FINAL
DRAFT

INTERNATIONAL
STANDARD

ISO/IEC
FDIS
17025

ISO/CASCO
Secretariat: ISO

Voting begin on:
2017-08-14

Voting terminates on:
2017-10-09

General requirements for the competence of testing and calibration laboratories
检测和校准实验室能力的通用要求

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/IEC FDIS 17025:2017(E)

Foreword	**前言**
ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).	ISO(国际标准化组织)是一个世界性的国家标准机构联合会(ISO 成员机构)。国际标准的编制工作通常是通过 ISO 技术委员会进行的。各成员机构对设立技术委员会的主题感兴趣，有权代表该委员会。国际组织、政府和非政府组织以及 ISO，也参与了这项工作。在符合性评估领域，ISO 和国际电工委员会(IEC)在符合性评估委员会(ISO / CASCO)的管理下制定了 ISO / IEC 联合文件。
The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www .iso .org/ directives).	在 ISO / IEC 指示第 1 部分中描述了用于开发本文件的程序和用于进一步维护的程序。特别需要注意的是不同类型的 ISO 文件需要不同的审批标准。本文件是根据 ISO / IEC 指令，第 2 部分(见 www .iso .org/指令)的编辑规则起草的.
Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www .iso .org/ patents).	提请注意本文件的某些内容可能是专利权的主题。ISO 不应负责识别任何或所有这些专利权。在本文件的开发过程中所确定的任何专利权的细节，将在所收到的专利声明的 ISO 列表中介绍 (见 www .iso .org/专利).
Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.	本文件所使用的任何商业名称都是为方便用户而提供的信息，不构成背书。
For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www .iso .org/ iso/ foreword .html.	对于标准的自愿性质说明，ISO 特定术语的含义与符合性评估有关的表达，以及 ISO 在贸易技术壁垒中遵守世界贸易组织(WTO)原则的信息，请参阅以下网址:www .iso .org/ iso/ foreword .html
This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.	该文件由 ISO 评定委员会(CASCO)编写，并分发给 ISO 和 IEC 的国家机构投票，并得到两个组织的批准。
The main changes compared to the previous edition are as follows: — the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements; — there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities; — a definition of "laboratory" has been added (see 3.6).	与上一版相比，主要变化如下: ——本版所采用的基于风险的思想，使一些规定性的需求减少，并以基于业绩的要求取代它们; ——在过程、程序、成文信息和组织责任方面，比以前的版本有更大的灵活性; ——增加了"实验室"的定义(见 3.6)。

Introduction	**引言**
This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.	制定本标准的目的是增强对实验室运作的信任。本标准包含了实验室能够证明其运作能力，并且能够产生出有效结果的要求。符合本标准的实验室通常也是依据 ISO9001 的原则来运作的。
This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.	本标准要求实验室计划并采取措施应对风险和机遇。同时应对风险和机遇是提升管理体系有效性、取得改进效果、以及预防负面效应的基础。实验室有责任确定要应对哪些风险和机遇。
The use of this document will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if laboratories conform to this document.	使用本标准将促进实验室与其他机构的合作，有助于相互间信息和经验的交流，也有助于标准和程序的协调统一。如果实验室符合本标准，将促进结果的国际互认。
In this document, the following verbal forms are used: — “shall” indicates a requirement; — “should” indicates a recommendation; — “may” indicates a permission; — “can” indicates a possibility or a capability. Further details can be found in the ISO/IEC Directives, Part 2.	在本标准中，使用了以下动词形式： ——“应”表示要求； ——“应当”表示建议； ——“可”表示可以； ——“能”表示可能或能力。 ISO/IEC 工作导则第 2 部分中对这些动词做了更详细的说明。

ISOIEC 17025:2017 General requirements for the competence of testing and calibration laboratories		ISOIEC 17025:2017 检测和校准实验室能力的通用要求	
1	SCOPE	1	范围
	This document specifies the general requirements for competence, impartiality and consistent operation of laboratories.		本标准规定了实验室能力、公正性以及持续运作的通用要求。
	This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel		本标准适用于所有从事实验室活动的组织，不论其人员数量多少。
	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		实验室的客户、法定管理机构、采用同行评审的组织和制度、认可机构及其他机构使用本标准确认或认可实验室能力。
2	Normative references	2	规范性引用文件
	The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.		本标准引用了下列文件，这些文件的部分或全部内容构成了本标准的要求。对注明日期的参考文件，只采用引用的版本；对没有注明日期的参考文件，采用最新的版本（包括任何的修订）。
	ISO/IEC Guide 991), International vocabulary of metrology — Basic and general concepts and associated terms (VIM) ISO/IEC 17000, Conformity assessment — Vocabulary and general principles		ISO/IEC 指南 99 国际计量学词汇—基本和通用概念及相关术语 ISO/IEC 17000 合格评定—词汇和通用原则
3	Terms and definitions	3	术语和定义
	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/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。
	ISO and IEC maintain terminological databases for use in standardization at the following addresses: — ISO Online browsing platform: available at https:// www .iso .org/ obp — IEC Electropedia: available at http:// www .electropedia .org/		ISO 和 IEC 维护的用于标准化的术语数据库地址如下： ——ISO 在线浏览平台：http://www.iso.org/obp ——IEC 电子开放平台：http://www.electropedia.org/
3.1	impartiality	3.1	公正性
	presence of objectivity		客观性的存在。
	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 1：客观性意味着利益冲突不存在或已解决，不会对实验室（3.6）的活动产生不利影响。
	Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.		注 2：其他可用于表示公正性的要素的术语有：客观、独立、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。

	[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “the certification body” have been replaced by “the laboratory” in Note 1 to entry.]		[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”]
3.2	Complaint	3.2	投诉
	expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected		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。
	[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “other than appeal” have been deleted, and the words “a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory”.]		[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”]
3.3	interlaboratory comparison	3.3	实验室间比对
	organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions		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。
	[SOURCE: ISO/IEC 17043:2010, 3.4]		[源自: ISO/IEC 17043:2010, 3.4]
3.4	intralaboratory comparison	3.4	实验室内比对
	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		按照预先规定的条件，在同一实验室（3.6）内部对相同或类似的物品进行测量或检测的组织、实施和评价。
3.5	proficiency testing	3.5	能力验证
	evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)		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。
	[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]		[源自: ISO/IEC 17043:2010, 3.7—修改:删除了注]
3.6	Laboratory	3.6	实验室
	body that performs one or more of the following activities: — testing — calibration — sampling, associated with subsequent testing or calibration		从事下列一个或多个活动的机构 ——检测 ——校准 ——与后续检测或校准相关的抽样
	Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.		注 1：在本标准中，“实验室活动”指上述三种活动。
3.7	decision rule	3.7	判定规则
	rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement		当声明符合规定要求时，描述如何考虑测量不确定度的规则。
3.8	Verification	3.8	验证
	provision of objective evidence that a given item fulfils specified requirements		提供客观证据证明给定项目满足规定要求。

	EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg. EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved. EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.		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而言，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或法定要求。 例 3：证实满足目标测量不确定度。
	Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration. Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system. Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met. Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system. Note 5 to entry: Verification should not be confused with calibration. Not every verification is a validation (3.9). Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity. [SOURCE: ISO/IEC Guide 99:2007, 2.44]		注 1：适用时，应当考虑测量不确定度。 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：规定要求可以是如满足生产商的规定。 注 4：法制计量中的验证，如在 VIML 和通常的合格评定中的定义，是指对测量系统的检查并加标记和/或出具验证证书。（译者注：在我国的法制计量领域，“verification”翻译为“检定”） 注 5：验证不应当与校准混淆。不是每个验证都是确认。 注 6：在化学中，验证活性或所含实体的特性时，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]
3.9	Validation	3.9	确认
	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）。
	EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.		示例：一个通常用于测量水中氮的质量浓度的测量程序，也可被确认为可用于测量人体血清中氮的质量浓度。
	[SOURCE: ISO/IEC Guide 99:2007, 2.45]		[源自: ISO/IEC 指南 99:2007，2.45]
4	General requirements	4	通用要求
4.1	Impartiality	4.1	公正性
4.1.1	Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.	4.1.1	实验室活动应公正地实施，并从组织结构和管理上保证公正性。
4.1.2	The laboratory management shall be committed to impartiality.	4.1.2	实验室管理层做出公正性承诺。
4.1.3	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.	4.1.3	实验室应对其实验室活动的公正性负责，不允许商业、财务或其他方面的压力损害其公正性。

4.1.4	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.	4.1.4	实验室应持续识别影响公正性的风险。这些风险来源应来自其活动、实验室的各种关系，或者源于实验室人员的关系。然而，这些关系并非一定会对实验室的公正性产生风险。
	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.		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。
4.1.5	If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.	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。
4.2	Confidentiality	4.2	保密性
4.2.1	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.	4.2.1	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利信息，应予保密。
4.2.2	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.	4.2.2	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。
4.2.3	Information about the customer obtained from sources than the customer (e.g. complainant, regulators) shall be confidential between the customer and laboratory. The provider (source) of this information shall be confidential between the customer and laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with customer, unless agreed by source.	4.2.3	从客户以外渠道（如投诉人、监管机构）获取有关客户的信息，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）
4.2.4	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.	4.2.4	人员，包括委员会委员、合同方、外部机构人员、或代表实验室的个人，应对在实施实验室活动过程中所获得或产生的所有信息保密。
5	Structural requirements	5	结构要求
5.1	The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.	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，该实体对实验室活动承担法律责任。

	NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.		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。
5.2	The laboratory shall identify management that has overall responsibility for the laboratory.	5.2	实验室应确定对实验室全权负责的管理层。
5.3	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.	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。
5.4	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.	5.4	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、固定设施以外的地点，或在临时或移动设施、客户的设施中实施的实验室活动。
5.5	The laboratory shall: a) 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; b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.	5.5	实验室应： 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； b)规定对实验室活动结果有影响的所有管理、操作和验证人员的职责、权力和相互关系； c)将程序制定成文件，形成文件的程度以确保实验室活动应用的一致性和结果有效性为原则。
5.6	The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance and improvement of the management system; b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimize such deviations; d) reporting to laboratory management on the performance of the management system and any need for improvement; e) ensuring the effectiveness of laboratory activities.	5.6	实验室应有人员具有履行职责所需的权利和资源(不论其他职责)，包括： a)实施、保持和改进管理体系； b)识别与管理体系或实验室活动程序的偏离； c)采取预防或最大程度减少这类偏离的措施； d)向实验室管理层报告管理体系运行状况和改进的需求； e)确保实验室活动的有效性。
5.7	Laboratory management shall ensure that: a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; b) the integrity of the management system is	5.7	实验室管理层应确保： a)在管理体系有效性、以及满足客户和其他要求的重要性方面进行沟通； 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。

	maintained when changes to the management system are planned and implemented.		
6	Resource requirements	6	资源要求
6.1	General	6.1	总则
	The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.		实验室应配备管理和从事实验室活动所需的人员、设施、设备、系统及支持服务。
6.2	Personnel	6.2	人员
6.2.1	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.	6.2.1	所有可能影响实验室活动的人员，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。
6.2.2	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.	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。
6.2.3	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.	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，并能够评估偏离的影响程度。
6.2.4	The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.	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。
6.2.5	The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring of competence of personnel.	6.2.5	实验室应有以下程序并保存记录： a) 确定能力要求 b) 人员选择 c) 人员培训 d) 人员监督 e) 人员授权 f) 人员能力监控。
6.2.6	The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: a) development, modification, verification and validation of methods; b) analysis of results, including statements of conformity or opinions and interpretations; c) report, review and authorization of results.	6.2.6	实验室应对从事特定实验室活动的人员授权，包括但不限于下列活动： a) 开发、修改、验证和确认方法 b) 分析结果，包括符合性声明或意见和解释 c) 报告、审查和批准结果。
6.3	Facilities and environmental conditions	6.3	设施和环境条件
6.3.1	The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.	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良影响。

	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.		注：对结果有效性有不良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。
6.3.2	The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.	6.3.2	应将从事实验室活动所必需的设施及环境条件的要求制定成文件。
6.3.3	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.	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。
6.3.4	Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: a) access to and use of areas affecting laboratory activities; b) prevention of contamination, interference or adverse influences on laboratory activities; c) effective separation between areas with incompatible laboratory activities.	6.3.4	应实施、监控并定期评审控制设施的措施，这些措施应包括但不限于： a) 进入和使用影响实验室活动的区域； b) 预防对实验室活动的污染、干扰或不良影响； c) 有效隔离不相容实验室活动的区域。
6.3.5	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.	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。
6.4	Equipment	6.4	设备
6.4.1	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 which is required for the correct performance of laboratory activities and which can influence the result.	6.4.1	实验室应配置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。
	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. Reference materials from producers meeting the requirements of ISO 17034 come 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. Reference materials should be used from producers that meet ISO 17034.		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。满足 ISO 17034 要求的标准物质生产者提供的标准物质会附有产品信息单/证书，除其他特性外至少包含规定特性的均匀性及稳定性，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。(译者注：考虑我国也将标准物质称为标准样品，因此增加“标准样品”。) 应当使用满足 ISO 17034 的标准物质生产者提供的标准物质。

	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.		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。
6.4.2	In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	6.4.2	实验室使用永久控制以外的设备时，应确保满足本标准对设备的要求。
6.4.3	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.	6.4.3	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。
6.4.4	The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.	6.4.4	当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。
6.4.5	The equipment used for measurement shall be capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result.	6.4.5	用于测量的设备应能够达到所需的测量准确度或测量不确定度，以提供有效的结果。
6.4.6	Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, or — calibration of the equipment is required to establish the metrological traceability of the reported result. 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.	6.4.6	在下列情况下，测量设备应进行校准： ——当测量准确度或测量不确定度影响报告结果的有效性，或 ——为建立所报告结果的计量溯源性，要求对设备进行校准。 注：影响报告结果有效性的设备类型可能包括： ——用于直接测量被测量的设备，例如，使用天平测量质量； ——用于修正测量值的设备，例如温度测量； ——用于从多个测量值计算获得测量结果的设备。
6.4.7	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.	6.4.7	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。
6.4.8	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.	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的状态或有效期。
6.4.9	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	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。实验室应核查设备缺陷或偏离规定要求的影响，

	management of nonconforming work procedure (see 7.10).		并应启动不符合工作管理程序（见 7.10）。
6.4.10	When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	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。
6.4.11	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.	6.4.11	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。
6.4.12	The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.	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。
6.4.13	Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: a) the identity of equipment, including software and firmware version; b) the manufacturer's name, type identification, and serial number or other unique identification; c) evidence of verification that equipment conforms with specified requirements; d) the current location; e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval; f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity; g) the maintenance plan and carried out to date, where relevant performance of equipment; h) details of any damage, malfunction, modification to, or repair of, the equipment.	6.4.13	应保存对实验室活动有影响的设备的记录。 记录应包括以下适用的内容： a）设备的识别，包括软件和硬件版本； b）制造商名称、型号、系列号或其他唯一性标识； c）设备符合规定要求的验证证据； d）当前的位置； e）校准日期、校准结果、设备调整、验收准则以用下次校准的预定日期或校准周期； f）标准物质的文件、结果、验收准则、相关数据和有效期； g）与设备性能相关的维护计划和已进行的维护。 h）设备的损坏、故障、改装或维修的详细信息。
6.5	Metrological traceability	6.5	计量溯源性
6.5.1	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.	6.5.1	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。
	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". NOTE 2 See Annex A for additional information on 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" 注 2：关于计量溯源性的进一步

			信息见附录 A。
6.5.2	The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through one of the following: a) calibration provided by a competent laboratory; NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent. b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent. c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.	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）： a) 具备能力的实验室提供的校准； 注 1：满足本标准要求的实验室可视为是有能力的。 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； 注 2：满足 ISO 17034 要求的标准物质生产者被认为是有能力的。 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。 注 3：SI 手册给出了一些重要单位定义的实际复现的详细信息。
6.5.3	When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g. a) certified values of certified reference materials provided by a competent producer; b) 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.	6.5.3	技术上不可能计量溯源到 SI 单位时，实验室应通过下列方式证明可溯源至适当的参考标准，如： a) 具备能力的标准物质生产者提供的有证标准物质的标准值； b) 使用参考测量程序、规定方法或描述清晰的协议标准，其测量结果满足预期用途，并通过适当比对予以保证。
6.6	Externally provided products and services	6.6	外部提供的产品和服务
6.6.1	The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a) are intended for incorporation into the laboratory's own activities; b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c) are used to support the operation of laboratory. 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.	6.6.1	实验室应确保影响实验室活动的外部产品和服务的适用性，包括： a）将外部提供的产品和服务用于实验室自身的活动； b）将外部提供的部分或全部产品和服务直接提供给客户时； c）用于支持实验室的运作。 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。

6.6.2	The laboratory shall have a procedure and retain records for: a) defining, reviewing and approving the laboratory's requirements for externally provided products services; b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; c) 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) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.	6.6.2	实验室应有以下活动的程序和记录： a）确定、审查和批准实验室对外部产品和服务的要求； b）确定对外部供应商的评价、选择、表现监控和重新评价标准； 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； 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。
6.6.3	The laboratory shall communicate its requirements to external providers for: a) the products and services to be provided; b) the acceptance criteria; c) competence, including any required qualification of personnel; d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.	6.6.3	实验室应与外部供应商沟通以明确以下要求： a）需提供的产品和服务； b）验收准则； c）能力，包括人员所具备的资格； d）实验室或其客户拟在外部供应商的场所进行的活动。
7	Process requirements	7	过程要求
7.1	Review of requests, tenders and contracts	7.1	要求、标书和合同的评审
7.1.1	The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: a) the requirements are adequately defined, documented and understood; b) the laboratory has the capability and resources to meet requirements; c) 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; 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. d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.	7.1.1	实验室应有评审要求、标书和合同的程序。该程序应确保： a) 明确规定要求，形成文件，并被理解； b) 实验室有能力和资源满足这些要求； 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； 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，然而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和能力。 d) 选择适当的方法或程序，并能满足客户的要求。 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。
7.1.2	The laboratory shall inform the customer when the method requested by the customer is considered to	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。

	be inappropriate or out of date.		
7.1.3	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.	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。
	NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.		注：符合性声明的进一步指南见 ISO/IEC 98-4。
7.1.4	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.	7.1.4	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。
7.1.5	The customer shall be informed of any deviation from the contract.	7.1.5	与合同的任何偏离应通知客户。
7.1.6	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.	7.1.6	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。
7.1.7	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.	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。
	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.		注：这种合作可包括： 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。
7.1.8	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.	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。
7.2	Selection, verification and validation of methods	7.2	方法的选择、验证和确认
7.2.1	Selection and verification of methods	7.2.1	方法的选择和验证
7.2.1.1	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.	7.2.1.1	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。
	NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.		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。

7.2.1.2	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).	7.2.1.2	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）
	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.		实验室应确保使用最新有效版本的方法，除非不合适或不可能做到。必要时，应补充方法使用的细节以确保应用的一致性。
	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.		注： 如果国际的、区域的或国家的标准，或其他公认的规范已包含了如何进行实验室活动的简明和充分信息，并且这些标准是以可被实验室操作人员使用的方式书写时，则不需再进行补充或改写为内部程序。对方法中的可选择步骤，可能有必要制定附加细则或补充文件。
7.2.1.4	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.	7.2.1.4	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、区域标准或国家标准发布的方法，或由知名技术组织或由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。
7.2.1.5	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.	7.2.1.5	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。
	7.2.1.6 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 customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.		当需要制定方法时，应予策划，并指定具有足够资源并有能力的人员进行。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。
7.2.1.7	Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	7.2.1.7	实验室活动与方法的偏离，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。
	NOTE Customer acceptance of deviations can be agreed in advance in the contract.		注：客户接受偏离可以事先在合同中约定。
7.2.2	Validation of methods	7.2.2	方法确认

7.2.2.1	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.	7.2.2.1	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标准方法、或其他修改的标准方法进行确认。确认应尽可能全面，以满足预期用途或应用领域的需要。
	NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) 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.		注 1：确认可包括对抽样、检测或校准物品的处置和运输程序的确认。 注 2：可用以下一种或多种技术进行方法确认： 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； b）对影响结果的因素做系统性评审； 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； d）与其他已确认的方法进行结果比对； e）实验室间比对； f）根据对方法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。
7.2.2.2	When changes are made to a validated method, the influence of such shall be determined and where they are found to affect the original validation, a new method validation shall be performed.	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。
7.2.2.3	The performance characteristics of validated methods as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.	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。
	NOTE Performance characteristics can include, but are not limited to, the measurement range, accuracy, the 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.		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。
7.2.2.4	The laboratory shall retain the following records of validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics method; d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use.	7.2.2.4	实验室应保存以下确认记录： a）使用的确认程序； b）规定的要求； c）确定的方法性能特性； d）获得的结果； e）方法有效性声明,并详述与预期用途的适宜性。
7.3	Sampling	7.3	抽样

7.3.1	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.	7.3.1	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。
7.3.2	The sampling method shall describe: a) the selection of samples or sites; b) the sampling plan; c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration. NOTE When received into the laboratory, further handling can be required as specified in 7.4.	7.3.2	抽样方法应描述： a）样品或位置的选择； b）抽样计划； 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。 注：实验室接收样品后，进一步处理要求见 7.4 的规定。
7.3.3	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) reference to the sampling method used; b) date and time of sampling; c) data to identify and describe the sample (e.g. number, amount, name); d) identification of the personnel performing sampling; e) identification of the equipment used; f) environmental or transport conditions; g) diagrams or other equivalent means to identify the sampling location when appropriate; h) deviations, additions to or exclusions from the sampling method and sampling plan.	7.3.3	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： a）所用的抽样方法； b）抽样日期及时间； c）识别和描述样品的数据（如编号、数量和名称）； d）抽样人识别信息; e）所用设备的识别； f）环境或运输条件； g）适当时，识别抽样位置的图示或其他等效方式； h）与抽样方法和抽样计划的偏离或增减。
7.4	Handling of test or calibration items	7.4	检测和校准物品的处置
7.4.1	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.	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、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。
7.4.2	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	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

	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.		组物品的细分和物品的传递。
7.4.3	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.	7.4.3	接收检测或校准物品时，应记录与规定条件的偏离。当对物品是否适于检测或校准有疑问，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。
7.4.4	When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.	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。
7.5	Technical records	7.5	技术记录
7.5.1	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.	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审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。
7.5.2	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 kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.	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。
7.6	Evaluation of measurement uncertainty	7.6	测量不确定度的评定
7.6.1	Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions which are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.	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。
7.6.2	A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.	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。

7.6.3	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.	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。
	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. 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 identified critical influencing factors are under control. NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 5725 and ISO 21748.		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。 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，则不需要对每个结果评定测量不确定度。 注 3 更多信息参见 ISO/IEC 指南 98-3、ISO 5725 和 ISO 21748.
7.7	Ensuring the validity of results	7.7	确保结果的有效性
7.7.1	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: a) use of reference materials or quality control materials; b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; f) replicate tests or calibrations using the same or different methods; g) retesting or recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; j) intralaboratory comparisons; k) testing of blind sample(s).	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评审，监控应包括但不限于以下适当的方式： a）使用标准物质或质量控制物质； b）使用其他已校准能够提供可溯源结果的仪器； c）测量和检测设备的功能核查； d）适用时，使用核查或工作标准，并制作控制图； e）测量设备的期间核查； f）使用相同或不同方法进行重复检测或校准； g）保存样品的重复检测或重复校准； h）物品不同特性结果之间的相关性； i）审查报告的结果； j）实验室内比对； k）盲样测试。

7.7.2	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) participation in proficiency testing; 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. b) participation in interlaboratory comparisons other than proficiency testing.	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： a）参加能力验证； 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。 b）参加除能力验证之外的实验室间比对。
7.7.3	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.	7.7.3	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。
7.8	Reporting of results	7.8	报告结果
7.8.1	General	7.8.1	总则
7.8.1.1	The results shall be reviewed and authorized prior to release.	7.8.1.1	结果在发出前应经过审查和批准。
	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.		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。
	NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively. NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.		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。 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。
7.8.1.2	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.	7.8.1.2	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。
7.8.2	Common requirements for reports (test, calibration or sampling)	7.8.2	报告（检测、校准或抽样）的通用要求

7.8.2.1	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) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”); b) the name and address of the laboratory; c) 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) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; e) the name and contact information of the customer; f) identification of the method used; g) a description, unambiguous identification, and, when necessary, the condition of the item ; h) 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) the date(s) of performance of the laboratory activity; j) the date of issue of the report; k) 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) a statement to the effect that the results relate only to the items tested, calibrated or sampled; m) the results with, where appropriate, the units of measurement; n) additions to, deviations, or exclusions from the method; o) identification of the person(s) authorizing the report; p) clear identification when results are from external providers.	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： a) 标题（例如“检测报告”、“校准证书”或“抽样报告”）； b) 实验室的名称和地址； 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； 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； e)客户的名称和联络信息 ； f) 所用方法的识别； g)物品的描述、明确的标识以及必要时物品的状态； h)检测或校准的接收日期，以及对结果的有效性和应用至关重要的抽样日期； i)实验室活动的开展日期； j)报告的发布日期； 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； l)结果仅与被检测、被校准或被抽物品有关的声明； m)结果，适当时，带有测量单位； n)对方法补充、偏离或删减； o) 报告批准人的识别； p)当结果来自于外部提供者时，清晰标识
	The laboratory should include a statement specifying that the report shall not be reproduced except in full, without approval of the laboratory.		实验室应当做出未经实验室批准，不得复制报告的声明（全文复制除外）。
7.8.2.2	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.	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。

7.8.3	Specific requirements for test reports	7.8.3	检测报告的特定要求
7.8.3.1	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) information on specific test conditions, such as environmental conditions; b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); c) 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: — it is relevant to the validity or application of the test results; — a customer's instruction so requires, or — the measurement uncertainty affects conformity to a specification limit; d) where appropriate, opinions and interpretations (see 7.8.7); e) additional information which may be required by specific methods, authorities, customers or groups of customers.	7.8.3.1	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： a) 特定的检测条件信息，如环境条件； b) 相关时，与要求或规范的符合性声明（7.8.6）； c) 适用时，在下列情况下，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）： —测量不确定度与检测结果的有效性或应用有关时； —客户有要求时； —测量不确定度影响到与规范限量的符合性时。 d) 适当时，意见和解释（见7.8.7）； e) 特定方法、法定管理机构或客户要求的其他信息。
7.8.3.2	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.	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。
7.8.4	Specific requirements for calibration certificates	7.8.4	校准证书的特定要求
7.8.4.1	In addition to the requirements listed in 7.8.2, calibration certificates shall include the following: a) 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); NOTE According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty. b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; c) a statement identifying how the measurements are metrologically traceable (see Annex A); d) the results before and after any adjustment or repair, if available; e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); f) where appropriate, opinions and interpretations (see 7.8.7).	7.8.4.1	除 7.8.2 的要求外，校准证书应包含以下信息： 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）； 注：根据 JCGM 200:2012，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。 b) 校准活动中对测量结果有影响的条件（如环境条件）； c) 测量如何计量溯源的声明（见附录 A）； d) 如可获得，调整或修理前后的结果； e) 相关时，与要求或规范的符合性声明 （7.8.6）； f) 适当时，意见和解释（见7.8.7）.
7.8.4.2	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 test results.	7.8.4.2	当实验室负责抽样活动时，如果解释检测结果需要， 校准证书应满足 7.8.5 条款的要求。

7.8.4.3	A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.	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。
7.8.5	Reporting sampling – specific requirements	7.8.5	报告抽样——特殊要求
	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) the date of sampling; b) 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); c) the location of sampling, including any diagrams, sketches or photographs; d) a reference to the sampling plan and sampling method; e) details of any environmental conditions during sampling that affect the interpretation of the test results; f) information required to evaluate measurement uncertainty for subsequent testing or calibration.		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： a) 抽样日期； 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）； c) 抽样位置，包括图示、草图或照片； d) 抽样计划和抽样方法； e) 抽样过程中影响测试结果解释的详细环境条件信息； f) 评定后续检测或校准的测量不确定度所需的信息。
7.8.6	Reporting statements of conformity	7.8.6	报告符合性声明
7.8.6.1	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.	7.8.6.1	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。
	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.		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。
7.8.6.2	The laboratory shall report on the statement of conformity, such that the statement clearly identifies: a) to which results the statement of conformity applies; b) which specifications, standards or parts thereof are met or not met; c) the decision rule applied (unless it is inherent in the requested specification or standard).	7.8.6.2	实验室在报告符合性声明时应清晰标识： a) 符合性声明适用于哪些结果； b) 满足或不满足哪个规范、标准或其中的部分； c) 使用的判定规则（除非规范或标准中已包含）。
	NOTE For further information, see ISO/IEC Guide 98-4.		注：进一步信息见 ISO/IEC 指南 98-4。
7.8.7	Reporting opinions and interpretations	7.8.7	报告意见和解释
7.8.7.1	When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.	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。

	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.		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。
7.8.7.2	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.	7.8.7.2	报告中的意见和解释应基于被检测或校准物品的结果，并清晰地予以标识。
7.8.7.3	When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.	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。
7.8.8	Amendments to reports	7.8.8	修改报告
7.8.8.1	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.	7.8.8.1	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。
7.8.8.2	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.	7.8.8.2	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
7.8.8.3	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.	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。
7.9	Complaints	7.9	投诉
7.9.1	The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.	7.9.1	实验室应有制订成文件的过程来接收和评价投诉，并对投诉做出决定。
7.9.2	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.	7.9.2	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。
7.9.3	The process for handling complaints shall include at least the following elements and methods: a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions undertaken to resolve them; c) ensuring that any appropriate action is taken.	7.9.3	处理投诉的过程应至少包括以下要素和方法： 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； b) 跟踪并记录投诉，包括为解决投诉所采取的措施； c) 确保采取适当的措施。
7.9.4	The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the 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。

7.9.5	Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.	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。
7.9.6	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. NOTE This can be performed by external personnel.	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做出，或审查和批准。 注：可由外部人员实施。
7.9.7	Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.	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。
7.10	Nonconforming work	7.10	不符合工作
7.10.1	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:	7.10.1	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：
	a) the responsibilities and authorities for the management of nonconforming work are defined; b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; d) a decision is taken on the acceptability of the nonconforming work; e) where necessary, the customer is notified and work is recalled; f) the responsibility for authorizing the resumption of work is defined.		a) 确定不符合工作管理的职责和权力； 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）； c) 评价不符合工作的严重性，包括分析对先前结果的影响； d) 对不符合工作的可接受性做出决定； e) 必要时，通知客户并取消工作； f) 规定批准恢复工作的职责。
7.10.2	The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).	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。
7.10.3	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.	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。
7.11	Control of data and information management	7.11	数据控制和信息管理
7.11.1	The laboratory shall have access to the data and information needed to perform laboratory activities.	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。
7.11.2	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	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

	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.		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；
	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. NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.		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。 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。
7.11.3	The laboratory information management system(s) shall: a) be protected from unauthorized access; b) be safeguarded against tampering and loss; c) be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; d) be maintained in a manner that ensures the integrity of the data and information; e) include recording system failures and the appropriate immediate and corrective actions.	7.11.3	实验室信息管理系统应： a) 防止未经授权的访问； b) 安全保护以防止篡改或丢失； c) 在符合供应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； d) 以确保数据和信息完整性的方式进行维护； e) 包括系统失效记录和适当的紧急措施及纠正措施。
7.11.4	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.	7.11.4	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。
7.11.5	The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.	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、手册和参考资数据。
7.11.6	Calculations and data transfers shall be checked in an appropriate and systematic manner.	7.11.6	应对计算和数据转换进行适当和系统的检查。
8	Management system requirements	8	管理体系要求
8.1	Options	8.1	方式
8.1.1	General	8.1.1	总则
	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.		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。
	NOTE See Annex B for more information.		注：更多信息参见附录 B。

8.1.2	Option A	8.1.2	方式 A
	As a minimum, the management system of the laboratory shall address the following: — management system documentation (see 8.2); — control of management system documents (see 8.3); — control of records (see 8.4); — actions to address risks and opportunities (see 8.5); — improvement (see 8.6); — corrective action (see 8.7); — internal audits (see 8.8); — management reviews (see 8.9).		实验室管理体系至少应包括下列内容： —管理体系文件（见 8.2） —管理体系文件的控制（见 8.3） —记录控制（见 8.4） —应对风险和机遇的措施（见 8.5） —改进（见 8.6） —纠正措施（见 8.7） —内部审核（见 8.8） —管理评审（见 8.9）
8.1.3	Option B	8.1.3	方式 B
	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.		实验室按照 ISO9001 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 条款至第 8.9 条款中规定的管理体系要求。
8.2	Management system documentation (Option A)	8.2	管理体系文件（方式 A）
8.2.1	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.	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。
8.2.2	The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.	8.2.2	政策和目标应能体现实验室的能力、公正性和一致运行。
8.2.3	Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	8.2.3	实验室管理层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。
8.2.4	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.	8.2.4	管理体系应包含、引用或链接与满足本标准要求相关的所有文件、过程、系统、记录等。
8.2.5	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.	8.2.5	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。
8.3	Control of management system documents (Option A)	8.3	管理体系文件的控制（方式 A）
8.3.1	The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.	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。
	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.		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、软件、图纸、计划等。这些文件可能承载在各种载体上，例如硬拷

			贝或数字形式。
8.3.2	The laboratory shall ensure that: a) documents are approved for adequacy prior to issue by authorized personnel; b) documents are periodically reviewed, and updated as necessary; c) changes and the current revision status of documents are identified; d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; e) documents are uniquely identified; f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.	8.3.2	实验室应确保： a) 文件发布前由授权人员批准其充分性； b) 定期审查文件，必要时更新； c) 识别文件更改和当前修订状态； d) 在使用地点应可获得适用文件的相应版本，必要时，应受控其发放。 e) 文件有唯一性标识； 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。
8.4	Control of records (Option A)	8.4	记录控制（方式 A）
8.4.1	The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.	8.4.1	实验室应建立和保存清晰的记录以证实满足本标准的要求。
8.4.2	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.	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。
	NOTE Additional requirements regarding technical records are given in 7.5.		注：对技术记录的其他要求见 7.5。
8.5	Actions to address risks and opportunities (Option A)	8.5	应对风险和机遇的措施（方式 A）
8.5.1	The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to: a) give assurance that the management system achieves its intended results; b) enhance opportunities to achieve the purpose and objectives of the laboratory; c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d) achieve improvement.	8.5.1	实验室应考虑与实验室活动有关联的风险和机遇，以： a) 确保管理体系能够实现其预期结果； b) 增强实现实验室目的和目标的机遇； c) 预防或减少实验室活动中的不利影响和可能的失败； d) 实现改进。
8.5.2	The laboratory shall plan: a) actions to address these risks and opportunities; b) how to: — integrate and implement the actions into its management system; — evaluate the effectiveness of these actions.	8.5.2	实验室应策划： a) 应对这些风险和机遇的措施； b) 如何： —在管理体系中整合并实施这些措施； —评价这些措施的有效性。

	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.		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广泛的风险管理方法，如：通过应用其它指南或标准。
8.5.3	Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.	8.5.3	应对风险和机遇的措施应与其对实验室结果有效性的潜在影响相适应。
	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. 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.		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。 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。
8.6	Improvement (Option A)	8.6	改进（方式 A）
8.6.1	The laboratory shall identify and select opportunities for improvement and implement any necessary actions.	8.6.1	实验室应识别和选择改进机会，并采取必要的措施。
	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.		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。
8.6.2	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. NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.	8.6.2	实验室应向客户征求反馈，无论是正面的还是负面的。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。 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价报告。
8.7	Corrective action (Option A)	8.7	纠正措施（方式 A）【参考 9001】

8.7.1	When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the management system, if necessary.	8.7.1	当发生不符合时，实验室应： a) 适用时，对不符合做出应对： —采取措施以控制和纠正不符合； —处置后果； b) 通过下列活动，评价是否需要采取措施，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： —评审和分析不符合； —确定不符合的原因； —确定是否存在或可能发生类似的不符合。 c) 实施所需的措施； d) 评审所采取的纠正措施的有效性； e) 必要时，更新在策划期间确定的风险和机遇； f) 必要时，变更管理体系。
8.7.2	Corrective actions shall be appropriate to the effects of the nonconformities encountered.	8.7.2	纠正措施应与不符合产生的影响相适应。
8.7.3	The laboratory shall retain records as evidence of: a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action.	8.7.3	实验室应保留记录，作为下列事项的证据： a） 不符合的性质、产生原因和随后所采取的措施； b） 纠正措施的结果
8.8	Internal audits (Option A)	8.8	内部审核 (方式 A)
8.8.1	The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system: a) conforms to: — the laboratory's own requirements for its management system, including the laboratory activities; — the requirements of this document; b) is effectively implemented and maintained.	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： a) 是否符合： —实验室自身的管理体系要求，包括实验室活动； —本标准的要求； b) 是否得到有效的实施和保持。
8.8.2	The laboratory shall: a) 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; b) define the audit criteria and scope for each audit; c) ensure that the results of the audits are reported to relevant management; d) implement appropriate correction and corrective actions without undue delay; e) retain records as evidence of the	8.8.2	实验室应： 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。 b) 规定每次审核的审核准则和范围； c) 确保将审核结果报告给相关管理者； d) 及时采取适当的纠正和纠正措施；

	implementation of the audit programme and the audit results. NOTE ISO 19011 provides guidance for internal audits.		e) 保留记录，作为实施审核方案以及审核结果的证据。 注：内部审核相关指南参见 ISO 19011
8.9	Management reviews (Option A)	8.9	管理评审（方式 A）
8.9.1	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.	8.9.1	实验室的管理层应按照策划的时间间隔对实验室的管理体系进行评审，以确保其持续的适宜性、充分性和有效性，包括执行本标准的相关方针和目标。
8.9.2	The inputs to management review shall be recorded and shall include information related to the following: a) changes in internal and external issues that are relevant to the laboratory; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcome of recent internal audits; f) corrective actions; g) assessments by external bodies; h) changes in the volume and type of the work or in the range of laboratory activities; i) customer and personnel feedback; j) complaints; k) effectiveness of any implemented improvements; l) adequacy of resources; m) results of risk identification; n) outcomes of the assurance of the validity of results; and o) other relevant factors, such as monitoring activities and training.	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： a）与实验室相关的内外部因素的变化； b）目标实现； c）政策和程序的适宜性； d）以往管理评审所采取措施的情况； e）近期内部审核的结果； f）纠正措施； g）由外部机构进行的评审； h）工作量和工作类型的变化或实验室活动范围的变化； i）客户和员工的反馈； j）投诉； k）实施改进的有效性； i）资源的充分性； m）风险识别的结果； n）保证结果有效性的输出； o）其他相关因素，如监测活动和培训。
8.9.3	The outputs from the management review shall record all decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; d) any need for change.	8.9.3	管理评审的输出至少应记录与下列事项相关的决定和措施： a）管理体系及其过程的有效性； b）履行本标准要求相关的实验室活动的改进； c）提供所需的资源； d）所需的变更。

Annex A	(informative)Metrological traceability	Annex A	（资料性）计量溯源性
A.1	General	A.1	总则
	This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.		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。
A.2	Establishing metrological traceability	A.2	建立计量溯源性
A.2.1	Metrological traceability is established by considering, and then ensuring, the following: a) the specification of the measurand (quantity to be measured); b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards); c) measurement uncertainty for each step in the traceability chain measurement uncertainty is evaluated according to agreed methods; d) each step of the chain is performed in accordance with appropriate methods, and the measurement results and associated, recorded measurement uncertainties; e) the laboratories performing one or more steps in the chain supply evidence for their technical competence.	A.2.1	通过考虑并确保以下内容建立计量溯源性： a) 规定被测量（被测量的量）； b) 一个形成文件的不间断的校准链，可以溯源到声明的适当的参考标准（适当的参考标准包括国家或国际标准以及自然基准）； c) 按照约定的方法评定溯源链中每步校准的测量不确定度； d) 溯源链的每步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； e) 在溯源链中执行一步或多步校准的实验室应提供其技术能力的证据。
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.2.2	当被校准的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.2.3	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: — the use of an appropriate decision rule to establish conformity; — the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.	A.2.3	有能力的实验室报告测量标准的信息，如果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： —使用合适的判定规则确定符合性； —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 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.		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。

	EXAMPLE The use of OIML R 111 class weights to calibrate a balance.		例. 法制计量委员会的国际建议 111（OIML R111：2004)中使用等级砝码来校准天平。
A.3	Demonstrating metrological traceability	A.3	计量溯源性的证明
A.3.1	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, i.e. 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.3.1	实验室负责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标准值具有计量溯源性。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：
	a) Calibration and measurement capabilities provided by national metrology institutes and designated institues that have been subject to suitable peer-review processes. Such peer -review is conducted undereview is conducted the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service. b) 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）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相互承认协议(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相互承认协议下实施的。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. 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。
A.3.2	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.	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。

Annex B	(informative) Management system optionsManagement system options	Annex B	（资料性附录）管理体系方式
B.1	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.	B.1	随着管理体系的广泛应用，对于实验室，要求其按照既符合 ISO 9001 又符合本标准的管理体系运作的需求也在增长。因此，本标准提供了实施管理体系相关要求的两种方式。
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.	B.2	方式 A（见 8.1.2）列出实验室管理体系实施的最低要求，其已纳入 ISO 9001 中与实验室活动范围相关的管理体系所有要求。因此，遵循了本标准第 4 条款至第 7 条款，并实施第 8 条款方式 A 的实验室，其运作也基本符合 ISO 9001 的原则。
B.3	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.	B.3	方式 B（见 8.1.3）允许实验室按照 ISO 9001 的要求建立和维持管理体系，并能支持和证明持续符合第 4 条款至第 7 条款的要求。因此实验室实施第 8 条款的方式 B，也是按照 ISO 9001 运作的。实验室管理体系符合 ISO 9001 的要求，并不证明实验室具有出具技术上有效的数据和结果的能力。此时，实验室还应符合第 4 条款至第 7 条款。
B.4	Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.	B.4	两种方式的目的都是为了达到相同的结果，既符合管理体系的要求又遵循第 4 条款至第 7 条款的要求。
	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.		注：如同 ISO9001 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。
B.5	Figure B.1 illustrates an example of a possible schematic representation of the operational processes of a laboratory, as described in Clause 7.	B.5	图B.1给出了可能代表实验室运作过程中一个示意图，如第 7 条款的描述。

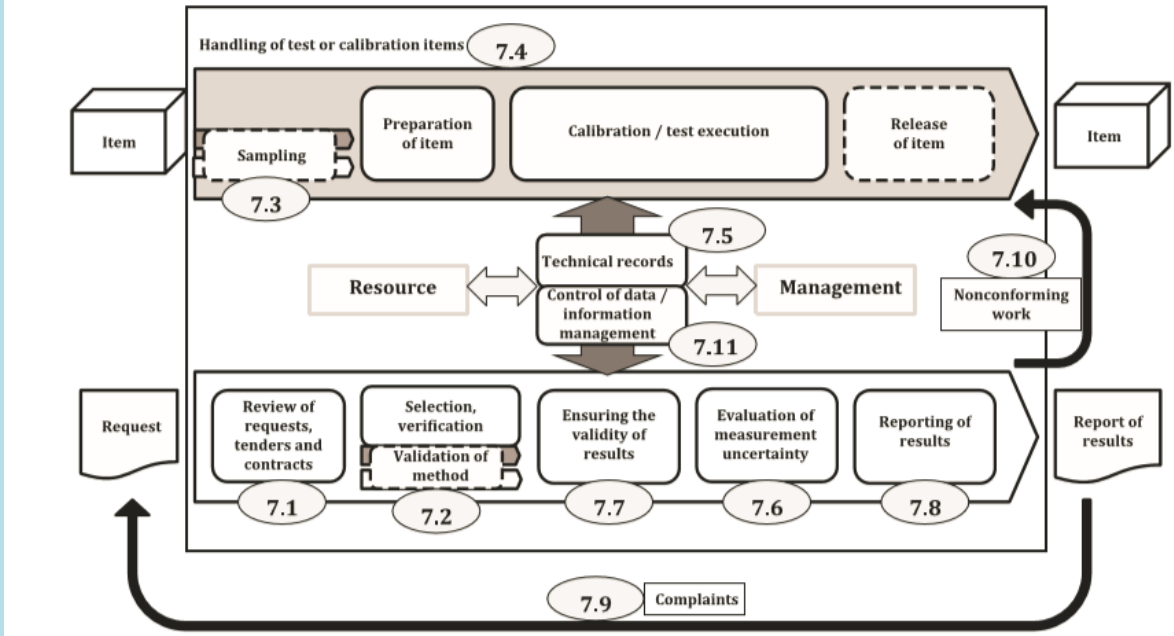

Figure B.1 — Possible schematic representation of the operational processes of a laboratory

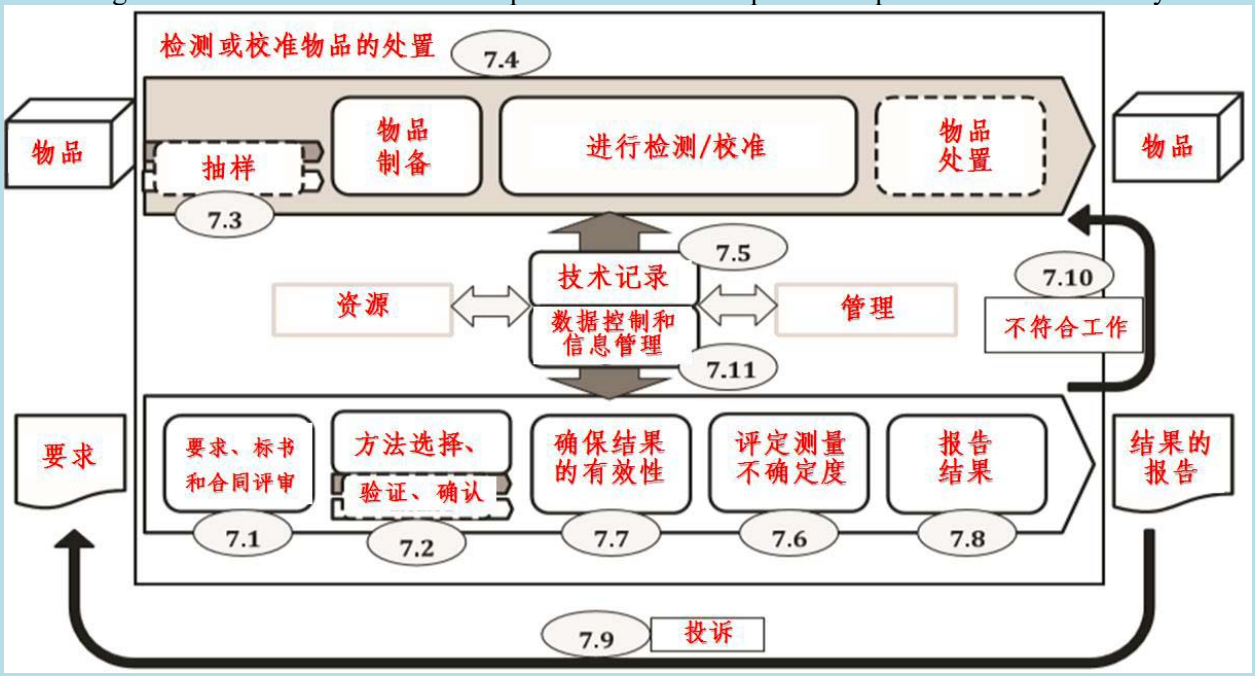

图 B.1-- 可能代表实验室运作过程的示意图

Bibliography	参考文献
[1] ISO 5725-1, Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions [2] ISO 5725-2, Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method [3] ISO 5725-3, Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method [4] ISO 5725-4, Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method [5] ISO 5725-6, Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values [6] ISO 9000, Quality management systems — Fundamentals and vocabulary [7] ISO 9001, Quality management systems — Requirements [8] ISO 10012, Measurement management systems — Requirements for measurement processes and measuring equipment [9] ISO/IEC 12207, Systems and software engineering — Software life cycle processes [10] ISO 15189, Medical laboratories — Requirements for quality and competence [11] ISO 15194, In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation [12] ISO/IEC 17011, Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies [13] ISO/IEC 17020, Conformity assessment — Requirements for the operation of various types of bodies performing inspection [14] ISO/IEC 17021-1, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements [15] ISO 17034, General requirements for the competence of reference material producers [16] ISO/IEC 17043, Conformity assessment — General requirements for proficiency testing [17] ISO/IEC 17065, Conformity assessment — Requirements for bodies certifying products, processes and services [18] ISO 17511, In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials [19] ISO 19011, Guidelines for auditing management	[1] GB/T 6379.1-2004 , 测量方法与结果的准确度(正确度与精密度) 第 1 部分:总则与定义 [2] GB/T 6379.2-2004, 测量方法与结果的准确度(正确度与精密度) 第 2 部分:确定标准测量方法重复性与再现 性的基本方法 [3] GB/T 6379.3-2012, 测量方法与结果的准确度(正确度与精密度) 第 3 部分:标准测量方法精密度的中间度量 [4] GB/T 6379.4-2006, 测量方法与结果的准确度（正确度与精密度） 第 4 部分：确定标准测量方法正确度的基 本方法 [5] GB/T 6379.6-2009, 测量方法与结果的准确度（正确度与精密度） 第 6 部分：准确度值的实际应用 [6] GB/T 19000-2016, 质量管理体系 基础和术语 [7] GB/T 19001-2016, 质量管理体系 要求 [8] GB/T 19022-2003, 测量管理体系 测量过程和测量设备的要求 [9] GB/T 8566-2007,信息技术 软件生存周期过程 [10] GB/T 22576-2008,医学实验室 质量和能力的专用要求 [11] GB/T 19703-2005, 体外诊断医疗器械生物源性样品中量的测量 参考物质的说明 [12] GB/T 27011-2005 合格评定--认可机构通用要求 [13] GB/T 27020-2016, 合格评定 各类检验机构的运作要求 [14] ISO/IEC 17021-1, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements [15] ISO 17034, General requirements for the competence of reference material producers [16] GB/T 27043-2012, 合格评定 能力验证的通用要求 [17] GB/T 27065-2015, 合格评定 产品、过程和服务认证机构要求 [18] GB/T 21415-2008, 体外诊断医疗器械生物样品中量的测量 校准品和控制物质赋值的计量学溯源性

systems [20] ISO 21748, Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation [21] ISO 31000, Risk management — Principles and guidelines [22] ISO Guide 30, Reference materials — Selected terms and definitions [23] ISO Guide 31, Reference materials — Contents of certificates, labels and accompanying documentation [24] ISO Guide 33, Reference materials — Good practice in using reference materials [25] ISO Guide 35, Reference materials — General and statistical principles for certification [26] ISO Guide 80, Guidance for the in-house preparation of quality control materials (QCMs) [27] ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM) [28] ISO/IEC Guide 98-4, Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment [29] IEC Guide 115, Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector [30] Joint B.I.P.M. OIML, ILAC and ISO declaration on metrological traceability, 2011 2) [31] International Laboratory Accreditation Cooperation (ILAC) 3) [32] International vocabulary of terms in legal metrology (VIML), OIML V1: 2013 [33] JCGM 106:2012, Evaluation of measurement data — The role of measurement uncertainty in conformity assessment [34] The Selection and Use of Reference Materials, EEE/RM/062rev3, Eurachem 4) [35] SI Brochure: The International System of Units (SI), BIPM 5)	[19] GB/T 19011-2013,管理体系审核指南 [20] ISO 21748, Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation [21] ISO 31000, Risk management — Principles and guideline [22] GB/T 15000.2-1994, 标准样品工作导则(2) 标准样品常用术语及定义 [23] ISO Guide 31, Reference materials — Contents of certificates, labels and accompanying documentation GB/T 15000.4-2003 标准样品工作导则(4) 标准样品证书和标签的内容 [24] ISO Guide 33, Reference materials — Good practice in using reference materials GB/T 15000.8-2003 标准样品工作导则(8) 有证标准样品的使用 [25] ISO Guide 35, Reference materials — General and statistical principles for certification GB/T 15000.3-1994 废止 标准样品工作导则(3) 标准样品定值的一般原则和统计方法 [26] ISO Guide 80, Guidance for the in-house preparation of quality control materials (QCMs) [27] ISO/IEC Guide 98-3, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM) [28] ISO/IEC Guide 98-4, Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment [29] IEC Guide 115, Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector [30] Joint B.I.P.M. OIML, ILAC and ISO declaration on metrological traceability, 2011 2) [31] International Laboratory Accreditation Cooperation (ILAC) 3) [32] International vocabulary of terms in legal metrology (VIML), OIML V1: 2013 [33] JCGM 106:2012, Evaluation of measurement data — The role of measurement uncertainty in conformity assessment [34] The Selection and Use of Reference Materials, EEE/RM/062rev3, Eurachem 4) [35] SI Brochure: The International System of Units (SI), BIPM 5)