



华认标准技术服务（苏州）有限公司  
CCATS (SuZhou) Co., Ltd

质量管理体系认证规则

Quality Management System Certification Rules

制定修订 Formulate or modify			修订内容摘要 Revision Summary	制定 Formulated	审核 Checked	核准 Approved
修订日期 Date	版 Versions	次 No.				
2018 年 6 月 1 日	A	0	新发行 New Issue	马兵兵	薛庄.	薛庄.

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## 1.目的 General

为规范质量管理体系认证活动，提高认证有效性，促进质量管理体系认证工作健康发展，特制定本规则。These rules are formulated to standardize the quality management system certification activities, improve the effectiveness of certification, and promote the healthy development of quality management system certification.

## 2.适用范围 Scope

2.1 本规则用于规范依据 GB/T 19001/ISO 9001 《质量管理体系要求》标准在中国境内开展的质量管理体系认证活动。This rule is used to standardize the quality management system certification activities carried out in China according to GB/T 19001/ISO 9001 *Quality Management System Requirements*.

2.2 本规则依据认证认可相关法律法规，结合相关技术标准，对质量管理体系认证实施过程作出具体规定，明确 CCATS 对认证过程的管理责任，保证质量管理体系认证活动的规范有效。The Rules, in accordance with the relevant laws and regulations on certification and recognition, and in combination with the relevant technical standards, make specific provisions on the implementation process of the quality management system certification, define the management responsibility of CCATS for the certification process, and ensure the standardization and effectiveness of the quality management system certification activities.

2.3 本规则是 CCATS 在质量管理体系认证活动中的基本要求，CCATS 在该项认证活动中应当遵守本规则。These Rules are the basic requirements of CCATS in the quality management system certification activities, and CCATS shall comply with these Rules in this certification activity.

## 3. 对 CCATS 的基本要求 Basic requirements for certification bodies

3.1 获得国家认监委批准、取得从事质量管理体系认证的资质。Approved by CNCA and qualified for quality management system certification.

3.2 认证能力、内部管理和工作体系符合 GB/T 27021/ISO/IEC 17021-1 《合格评定 管理体系审核认证机构要求》。The certification capability, internal management and work system shall comply with GB/T 27021/ISO/IEC 17021-1 *Conformity assessment-Requirements for bodies providing audit and certification of management systems*.

3.3 建立内部制约、监督和责任机制，实现培训（包括相关增值服务）、审核和作出认证决定等工作环节相互分开，符合认证公正性要求。Establish internal restriction, supervision and

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responsibility mechanisms to separate training (including relevant value-added services), audit and certification decisions from each other, meeting the requirements of certification fairness.

3.4 鼓励 CCATS 通过国家认监委确定的认可机构的认可，证明其认证能力、内部管理和工作体系符合 GB/T 27021/ISO/IEC 17021-1 《合格评定 管理体系审核认证机构要求》。The certification bodies are encouraged to pass the accreditation of the accreditation bodies determined by the CNCA to prove that their certification capabilities, internal management and working systems comply with the requirements of GB/T 27021/ISO/IEC 17021-1 *Conformity assessment-Requirements for bodies providing audit and certification of management systems*.

3.5 不得将申请认证的组织（以下简称申请组织）是否获得认证与参与认证审核的审核员及其他人员的薪酬挂钩。It is not allowed to link whether the organization applying for certification (hereinafter referred to as the applicant organization) has obtained certification with the remuneration of auditors and other personnel participating in certification audit.

#### 4. 对认证审核人员的基本要求 Basic requirements for certification auditors

4.1 认证审核员应当取得国家认监委确定的认证人员注册机构颁发的质量管理体系审核员注册资格。The certification auditor shall obtain the registration qualification of quality management system auditor issued by the certification personnel registration authority determined by the CNCA.

4.2 认证人员应当遵守与从业相关的法律法规，对认证审核活动及相关认证审核记录和认证审核报告的真实性承担相应的法律责任。The certification personnel shall abide by the laws and regulations related to their work, and bear the corresponding legal responsibility for the authenticity of the certification audit activities, relevant certification audit records and certification audit reports.

#### 5. 初次认证程序 Initial certification procedure

##### 5.1 受理认证申请 Accept the certification application

5.1.1 CCATS 应向申请组织至少公开以下信息：CCATS shall disclose at least the following information to the applicant organization:

- (1) 可开展认证业务的范围，以及获得认可的情况。The scope of certification business and the accreditation.
- (2) 本规则的完整内容。The complete content of this rule.
- (3) 认证证书样式。Type of certificate.

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(4) 对认证过程的申投诉规定。Provisions on application and complaint of certification process.

5.1.2 CCATS 应当要求申请组织至少提交以下资料：CCATS shall require the applicant organization to submit at least the following materials:

(1) 认证申请书，申请书应包括申请认证的生产、经营或服务活动范围及活动情况的说明。The certification application, which shall include the description of the scope of production, business or service activities and the situation of the activities.

(2) 法律地位的证明文件的复印件。若质量管理体系覆盖多场所活动，应附每个场所的法律地位证明文件的复印件（适用时）。A copy of the legal status certificate. If the quality management system covers activities in multiple places, a copy of the legal status certificate of each place shall be attached (if applicable).

(3) 质量管理体系覆盖的活动所涉及法律法规要求的行政许可证明、资质证书、强制性认证证书等的复印件。Copies of administrative license, qualification certificate, compulsory certification, etc. required by laws and regulations involved in activities covered by the quality management system.

(4) 质量管理体系成文信息（适用时）。Documented information of the quality management system (if applicable).

5.1.3 CCATS 应对申请组织提交的申请资料进行评审，根据申请认证的活动范围及场所、员工人数、完成审核所需时间和其他影响认证活动的因素，综合确定是否有能力受理认证申请。CCATS shall review the application materials submitted by the applicant organization, and comprehensively determine whether it has the ability to accept the certification application according to the scope and place of the application, the number of employees, the time required to complete the audit and other factors affecting the certification activities.

对被执法监管部门责令停业整顿或在全国企业信用信息公示系统中被列入“严重违法企业名单”的申请组织，CCATS 不应受理其认证申请。CCATS shall not accept the certification application of the applicant organization that is ordered by the law enforcement supervision department to suspend business for rectification or listed in the "List of Serious Illegal Enterprises" in the national enterprise credit information publicity system.

5.1.4 对符合 5.1.2、5.1.3 要求的，CCATS 可决定受理认证申请；对不符合上述要求的，CCATS 应通知申请组织补充和完善，或者不受理认证申请。For those meeting the requirements

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of 5.1.2 and 5.1.3, CCATS may decide to accept the certification application; If the above requirements are not met, CCATS shall notify the applicant organization to supplement and improve, or reject the certification application.

#### 5.1.5 签订认证合同 Sign certification contract

在实施认证审核前，CCATS 应与申请组织订立具有法律效力的书面认证合同，合同应至少包含以下内容：Prior to the implementation of certification audit, CCATS shall conclude a legally effective written certification contract with the applicant organization, which shall at least include the following contents:

(1) 申请组织获得认证后持续有效运行质量管理体系的承诺。The applicant organization's commitment to continuously and effectively operate the quality management system after obtaining certification.

(2) 申请组织对遵守认证认可相关法律法规，协助认证监管部门的监督检查，对有关事项的询问和调查如实提供相关材料和信息的承诺。The applicant organization's commitment to comply with the relevant laws and regulations on certification and accreditation, assist the certification regulatory authority in supervision and inspection, and truthfully provide relevant materials and information for the inquiry and investigation of relevant matters.

(3) 申请组织承诺获得认证后发生以下情况时，应及时向 CCATS 通报：The applicant organization shall report to CCATS in a timely manner in case of any of the following situations after the certification:

① 客户及相关方有重大投诉。There are major complaints from clients and interested parties.

② 生产、销售的产品或提供的服务被质量或市场监管部门认定不合格。The products produced and sold or the services provided are deemed unqualified by the quality or market supervision department.

③ 发生产品和服务的质量安全事故。Quality and safety accidents of products and services occur.

④ 相关情况发生变更，包括：法律地位、生产经营状况、组织状态或所有权变更；取得的行政许可资格、强制性认证或其他资质证书变更；法定代表人、最高管理者变更；生产经营或服务的工作场所变更；质量管理体系覆盖的活动范围变更；质量管理体系和重要过程的重大变更等。Changes in relevant circumstances, including changes in legal status, production and operation status, organizational status or ownership; Change of administrative licensing

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qualification, compulsory certification or other qualification certificates obtained; Change of legal representative and top management; Change of workplace for production, operation or service; Changes in the scope of activities covered by the quality management system; Major changes in the quality management system and important processes.

⑤ 出现影响质量管理体系运行的其他重要情况。Other important situations that affect the operation of the quality management system occur.

(4) 申请组织承诺获得认证后正确使用认证证书、认证标志和有关信息，不利用质量管理体系认证证书和相关文字、符号误导公众认为其产品或服务通过认证。The applicant organization promises to correctly use the certification certificate, certification mark and relevant information after obtaining the certification, and not use the quality management system certification certificate and relevant words and symbols to mislead the public into believing that its products or services have passed the certification.

(5) 拟认证的质量管理体系覆盖的生产或服务的活动范围。The scope of production or service activities covered by the quality management system to be certified.

(6) 在认证审核实施过程及认证证书有效期内，CCATS 和申请组织各自应当承担的责任、权利和义务。The responsibilities, rights and obligations of CCATS and the applicant organization during the implementation of the certification audit and the period of validity of the certification certificate.

(7) 认证服务的费用、付费方式及违约条款。Fees, payment methods and default clauses of certification services.

## 5.2 审核策划 Audit planning

### 5.2.1 审核时间 Audit time

5.2.1.1 为确保认证审核的完整有效，CCATS 应以附录 A 所规定的审核时间为基础，根据申请组织质量管理体系覆盖的活动范围、特性、技术复杂程度、质量安全风险程度、认证要求和体系覆盖范围内的有效人数等情况，核算并拟定完成审核工作需要的时间。在特殊情况下，可以减少审核时间，但减少的时间不得超过附录 A 所规定的审核时间的 30%。In order to ensure the integrity and effectiveness of the certification audit, CCATS shall, based on the audit time specified in Appendix A, calculate and determine the time required to complete the audit according to the scope of activities, characteristics, technical complexity, quality and safety risk degree, certification requirements, effective number of people within the scope of the quality management system of the applicant organization. Under special circumstances, the audit time can



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be reduced, but the reduced time shall not exceed 30% of the audit time specified in Appendix A.

5.2.1.2 整个审核时间中，现场审核时间不应少于总审核时间的 80%。In the whole audit time, the on-site audit time shall not be less than 80% of the total audit time.

## 5.2.2 审核组 Audit team

5.2.2.1 CCATS 应当根据质量管理体系覆盖的活动的专业技术领域选择具备相关能力的审核员组成审核组，必要时可以选择技术专家参加审核组。审核组中的审核员承担审核任务和责任。CCATS shall select auditors with relevant capabilities to form an audit team according to the professional and technical fields of the activities covered by the quality management system, and may select technical experts to participate in the audit team when necessary. The auditors in the audit team shall undertake the audit tasks and responsibilities.

5.2.2.2 技术专家主要负责提供认证审核的技术支持，不作为审核员实施审核，不计入审核时间，其在审核过程中的活动由审核组中的审核员承担责任。The technical experts are mainly responsible for providing technical support for certification audit. They will not perform the audit as auditors and will not be included in the audit time. The auditors in the audit team will be responsible for their activities in the audit process.

5.2.2.3 审核组可以有实习审核员，其要在审核员的指导下参与审核，不计入审核时间，不单独出具记录等审核文件，其在审核过程中的活动由审核组中的审核员承担责任。The audit team may have trainee auditors, who shall participate in the audit under the guidance of the auditors, shall not be included in the audit time, and shall not issue audit documents such as records separately. The auditors in the audit team shall be responsible for their activities in the audit process.

## 5.2.3 审核计划 Audit plan

5.2.3.1 CCATS 应为每次审核制定书面的审核计划（第一阶段审核不要求正式的审核计划）。审核计划至少包括以下内容：审核目的，审核准则，审核范围，现场审核的日期和场所，现场审核持续时间，审核组成员（其中：审核员应标明认证人员注册号；技术专家应标明专业代码、工作单位及专业技术职称）。CCATS shall formulate a written audit plan for each audit (no formal audit plan is required for the stage 1 audit). The audit plan shall at least include the following contents: audit purpose, audit criteria, audit scope, date and place of on-site audit, duration of on-site audit, and members of the audit team (among which, auditors shall indicate the registration number of certified personnel; technical experts shall indicate the professional code, work unit and professional title).

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5.2.3.2 如果质量管理体系覆盖范围包括在多个场所进行相同或相近的活动，且这些场所都处于申请组织授权和控制下，CCATS 可以在审核中对这些场所进行抽样，但应根据相关要求实施抽样以确保对所抽样本进行的审核对质量管理体系包含的所有场所具有代表性。如果不同场所的活动存在明显差异、或不同场所间存在可能对质量管理有显著影响的区域性因素，则不能采用抽样审核的方法，应当逐一到各现场进行审核。If the coverage of the quality management system includes the same or similar activities in multiple places, and these places are under the authorization and control of the applicant organization, CCATS can sample these places in the audit, but it shall implement sampling according to relevant requirements to ensure that the audit of the samples is representative of all places included in the quality management system. If there are obvious differences in activities in different places, or there are regional factors that may have a significant impact on quality management in different places, the method of sampling audit cannot be adopted, and the audit should be carried out on each site one by one.

5.2.3.3 为使现场审核活动能够观察到产品生产或服务活动情况，现场审核应安排在认证范围覆盖的产品生产或服务活动正常运行时进行。In order to enable the on-site audit activities to observe the product production or service activities, the on-site audit shall be arranged when the product production or service activities covered by the certification are in normal operation.

5.2.3.4 在审核活动开始前，审核组应将审核计划交申请组织确认，遇特殊情况临时变更计划时，应及时将变更情况通知申请组织，并协商一致。Before the audit, the audit team shall submit the audit plan to the applicant organization for confirmation. In case of temporary changes to the plan under special circumstances, the applicant organization shall be informed of the changes in time and reach consensus through consultation.

### 5.3 实施审核 Implementation audit

5.3.1 审核组应当按照审核计划的安排完成审核工作。除不可预见的特殊情况外，审核过程中不得更换审核计划确定的审核员。The audit team shall complete the audit work according to the audit plan. Except for unforeseen special circumstances, the auditor determined in the audit plan shall not be changed during the audit.

5.3.2 审核组应当会同申请组织按照程序顺序召开首、末次会议，申请组织的最高管理者及与质量管理体系相关的职能部门负责人员应该参加会议。参会人员应签到，审核组应当保留首、末次会议签到表。申请组织要求时，审核组成员应向申请组织出示身份证明文件。The audit team shall, together with the applicant organization, hold the opening and closing meetings in the order of procedure. The top management of the applicant organization and the responsible



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personnel of the functional departments related to the quality management system shall attend the meeting. Participants shall sign in, and the audit team shall keep the sign in forms for the opening and closing meetings. When requested by the applicant organization, the members of the audit team shall show their identity documents to the applicant organization.

### 5.3.3 审核过程及环节 Audit process and link

5.3.3.1 初次认证审核，分为第一、二阶段实施审核。The initial certification audit is divided into the stage 1 and stage 2.

5.3.3.2 第一阶段审核应至少覆盖以下内容：The stage 1 audit shall at least cover the following contents:

(1) 结合现场情况，确认申请组织实际情况与质量管理体系成文信息描述的一致性，特别是体系成文信息中描述的产品和服务、部门设置和职责与权限、生产或服务过程等是否与申请组织的实际情况相一致。Confirm the consistency between the actual situation of the applicant organization and the documented information description of the quality management system, especially whether the products and services described in the documented information of the system, department settings, responsibilities and authorities, production or service processes are consistent with the actual situation of the applicant organization.

(2) 结合现场情况，审核申请组织理解和实施 GB/T 19001/ISO 9001 标准要求的情况，评价质量管理体系运行过程中是否实施了内部审核与管理评审，确认质量管理体系是否已运行并且超过 3 个月。In combination with the site conditions, the audit application organization shall understand and implement the requirements of GB/T 19001/ISO 9001 standard, evaluate whether the internal audit and management review have been carried out during the operation of the quality management system, and confirm whether the quality management system has been operated for more than 3 months.

(3) 确认申请组织建立的质量管理体系覆盖的活动内容和范围、体系覆盖范围内有效人数、过程和场所，遵守适用的法律法规及强制性标准的情况。Confirm the content and scope of activities covered by the quality management system established by the applicant organization, the effective number of people, processes and places covered by the system, and the compliance with applicable laws, regulations and mandatory standards.

(4) 结合质量管理体系覆盖产品和服务的特点识别对质量目标的实现具有重要影响的关键点，并结合其他因素，科学确定重要审核点。Identify key points that have an important impact on the realization of quality objectives based on the characteristics of products and services covered

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by the quality management system, and scientifically determine important audit points in combination with other factors.

(5) 与申请组织讨论确定第二阶段审核安排。对质量管理体系成文信息不符合现场实际、相关体系运行尚未超过 3 个月或者无法证明超过 3 个月的，以及其他不具备二阶段审核条件的，不应实施二阶段审核。Discuss with the applicant organization to determine the stage 2 audit arrangement. If the documented information of the quality management system does not conform to the actual situation on site, the relevant system has not been operated for more than 3 months or cannot be proved for more than 3 months, and other conditions for the stage 2 audit are not met, the stage 2 audit shall not be implemented.

5.3.3.3 在下列情况，第一阶段审核可以不在申请组织现场进行，但应记录未在现场进行的原因：In the following cases, the stage 1 audit may not be conducted on the site of the applicant organization, but the reasons for not being conducted on the site shall be recorded:

(1) 申请组织已获本 CCATS 颁发的其他有效认证证书，CCATS 已对申请组织质量管理体系有充分了解。The applicant organization has obtained other valid certificates issued by CCATS, and CCATS has fully understood the quality management system of the applicant organization.

(2) CCATS 有充足的理由证明申请组织的生产经营或服务的技术特征明显、过程简单，通过对其提交文件和资料的审查可以达到第一阶段审核的目的和要求。CCATS has sufficient reasons to prove that the technical characteristics of the production, operation or service of the applicant organization are obvious and the process is simple. The purpose and requirements of the stage 1 audit can be achieved through the review of the documents and materials submitted.

(3) 申请组织获得了其他经认可机构认可的 CCATS 颁发的有效的质量管理体系认证证书，通过对其文件和资料的审查可以达到第一阶段审核的目的和要求。The applicant organization has obtained an effective quality management system certificate issued by another certification body recognized by the accreditation body. The purpose and requirements of the stage 1 of audit can be achieved through the review of its documents and materials.

除以上情况之外，第一阶段审核应在受审核方的生产经营或服务现场进行。In addition to the above, the stage 1 audit shall be conducted at the production, operation or service site of the auditee.

5.3.3.4 审核组应将第一阶段审核情况形成书面文件告知申请组织。对在第二阶段审核中可能被判定为不符合项的重要关键点，要及时提醒申请组织特别关注。The audit team shall

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inform the applicant organization of the stage 1 audit in written form. Important key points that may be judged as non conformances in the stage 2 audit shall be timely reminded to the applicant organization to pay special attention.

5.3.3.5 第二阶段审核应当在申请组织现场进行。重点是审核质量管理体系符合 GB/T 19001/ISO 9001 标准要求和有效运行情况，应至少覆盖以下内容：The stage 2 audit shall be conducted on the site of the applicant organization. The key point is to review the quality management system's compliance with the requirements of GB/T 19001/ISO 9001 standard and its effective operation, which shall at least cover the following contents:

(1) 在第一阶段审核中识别的重要审核点的过程控制的有效性。Effectiveness of process control of important audit points identified in the stage 1 audit.

(2) 为实现质量方针而在相关职能、层次和过程上建立质量目标是否具体适用、可测量并得到沟通、监视。Whether the quality objectives established in relevant functions, levels, and processes to achieve the quality policy are specifically applicable, measurable, communicated, and monitored.

(3) 对质量管理体系覆盖的过程和活动的管理及控制情况。Management and control of processes and activities covered by the quality management system.

(4) 申请组织实际工作记录是否真实。对于审核发现的真实性存疑的证据应予以记录并在做出审核结论及认证决定时予以考虑。Whether the actual work records of the applicant organization are true. Evidence with doubts about the authenticity of audit findings shall be recorded and considered when making audit conclusions and certification decisions.

(5) 申请组织的内部审核和管理评审是否有效。Whether the internal audit and management review of the applicant organization are effective.

5.3.4 发生以下情况时，审核组应向 CCATS 报告，经 CCATS 同意后终止审核。In the following cases, the audit team shall report to CCATS and terminate the audit with the approval of CCATS.

(1) 受审核方对审核活动不予配合，审核活动无法进行。The auditee did not cooperate with the audit activities, and the audit activities could not be carried out.

(2) 受审核方实际情况与申请材料有重大不一致。The actual situation of the auditor is significantly inconsistent with the application materials.

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(3) 其他导致审核程序无法完成的情况。Other circumstances that lead to the failure to complete the audit procedure.

#### 5.4 审核报告 Audit report

5.4.1 审核组应对审核活动形成书面审核报告，由审核组组长签字。审核报告应准确、简明和清晰地描述审核活动的主要内容，至少包括以下内容：The audit team shall prepare a written audit report for the audit activities, which shall be signed by the audit team leader. The audit report shall accurately, concisely and clearly describe the main contents of the audit activities, at least including the following contents:

- (1) 申请组织的名称和地址。Name and address of the applicant organization.
- (2) 申请组织活动范围和场所。Scope and place of activities of the application organization.
- (3) 审核的类型、准则和目的。The type, criteria and purpose of the audit.
- (4) 审核组组长、审核组成员及其个人注册信息。Audit team leader, audit team members and their personal registration information.
- (5) 审核活动的实施日期和地点，包括固定现场和临时现场；对偏离审核计划情况的说明，包括对审核风险及影响审核结论的不确定性的客观陈述。Implementation date and place of audit activities, including fixed site and temporary site; Description of deviations from the audit plan, including objective statements on audit risks and uncertainties affecting audit conclusions.
- (6) 叙述从 5.3 条列明的程序及各项要求的审核工作情况，其中：对 4.3.3.5 条的各项审核要求应逐项描述或引用审核证据、审核发现和审核结论；对质量目标和过程及质量绩效实现情况进行评价。Describe the audit work of the procedures and requirements listed in 5.3, including: describe or quote audit evidence, audit findings and audit conclusions item by item for the audit requirements in 4.3.3.5; Evaluate the realization of quality objectives, processes and quality performance.

(7) 识别出的不符合项。Identified nonconformities.

(8) 审核组对是否通过认证的意见建议。Opinions and suggestions of the audit team on whether the certification is passed.

5.4.2 CCATS 应保留用于证实审核报告中相关信息的证据。CCATS shall retain the evidence used to verify the relevant information in the audit report.

5.4.3 CCATS 应在作出认证决定后 30 个工作日内将审核报告提交申请组织，并保留签收

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或提交的证据。CCATS shall submit the audit report to the applicant organization within 30 working days after making the certification decision, and retain the evidence of signature or submission.

5.4.4 对终止审核的项目，审核组应将已开展的工作情况形成报告，CCATS 应将此报告及终止审核的原因提交给申请组织，并保留签收或提交的证据。For the items terminated from the audit, the audit team shall form a report on the work carried out, and CCATS shall submit this report and the reasons for the termination of the audit to the applicant organization, and retain the evidence of receipt or submission.

5.5 不符合项的纠正和纠正措施及其结果的验证 Correction of nonconformities, corrective measures and verification of results

5.5.1 对审核中发现的不符合项，CCATS 应要求申请组织分析原因，并提出纠正和纠正措施。对于严重不符合，应要求申请组织在最多不超过 6 个月期限内采取纠正和纠正措施。CCATS 应对申请组织所采取的纠正和纠正措施及其结果的有效性进行验证。如果未能在第二阶段结束后 6 个月内验证对严重不符合实施的纠正和纠正措施，则应按 5.6.5 条处理，或者按照 5.3.3.5 条重新实施第二阶段审核。For the nonconformities found in the audit, CCATS shall require the applicant organization to analyze the causes and propose corrective measures. For serious nonconformities, the applicant organization shall be required to take corrective measures within a maximum period of 6 months. CCATS shall verify the effectiveness of the corrective measures and results taken by the applicant organization. If the correction and corrective measures for serious nonconformities are not verified within 6 months after the end of the second phase, it shall be handled according to Article 4.6.5, or the second phase audit shall be implemented again according to Article 4.3.3.5.

5.6 认证决定 Certification decision.

5.6.1 CCATS 应该在对审核报告、不符合项的纠正和纠正措施及其结果进行综合评价基础上，作出认证决定。CCATS shall make a certification decision on the basis of a comprehensive evaluation of the audit report, the correction and corrective measures of nonconformities and their results.

5.6.2 认证决定人员应为 CCATS 管理控制下的人员，审核组成员不得参与对审核项目的认证决定。The certification decision personnel shall be the personnel under the management and



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control of CCATS, and the members of the audit team shall not participate in the certification decision of the audit project.

5.6.3 CCATS 在作出认证决定前应确认如下情形：CCATS shall confirm the following situations before making a certification decision:

(1) 审核报告符合本规则第 5.4 条要求，审核组提供的审核报告及其他信息能够满足作出认证决定所需要的信息。The audit report meets the requirements of Article 5.4 of the Rules, and the audit report and other information provided by the audit team can meet the information required for making the certification decision.

(2) 反映以下问题的不符合项，CCATS 已评审、接受并验证了纠正和纠正措施的有效性。CCATS has reviewed, accepted and verified the effectiveness of correction and corrective measures for the nonconformities reflecting the following problems.

① 在持续改进质量管理体系的有效性方面存在缺陷，实现质量目标有重大疑问。There are defects in the effectiveness of continuous improvement of the quality management system, and there are major doubts about achieving the quality objectives.

② 制定的质量目标不可测量、或测量方法不明确。The established quality objectives cannot be measured, or the measurement method is not clear.

③ 对实现质量目标具有重要影响的关键点的监视和测量未有效运行，或者对这些关键点的报告或评审记录不完整或无效。The monitoring and measurement of key points that have an important impact on the realization of quality objectives are not effectively operated, or the reports or review records of these key points are incomplete or invalid.

④ 其他严重不符合项。Other serious nonconformities.

(3) CCATS 对其他一般不符合项已评审，并接受了申请组织计划采取的纠正和纠正措施。CCATS has reviewed other general non conformances and accepted the corrective measures planned by the applicant organization.

5.6.4 在满足 5.6.3 条要求的基础上，CCATS 有充分的客观证据证明申请组织满足下列要求的，评定该申请组织符合认证要求，向其颁发认证证书。On the basis of meeting the requirements of Article 5.6.3, if CCATS has sufficient objective evidence to prove that the applicant organization meets the following requirements, it shall assess that the applicant organization meets the certification requirements and issue a certification certificate to it.



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(1) 申请组织的质量管理体系符合标准要求且运行有效。The quality management system of the applicant organization meets the standard requirements and operates effectively.

(2) 认证范围覆盖的产品和服务符合相关法律法规要求。The products and services covered by the certification scope meet the requirements of relevant laws and regulations.

(3) 申请组织按照认证合同规定履行了相关义务。The applicant organization has fulfilled relevant obligations in accordance with the certification contract.

5.6.5 申请组织不能满足上述要求或者存在以下情况的，评定该申请组织不符合认证要求，以书面形式告知申请组织并说明其未通过认证的原因。If the applicant organization fails to meet the above requirements or the following circumstances exist, it shall be assessed that the applicant organization does not meet the certification requirements, notify the applicant organization in writing and explain the reasons for its failure to pass the certification.

(1) 受审核方的质量管理体系有重大缺陷，不符合 GB/T 19001/ISO 9001 标准的要求。The auditee's quality management system has major defects and does not meet the requirements of GB/T 19001/ISO 9001.

(2) 发现受审核方存在重大质量问题或有其他与产品和服务质量相关严重违法违规行为。It is found that the auditee has major quality and safety problems or other serious violations related to product and service quality.

5.6.6 CCATS 在颁发认证证书后，应当在 30 个工作日内按照规定的要求将认证结果相关信息报送国家认监委。CCATS shall, within 30 working days after issuing the certification certificate, submit the information related to the certification results to the CNCA in accordance with the specified requirements.

## 6. 监督审核程序 Surveillance audit procedures

6.1 CCATS 应对持有其颁发的质量管理体系认证证书的组织（以下称获证组织）进行有效跟踪，监督获证组织持续运行质量管理体系并符合认证要求。CCATS shall effectively track the organization (hereinafter referred to as the certificated organization) holding the quality management system certification issued by it, and supervise the certificated organization to continuously operate the quality management system and meet the certification requirements.

6.2 为确保达到 6.1 条要求，CCATS 应根据获证组织的产品和服务的质量风险程度或其他特性，确定对获证组织的监督审核的频次。In order to ensure that the requirements of Article 6.1

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are met, CCATS shall determine the frequency of surveillance audit of the certificated organization according to the quality risk degree or other characteristics of the certificated organization's products and services.

6.2.1 作为最低要求，初次认证后的第一次监督审核应在认证证书签发日起 12 个月内进行。此后，监督审核应至少每个日历年（应进行再认证的年份除外）进行一次，且两次监督审核的时间间隔不得超过 15 个月。As a minimum requirement, the first surveillance audit after the initial certification shall be conducted within 12 months from the date of issuance of the certification certificate. Thereafter, the surveillance audit shall be conducted at least once every calendar year (except the year in which re certification is required), and the interval between the two surveillance audits shall not exceed 15 months.

6.2.2 超过期限而未能实施监督审核的，应按 8.2 或 8.3 条处理。If the surveillance audit is not carried out after the deadline, it shall be handled according to Article 8.2 or 8.3.

6.2.3 获证企业的产品在产品质量国家监督抽查中被查出不合格时，自国家质检总局发出通报起 30 日内，CCATS 应对该企业实施监督审核。If the products of the certified enterprise are found to be unqualified in the national supervision and random inspection of product quality, CCATS shall surveillance audit the enterprise within 30 days from the notification issued by the AQSIQ.

6.3 监督审核的时间，应不少于按 5.2.1 条计算审核时间人日数的 1/3。The time of surveillance audit shall not be less than 1/3 of the number of people and days calculated according to Article 5.2.1.

6.4 监督审核的审核组，应符合 5.2.2 条和 5.3.1 条的要求。The audit team of the surveillance audit shall meet the requirements of Article 5.2.2 and 5.3.1.

6.5 监督审核应在获证组织现场进行，且应满足第 5.2.3.3 条确定的条件。由于市场、季节性等原因，在每次监督审核时难以覆盖所有产品和服务的，在认证证书有效期内的监督审核需覆盖认证范围内的所有产品和服务。The surveillance audit shall be conducted on the site of the certificated organization and shall meet the conditions determined in Article 5.2.3.3. If it is difficult to cover all products and services in each surveillance audit due to market, seasonal and other reasons, the surveillance audit within the validity period of the certificate shall cover all products and services within the scope of certification.

6.6 监督审核时至少应审核以下内容：At least the following contents shall be reviewed during surveillance audit:

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(1) 上次审核以来质量管理体系覆盖的活动及影响体系的重要变更及运行体系的资源是否有变更。 Whether the activities covered by the quality management system, important changes affecting the system and resources for operating the system have changed since the last audit.

(2) 按 5.3.3.2 (4) 条要求已识别的重要关键点是否按质量管理体系的要求在正常和有效运行。 Whether the key points identified according to 5.3.3.2 (4) are operating normally and effectively according to the requirements of the quality management system.

(3) 对上次审核中确定的不符合项采取的纠正和纠正措施是否继续有效。 Whether the corrections and corrective measures taken for the non-conformities identified in the last audit are still effective.

(4) 质量管理体系覆盖的活动涉及法律法规规定的，是否持续符合相关规定。 If the activities covered by the quality management system involve laws and regulations, whether they continue to comply with the relevant provisions.

(5) 质量目标及质量绩效是否达到质量管理体系确定值。如果没有达到，获证组织是否运行内审机制识别了原因、是否运行管理评审机制确定并实施了改进措施。 Whether the quality objectives and quality performance reach the determined value of the quality management system. If not, whether the certified organization has run the internal audit mechanism to identify the causes, and whether the management review mechanism has determined and implemented improvement measures.

(6) 获证组织对认证标志的使用或对认证资格的引用是否符合《中华人民共和国认证认可条例》及其他相关规定。 Whether the use of the certification mark or the reference of the certification qualification by the certificated organization conforms to the *Regulations of the People's Republic of China on Certification and Accreditation* and other relevant provisions.

(7) 内部审核和管理评审是否规范和有效。 Whether the internal audit and management review are standardized and effective.

(8) 是否及时接受和处理投诉。 Whether complaints are received and handled in a timely manner.

(9) 针对体系运行中发现的问题或投诉，及时制定并实施了有效的改进措施。 For problems or complaints found in the system operation, effective improvement measures have been formulated and implemented in a timely manner.

6.7 在监督审核中发现的不符合项，CCATS 应要求获证组织分析原因，规定时限要求获证组织完成纠正和纠正措施并提供纠正和纠正措施有效性的证据。 For the non-conformities

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found in the surveillance audit, CCATS shall require the certificated organization to analyze the causes, specify a time limit and require the certificated organization to complete the correction and corrective measures and provide evidence of the effectiveness of the correction and corrective measures.

CCATS 应采用适宜的方式及时验证获证组织对不符合项进行处置的效果。CCATS shall adopt appropriate methods to timely verify the effect of the certified organization's disposal of non conformance.

6.8 监督审核的审核报告，应按 6.6 条列明的审核要求逐项描述或引用审核证据、审核发现和审核结论。The audit report of the surveillance audit shall describe or quote the audit evidence, audit findings and audit conclusions item by item according to the audit requirements listed in Article 6.6.

6.9CCATS 根据监督审核报告及其他相关信息，作出继续保持或暂停、撤销认证证书的决定。CCATS makes a decision to continue to maintain or suspend, withdraw the certification certificate based on the surveillance audit report and other relevant information.

## 7. 再认证程序 Re-certification procedure

7.1 认证证书期满前，若获证组织申请继续持有认证证书，CCATS 应当实施再认证审核，并决定是否延续认证证书。Before the expiration of the certification certificate, if the certified organization applies for continuing to hold the certification certificate, CCATS shall conduct re-certification audit and decide whether to continue the certification certificate.

7.2CCATS 应按 5.2.2 条和 5.3.1 条要求组成审核组。按照 5.2.3 条要求并结合历次监督审核情况，制定再认证审核计划交审核组实施。CCATS shall form an audit team according to the requirements of 5.2.2 and 5.3.1. According to the requirements of Article 5.2.3 and in combination with previous surveillance audit, the re-certification audit plan shall be formulated and submitted to the audit team for implementation.

在质量管理体系及获证组织的内部和外部环境无重大变更时，再认证审核可省略第一阶段审核，但审核时间应不少于按 5.2.1 条计算人日数的 2/3。If there is no significant change in the internal and external environment of the quality management system and the certificated organization, the stage 1 of the re-certification audit may be omitted, but the audit time shall not be less than 2/3 of the man days calculated according to Article 5.2.1.

7.3 对再认证审核中发现的严重不符合项，CCATS 应规定时限要求获证组织实施纠正与

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纠正措施，并在原认证证书到期前完成对纠正与纠正措施的验证。For serious non-conformities found in the re-certification audit, CCATS shall specify a time limit to require the certificated organization to implement corrections and corrective measures, and complete the verification of the corrections and corrective measures before the expiration of the original certification certificate.

7.4CCATS 按照 5.6 条要求作出再认证决定。获证组织继续满足认证要求并履行认证合同义务的，向其换发认证证书。CCATS shall make a re-certification decision according to the requirements of Article 5.6. If the certificated organization continues to meet the certification requirements and fulfill its contractual obligations, it shall be issued a new certificate.

7.5 如果在当前认证证书的终止日期前完成了再认证活动并决定换发证书，新认证证书的终止日期可以基于当前认证证书的终止日期。新认证证书上的颁证日期应不早于再认证决定日期。If the re-certification activity is completed before the termination date of the current certificate and the certificate is replaced, the termination date of the new certificate can be based on the termination date of the current certificate. The issuing date on the new certification certificate shall not be earlier than the date of re certification decision.

如果在当前认证证书终止日期前，CCATS 未能完成再认证审核或对严重不符合项实施的纠正和纠正措施未能进行验证，则不应予以再认证，也不应延长原认证证书的有效期。If CCATS fails to complete the re-certification audit or fails to verify the correction and corrective measures implemented for serious non-conformities before the termination date of the current certification certificate, it shall not be re-certified and the validity of the original certification certificate shall not be extended.

在当前认证证书到期后，如果 CCATS 能够在 6 个月内完成未尽的再认证活动，则可以恢复认证，否则应至少进行一次第二阶段审核才能恢复认证。认证证书的生效日期应不早于再认证决定日期，终止日期应基于上一个认证周期。After the expiration of the current certification certificate, if CCATS can complete the unfinished re-certification activities within 6 months, it can resume certification, otherwise it should conduct at least one stage 2 audit to resume certification. The effective date of the certification certificate shall not be earlier than the date of re-certification decision, and the termination date shall be based on the previous certification cycle.

## 8. 暂停或撤销认证证书 Suspending or withdrawing of certificate

8.1CCATS 应制定暂停、撤销认证证书或缩小认证范围的规定和文件化的管理制度，规定



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和管理制度应满足本规则相关要求。CCATS 对认证证书的暂停和撤销处理应符合其管理制度，不得随意暂停或撤销认证证书。CCATS shall formulate provisions and documented management systems for suspending, withdrawing certification certificates or reducing the scope of certification, and the provisions and management systems shall meet the relevant requirements of these rules. The suspension and revocation of the certification certificate by CCATS shall comply with its management system and shall not be arbitrarily suspended or withdrew.

## 8.2 暂停证书 Suspend Certificate

8.2.1 获证组织有以下情形之一的，CCATS 应在调查核实后的 5 个工作日内暂停其认证证书。In any of the following circumstances, CCATS shall suspend its certification certificate within 5 working days after investigation and verification.

(1) 质量管理体系持续或严重不满足认证要求，包括对质量管理体系运行有效性要求的。The quality management system continuously or seriously fails to meet the certification requirements, including the requirements for the operation effectiveness of the quality management system.

(2) 不承担、履行认证合同约定的责任和义务的。Failing to assume or perform the responsibilities and obligations stipulated in the certification contract.

(3) 被有关执法监管部门责令停业整顿的。Being ordered to suspend business for rectification by the relevant law enforcement and supervision department.

(4) 持有的与质量管理体系范围有关的行政许可证明、资质证书、强制性认证证书等过期失效，重新提交的申请已被受理但尚未换证的。The administrative license certificate, qualification certificate, compulsory certification certificate, etc. held in relation to the scope of the quality management system have expired, and the resubmitted application has been accepted but has not been replaced.

(5) 主动请求暂停的。Actively requesting suspension.

(6) 其他应当暂停认证证书的。Other cases where the authentication certificate should be suspended.

8.2.2 认证证书暂停期不得超过 6 个月。但属于 8.2.1 第（4）项情形的暂停期可至相关单位作出许可决定之日。The suspension period of the certificate shall not exceed 6 months. However, the suspension period in the case of Item 8.2.1 (4) can be extended to the date when the relevant



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unit makes a decision on permission.

8.2.3 CCATS 应以适当方式公开暂停认证证书的信息，明确暂停的起始日期和暂停期限，并声明在暂停期间获证组织不得以任何方式使用认证证书、认证标识或引用认证信息。CCATS shall disclose the information about the suspension of the certification certificate in an appropriate way, specify the starting date and duration of the suspension, and state that the certificated organization shall not use the certification certificate, certification mark or reference the certification information in any way during the suspension.

### 8.3 撤销证书 Withdraw certificate

8.3.1 获证组织有以下情形之一的，CCATS 应在获得相关信息并调查核实后 5 个工作日内撤销其认证证书。In any of the following circumstances, CCATS shall withdraw its certification certificate within 5 working days after obtaining relevant information and investigating and verifying.

(1) 被注销或撤销法律地位证明文件的。The legal status certificate is cancelled or withdrew.

(2) 被国家质量监督检验检疫总局列入质量信用严重失信企业名单。Listed in the list of enterprises with serious quality and credit loss by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.

(3) 拒绝配合认证监管部门实施的监督检查，或者对有关事项的询问和调查提供了虚假材料或信息的。Refusing to cooperate with the supervision and inspection carried out by the certification supervision department, or providing false materials or information for the inquiry and investigation of relevant matters.

(4) 拒绝接受国家产品质量监督抽查的。Refusing to accept the random inspection of national product quality supervision.

(5) 出现重大的产品和服务等质量安全事故，经执法监管部门确认是获证组织违规造成的。Major product and service quality and safety accidents are confirmed by law enforcement and supervision departments to be caused by the violation of the certificated organization.

(6) 有其他严重违反法律法规行为的。Other serious violations of laws and regulations.

(7) 暂停认证证书的期限已满但导致暂停的问题未得到解决或纠正的（包括持有的与质量管理体系范围有关的行政许可证明、资质证书、强制性认证证书等已经过期失效但申请未

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获批准）。The period of suspension of the certification certificate has expired but the problem causing the suspension has not been solved or corrected (including the administrative license certificate, qualification certificate, compulsory certification certificate, etc. held in relation to the scope of the quality management system that has expired but has not been approved).

(8) 没有运行质量管理体系或者已不具备运行条件的。The quality management system has not been operated or the operation conditions have not been met.

(9) 不按相关规定正确引用和宣传获得的认证信息，造成严重影响或后果，或者 CCATS 已要求其纠正但超过 2 个月仍未纠正的。The certification information obtained is not correctly quoted and publicized according to the relevant provisions, causing serious impact or consequences, or CCATS has required it to correct but has not corrected it for more than 2 months.

(10) 其他应当撤销认证证书的。Other certificates that should be withdrew.

8.3.2 撤销认证证书后，CCATS 应及时收回撤销的认证证书。若无法收回，CCATS 应及时在相关媒体和网站上公布或声明撤销决定。After the certificate is withdrew, CCATS shall withdraw the revoked certificate in a timely manner. If it cannot be withdrawn, CCATS shall publish or declare the revocation decision on relevant media and websites in a timely manner.

8.4CCATS 暂停或撤销认证证书应当在其网站上公布相关信息，同时按规定程序和要求报国家认监委。CCATS shall publish relevant information on its website when suspending or withdrawing the certification certificate, and report to the CNCA according to the specified procedures and requirements.

8.5CCATS 应采取有效措施避免各类无效的认证证书和认证标志被继续使用。CCATS shall take effective measures to avoid the continued use of various invalid certification certificates and certification marks.

## 9. 认证证书要求 Certification requirements

9.1 认证证书应至少包含以下信息：The certificate shall contain at least the following information:

(1) 获证组织名称、地址和统一社会信用代码（或组织机构代码）。该信息应与其法律地位证明文件的信息一致。Name, address and unified social credit code (or organization code) of the certificated organization. This information should be consistent with the information in the legal status certificate.

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(2) 质量管理体系覆盖的生产经营或服务的地址和业务范围。若认证的质量管理体系覆盖多场所，表述覆盖的相关场所的名称和地址信息。Address and business scope of production, operation or service covered by the quality management system. If the certified quality management system covers multiple sites, state the name and address of the relevant sites covered.

(3) 质量管理体系符合 GB/T 19001/ISO 9001 标准的表述。The quality management system conforms to GB/T 19001/ISO 9001.

(4) 证书编号。Certificate No.

(5) CCATS 名称。Name of certification authority.

(6) 有效期的起止年月日。The period of validity starts and ends on.

证书应注明：获证组织必须定期接受监督审核并经审核合格此证书方继续有效的提示信息。The certificate shall indicate that the certificated organization must be subject to regular Surveillance audit and pass the audit before the certificate can continue to be effective.

(7) 相关的认可标识及认可注册号（适用时）。Relevant approval marks and approval registration numbers (if applicable).

(8) 证书查询方式。CCATS 除公布认证证书在本机构网站上的查询方式外，还应当在证书上注明：“本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询”，以便于社会监督。Certificate query method. In addition to publishing the query method of the certification certificate on the website of CCATS, CCATS shall also indicate on the certificate: "The information of this certificate can be queried on the official website of the Certification and Accreditation Administration of the People's Republic of China (www.cnca. gov.cn)" for the convenience of social supervision.

9.2 初次认证证书有效期最长为 3 年。再认证的认证证书有效期不超过最近一次有效认证证书截止期再加 3 年。The validity period of the initial certification certificate is 3 years at most. The validity of the re-certification certificate shall not exceed the deadline of the latest valid certificate plus 3 years.

9.3 CCATS 应当建立证书信息披露制度。除向申请组织、认证监管部门等执法监管部门提供认证证书信息外，还应当根据社会相关方的请求向其提供证书信息，接受社会监督。CCATS shall establish a certificate information disclosure system. In addition to providing certification certificate information to the application organization, certification supervision department and

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other law enforcement and supervision departments, they should also provide certificate information to relevant social parties at their request and accept social supervision.

## 10. 与其他管理体系的结合审核 Combined audit with other management systems

10.1 对质量管理体系和其他管理体系实施结合审核时，通用或共性要求应满足本规则要求，审核报告中应清晰地体现 5.4 条要求，并易于识别。When the quality management system and other management systems are audited together, the general or common requirements shall meet the requirements of the Rules. The audit report shall clearly reflect the requirements of Article 5.4 and be easy to identify.

10.2 结合审核的审核时间人日数，不得少于多个单独体系所需审核时间之和的 80%。The number of person days of combined audit shall not be less than 80% of the sum of audit time required by multiple individual systems.

## 11. 受理转换认证证书 Acceptance of conversion certificate

11.1 CCATS 应当履行社会责任，严禁以牟利为目的受理不符合 GB/T 19001/ISO 9001 标准、不能有效执行质量管理体系的组织申请认证证书的转换。CCATS shall perform its social responsibility, and it is strictly prohibited to accept for profit the conversion of certification certificates applied for by organizations that do not conform to GB/T 19001/ISO 9001 standards and cannot effectively implement the quality management system.

11.2 CCATS 受理组织申请转换为本机构的认证证书，应该详细了解申请转换的原因，必要时进行现场审核。CCATS accepts the organization's application for conversion to its own certification certificate. It should know the reason for the conversion in detail and conduct on-site audit if necessary.

11.3 转换仅限于现行有效认证证书。被暂停或正在接受暂停、撤销处理的认证证书以及已失效的认证证书，不得接受转换申请。The conversion is limited to the current valid certificate. The certificate that has been suspended or is being suspended or withdrew and the certificate that has expired shall not accept the conversion application.

11.4 被发证的 CCATS 撤销证书的，除非该组织进行彻底整改，导致暂停或撤销认证证书的情形已消除，否则不应受理其认证申请。If CCATS to which the certificate has been issued withdraw the certificate, its certification application shall not be accepted unless the organization has made a thorough rectification and the situation leading to suspending or withdrawing of the

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certificate has been eliminated.

## 12. 受理组织的申诉 Accepting complaints from organizations

申请组织或获证组织对认证决定有异议时，CCATS 应接受申诉并且及时进行处理，在 60 日内将处理结果形成书面通知送交申诉人。If the applicant organization or the certificated organization has any objection to the certification decision, CCATS shall accept the appeal and handle it in a timely manner, and send a written notice of the handling result to the complainant within 60 days.

书面通知应当告知申诉人，若认为 CCATS 未遵守认证相关法律法规或本规则并导致自身合法权益受到严重侵害的，可以直接向所在地认证监管部门或国家认监委投诉，也可以向相关认可机构投诉。The written notice shall inform the complainant that if CCATS believes that it has failed to comply with the relevant certification laws and regulations or these Rules and has caused serious infringement of its legitimate rights and interests, it can directly complain to the local certification regulatory authority or the CNCA, or it can also complain to the relevant accreditation authority.

## 13. 认证记录的管理 Management of certification records

13.1 CCATS 应当建立认证记录保持制度，记录认证活动全过程并妥善保存。CCATS shall establish a certification record keeping system to record the whole process of certification activities and keep them properly.

13.2 记录应当真实准确以证实认证活动得到有效实施。记录资料应当使用中文，保存时间至少应当与认证证书有效期一致。The records shall be true and accurate to verify the effective implementation of certification activities. Records shall be kept in Chinese for at least the same period as the validity of the certification certificate.

13.3 以电子文档方式保存记录的，应采用不可编辑的电子文档格式。If records are saved in electronic format, non editable electronic format shall be adopted.

13.4 所有具有相关人员签字的书面记录，可以制作成电子文档保存使用，但是原件必须妥善保存，保存时间至少应当与认证证书有效期一致。All written records signed by relevant personnel can be made into electronic documents for storage, but the original must be properly kept for at least the same period as the validity of the certificate.

## 14. 其他 Others

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14.1 本规则内容提及 GB/T 19001/ISO 9001 标准时均指认证活动时该标准的有效版本。认证活动及认证证书中描述该标准号时，应采用当时有效版本的完整标准号。The reference in this rule to GB/T 19001/ISO 9001 refers to the valid version of the standard at the time of certification. When the standard number is described in the certification activity and certificate, the complete standard number of the current valid version shall be used.

14.2 本规则所提及的各类证明文件的复印件应是在原件上复印的，并经审核员签字确认与原件一致。The copies of all kinds of certificates mentioned in the Rules shall be copied on the original, and shall be signed by the auditor to confirm that they are consistent with the original.

14.3 CCATS 可开展质量管理体系及相关技术标准的宣贯培训，促使组织的全体员工正确理解和执行质量管理体系标准。CCATS can carry out the publicity and implementation training of the quality management system and relevant technical standards, so as to promote all employees of the organization to correctly understand and implement the quality management system standards.



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## 附录 A Appendix A

### 质量管理体系认证审核时间要求

#### Time requirements for quality management system certification audit

有效人数 Effective number	审核时间 Audit time 第 1 阶段+第 2 阶段 Phase 1+Phase 2 (人天 Man and day)	有效人数 Effective number	审核时间 Audit time 第 1 阶段+第 2 阶段 Phase 1+Phase 2 (人天 Man and day)
1-5	1.5	626-875	12
6-10	2	876-1175	13
11-15	2.5	1176-1550	14
16-25	3	1551-2025	15
26-45	4	2026-2675	16
46-65	5	2676-3450	17
66-85	6	3451-4350	18
86-125	7	4351-5450	19
126-175	8	5451-6800	20
176-275	9	6801-8500	21
276-425	10	8501-10700	22
426-625	11	>10700	遵循上述递进规律 Follow the above progressive law

高风险指的是产品或服务的失效会造成经济上的灾难或致命的风险。以下是范例但不限于：食品、药物、飞行器、造船、承重组件和结构、复杂的建筑活动、电器和使用气体燃料的设备、医疗保健服务、捕捞、核燃料、化学品、化学产品和纤维。High risk : Where failure of the product or service causes economic catastrophe or puts life at risk. Examples include but are not limited to: Food; pharmaceuticals; aircraft; shipbuilding; load bearing components and structures; complex construction activity; electrical and gas equipment; medical and health services;

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fishing; nuclear fuel; chemicals, chemical products and fibres.

中度风险指的是产品或服务的失效可能造成伤害或生病的风险。以下是范例范例但不限于：非承重组件和结构、简单的建筑活动、基本金属与加工产品、非金属产品、家具、光学设备、休闲与个人服务。Medium risk: Where failure of the product or service could cause injury or illness. Examples include but are not limited to: Non load bearing components and structures; simple construction activities; basic metals and fabricated products; non-metallic products; furniture; optical equipment; leisure and personal services.

低风险指的是产品或服务的失效不大可能造成伤害或生病的风险。以下是范例范例但不限于：纺织与成衣制品、纸浆、造纸与纸制品、出版、办公室服务、教育、零售业、酒店业和餐饮业。Low risk: Where failure of the product or service is unlikely to cause injury or illness. Examples include but are not limited to: Textiles and clothing; pulp, paper and paper products; publishing; office services; education; retailing hotels and restaurants.

注Note: 预计被确定为低风险的业务活动可需要少于表 QMS1 计算的审核时间，被确定为中风险的业务活动将使用表 QMS1 计算审核时间，被定义为高风险的业务活动将使用多于表 QMS1 计算的审核时间。It is estimated that business activities identified as low risk may require less than the audit time calculated in Table QMS1. Business activities identified as medium risk will use Table QMS1 to calculate the audit time, and business activities defined as high risk will use more than the audit time calculated in Table QMS1.