是否符合conforms to:：

- 实验室自身管理体系要求，包括实验室活动
  - the laboratory's own requirements for its management system, including the laboratory activities;
- 本标准的要求；
  - the requirements of this document

b) 是否得到有效地实施和保持。

- is effectively implemented and maintained.

取消内部审核周期的建议

8.8内部审核（方式A）
Internal audits (Option A)

- 8.8.2 实验室应：The laboratory shall:
  - a) 根据实验室活动的重要性，影响实验室的变化和以前审核的结果，策划、制定、实施和保持审核方案，审核方案包括频次、方法、职责、策划要求和报告；
  - plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

8.8内部审核（方式A）
Internal audits (Option A)

b) 规定每次审核的审核准则和范围；

– define the audit criteria and scope for each audit;

c) 确保审核结果报告给相关管理者；

– ensure that the results of the audits are reported to relevant management;

d) 及时采取适当的纠正和纠正措施；

– implement appropriate correction and corrective actions without undue delay;

e) 保留记录，作为实施审核方案以及审核结果的证据。

– retain records as evidence of the implementation of the audit programme and the audit results

注：ISO 19011给出了内部审核指南。

NOTE ISO 19011 provides guidance for internal audits.

取消内部审核范围建议—全要素/活动，并不强调质量主管负责，内审员资格要求删除

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

8.8内部审核（方式A）
Internal audits (Option A)

- 删除：
  - 4.14.1
  - 内部审核计划应涉及管理体系的全部要素，包括检测和/或校准活动。质量主管负责按照日程表的要求和管理层的需要策划和组织内部审核。审核应由经过培训和具备资格的人员来执行，只要资源允许，审核人员应独立于被审核的活动。

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

- 8.9.1 实验室管理层应按照策划的时间间隔评审其管理体系，以确保其持续的适宜性、充分性和有效性，包括为满足本标准而声明的政策和目标。
- The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

取消管理评审周期的建议

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.

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- 4.15.1
- 注 1：管理评审的典型周期为12 个月。
- 注 2：评审结果应当输入实验室策划系统，并包括下年度的目的、目标和活动计划。
- 注 3：管理评审包括对日常管理会议中有关议题的研究。
- NOTE 1 A typical period for conducting a management review is once every 12 months.
- NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action
- plans for the coming year.
- NOTE 3 A management review includes consideration of related subjects at regular management meetings.

附录A （资料性） 计量溯源性
Annex A(informative) Metrological traceability

- **A.1 总则 General**
- 计量溯源性是为确保测量结果国内和国际可比较性的重要概念，本附录给出了计量溯源性的更详细的信息。
- This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.

A.2 建立计量溯源性
Establishing metrological traceability

- **A.2.1**通过考虑并确保以下要素建立计量溯源性
  - Metrological traceability is established by considering, and then ensuring, the following:
- a) 规定被测量（被测量的量）；
  - the specification of the measurand (quantity to be measured);
- b) 一个文件化的不间断的校准链，可以溯源到声明的适当的参考（适当的参考包括国家或国际标准以及自然基准）；
  - a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);

A.2 建立计量溯源性
Establishing metrological traceability

- c) 按照协定的方法评估溯源链中每次校准的测量不确定度；
  - measurement uncertainty for each step in the traceability chain measurement uncertainty is evaluated according to agreed methods;
- d) 溯源链的每次校准按照适当的方法进行，具有测量结果及相关的已记录的测量不确定度；
  - each step of the chain is performed in accordance with appropriate methods, and the measurement results and associated, recorded measurement uncertainties;
- e) 在溯源链中执行一个或多次校准的实验室应提供其技术能力的证据。
  - the laboratories performing one or more steps in the chain supply evidence for their technical competence.

A.2 建立计量溯源性
Establishing metrological traceability

- A.2.2 当被校设备用来将计量溯源性传递到实验室的测量结果时，应考虑该设备的系统测量误差（有时称为偏倚）。有几种机制来考虑测量计量溯源传递中的系统测量误差。
- **A.2.2** The systematic measurement error (sometimes called “bias”) of the calibrated equipment is taken into account to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement metrological traceability.

A.2 建立计量溯源性
Establishing metrological traceability

- **A.2.3**有能力的实验室报告测量标准的信息，如果信息中只有与规范的符合性声明（省略了测量结果和相关不确定度），该测量标准有时也可用于传递计量溯源性，其规范限量是不确定度的来源，但此方法取于：
- Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:
- — 使用适当的判定规则来确定符合性
  - the use of an appropriate decision rule to establish conformity;
- — 在随后不确定度评估中，以技术上合适的方式来处理规范限量
  - the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

A.2 建立计量溯源性
Establishing metrological traceability

- 此方式的技术基础在于与所声明的与规范符合性确定了测量值的范围，预计真值以规定的置信度在该范围内，该范围考虑了真值的偏倚以及测量不确定度。
  - The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

A.2 建立计量溯源性
Establishing metrological traceability

- 示例：使用OIML R 111级砝码来校准天平
- EXAMPLE The use of OIML R 111 class weights to calibrate a balance.

A.3 证明计量溯源性
Demonstrating metrological traceability

- **A.3.1**实验室有责任按本标准建立计量溯源性。符合本标准的实验室提供的校准结果具有计量溯源性。符合**ISO 17034**的标准物质生产者提供的有证标准物质的有证值具有计量溯源性。有不同的方式来证明与本标准的符合性，即第三方承认（如认可机构）、客户进行的外部评审或自我评审。国际上承认的途径包括，但不限于：
- Laboratories are responsible for establishing metrological traceability in accordance with this document. Calibration results from laboratories conforming to this document provide metrological traceability. Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability. There are various ways to demonstrate conformity with this document: third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to, the following.

A.3 证明计量溯源性
Demonstrating metrological traceability

- a）已通过适当同行评审的国家计量院及其指定机构提供的国际计量委员会互任协议(CIPM MRA)下的校准和测量能力。该同行评审是在国际计量委员会互任协议下实施的。CIPM MRA所覆盖的服务可以在国际计量局的关键比对数据库（BIPM KCDB）附录C中浏览，其给出了每项服务的范围和测量不确定度。
  - CIPM MRA Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

A.3 证明计量溯源性
Demonstrating metrological traceability

- b）签署国际实验室认可合作组织（ILAC）协议或ILAC承认的区域协议的认可机构认可的校准和测量能力能够证明具有计量溯源性。获认可的校准实验室的范围可从各个认可机构公开获得。
  - Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

A.3 证明计量溯源性
Demonstrating metrological traceability

- **A.3.2**当需要证明计量溯源链的国际承认时，BIPM、OIML（国际法制计量组织）、ILAC和ISO关于计量溯源性的联合声明提供了专门指南。
- The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

附录**B** （资料性） 管理体系方式
Annex B(informative) **Management system options**

- **B.1** 管理体系应用的不断增长也越来越需要实验室运作的管理体系也被视为符合**ISO 9001**和本标准，因此，本标准针对管理体系的实施提供了两种方式的要求。
- Growth in the use of management systems generally has increased the need to ensure that laboratories can operate a management system that is seen as conforming to ISO 9001, as well as to this document. As a result, this document provides two options for the requirements related to the implementation of a management system.

附录**B** （资料性） 管理体系方式
Annex B(informative) **Management system options**

- **B.2** 方式**A**（见**8.1.2**）给出了在实验室实施管理体系的最低要求，其已将**ISO 9001**中与实验室活动范围相关的所有管理体系应满足的要求纳入。实验室符合第**4**条至和**7**条款，并实施了第**8**条款的方式**A**，其运作也基本符合**ISO 9001**原则。
- **B.2** Option A (see 8.1.2) lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. Laboratories that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

附录**B** （资料性） 管理体系方式
Annex B(informative) **Management system options**

- **B.3** 方式**B**（见**8.1.3**）允许实验室按**ISO 9001**要求建立和维持管理体系，并能支持和证明持续符合第**4**条至第**7**条款。因此实验室实施第**8**条款的方式**B**也是按照**ISO 9001**运作。覆盖实验室的管理体系符合**ISO 9001**的要求本身并不能证明实验室具有出具技术有效的数据和结果的能力。此时，实验室还应符合第**4**条至第**7**条款。
- Option B (see 8.1.3) allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. Laboratories that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished through compliance with Clauses 4 to 7.

附录**B** （资料性） 管理体系方式
Annex B(informative) **Management system options**

- **B.4**这两种方式旨在管理体系的运行和符合第4条至第7条要求方面达到同样的结果。
- Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.

附录B （资料性） 管理体系方式
Annex B(informative) Management system options

- 注：如同ISO 9001和其他管理体系标准，文件、数据和记录是制定成文件的信息的组成部分。8.3条款规定文件控制。8.4和7.5条款规定了记录控制。7.11条款规定了有关实验室活动的数据控制。
- NOTE Documents, data and records are components of documented information as used in ISO 9001 and other management system standards. Control of documents is covered in 8.3. The control of records is covered in 8.4 and 7.5. The control of data related to the laboratory activities is covered in 7.11.

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

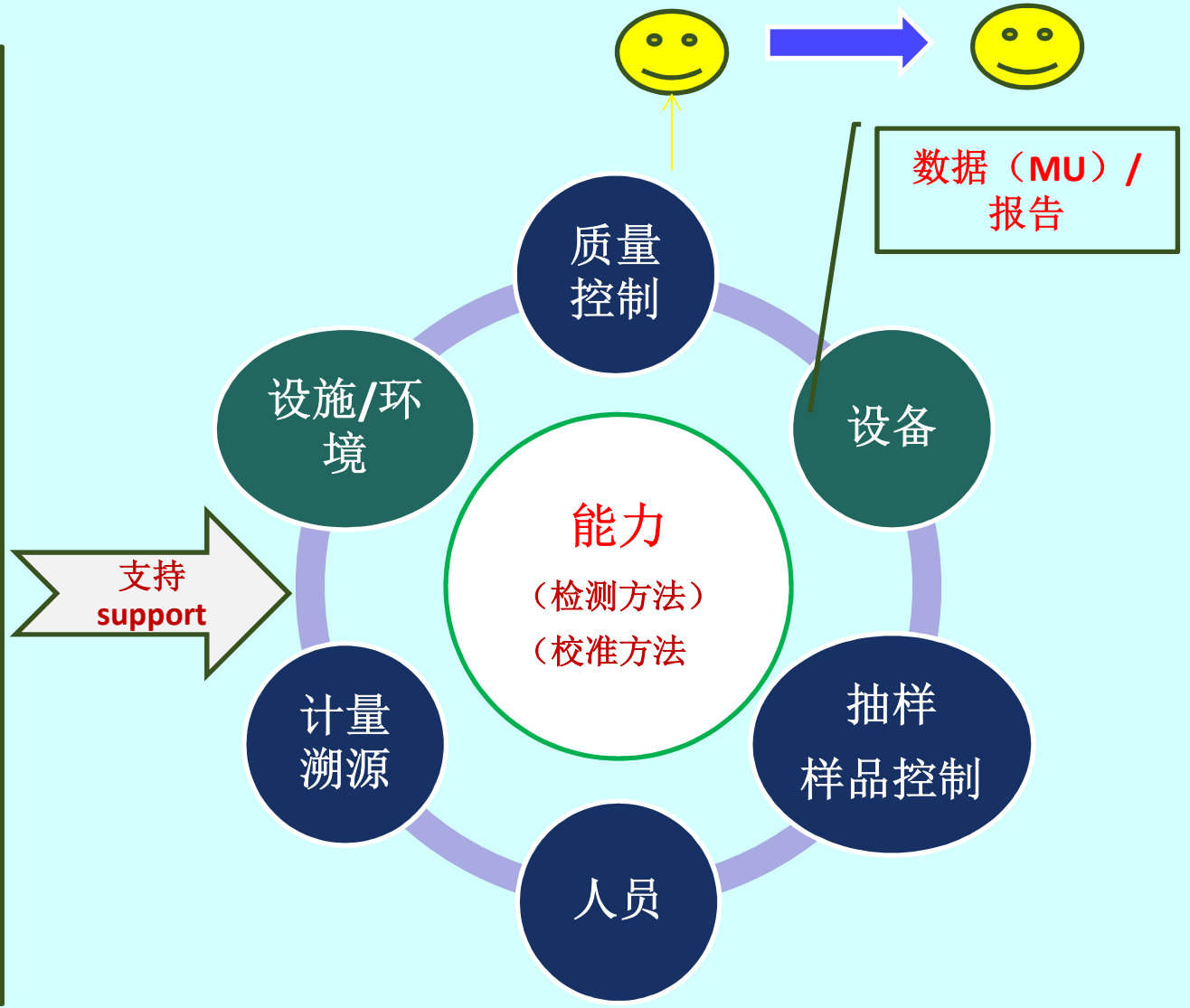
设备/溯源

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

……



感谢CNAS张明霞处长提供了2017年12月13日在太原机械行业工作会议上所做报告的PPT文稿和ISO发布的17025新旧版本差异对照ppt原文；感谢NSF International中国实验室张泽楷质量经理提供了加密pdf版 ISO/IEC 17025:2017 原文。

Thank you

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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