

安诺尔认证服务（上海）有限公司

AENOR Certification Services (Shanghai) Ltd.

认证审核的过程

Certification Audit Process

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1 认证申请 Certification application

1.1 申请组织应建立符合标准要求的管理体系按照标准要求文件化，在申请认证之前应完成内部审核和管理评审，并保证管理体系的有效、充分运行三个月以上。

The applicant organization should establish a management system that meets the requirements of the standard and document it in accordance with the requirements of the standard. Before applying for certification, it should complete the internal audit and management review, and ensure the effective and sufficient operation of the management system for more than three months.

1.2 市场人员负责接收申请组织的申请信息，并组织合同评审，合同评审通过后负责与申请组织签订合同，并将以下资料传递给认证部，作为计划管理人员进行审核方案策划的依据。

The marketing personnel are responsible for receiving the application information of the applicant organization, and organizes the contract review. After the contract review is passed, it is responsible for signing the contract with the applicant organization, and transmits the following information to the Certification Department as the basis for the planning management personnel to plan the audit plan.

- 1) 《认证申请表》； "Certification Application Form";
- 2) 《认证合同评审表》； "Certification Contract Review Form";
- 3) 申请组织提交的其它相关合同附件资料。 Other relevant contract attachments submitted by the applicant organization.

1.3 认证部依据认证合同评审意见及申请方的申请资料附件，组织实施认证审核活动。

The certification department organizes and implements certification audit activities based on the review opinions of the certification contract and the application materials attached to the applicant.

1.3.1 审核活动的种类 Types of audit activities

1) 管理体系初次认证审核分两阶段实施：管理体系认证审核由第一阶段审核和第二阶段审核组成。通常情况下，要求第一阶段审核活动应在申请认证组织的场所进行，如不安排第一阶段现场审核，应说明充分的理由。产品认证审核按照实施规则要求，一般不进行一阶段审核。

The initial certification audit of the management system is implemented in two stages: the

management system certification audit consists of the first stage audit and the second stage audit. Usually, it is required that the first-stage audit activities should be carried out at the site of the applicant organization. If the first-stage on-site audit is not arranged, sufficient reasons should be given. The product certification audit is in accordance with the requirements of the implementation rules, and generally does not conduct a first-stage audit.

- 2) 监督审核; Surveillance audit;
- 3) 再认证审核（再认证换证审核）; Re-certification audit (re-certification renewal audit);
- 4) 特殊审核(扩大认证范围、追踪审核); Special audit (expanding the scope of certification, follow-up audit);
- 5) 证书转换审核（详见认证证书的转换程序）。Certificate conversion audit (refer to the conversion procedure of certification certificate for details).

1.4.2 审核方案管理人员确定审核人日。The audit program manager determines the audit day.

1.4.3 审核启动 Audit Start

1.4.3.1 任命审核组长，签发《审核任务书》，在任务书中确定审核目的、范围和准则，并向其提供适用的审核资料。

Appoint the audit team leader, issue the "Audit Task Book", determine the audit purpose, scope and criteria in the task book, and provide them with applicable audit materials.

1.4.3.2 审核组的组成 Composition of the audit team

1) 根据合同评审的结果委派适合的审核组，为审核组指定一名审核组长，审核组长应在整个审核过程中起到领导的作用，包括文审、制定审核计划、分配审核任务、对审核过程进行有效的控制和管理，编制完成审核报告等；

According to the results of the contract review, assign a suitable audit team, and designate an audit team leader for the audit team. The audit team leader should play a leading role in the entire audit process, including document review, development of audit plans, assignment of audit tasks, Effectively control and manage the audit process, prepare and complete the audit report, etc.;

2) 审核组专业能力应与所要求的受审组织的专业相匹配，有能力对受审核组织形成产品专业特点的活动进行控制的有效性做出评价，并依据审核计划的安排开展审核工作。

The professional competence of the audit team should match the required profession of the audited organization, and have the ability to evaluate the effectiveness of the audited

organization's activities to form the professional characteristics of the product, and conduct the audit work according to the arrangement of the audit plan.

3) 当审核组的专业能力不足时，应配备技术专家，技术专家的选择应避免对审核产生不公正的影响。技术专家不能独立承担审核任务，应在审核员的指导下进行工作。

When the professional ability of the audit team is insufficient, it should be equipped with technical experts, and the selection of technical experts should avoid unfair influence on the audit. Technical experts cannot undertake audit tasks independently and should work under the guidance of auditors.

4) 当审核组不具备与受审核方语言的沟通能力时，可考虑使用翻译人员，翻译人员的选择要避免他们对审核产生不正当影响。

When the audit team does not have the ability to communicate with the language of the auditee, the use of translators can be considered. The selection of translators should prevent them from having an undue influence on the audit.

5) 审核组可以只有一名审核员，但此审核员应满足以上对审核组的全部要求；

The audit team may have only one auditor, but this auditor should meet all the above requirements for the audit team;

6) 为保证审核的连续性，管理体系审核尽量安排一阶段审核的组长参与二阶段的审核；

In order to ensure the continuity of the audit, the management system audit should try to arrange the leader of the first-stage audit to participate in the second-stage audit;

7) 审核组成员应遵循“公正性与保密声明”，不从事合同以外的工作。

The members of the audit team should follow the "Declaration of Impartiality and Confidentiality" and do not engage in work outside the contract.

1.4.3.3 审核组长与受审核方就审核的事宜建立初步联系。

The audit team leader establishes initial contact with the auditee on the audit matters.

1.5 现场审核准备 On-site audit preparation

1.5.1 编制审核计划 Prepare an audit plan

1) 审核组长编制审核计划，审核计划应经公司批准，并提交给受审核方。

The audit team leader prepares the audit plan, which shall be approved by the company and submitted to the auditee.

2) 审核计划可随着现场审核情况，允许更改，但更改应征得认证部的批准。

The audit plan can be changed according to the on-site audit situation, but the change should be approved by the certification department.

1.5.2 准备工作文件 Preparing working documents

1) 审核项目管理人员为审核组准备必要的工作文件（如：审核记录表单等），用于审核过程的参考和记录。

The audit project management personnel prepare the necessary working documents (such as: audit record form, etc.) for the audit team for the reference and record of the audit process.

3) 审核工作文件，应至少保存到审核结束，在审核结束后，审核组长应将所有的文件和记录按顺序整理，提交与认证部。审核组成员在任何时候都应当妥善保管涉及保密或知识产权信息的工作文件。

The audit working documents should be kept at least until the end of the audit. After the audit, the audit team leader should sort out all the documents and records in order and submit them to the certification department. Audit team members should keep working documents involving confidential or intellectual property information in a safe place at all times.

1.6 文件评审 Document Review

1) 文审通常由审核组长进行，也可由组长委托的专业审核员进行，以确定文件与审核准则的符合性以及相关法律法规要求的符合性。

Document review is usually carried out by the audit team leader, or by professional auditors entrusted by the team leader to determine the compliance of the documents with the audit criteria and with the requirements of relevant laws and regulations.

2) 当组长不具备相关专业能力时，组长应与审核员/技术专家参与文审进行沟通。

When the team leader does not have the relevant professional competence, the team leader should communicate with the auditor/technical expert to participate in the document review.

3) 文审的结果应书面通知受审核方，如有不符合，受审核方应根据组长的要求在现场审核前予以纠正，并进行验证。

The result of the document review shall be notified to the auditee in writing. If there is any non-compliance, the auditee shall correct and verify it before the on-site audit according to the requirements of the team leader.

1.7 初次认证审核 Initial Certification Audit

1.7.1 第一阶段审核 Phase 1 Audit

通常情况下，第一阶段审核活动应在申请认证组织的场所进行，如不安排第一阶段现场审核，应说明理由。

Normally, the first-stage audit activities should be carried out at the site of the applicant organization. If the first-stage on-site audit is not arranged, the reasons should be explained.

1.7.1.1 第一阶段审核目的: The purpose of the first stage audit:

1) 确定受审核方已按约定标准建立并运作了一个管理体系，并依此确认受审核方对审核的准备程度；

Confirm that the auditee has established and operated a management system according to the agreed standard, and confirm the readiness of the auditee for the audit accordingly;

2) 为认证机构第二阶段审核的顺利实施作充分的准备工作，如： Make adequate preparations for the successful implementation of the second stage audit of the certification body, such as:

- 为策划第二阶段审核提供关注点； Provide focus for planning the second phase of the audit;

- 审查第二阶段审核所配置资源（包括审核组能力和审核员时间）的充分性。 Review the adequacy of resources allocated for the second stage audit (including audit team capacity and auditor time).

1.7.2 第一阶段审核的后续工作 Follow-up work of the first stage audit

1) 第一阶段现场审核发现的问题或不符合项（包括文件审核发现的问题），应书面告知受审核方予以纠正，待第一阶段审核发现不符合项全部纠正完成后（需有相应的证明材料），进行第二阶段审核； The problems or non-conformities found in the first-stage on-site audit (including the problems found in the document audit) shall be notified to the auditee in writing to correct them. supporting materials), and conduct the second-stage review;

2) 审核组长确认一阶段问题已整改关闭后，应经认证部批准，由审核项目管理人员策划二阶段的现场审核；如确认受审核方仍然存在不符合情况时，不能进行二阶段现场审核。 After the audit team leader confirms that the problems in the first stage have been rectified and closed, it should be approved by the certification department, and the audit project management personnel will plan the second-stage on-site audit; if it is confirmed that the auditee still has non-compliance, the second-stage on-site audit cannot be carried out.

1.7.3 第二阶段现场审核 Stage 2 on-site audit

1.7.3.1 审核目的：评价受审核方管理体系的符合性和实施的有效性。Audit purpose: To evaluate the compliance of the auditee's management system and the effectiveness of its implementation.

1.7.3.2 审核要求 Audit Requirements

基于第一阶段审核的结果，对受审核方的管理体系实施情况进行全面的符合性、适宜性和有效性评价；Based on the results of the first-stage audit, conduct a comprehensive evaluation of the compliance, suitability and effectiveness of the auditee's management system implementation;

1.7.3.3 第二阶段审核应在受审核方的现场进行，并至少覆盖以下方面：The second stage audit shall be conducted on site of the auditee and shall cover at least the following:

- 1) 与适用的管理体系标准或其他规范性文件的所有要求的符合情况及证据；compliance with and evidence of all requirements of applicable management system standards or other normative documents;
- 2) 根据关键绩效目标、指标，对绩效进行监视、测量、报告和评审的情况；The monitoring, measurement, reporting and review of performance against key performance objectives and indicators;
- 3) 内审和管理评审；Internal audit and management review;
- 4) 基于受审核方的管理职责；Based on the auditee's management responsibilities;
- 5) 受审核方过程的运作情况；the operation of the auditee's processes;
- 6) 受审核方的管理体系和绩效中与遵守法律有关的方面；aspects of the auditee's management system and performance relevant to compliance with the law;
- 7) 规范性要求、方针、目标、指标、适用的法规要求、职责、人员能力、运作、程序、绩效数据和内审发现及结论之间的关系。The relationship between normative requirements, policies, objectives, indicators, applicable regulatory requirements, responsibilities, personnel competencies, operations, procedures, performance data and internal audit findings and conclusions.

1.7.3.4 第二阶段现场审核及审核的后续活动的实施：Implementation of the second stage on-site audit and follow-up activities of the audit:

1) 首次会议 opening meeting

首次会议由审核组长主持召开，时间一般应控制在 0.5 小时之内。首次会议的参加者

应签到。The opening meeting is hosted by the audit team leader, and the time should generally be controlled within 0.5 hours. Participants of the first meeting should sign in.

2) 开具的不符合项分为一般不符合和严重不符合。不符合项应在规定的时间内提出纠正措施, 经组长验证后, 方可推荐认证注册, 否则不予推荐注册。The non-conformities issued are divided into general non-conformities and serious non-conformities. For non-conforming items, corrective measures should be proposed within the specified time. After verification by the team leader, the certification and registration can be recommended. Otherwise, the recommended registration will not be recommended.

3) 内部沟通会: 每天的审核工作结束后, 审核组内部召开沟通会。

Internal communication meeting: After the daily audit work is over, a communication meeting will be held within the audit team.

4) 与受审核方的交流会 Communication meeting with the auditee

审核组应在现场审核结束后与受审核方管理层交流审核情况, 就审核结论或不符合项报告内容与受审核方达成一致意见。The audit team shall communicate the audit situation with the auditee management after the on-site audit, and reach an agreement with the auditee on the audit conclusion or the content of the non-conformity report.

5) 末次会议 Closing meeting

审核组长应召开末次会, 时间一般控制在 0.5-1 小时。参会者应签到; The audit team leader should hold the final meeting, and the time is generally controlled within 0.5-1 hour. Participants should sign in;

6) 审核组长应与组员充分讨论的基础上, 编制审核报告; The audit team leader should prepare the audit report on the basis of full discussion with the team members;

7) 审核报告应经公司授权的人员进行评审, 经评审的审核报告应当分发给受审核组织; The audit report shall be reviewed by personnel authorized by the company, and the reviewed audit report shall be distributed to the audited organization;

8) 审核结束后, 审核组长按审核清单上报资料, 认证部确认无材料遗漏后提交认证决定人员进行审定并做出认证决定。After the audit, the audit team leader submits the materials according to the audit list, and the certification department confirms that there is no material omission and submits it to the certification decision-making personnel for verification and a certification decision.

1.8 监督审核 Surveillance audit

1.8.1 监督审核的目的：Purpose of surveillance audit:

在获证组织的证书有效期（三年）应定期接受监督审核，以验证其管理体系是否持续满足认证要求，保持认证资格；

During the validity period of the certificate of the certified organization (three years), it should undergo regular surveillance audits to verify whether its management system continues to meet the certification requirements and maintain certification qualifications;

1.8.2 监督审核的频次 Frequency of surveillance audits

在认证证书有效期内，按照认证合同和认证规则的要求，对获证组织进行 2-3 次的监督审核。During the validity period of the certification certificate, according to the requirements of the certification contract and certification rules, 2-3 surveillance audits will be conducted on the certified organization.

1.8.3 监督审核的内容及要求 Content and requirements of surveillance audit

1.8.3.1 针对不同的受审核方的实际情况，监督审核抽取有代表性的区域和职能，对关键的过程和职能每年都要接受监督审核。

According to the actual situation of different auditees, the surveillance audit selects representative areas and functions, and the key processes and functions are subject to surveillance audit every year.

1.8.3.2 监督审核前受审核方应按规定的时间间隔实施了内审和管评；

Before the surveillance audit, the auditee shall implement the internal audit and management evaluation at the specified time interval;

1.8.3.3 监督审核至少包括以下方面的审核 Surveillance audits include at least the following audits

- 1) 内部审核和管理评审； Internal audit and management review;
- 2) 上次审核确定的不符合项所采取的措施； Actions taken for non-conformities identified in the last audit;
- 3) 投诉处理的情况； Complaint handling;
- 4) 证书及标志的使用情况； The use of certificates and logos
- 5) 变更的情况； Changes in circumstances;
- 6) 管理体系在实现获证客户目标方面的有效性；

The effectiveness of the management system in achieving the objectives of certified clients;

7) 持续的运作控制; Continuous operational control;

8) 为持续改进而策划的活动的进展。Progress of activities planned for continuous improvement.

1.8.3.4 监督审核的准备与实施要求同初审。

The requirements for the preparation and implementation of surveillance audit are the same as those for the initial audit.

1.8.3.5 监督审核报告除应包括初审审核报告要求的全部内容外还应包括对前次审核发现的不符合的纠正情况。

Surveillance audit report shall include all the contents required by the preliminary audit report, and shall also include the correction of the non-conformities found in the previous audit.

1.9 特殊审核 Special Audit

1.9.1 特殊审核的目的：为确保获证组织的管理体系因非常规的变更而持续有效；

The purpose of the special audit: To ensure that the management system of the certified organization continues to be effective due to unconventional changes;

1.9.2 获证组织在认证证书有效期内出现以下情况时，应进行特殊审核：

The certified organization shall conduct a special audit when the following situations occur within the validity period of the certification certificate:

1) 获证组织出现重大变更可能影响组织的活动与运行（例如：组织的所有权、人员或设备的改变等）；

Significant changes in the certified organization may affect the activities and operations of the organization (for example: the ownership of the organization, changes in personnel or equipment, etc.);

2) 获证组织发生了影响到其认证基础的更改（如：体系认证标志变更或体系认证范围扩大或缩小）；

The certified organization has undergone a change that affects its certification basis (such as: system certification mark change or system certification scope expansion or reduction);

3) 发生了重大质量/环境/安全事故； A major quality/environment/safety incident occurred;

4) 相关方严重投诉、抱怨，或其他来自相关方的信息的分析，表明已获证的组织不再满足认证机构的要求；

Analysis of serious complaints, grievances, or other information from interested parties, indicating that the certified organization no longer meets the requirements of the certification body;

4) 已获证组织由于其认证范围的扩大、地址的变迁、组织机构发生重大变化;

The certified organization has undergone major changes due to the expansion of its certification scope, the change of address, and the organizational structure;

6) 距上次现场审核时间超过合同规定时间, 且办理过暂停手续后再次恢复的监督审核。

Surveillance audits that have been resumed after the last on-site audit has exceeded the time specified in the contract and have gone through the suspension procedures.

1.9.3 特殊审核的实施 Implementation of special audits

a) 现场审核人日数、审核目的、审核内容、审核范围等应按审核方案策划实施; The number of on-site audit days, audit purpose, audit content, audit scope, etc. shall be planned and implemented according to the audit plan;

b) 对已获证组织申请扩大认证范围, 获证组织需填写书面申请, 经认证机构评审后, 由审核项目管理人员策划审核方案, 根据新的审核范围所涉及活动/产品的复杂性、可能的风险等级、组织新增规模等因素确定增加的审核人日。

To apply to expand the scope of certification for certified organizations, the certified organizations need to fill in a written application. After being reviewed by the certification body, the audit project management personnel will plan the audit plan. According to the complexity and possibility of activities/products involved in the new audit scope Factors such as the risk level of the organization and the new size of the organization determine the additional audit man-days.

c) 应考虑审核组的专业能力, 尽可能安排一名上次审核组成员参与本次审核, 如不能安排时, 应向审核组提供上次审核相关背景资料和信息, 使其做好充足的审核前的准备工作。

The professional ability of the audit team should be considered, and a member of the previous audit team should be arranged to participate in this audit as much as possible. Preparations before the audit.

1.9.4 “提前较短时间通知的审核”的情形 Circumstances for “Short-Notice Audits”:

当发生涉及获证组织 QMS 认证范围的投诉、质量事故、变更或有需要跟踪被暂停

的认证证书的，机构在评估认证有效性可能遇到的威胁后，可能会安排提前较短时间通知的审核。由于获证组织缺乏对审核组成员的任命表示反对的机会，计划管理人员将在指派审核组时给予更多的关注。

When complaints, quality incidents, changes, or the need to follow up on suspended certificates arise that affect the certified organization's QMS scope, the certification body may schedule short-notice audits after assessing potential threats to certification validity. Since the certified organization lacks the opportunity to object to the appointment of audit team members, the plan management personnel will exercise greater care when assigning the audit team.

1.10 再认证 Recertification

1.10.1 再认证的目的 Purpose of Recertification

再认证的目的是为了验证获证组织的管理体系整体上是否持续符合管理体系标准的要求，运行是否持续有效，以确定是否更新认证资格。

The purpose of re-certification is to verify whether the management system of the certified organization continues to meet the requirements of the management system standards as a whole, and whether the operation continues to be effective, so as to determine whether to renew the certification qualification.

1.10.2 再认证的受理要求 Acceptance requirements for recertification

认证机构在获证组织注册证书有效期满前三个月向客户发出通知。The certification body shall notify the client three months before the expiration of the certificate of registration of the certified organization.

1.10.3 再认证的内容及要求：Contents and requirements of re-certification:

1.10.3.1 再认证前还需对组织管理体系在上一个认证周期的实施与绩效的考核进行一次评审； Before re-certification, it is necessary to conduct a review on the implementation and performance assessment of the organization's management system in the previous certification cycle;

1.10.3.2 再认证的准备与实施要求同初审。The preparation and implementation requirements for re-certification are the same as those for the initial audit.

1.10.3.3 再认证报告除应包括初审审核报告要求的全部内容外还应包括对前次审核发现的不符合的纠正情况。The re-certification report shall include all the contents required by the

preliminary audit report and also include the correction of the non-conformities found in the previous audit.