

099 Procedure Certification procedures

认证过程管理程序

Apply for
适用于

TÜV Thüringen e.V.
TÜV Thüringen 集团

(For accredited management system certifications)
(管理体系认证认可)

And apply for its subsidiary TÜV Thüringen Shanghai Co., Ltd.
并适用于其下属分支机构
特灵顿（上海）检测认证服务有限公司

(When there is a deference between the Chinese and English versions, please refer to
the English version)
(中英文对照如有差异，请以英文为准)

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1. Purpose 目的

This procedure instruction regulates the responsibilities and the procedures for the certification of management systems, which are determined according to the scope of DIN EN ISO/IEC 17021-1:2015. The procedure of internal processes at the certification body is described in the process description "099 VA certification flow chart" (099 VA Zertifizierungsablauf").

本程序文件是根据 DIN EN ISO 17021-1:2011 确定范围并规定的职责和管理体系认证的程序。认证机构内部流程的过程描述在“099 VA 认证流程图”中加以描述。

2. Scope 范围

This procedure instruction applies to all personnel of the certification body and branch offices of TÜV Thüringen e.V., which are involved in the auditing and certification activities according to the branch office specific rules for each branch office as well as to the appointed auditors of the certification body.

Deviations from the regulations in these procedural instructions are possible due to special unforeseeable social events of magnitude such as pandemics. The resulting changes to processes / deadlines are regulated separately and are not included in these procedural instructions.

Additional area specific regulations can be found in Annex 1 to this procedure instruction – see other applicable documents.

本程序说明适用于 TÜV Thüringen e.V. 认证机构和分支机构的所有人员，这些人员根据各分支机构的分支机构特定规则参与审计和认证活动，以及认证机构的指定审计员。

由于流行病等重大的特殊不可预见的事件，可能会偏离这些程序说明中的规定。对流程/截止日期的变更是单独规定的，不包括在这些程序说明中。

其他特定区域的规定见本程序说明附件 1– 见其他适用文件。

3. Responsibilities 职责

3.1 Head of the certification body 认证机构负责人

- For selection and appointment of auditors
- For the inspection of the certification procedure regarding the content and compliance of the procedural regulations
- For the approval and issuance of the certificate
- Definition of further responsibilities and delegation of tasks

选择和任命审核员

根据内容和程序的符合程度检查认证程序

批准和签发证书

定义的其他职责和义务

3.2 Branch offices 分支机构

In the notified branch offices of the certification body some tasks of the audit and certification process, which were determined by the certification body, can be performed autonomously.

Respective regulations concerning the branch offices are described in the branch office specific regulations (procedures, work instructions) as well as in "099 VA Ausgliederung" (outsourcing procedure instruction).

在认证机构的各个分支机构，由认证机构确定的审核和认证过程中的一些任务可以自主执行。

分支机构具体规定各自的规章制度“099 VA Ausgliederung”（程序、作业指导书）以及外包程序。

3.3 Auditors / Lead-auditors / technical experts 审核员/审核组长/技术专家

Auditors are responsible for:

- Inspection and evaluation of the documented information on the management system of the customer,
- Inspection and evaluation of the applied management system in praxis (during the audit): preparation of necessary proof documents

The lead-auditor is responsible for the following tasks within the audit team:

- Overall responsibility for the audit
- Audit planning and coordination of dates with the customer/client
- Creation of the audit plan
- Leading of interviews in the audit
- Preparation of the audit documentation in coordination with the audit team
- Documentation of audit results
- Decision about the issuance of nonconformities in coordination with the audit team
- Decision about the performance of a re-audit or audit termination

全面负责审核工作

- 与客户/客户策划审核计划和协调日期
- 编制审核计划
- 在审核中领导访谈
- 与审核组协调编制审核文件
- 审核结果的文件
- 决定不符合发行配合审核小组
- 关于重新审核或审核终止的决定

The technical expert is responsible in the audit team for following tasks:

- support of the audit team in the audit regarding subject-specific questions
- preparation of a technical expert report or expert input for the audit report forwarded to the lead auditor

技术专家负责审核小组完成下列任务:

- 支持审核组就特定技术问题进行审核
- 编写审核报告的技术专家报告或专家输入提供给审核组长

4. Preparation for the certification 认证准备

4.1 Inspection and acceptance of the application for certification 认证申请的检查和接受

The applicant organization transmits in the customer questionnaire all information which is necessary for the application to the certification body.

Before accepting the application and prior to offer or audit programme preparation, the appointed person of the certification body checks on the basis of the filled out questionnaire and eventually clarifications with the applicant organization as well as documents whether a scope-competent audit team and necessary competence for certification decision after performance of the audit are given. This check must be done according to available schemes of the certification body. In case of any restriction a note in the application evaluation must be done.

Should the application be rejected and no offer for certification can be sent to the applicant organization, so the reasons for rejection must be recorded by the certification body and the applicant organization must be informed about it.

After the feasibility of the audit and the certification process was checked and documented the audit programme must be prepared.

申请组织在客户调查表中将申请所需的所有信息发给认证机构。

在受理申请并提供或审核计划编制前, 认证机构由指定负责人进行检查的基础上, 填写问卷并最终澄清与申请机构以及文件是否确定范围, 审核组和必要的审核要求和必要的认证决定的能力。这种检查必须根据认证机构的现有计划进行。如有任何限制, 必须在申请评估中注明。

如果申请被拒绝, 并且没有向认证机构提交认证申请, 那么拒绝理由必须由认证机构记录, 并且必须通知申请者组织。

在审核可行性和认证过程进行审核和记录之后，必须准备审核方案。

4.2 Development of the audit programme 审核方案开发

The audit programme contains the two-stage initial audit, surveillance audits in the first and second years as well as a re-certification audit in the third year before the expiration of the certification. The first three-year certification cycle begins with the decision for a certification or a re-certification. Subsequent cycles begin with the re-certification decision.

If the triannual certification cycle is not given e.g. by a takeover of certified companies, the audit programme must be adapted with regard to validity dates and content. Refer in this case to procedural instructions "099 VA transfer of accredited certification" ("099 VA Übertragung akkreditierter Zertifizierungen").

Instructions for creating of the audit program for companies with several branch offices can be found in "099 VA Zertifizierung Verbund" (procedure for multi-site certification).

Instructions for creating of the audit program for companies with integrated management systems can be found in "099 VA certification IMS" (integrated management systems).

For the single audits mentioned in the audit programme as well as for each further necessary audit a separate audit plan must be prepared.

Following conditions of the applicant organization must be considered among others during creation of the audit programme:

- Size of the organization
- Scope of application / scope of the certification
- Number of employees
- Number and temporal structure of shifts
- Locations and branches which have to be audited
- Existing construction sites or projects which have to be checked on-site in compliance with the scope
- Complexity of the management system, e.g. integrated management system
- Complexity of processes, sensitivity or risk of products and services
- Outsourced activities
- Language of the customer organization and of the audit team
- Results of former audits
- Customer complaints

With the audit programme the audit objectives and audit extent according to the calculation will be determined.

The audit programme for the triannual certification cycle consists of following documents and will be documented in the offer for the triannual certification cycle and additionally for re-certification:

- Calculation explanations and calculations (CA, 1st and 2nd surveillance audits and re-certification audit) according to the standard specific determinations
- Sample chart for organizations with several **sites**

Taking into consideration the valid standard specific documents or calculation guidelines, the calculation must be made by a notified and competent person of the certification body / of the branch office.

The competence for the group of people who are authorized to examine the application/ approve calculations can be seen in the competence matrix at the certification body. If the technical expert is required in the audit, it does not affect the reduction of man-days!

The offer will be sent to the applicant organization.

With the written acceptance of the order to the offer the applicant organization confirms that it has accepted the offer.

审核方案包括两个阶段的初次审核、在第一年和第二年进行的监督审核和第三年证书失效前的再认证。最初三年的审核周期起始于认证或再认证决定日期。随后的循环以再认证决定开始。

如果认证周期不明确，比如被认证组织的收购等，审核方案需要根据有效日期和内容来确定。这种情况参考程序转机构认证。

多场所认证方案见（多场所认证程序）

审核方案中的每个审核和后续必要的审核必须策划单独的审核计划。

在审核方案策划中必须考虑一下因素

- 组织规模
- 申请范围/认证范围
- 雇员人数
- 分班人数和结构
- 审核场所和分支
- 根据审核范围必须要审核的工程现场或项目
- 管理体系的负责程度，比如结合管理体系审核
- 过程复杂程度，产品和服务的敏感性或风险
- 外包过程
- 客户组织和审核组使用的语言
- 其他审核结果
- 客户投诉

根据审核方案，确定审核目标和范围。

认证周期的审核程序包括以下文件，并将被记录为认证周期并再认证的报价中：

- 根据特定标准计算解释和运算（初次审核、第一次监督和第二次监督审核、再认证）
- 多场所组织的抽样计划

考虑有效使用标准专用文件或计算指南，该运算必须由认证机构/分支机构任命的合格人员进行。

授权审查应用程序/批准计算的人员的权限可在认证机构的权限矩阵中看到。如果在审核中需要技术专家，则不导致审核人日的减少！

如收到申请组织的书面回复，则表示接受该认证报价。

4.3 Adjustment of the audit programme 审核方案调整

If necessary, the audit programme has to be adjusted to eventual changed circumstances of the certified organization during of the certification cycle. The certified organizations are contractually obliged to inform the certification body about all relevant changes in the organizational structure and operational structure as well as in their management system within the preparation for audits (e.g. surveillance audits, extension audits or re-audits).

The certification body checks and confirms with the approval of audit documents that the audit programme is appropriate or eventually makes changes in the audit programme.

The certified organization must be informed about the changed audit programme by writing a new offer with corresponding changes.

如有必要，审核方案必须在认证周期内对经认证的组织最终改变的情况进行调整。认证机构的合同义务通知认证机构对所有相关变化的组织结构和业务结构以及它们在管理体系内审核的准备（例如监督审核，扩充审核或重新审核）。

认证机构通过审核文件的审核和确认，审核方案是适当的，或最终改变审核方案。

认证机构必须通过修改新的报价通知变更的审核计划。

5. Execution of the initial certification 初次认证的实施

The initial certification audit will be performed according to the determinations in ISO 17021-1 in two stages (stage-1 and stage-2 audit). All standard requirements must be checked during this audit.

If the company has several branches (multi-site certification) the defined headquarter of the company must always be audited, see also "099 VA multi-site certification" ("099 VA Zertifizierung Verbund").

Already certified companies, which added a new standard to their management system, a stage-1 for this new standard must be performed (see 11.1.1 "extension on a new standard").

初次认证审核将根据两阶段进行 ISO 17021-1（第一阶段和第二阶段）。在审核过程中必须检查所有标准要求。

如果公司有多个分支机构（多场所认证），公司的定义总部必须每次审核，请参见“099 VA 场所认证”。

已认证的企业，如他们的管理体系中增加了一个新的标准，这新标准后必须进行第一阶段审核（见 11.1.1“新标准”的延伸）。

5.1 Specification of the audit team 审核组的要求

The audit team is determined by the certification body on the basis of the currently valid appointment and scope overviews.

Basic regulations:

- Employment of auditors with a valid appointment for the particular certification field
- If necessary employment of technical experts with valid appointment
- The technical expert must always be accompanied by an auditor.
- The audit team is not allowed to have rendered consultation services at the applicant organization until 2 years before the respective audit
- The customer will be informed about the determined audit team in the order confirmation.

The scope competence in the audit team must be ensured for every audit.

The auditors, which were employed in the stage-1 audit should be employed also in the stage-2 audit. In case of technical specific problems a respective technical expert / specialist can be included in the audit team. This technical expert must be previously appointed by the certification body.

The number of auditors and the required number of man-days for the audit depend on the size of the company and on the complexity of the processes. It is possible that the audit team consists of only one lead auditor. The participation of an auditor with the competence of a lead-auditor is required in all audits.

Within surveillance audits it is possible in exceptional cases that an auditor fulfils the tasks of a lead-auditor, on condition that the auditor:

- was member of the audit team (no trainee-auditor) during the certification audit or re-certification audit **and**
- has audit experience of minimum 5 audits **and**
- has necessary scope and standard competences

审核组由认证机构根据当前有效的任命和范围概述确定。

基本准则

-
- 为特定认证领域任命特定审核员
- 如有必要聘请必要的技术专家
- 技术专家必须随时陪同审核员。
- 审核组在各自审核前 2 年内不得向申请人组织提供咨询服务。
- 客户将在订单确认中了解确定的审核团队。

每一次审核都必须确保审核团队的范围权限。

第一阶段的审核员应参与第二阶段审核。技术具体问题可以使用技术专家，专家包括在审核组中。该技术专家必须事先由认证机构指定。

审核人员的数量和审核所需的人日数取决于公司的规模和流程的复杂性。审核小组可能只有一名审核组长。在所有审核中，都需要有一名审核员具有审核组长的能力。

在监督审核中，在特殊情况下，审核员可以完成审核组长的任务，但条件是：

- 作为初次审核或再认证的审核员（非实习审核员）和
- 具有最少 5 次审核经验和
- 具有必要的专业 and 标准能力

5.2 Audit planning 审核策划

5.2.1 General principles 总原则

The members of the audit team receive before the audit the following documents:

- a subcontract with all the necessary information from the audit program on the company to be audited (including norm specific characteristics)

- the customer questionnaire submitted by the company to the certification body for the preparation of an offer
- at least the audit report of the last audit, when re-certification the last two reports of the surveillance audits.

The complete scope must be audited.

If the company has extensive activities then in exceptional cases, after consultation with the certification body it can be decided, that only parts of the scope will be proved in the surveillance audits; but it must be ensured, that the entire scope of the company will be proved until the re-certification audit.

Before audit will be performed, the lead auditor should ask the company for eventually needed personal protective equipment and if necessary for further security measures and forward this information to the audit team.

Seasonal conditions (e.g. grape harvest) as well as industry-specific working times (e.g. cleaning, security guards) must be taken into account.

If shift work is performed, shift handover must be audited.

The orientating company/site tour for the whole audit team must be planned. The company tour must be done by every audit team member, in order to be able to evaluate the location and site-specific conditions of the customer.

It may be necessary in some situations to adapt the conduction of the company tour to the company needs: when the area of the company is very large, then the parts of this area should be divided between the competent auditors and the results should be evaluated and discussed afterward by the auditors together, in condition that this is possible.

Required construction / cleaning sites or sites, where security services will be performed must be audited according to the scope of the company. The focus of the audit planning is, that the activity, which is covered by the scope of the company must be also audited.

Travel time and breaks must be planned and are not part of the audit time.

Documentation: Audit plan according to the actual template. An audit plan must be prepared for every audit and for every stage of the audit programme.

Basis: Standard specific requirements (see also audit protocols and regulatory guidelines).

Audit time: As a rule the audit day lasts 8 hours plus travel time and time for breaks. The audit day with maximum 10 hours auditing time should be an exception. Example: the audit with 3,6 man-days must be planned 3 times for 1 man-day and 0,6 man-days, and not 3 times for 1,2 man-days.

Content of audit plan: Among others: information about audited organization units / contact person / branches in accordance with offer or subcontract / projects / construction sites / processes, which must be checked / information about the standard requirements to be audited including chapter / clause or section number / separation of the audit team / travel times and times for breaks:
The times must be written "from" - "until".

Only the relevant standard chapter of the main process must be mentioned, which describes and characterizes the main process. The enumeration of all standard chapters in each organizational unit is not useful and enables no good planning for the company and no optimal evaluation by the certification body.

In case of the integrated management system audit (combined audit) the standard competence of each auditor must be mentioned in the header data.

In case of the integrated management system audit (combined audit) the planned man-days for each standard must be mentioned at the end of the audit plan.

Date of preparation: In an appropriate time before the audit, recommended time: 2 weeks prior to the audit

Distribution: client and members of the audit team

Following must be considered in the audit plan during the audit planning:

- Introductory conversation according to ISO 17021-1 (see “099 F introduction and final conversation”) with introducing of the team and functions, description of the procedure, recording of the participants and their signatures in the participant list
- Auditing for the purpose of the review and evaluation of the efficiency of the management system according to standard specific requirements
- Interim consultations of the audit team for coordination during the course of the audit
- Auditing activities from a distance must be planned and recognizable in the audit plan
- Final discussion by the audit team according to ISO 17021-1 (see “099 F opening and closing meeting”) with a presentation of the audit results, nonconformities, recording of the participants and their signatures in the participant list
- Explanations and agreement about the content of the certificate according to offer and contract

Separation of auditors and calculating of the audit time:

If one audit team is planned for the audit, then the most part of the audit (more than 50% of the total man-days) must be audited separately, if the audit time (for 2 auditors) should be counted double (if there are 3 auditors in the team, then correspondingly more time must be planned). The more man-days are planned, the longer the auditors have to audit separately, in order to be able to count this audit time double. Should the auditors audit less than 50% of the audit time separately, then more audit time on site must be planned.

Example: audit time on-site – 4 man days (1 Auditor x 4 man days) can be spread over 2 Auditors (2 man-days x 2 auditors). The auditors must separate more than 50% of the audit time during these 2 days: e.g. 1,5 days separate auditing and 0,5 days common auditing.

During the separation of auditors it must be secured that for every auditor at least one contact person from the company is available and that the corresponding processes are checked by someone with professional competence.

In case of auditing of the multi-site companies the separation of the auditors to single sites is useful. The necessary professional competence must be ensured in this case on every location.

Introductory conversation, closing meeting, interim consultations of auditors and company / site tour must be conducted together. The audited time from introduction and final conversation, internal evaluation / interim consultations of auditors as well as the company / site tour can be counted for all auditors involved respectively as their audit time.

With parallel examination of one organizational unit by several auditors different projects / documents can be checked or different contact persons be interviewed in parallel. This audit time can be counted for each auditor respectively in case that the separation and the tasks are outlined comprehensibly in the audit plan.

The following has to be considered at the employment of an expert:

During stage-1 audit:

If the lead auditor does not have the professional competence in the business field or risk category, then a technical expert must be used in stage-1 audit.

If necessary, varying standard specific regulations must be considered!

During stage-2 audit:

During the employment of technical experts it must be ensured that the expert participates at the auditing of scope specific processes, in general these are at least the processes about management of resources and product or service realization, what means, that more than 50% of the audit time on-site must be audited scope-competently. The technical expert has to participate in the final discussion.

If the professional competence is absent in the audit team, the participation of a technical expert during the company / site tour is required.

The expert has to report the lead auditor about his own evaluations and to record these evaluations in an expert report (or integrated in the audit report, with visual distinction from the audit report, written by the auditor).

Further standard specific requirements can be found in standard specific regulations in attachment to this procedure.

审核组成员需在审核之前收到下列文件：

- 与审核项目有关的所有必要信息的分包合同（包括规范的具体特征）
- 公司向认证机构提交的报价单
- 至少是上次审核的审核报告，在再认证时需要监督审核的最后两份报告。

必须审核完整的范围。

如果公司有广泛的活动，那么在特殊情况下，经过与认证机构的协商，可以决定，只有部分范围将在监督审核中得到证明；但必须确保，该公司的整个范围将被审核到，直到再认证为止。

在进行审核之前，审核组长应向公司提出需要的个人防护装备，必要时应采取进一步的安全措施，并将该信息转发给审核组。

季节性因素（如葡萄收获）以及特定行业的工作时间（如清洁、保安）必须考虑在内。

如果组织有轮班工作，必须进行交接班审核。

整个审核团队必须有计划进行公司/工厂参观。公司参观必须由每个审核团队成员完成，以便能够评估客户的位置和具体情况。

在某些情况下，可能有必要请公司提供必要的参观指导，以适应公司需要：可能情况下，当公司的面积很大时，各区域部分应审核组成员之间进行划分，结果应由审核员一起进行评估和讨论。

必须进行安全服务的建筑/清洁场所或场所必须根据公司的范围进行审核。审核计划的重点是，公司范围所涵盖的活动也必须进行审核。

交通时间和休息时间必须有计划，但不是审核时间的一部分。

根据实际情况编制审核计划。计划必须为每一次审核和计划的每一阶段做好准备。

基础：标准特定要求（见审核检查表和要求）

审核时间：一般来说，审核一日为 8 小时，再加上交通时间和休息时间。审核日一日最多 10 小时审核时间，但应为例外。例如：3.6 人天应当策划为 3 个 1 人天和 0.6 人天，而不是 3 个 1.2 人天。。

审核计划内容：

其中：信息审核组织单位/联系人/分支机构提供或分包合同/项目/工地/流程一致，必须检查有关标准的要求，审核包括章/条款或审核小组/交通休息时间和次数/休息：

时间必须标明起始。

必须提及主要过程的相关标准章节，描述和描述主要过程。每个组织单元中所有标准章节的列举是没有必要的，没有良好的策划，认证机构无法正面评价。

在结合管理体系审核（共同审核）的情况下，每个审核员的标准能力必须在表头数据中提到。

在结合管理体系审核（共同审核）的情况下，每个标准的计划人日必须在审核计划的最后提到。

准备日期 在审核前的适当时间，建议的时间：审核前 2 周

发布 客户和审核组成员

在审核策划中，以下内容应包含在审核计划中

- 介绍 ISO17021-1 的要求（见“099 F 介绍和论坛”），介绍小组和职能、程序的说明、参与者的记录和参与者名单中的签名。
- 根据标准的具体要求审核和评估管理体系的绩效
- 审核组在审核过程中进行协调的临时协商
- 审核活动必须在审核计划中进行规划和识别。
- 最后讨论了审核组根据 ISO 17021-1（见“099 F 的开始和末次会议”）一个审核结果的演示文稿，不合格的描述，与会者的名单和他们的签名记录
- 根据报价和合同对证书内容作出解释和协议

审核员分工和审核时间计算

如果一个审核小组计划进行审核，那么大部分审核时间（超过 50%的总人日）必须分别审核，如果审核时间（2 个审核员）应加倍计算（如果团队中有 3 名审核员，则必须相应地安排更多的时间）。计划的人日越多，

审核员必须分开审核的时间越长，以便能够将审核时间翻倍。如果审核员分别审核不到 50%的时间，则必须安排更多的现场审核时间。

比如：现场审核时间-4 人天（1 位审核员*4 人天）可以分为 2 位审核员（2 人天*2 审核员）。审核员在 2 天的审核中必须有超过 50%的时间分组审核：比如 1.5 天的分组审核和 0.5 天的共同审核。

在审核员分组过程中，必须确保每个审核员至少有一个公司联系人，并且相应的程序由有专业能力的人检查。在对多场所公司进行审核的情况下，审核员分别到不同的现场是有益的。

在这种情况下，必须确保每个地点都具备必要的专业能力。

必须进行介绍性谈话、闭幕会议、审核员临时磋商和公司/现场参观。介绍和末次会议、内部评估/中期审核以及公司/现场参观的审核时间可分别作为所有审核员的审核时间进行计算。

通过多个审核员对一个组织单位进行平行检查，可以检查不同的项目/文件，或对不同的联系人进行平行采访。全面细致的审核计划中如果具体描述每位审核员的各自具体的不同的审核任务，各自审核的时间可以计算为每个审核员的审核时间。

雇佣审核专家时考虑下列因素

在第一阶段审核：

如果组长不在相应领域或风险类别具有专业能力，那么技术专家必须使用。

必要时，必须考虑不同的标准规定。

在第二阶段审核：

技术专家在雇佣过程中一定要保证专家参与的范围具体过程的审核，一般至少是过程管理的资源和产品或服务的实现，超过 50%的现场审核时间必须审核范围能力。技术专家必须参加最后讨论。

如果在审核团队中缺乏专业能力，则需要技术专家参加公司/现场参观。

专家必须向审核组长报告自己的评价，并将这些评价记录在一份专家报告（或纳入审核报告中，与审核报告中的审核员报告有着明显的区别）。

进一步标准的具体要求，可以参考附件标准的具体规定程序。

5.2.2 Audit planning stage-1 and stage-2 第一阶段和第二阶段审核策划

During the audit planning of stage-1 and stage-2 audit it has to be considered that the client has enough time to eliminate weak points, which were found in stage-1 audit (see 5.3.1) in time before stage-2 audit will be performed.

If as result of the stage-1 audit necessary changes as time and content changes for the already planned audit stage 2 occur, the planning of stage-2 audit has to be revised and adapted.

Special case a)

A planning of the stage-2 audit together with the stage-1 audit is an exception and only acceptable after the approval of the certification body and under the following conditions:

- small company size up to 5 employees **and**
- simple services or simple production processes

In this case the planning of stage-1 and stage-2 follows integrated in one audit plan without temporary separation between stage-1 and stage-2 audit.

After the audit the audit report for stage-2 and the standard specific annex must be written.

Special case b)

In justified special cases and after approval of the certification body, the stage-2 audit can be performed directly after stage-1 audit (e.g. at a long arrival way to the company). It is absolutely necessary to make the client demonstrably aware that despite of this planning a subsequent shift of stage-2 audit still can happen (e.g. because of found nonconformities during stage-1). The audit plan must be written with a time separation between the stage-1 and stage-2 audit. After the plan for stage-1 a note about possible postponement of the stage-2 audit because of found nonconformities must be written.

After the audit the audit report for stage-2 and the standard specific annex must be written.

在第一和第二阶段审核计划必须考虑到客户在第二阶段审核前有足够的时间来消除第一阶段审核中发现的弱项（见 5.3.1）。

当第一阶段审核审核结果显示有必要的时间或内容的改变，第二阶段审核计划应进行修改和调整。

特殊情况 a)

审核第二阶段审核接连第一阶段审核的情况必须得到发证机构的批准和接受，必须符合以下条件：

- 小于 5 个人的小规模企业
- 简单的服务或简单的生产过程

在这种情况下，第一阶段和第二阶段审核计划将整合在一起不分开。

在审核完成后，必须出具第二阶段审核报告和附件说明。

特殊情况 b)

在决定特殊情况和在获得发证机构批准后，第二阶段审核可以接在第一阶段审核后实施（比如：需要长途到达企业）。绝对必要让客户认识到尽管策划和连续的审核，但仍可能第二阶段分开审核的情况（如：第一阶段发现不符合）。审核计划必须在第一阶段和第二阶段间进行时间分割。在第二阶段审核计划后，需要时做出如发现不符合则第二阶段可能推迟的说明。在审核完成后，必须出具第二阶段审核报告和附件说明。

5.3 Audit performance 审核绩效

The review of documents forms a part of the stage-1 audit. It serves as determination whether the management documentation meets the requirements of the standard in general; simultaneously the review of the management documentation (documented information) serves the auditor for preparation to the certification audit. The review of management system documents will be documented and will be given to the client as information.

The document review is finished till beginning of the stage-2 audit.

Minimum contents of stage-1 audit:

- Auditing the documented information on the management system
- Evaluating the client's location and site-specific conditions
- Assessment of the processes and the means of work used (including outsourced processes).
- Fixed steering levels (especially for customers with multiple locations).
- Discussion with the clients' personnel to determinate the readiness for stage-2 audit
- Assessment of client's understanding regarding requirements of the standard, in particular with respect to identification of the key performances, processes and objectives in the company
- Checking of compliance of the scope with regard to the processes and sites compared with the subcontract as well as collecting of information regarding legal and official requirements and their compliance
- Review of allocation of resources for the stage-2 audit
- Coordination about main points of stage-2 audit with the customer
- Evaluation of planning and performance of internal audits and management reviews
- Documentation of nonconformities and remarks to identified weak points for the stage-2 audit
- Documentation of improvement potentials

At the end of stage-1 audit, the lead-auditor evaluates if the company is capable to be certified and informs the company about the evaluation.

- No, not capable to be certified: The audit stage-1 will be completed. The critical or non-critical nonconformities will be documented. The respective corrective measures **of the critical non-conformities** have to be implemented within 6 months after stage-1 audit, **at the latest at the beginning of the stage-2 audit** to proceed with the stage-2 audit. **The concrete implementation is checked in the audit stage 2 on site**. If the verification of the corrective actions **of the critical non-conformities** by the certification body (**Auditor**) results that 6 months are not enough for the correction of the nonconformities, then the audit programme has finished and it has to be executed a new stage-1 audit. A beginning of stage-2 audit without prior verified elimination of non-critical or critical nonconformities from the stage-1 audit is not possible.
- Yes, capable to be certified: No critical or non-critical nonconformities were found. The stage-2 audit can be planned and executed according to the audit programme. **Insofar as non-critical deviations were found, these can be checked in the stage 2 audit or in the subsequent audit.**

The clients' organization receives a report about stage-1 audit including the evaluation of the management system documents.

The certification body will be informed about found deviations to the subcontract/ audit programme by the lead-auditor. **If the results of the stage 1 audit do not enable the stage 2 audit to be continued within the 6 month period, the customer will be informed by the certification body.**

Minimum contents of stage-2 audit:

- Evaluation of implementation and effectiveness of the client's management system
- Collecting of information and evidence about conformity to all requirements of the respective standard and other applicable normative documents
- monitoring, measuring, reporting and reviewing against key performance objectives and targets;
- Evaluation of the client's management system and performance as regards legal compliance;
- Evaluation of the company control/ management of processes of the client;
- Evaluation of internal auditing and management review;
- Evaluation of the management responsibility for the general regulations of the client;
- Evaluation of the connections between the normative requirements, policy, performance objectives and targets, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and findings as well as conclusions of internal audits
- Evaluation of the effectiveness of corrective actions to findings of stage-1 audit or of other previously performed audits

文件审核是第一阶段审核的一部分。它可以确定管理文件是否符合一般标准的要求；同时对管理文件（记录的信息）的审核为审核员准备认证审核提供服务。管理体系文件的评审将被记录，并将作为信息给客户。管理体系文件审核在第二阶段审核前完成。

第一阶段审核至少内容：

- 管理体系的文件信息
 - 评估客户的位置和特定场所的条件
 - 评估所使用的过程和工作方法（包括外包过程）。
 - 确定水平（特别是针对多场所的客户）。
 - 与客户人员讨论确定第二阶段审核准备
 - 评估客户对标准要求的理解，特别是在确定公司主要业绩、过程和目标方面的理解。
 - 检查与分包合同相比较的过程和地点的范围的遵守情况，以及收集有关法律和官方要求及其遵守情况的信息
 - 对于第二阶段资源配置综述
 - 和客户协调主要第二阶段审核要点
 - 对内部审核和管理评审的规划和执行情况进行评价
 - 不合格和备注，确定第二阶段审核识别潜在的弱项
 - 改进建议的文件在第一阶段审核结束时，审核组长评估组织是否具备发证的能力，并告知组织结果
- 不可发证：第一阶段审核完成。严重或非严重的不合格将被记录；不符合项将记录在案。严重不符合项的相应纠正措施必须在第一阶段审核后 6 个月内实施，最迟在第二阶段审核开始时实施，以继续第二阶段审核。具体实施情况在现场第 2 阶段审核中检查。如果认证机构（审核员）对严重不符合项纠正措施的验证结果表明，6 个月不足以纠正不符合项，则审核计划已经完成，必须执行新的第 1 阶段审核。在未事先验证消除第 1 阶段审核中的非严重或严重不符合项的情况下，不可开始第 2 阶段审核。
 - 可接受发证：无严重或非严重不符合被发现。第二阶段审核可以按照审核方案策划并实施。如果发现非严重偏差，可在第 2 阶段审核或后续审核中检查。

客户组织收到关于第一阶段审核的报告，包括管理体系文件评审报告。如果第 1 阶段审核的结果不能使第 2 阶段审核在 6 个月内继续进行，认证机构将通知客户。

认证机构将被告知审核组长发现对分包/审核方案的偏差。认证机构应通知客户，第一阶段的审核结果导致推迟或取消第 2 阶段审核。

第二阶段审核发生在认证机构和客户的组织之间将所有问题澄清。

- 评估客户管理体系的实施有效性
- 收集关于符合标准和其他适用规范文件的所有要求的信息和证据
- 监测、衡量、报告和审查关键绩效目标和指标；
- 评估客户的管理制度和法律遵守情况的表现；
- 评估公司对客户过程的控制/管理；
- 内部审核和管理评审的评价；
- 对组织一般要求的管理责任进行评价；
- 评估规范性要求、政策、业绩目标和指标、任何适用的法律要求、责任、人员能力、业务、程序、业绩数据和调查结果之间的联系，以及内部审核的结论
- 对纠正措施的第一阶段审核结果或其他先前进行的审核的有效性评价

5.3.1 Critical and non-critical nonconformities; improvement potential 严重和一般不符合；潜在改进

In the audit identified critical or non-critical nonconformities will be documented in the audit report and in the form „Nonconformity report“.

As part of the approval of the certification procedure, the certification body can make a different classification of critical and non-critical nonconformities in contrast to the lead auditor after the final evaluation of the fulfilment of standard requirements.

Critical nonconformity: (Corresponds to the definition from ISO 17021-1 of a substantial non-conformity)

A critical nonconformity exists when:

- one (process-)element as a whole is not described in the required extent and/ or is not implemented
 - delivery of faulty products/ services is likely to occur
 - if considerable doubt about that effective process control exists or that product or service conforms to specified requirements;
 - a failure of the management system is possible
 - Several noncritical deviations related to the same requirement or the same problem could represent a system-related error and thus result in a critical nonconformity.
 - hazard potential for employees is existing
 - a non-critical nonconformity was not corrected in suitable way.
- Critical nonconformity lead to a re-audit – determined by the lead auditor (see 5.3.2.) and / or to submission of new documentation. Only after implementing the corrective action and confirmation by the lead auditor, a certificate / certificate continuation can be recommended.
 - In case of critical nonconformities certification body can decide to immediately suspend the certificate.
 - After expiry of max. 6 months after the stage-1 audit without evident elimination of the critical nonconformity, a new audit programme is necessary and a new stage-1 audit has to be initiated.
 - Period for corrections and corrective measures performed after stage-2 audit, surveillance audit, re-certification audit or other audits: max. 6 months.
If 6 months are exceeded, a repeated stage-2 audit is necessary.
 - Verification of subsequently filed documents for nonconformities is documented in the audit report.

The company must define the planned correction, root cause analysis and planned corrective action for the identified critical nonconformity in nonconformity report: within 2 weeks after the audit.

The effectiveness of the performed correction and corrective action will be evaluated by the lead auditor on the basis of submitted documents by the company in the nonconformity report. By means of approval of the certification process the effectiveness of the corrections and corrective actions applies as being confirmed.

If necessary, the certification body determines an additional audit or documentary evidence and informs the customer organization concerning this.

在审核中发现的重要不符合项或一般不符合将在审核报告和不合格报告的形式进行“记录”。

作为认证批准程序的一部分，认证机构可以根据与审核组长的报告对不合格按照严重或一般作为不同等级的分类。

严重不符合（根据 ISO17021-1 的定义重要的不符合）

严重不符合存在于：

- 一个（过程）要素作为一个整体没有按照要求和/或没有实施。
- 有可能出现有缺陷的产品/服务
- 可能导致对有效的过程控制，或者产品或服务符合规定的要求产生疑问；
- 管理体系的失败是可能的
- 同样的要求或同一问题的几个相关的非关键偏差可以代表一个体系相关的错误，从而导致严重后果不合格。

- 对雇员的潜在危险是存在的
- 非严重不符合没有得到适当的纠正。

严重不合格将导致组长决定重新审核-（参见 5.3.2。）和/或提交新文件。只有在执行纠正行动给审核组长确认之后，才能推荐办法证书/维持证书。

如产生严重不合格，认证机构可以决定立即暂停证书。

在第一阶段审核后 6 个月还没有证据证明严重不符合没有得到明显消除，期满后，一个新的审核流程是必要的，一个新的阶段审核已经开始。

第二阶段审核、监督审核、再认证审核或其他评审采取纠正和纠正措施的时间最多 6 个月。

如果超过 6 个月，重复进行第二阶段审核是必要的。

随后提交报告记录中对不合格进行验证。

组织必须在审核后 2 周内，对不合格报告中所确定的严重不符合项进行计划纠正、进行根本原因分析和策划纠正措施。

实施纠正和纠正措施的有效性将由审核组长根据公司提交的不合格报告文件进行评估。通过认证程序的批准，纠正和纠正措施的有效性得到确认。

必要时，认证机构确定需要额外审核或提交书面证据，并通知客户组织。

Non-critical nonconformity: (Corresponds to the definition from ISO 17021-1 of a subordinate nonconformity) 一般不符合（根据 ISO17021-1 的定义次要不符合）

A non-critical nonconformity exists when:

- Nonconformity that does not affect the ability of the management system to achieve the intended results
 - there is an insufficiency that neither leads to a failure of the management system nor restricts its ability to secure process and product quality
 - a insufficiency is detected in one part of the documentation of the management system
 - a weakness is detected within the evidence of compliance of a single (process-) element requirement.
- In case of a non-critical nonconformity a certificate / certificate continuance can be recommended.
 - A certificate can be issued only after the company determined corrections, root cause analysis and corrective actions which must be evaluated by the auditor and found as suitable for elimination of the nonconformity.
 - non-critical nonconformities will be documented by the lead auditor in the audit report and in the form „Nonconformity report“
 - Maximum term for proposals to corrections, root cause analysis and corrective action: within 2 weeks after the audit
 - The effectiveness of implementation of the correction and corrective action will be reviewed during next audit.
 - In case the correction or corrective action from the previous audit was proved to be not effective, a critical nonconformity has to be given in the current audit.

一般不符合存在于：

- 不影响管理体系达到预期结果的能力的不符合项
- 有存在一个不充分的因素既不会导致管理体系的失效，也不会限制其确保过程和产品质量的能力。
- 在管理体系文件的一部分中检测到不足之处。
- 在单一（过程）要素中检测到弱项的证据。
- 发生一般不合格证书/证书可推荐延续。
- 公司决定纠正、进行根本原因分析和采取纠正措施后，并且纠正措施必须由审核员的评价，并发现和不符合的性质相适宜的，证书才会签发。
- 一般不合格将通过审核报告和不合格报告的形式提交，组长记录”

- 建议审核后的 2 周内进行纠正，进行根本原因分析和采取纠正措施：
- 对纠正措施实施的有效性的审查将在下次审核中进行。
- 如果前次审核中不符合的纠正或纠正措施不是被有效实施，在本次审核中将成为严重不符合。

Improvement potential:潜在改进

- Is a way to improve a process which fulfils basically the standard requirements
- Must not necessarily be implemented by the company
- 是基本满足标准要求改进过程的方法
- 组织不一定要实施

5.3.2 Re-audit and termination of audit 重新审核和审核终止

A re-audit is necessary when for example

- one or more nonconformities are evaluated as critical, which can lead to failure of the management system
- documented regulations and continuous implementation to one or more standard requirements are missing.

The decision to perform a re-audit makes the lead auditor.

Before the re-audit is carried out the performed corrective action must be proven by the company to the lead auditor.

There will be audited those processes that were found as defective during the previous audit.

The re-audit will be charged to the company separately for expenditure.

Period:

- Period for re-audits after stage 2-audit and recertification audit: **max. 6 months**
- Period for re-audits after surveillance audits and extension audits: **max. 6 months**

Concerning the re-audit a re-audit report will be written by the auditor with the evaluation of the effectiveness of the correction and corrective action. With the approval of the certification process the effectiveness of the corrections and corrective actions is confirmed.

A certificate can be issued only after a positive re-audit is completed and a positive evaluation of the corrections and corrective actions.

Critical nonconformities in the re-audit lead to non-issuance of the certificate or withdrawal of the certificate.

A re-audit may not be repeated. There must be requested a new initial certification.

重新审核是必要的如

- 一个或更多的严重不符合，可能导致管理体系失效
- 一个或多个标准要求没有持续实施

由审核组长做出是否实施重新审核的决定。

在进行重新审核之前，公司必须向审核组长证明已执行的纠正措施。

将审核在前一次审核中发现有缺陷的那些过程。

重新审核将额外向公司收取费用。

周期

第二阶段和再认证后的重新审核的审核周期最多 6 个月

监督审核和扩充审核后的重新审核的审核周期最多 6 个月

关于重新审核，审核员将编写一份重新审核报告，并对纠正和纠正措施的有效性进行评估。经认证程序批准，更正和纠正措施的有效性得到确认。

只有在完成了积极的重新审核和对纠正和纠正措施的积极评价之后，才能颁发证书。

在重新审核重要不合格导致证书不能签发或证书撤销。重新审核不得重复。必须要求一个新的初次审核。

Termination of audit

If such serious critical nonconformities become obvious during an audit that the lead auditor cannot recommend the issue of the certificate or the maintenance of the certification, the audited company has to be informed about the termination of the audit. The audit documentation will be prepared for the already audited processes according to point 5.3.3. The company will be charged at least the aroused costs till the audit termination (including reporting).

The certification body communicates further actions with the company.

如果严重不合格在审核中十分明显，审核员不推荐办法证书或认证维持，该公司将被告知终止审核。审核文件准备根据点 5.3.3。至少在审核终止之前（包括报告），该公司将被收取至少所引起的相关费用。认证机构与公司沟通进一步的行动。

5.3.3 Documentation of audits 审核文件

With regard to time sequence of certification procedures, the documentation of the audit has to be available in the certification body usually 4 weeks after the audit at the latest.

To documentation belongs among others:

- Audit plan for each audit
- Audit report for each audit or combined audit reports for more than one standard
- If necessary statement of technical expert separately or integrated in the **annex of** audit report, with visual differentiation from **the text** written by the lead auditor
- List of participants with signatures of participants for every audit
- Nonconformity reports
- customer data sheet
- optionally annex multi-site certification
- if necessary remarks of the lead auditor concerning changes in company as information for the certification body
- Confirmation of the company's information provided to the lead auditor in the form of the customer questionnaire
- Confirmation by the Auditor that the audit targets were achieved
- Any deviation from the audit plan and the reasons for it.

Other standard specific documentation requirements can be found in the forms of the respective audit reports for every standard.

The audit report or the annex to the audit report must reflect an accurate, concise and clear record of the audit.

It must be understandable to which extent standard requirements were met by the company.

关于认证程序的时间顺序，审核文件将在 4 个星期后提供给认证机构。

包括以下文件

- 每次审核计划
- 包括每次审核和每个标准的审核报告
- 如必要，在审核报告附件中包括技术专家独立或整合的声明，和审核组长编写的审核报告内容相对比
- 每次审核参与者清单包括签字
- 不符合报告
- 客户信息表
- optionally annex multi-site certification 可选择的附件多场所证书
- 如必要，包括审核组提交给认证机构的关于组织变更的信息
- 根据客户问卷由审核组长确认的组织信息
- 审核员对审核目的达到的确认
- 对于审核计划中任何偏差及其原因

其他标准的文件要求可在每一标准的各自审核报告的形式规定。审核报告或报告附件必须反映审核的准确、简明和清楚的记录。

必须理解组织必须满足哪些标准要求。

5.4 Issuance of the certificate and preparation of the certificate 证书签发和证书准备

5.4.1 Issuance of the certificate 证书签发

After submitting the complete audit documents, the competent examination and approval of the certification procedure takes place by the head of certification body or by the specified personnel of the certification body, see competence matrix and “AA Fachkompetenz” (work instruction for scope competence) and standard specific determinations. The person making the decision to grant or refuse the certification, extension or restriction of the scope of the certification, suspension or restoration of the certification or renewal of the certification may not be a member of the Audtteam.

The entire audit documentation in accordance with point 5.3.3. is subject to examination and approval. If additional information or clarifications of the certification decision are used, these should be recorded.

The approval process is described in the “099 AA Approval of the certification procedure”.

If necessary it takes place an adjustment of the audit programme for the following audits, see point 4.3.

After the approval of the certification procedure the head of the certification body signs the certification contract, which will be sent together with the audit report and the certificates to the customer.

With integration of branch offices, the documents are sent to the branch offices for provable transmission to the clients, see the specific arrangements for branch offices.

提交完整的审核资料后，由认证机构负责人或由认证机构指定的人员按照能力矩阵和范围能力工作指导书的规定，按照认证程序批准时间进行评价。决定授予或拒绝证书，对认证范围做出的扩展或限制、中止或更新和恢复证书的决定的人员不可以是审核组成员。

根据 5.3.3 全部审核文件将进行评估和批准。如果认证机构做出认证决定需要额外信息和澄清，应被记录。

批准过程在程序 099 AA 审核程序批准中加以规定。如必要，见 4.3，在后续的审核中调整审核方案。

在认证机构负责人批准发证程序后将签署认证合同，合同将连同审核报告和证书一起提供给客户。

有分支机构的，将文件发送到各分支机构，以便向客户传递证据，查看分支机构的具体安排。

5.4.2 Preparation of the certificate 证书签发和证书准备

The validity or the duration of the certification is:

- First certification:
 - approval date + 3 years minus 1 day
- Re-Certification:
 - If the approval date is up to maximum 3 months before the expiry of the valid certificate and it is not an “premature” re-certification (see chapter 7), the new duration connects to the duration of the existing certificate: from the end of the previous term until the date of expiry of the existing certificate + 3 years (connecting certificate). The base date for following audits changes with the date of the re-certification decision.
 - If the approval is made after the expiry of the validity of the certificate, but within 6 months after expiry, the duration begins with the approval date of the re-certification procedure and ends with the date of expiry of the existing certificate + 3 years, what means, that no connecting certificate will be issued, the certification is restored. The base date for following audits changes with the date of the re-certification decision.

The preparation of certificates is regulated in the applicable work instruction for preparation of certificates, see “001 AA Certificate preparation” (“001 AA Zertifikatserstellung”).

证书有效期的规定

-第一次发证

批准日期+3年减少 1 天

-再认证

如果批准日期在有效证书到期之前 3 个月前签发，它不是一个“提前”的重新认证（见 7 章），新的时间连接到现有证书的时间：从上个到期日至现有证书的 3 年有效期届满日期（连接证书）。后续审核的基准日期随重新认证决定日期的变化而变化。

批准证书的有效期限届满后，但在 6 个月后到期，时间开始的重新认证程序的批准日期和结束为现有证书+ 3 年，意味着证书可衔接签发，证书维持有效。下列审核的基准日期随重新认证决定日期的变化而变化。

证书准备的程序见证书准备作业指导书(“001 AA 证书准备”)。

6. Surveillance audit 监督审核

Within the validity of the certificate once a year surveillance audits are performed. In a calendar year, two consecutive monitoring audits may not take place.

Starting from the last date of the certification or re-certification audit, the 1st Surveillance audit has to be performed max. 12 months after the certification decision.

Further shifting requires the approval of the certification body, if necessary in coordination with the accreditation body, or lead to the suspension / withdrawal of the certificate.

In case that no audit will be performed within the due date, the certificate will be suspended or withdrawn.

Due dates for the suspension / withdrawal are defined in the delinquency procedure of the certification body, see “099 AA Deadline monitoring” (“099 AA Terminüberwachung”).

A decision in individual case by the certification body remains possible in exception cases.

Planning and conduction of surveillance audits:

At the latest of 2 months before the target date for conduction of the surveillance audit, the certified customer is informed in written way and is asked to inform the certification body about changes and possible effects on the certification of his management system.

Should the current data of the company have significant changes to the currently valid audit program (e.g. changes in staff numbers in comparison to the last audit, extension of the scope, inclusion of new locations, changes in legislation, etc.), then the existing audit programme will be adjusted by the certification body and communicated to the customer. See point [4.3](#).

Basically, the definition of the audit team (see [5.1.](#)) and the audit planning (see [5.2.](#)) is analogous to the initial certification.

The subcontracts are sent to the whole audit participants according to the audit programme.

The audit time on site **corresponds to the calculation explanation**. Not all standard requirements will be checked. The audit of the standard points has to be split in such a way that with the second surveillance audit all standard requirements will have been checked (see also standard specific requirements, among other in form "standard requirement").

It is strongly recommended that projects which are not processed in the company continuously, but shall be certified according to scope (for example, development) will be checked already during the 1st surveillance audit in order to avoid that there is no corresponding project in the 2nd surveillance audit.

In addition to standard specific requirements among other following aspects have to be examined and evaluated in every surveillance audit:

- Changes in organization or management system of the certified customer
- Effectiveness of management system concerning the achieving of aims of the certified customer
- Internal audits
- Management review
- Corrective actions concerning nonconformities from the last audit
- Handling of complaints
- use of certificate and certification mark

Documentation and approval of surveillance audit:

The documentation of surveillance audits is analogous to [5.3.3](#) and the documentation has to be presented in the certification body at latest 4 weeks after the audit.

The approval is analogous to the certification audit.

With the approval of the surveillance procedure the audit programme is examined for further adequacy and is confirmed / changed by the certification body. Changes in the audit programme are submitted to the customer (e.g. new calculations and preparation of a respective offer).

After the approval of surveillance audit the audit report is sent to the customer.

With integration of branch offices, the documents are sent to the branch offices for provable transmission to the clients, see the specific arrangements for branch offices.

在证书有效期内，每年进行一次监督审核。在日历年度内，可能不会进行连续两次监督审核。从认证或重新认证审核的最后一天开始计算，第一次监督审核必须在认证决定后 12 个月内进行。

进一步的审核时间提前需要认证机构的批准，必要时与认证机构协调，或将导致证书的暂停/撤销。

如果没有在到期日内进行审核，证书将被暂停或撤回。

暂停/撤回的到期日期是在认证机构的推迟程序中定义的，见期限监督程序

在例外情况下，认证机构在个别示例中的决定仍然是可能的。

监督审核策划和实施

在进行监督审核的目标日期之前的 2 个月，以书面方式通知认证客户，并要求通知认证机构关于其管理体系认证的变化和可能的影响。

公司目前的数据有显著变化将导致审核程序的变化（例如，在最后一次审核，人数变化，范围变化，扩展新的地点，包括立法的变化等等），那么现有的审核程序将由认证机构调整和传达给客户。见 4.3

基本上，审核组的定义（见 5.1）和审核策划（见 5.2）类似于初次认证。

根据审核方案，提供给整个审核参与方审核合同。

现场审核时间与计算表相对应。并不是所有的标准要求都会被检查。对于标准要点的审核可以被拆分，即在第二次监督审核中，确保所有标准要求都被检查（参见标准的具体要求，除其他形式的“标准要求”外）。

强烈建议不在公司内连续处理的项目，根据范围（例如开发）在第一次监督审核期间进行认证，以避免在第二次监督审核中没有相应的项目。

- 认证客户的组织或管理制度的变化
- 实现认证客户目标的管理制度的有效性
- 内部审核
- 管理评审
- 上次审核的不符合项纠正
- 投诉处理
- 使用证书和认证标志

监督审核的文件和批准

监督审核的文件类似于 5.3.3，文件必须在审核后最迟 4 周提交给认证机构。

批准类似于认证审核。

在监督程序获得批准后，评审审核计划的进一步充分性，并由认证机构确认/更改。向客户提交审核计划的变更（例如，新的计算和相应报价的编制）。

监督审核批准后，将审核报告发送给客户。

随着分支机构的整合，文件被发送到分支机构，以便向客户进行可证明的传输，请参见分支机构的具体安排。

7. Re-certification 再认证

According to ISO 17021-1 the re-certification is conducted, including the certification decision, within the validity period of the certificate. All standard requirements will be checked.

Approx. 4 months before the expiry of the validity of the certificate, the certification body asks the client for the current company information.

On the basis of current customer data an application examination is conducted again – see 4.1 – and, if a re-certification can be conducted- a updated audit programme for the next 3 year circle is developed – see 4.2 – and is submitted to the client for confirmation / placing of order for the re-certification.

In general, a stage-1 audit in the frame of a re-certification is not necessary. In case of significant changes in the management system of the client or in connection with the functioning of the management system (e.g. amendment of legal requirements), a stage-1 audit is necessary.

If the re-certification activities are completed successfully before expiry of the existing certification, the expiration date of the new certification can be based on the expiration date of the existing certification. The date of issuance of the new certificate must correspond to the date of the re-certification decision or a later date.

If the certification body has not completed the re-certification audit before expiry of the certification date or is unable to verify the implementation of corrections and corrective actions for any substantial nonconformity, no recommendation for re-certification should be issued and the validity of the certification may not be extended become.

→ The customer will be informed in an information letter with the offer about the effects of not fully implementing a re-certification on time (audit duration + processing of non-Conformities) by the customer and the resulting consequences for the certificate to be created (connection certificate).

When the re-certification activities are completed, the certification can be restored within 6 months after the expiry of the certification, otherwise a new stage 2 audit is to be carried out. The certificate's expiration date must be the same as the re-certification date or later, and the expiration date must be based on the previous certification cycle.

If the certificate of the applicant organization already expired, a new offer for the initial certification must be written:

- new reference/order number
- new certificate number
- reductions are possible (for example, prior knowledge of the management system of the customer)
- stage-1 and Stage-2 can be combined (internal note is necessary), upon condition that no significant changes in the management system of the company happened since the last audit

A recertification audit must be performed maximum up to 3 months before the expiry of the certificate, in order to get the connecting certificate. Re-certification audit, carried out more than 3 months before the expiry of the certificate, are considered as "early re-certification audits". In this case no connecting certificate can be issued. The duration of the certificate begins with the approval and expires after 3 years minus 1 day, see 5.4.2. certificate preparation.

During the re-certification audit all standard requirements must be checked.

The aim of the re-certification audit is to check and to evaluate, if:

- the management system as a whole in the face of internal or external changes is still effective
- the continued relevance and applicability of the management system within the scope of the certification is given
- the given obligation to maintain the effectiveness and improvement of the management system to improve the overall performance is suitable
- the maintenance of the certified management system contributes to achieving policy and objectives of the organization.

Re-certification also includes the review of previous audits on monitoring audits and the performance of the management system over the most recent certification cycle. The transmission of these earlier audit reports is carried out by sending the subcontract.

The further audit planning, audit conduction and audit documentation as well as the approval and issue of certificate is analogous to the certification procedure – see point 5.

根据 ISO 17021-1, 在证书有效期内进行再认证, 包括认证决定。所有标准要求将被检查。

在证书有效期届满前约 4 个月内, 认证机构应要求客户提供当前信息。

根据目前的客户数据, 再进行一次申请审查——见 4.1——如果再认证可以进行, 则为下一个 3 年周期制定一个更新的审核方案——见 4.2——并提交给客户确认/采购再认证的订单。

一般来说，在一个再认证方案第一阶段审核是不必要的。在客户管理体系明显变化情况（例如修改法律的要求），第一阶段审核是必要的。

如果再认证活动在现有证书到期之前成功完成，则新认证的有效期可以基于现有证书的有效期。新证书的签发日期必须与再认证决定之日或以后日期相符。

如果认证机构在认证日期到期之前未完成再认证审核，或无法核实对任何重大不合格项的更正和纠正措施的实施，则不应发出再认证的建议，证书的有效期也不得扩大。在这里，必须立即通知客户，证书有效期不能延续到以前的证书。

---客户将在信息函中告知报价，告知客户未按时完全实施重新认证（审核持续时间+不合格处理）的影响，以及新获取证书（接续证书）的后果。

再认证活动结束后，认证可在认证期满后 6 个月内恢复，否则将进行新的第 2 阶段审核。证书的有效期必须与再认证日期或后一天相同，并且有效期必须基于以前的认证周期。

如果申请组织的证书已经过期，必须执行初次认证，提供新的报价：

- 新的参考/订单号
- 新的证书号码
- 可以减少审核人日（例如，事先了解客户的管理体系）
- 第一阶段和第二阶段审核结合（必要的注明），在这种情况下，在公司的管理体系自最后一次审核没有显著的变化发生

为了得到连接证书，换证审核必须在证书到期之前 3 个月内执行。再认证审核，在证书到期 3 个月前进行，被视为“提早的再认证审核”。在这种情况下，不能颁发连接证书。该证书的签发时间从批准日开始，到期日为+3 年减 1 天，见 5.4.2 证书的制备。

在再认证审核过程中，必须检查所有标准要求。

- 管理体系作为一个整体，在面对内部或外部的变化仍然有效。
- 管理体系在认证范围内的持续相关性和适用性
- 有义务保持管理体系的有效性和完善性，以提高整体绩效是合适的。
- 维持经核证的管理体系有助于实现本组织的政策和目标。

再认证还包括对以往监督审核和管理体系在最近一次认证周期中的表现的审查。这些之前的审核报告的传递是通过合约来进行的。

进一步的审核计划、审核实施和审核文件以及批准和颁发证书与初次认证程序类似——见第 5 点。

8. Suspension and withdrawal of the certificate; limitation of the certification scope 证书暂停、撤销，审核范围缩小

A suspension or withdrawal of certification will be conducted by the certification body, when:

- a certified management system of a customer does not fulfil the certification requirements permanent or serious
- the certified customer does not allow the necessary frequency of audit conductions (e.g. surveillance audits)
- the certified client asked voluntarily to receive the suspension
- the client has not fulfilled further contractual obligations towards the certification body

The timelines for suspensions and withdrawals are regulated in the delinquency procedure of the certification body, see “099 AA Terminüberwachung” (deadline monitoring).

Limitations of the scope of the certification are made by the certification body, when:

- the certified client has failed permanently or seriously to meet the certification requirements for parts of the scope of certification

The certification body clarifies further procedure with the customer. In case of limitations on the scope changed certificates with an unchanged validity will be issued.

当发生以下情况，认证机构将对认证实施暂停或撤销：

- 认证的客户管理体系永久或严重的不符合认证要求。
 - 注册客户不允许必要的审核频率（例如监督审核）
 - 经认证的客户自愿接受暂停
 - 客户没有履行对认证机构的进一步合同义务
- 在认证机构的诉讼程序中规定了暂停和撤销的时间表，见“099 AA”（期限监控）。
- 认证范围的限定由认证机构进行，当：
- 经认证的客户未能永久或严重地满足认证范围的部分认证要求。
- 认证机构与客户阐明进一步的程序。如仅对范围进行变更，证书有效期不变。

9. Application of electronically based audit techniques 基于电子化审核技术应用

The application of electronically based audit techniques (e.g. Documents review, checking of corrective and preventive measures, video conferences) has to be considered at the stage of contractual review and has to be documented, if applicable, in the audit plan (e.g. video conferences) and audit report. **see the corresponding work instructions for remote audits.**

基于电子化的审核技术的应用（例如文件的审核、纠正和预防措施，视频会议检查）必须在合同评审阶段进行考虑，并记录在案，如果适用，在审核计划（如视频会议）和审核报告，详见“099 AA 计算机辅助审核程序”，见远程审核作业指导书。

10. Auditing of temporary sites 临时场所审核

If temporary sites are available, assessments of these sites have to be considered in audit planning respectively. The necessity of on-site visits depends on the relevance with regard to the scope of the certification. The insertion of the temporary locations to the annex to the certificate is possible, as far as these were taken into account in the audit program, see “001 AA Certificate preparation” (“001 AA Zertifikatserstellung”).

如果有临时场所，审核计划中必须考虑对这些场所的评估。实地访问的必要性取决于认证范围的相关性。如在审核方案中加以考虑，临时位置可以放到证书附件中，详见“001 AA 证书准备”（“001 AA Zertifikatserstellung”）

11. Special audits 特殊审核

11.1 Extension Audit 扩大审核

If the scope of the existing certification shall be extended, the change can be performed within the frame of an extension audit. The performance of an extension audit can be done in connection with surveillance, repeat audit or at a separated date.

Extensions may cover

- changes / extension of the certification base (standard)
- extension of the scope of the already granted certification
- significant changes in the management system of the company (for example, the exclusions or non-applicable standard requirements)
- changes of locations

In this case the company will be asked for additional / changed information and the man-days will be calculated again; in some cases also subsequent audits can be influenced by these changes.

The existing audit programme is updated by the certification body and sent to the company with an offer for audit extension for confirmation / placing of order.

如果扩展现有证书的范围，可以在扩展审核框架内进行更改。扩大审核可以在监督审核、再认证或分开的审核日期来完成。

扩大可以覆盖

-认证基础的变更/延期（标准）

-已批准证书范围的扩大

-公司管理制度的重大变化（例如，排除或不适用的标准要求）

-地点的变化

在这种情况下，将要求组织提供额外的/更改的信息，并将重新计算人员日；在某些情况下，后续的审核也可能受到这些变更的影响。

现有的审核方案由认证机构进行更新，并向公司发出审核延期的通知，以确认/采购订单。

11.1.1 Extension on a new standard 扩大新标准

The calculation is based on the number of employees who work in the management system of the new standard. Man-days of a new certification must be calculated.

In case of the integrated management system, all employees are taken as a basis for the calculation.

The company will receive a revised offer in which the changed man-days for every standard and every audit are presented.

For the new standard stage-1 audit must be calculated and performed.

根据新标准管理体系设计的雇员人数计算。按照新认证的人日计算。

在整合管理体系的情况下，所有雇员都被作为计算的基础。

组织将收到一份修改后的报价，其中每一项标准和每一次审核都相应修改人日数。

新标准的第一阶段审核必须计算和执行。

11.1.2 Extension / modification of the scope 审核范围扩大、修改

The calculation of the extra time is based on the number of employees who are affected by the extension of the scope. The man-days for the due next audit will be calculated (SA or RA, not CA). If the number of employees has not changed according to existing offer, nonetheless additional extra time for the examination of new circumstances must be calculated.

The company will receive a revised offer in which the changed man-days for the following audit are presented.

根据受范围扩展影响的雇员人数计算额外时间。计算下一次审核的人员日数（按照监督或换证，而不是初次审核）。如果雇员人数按照现有报价没有变动，则必须计算额外的额外时间来检查新的情况。

公司将收到一份修改后的报价，其中审核人日数更改。

11.1.3 Substantial changes in the management system of the company 组织管理体系变更

Substantial changes in the management system of the company may also lead to an increase of man-days, for example, when a formerly excluded standard chapter was included in the management system again (for example, development). In this case the man-days according to corresponding standard specific calculation explanation must be re-calculated.

By reducing of the required demands a reduction of man-days can result depending on standard specific calculation explanation.

The company will receive a revised offer in which the changed man-days for every standard and every audit are presented.

组织管理制度的重大变化也可能导致人员日数的增加，例如，当原先被删除的标准章节再次列入管理体系（例如，开发）。在这种情况下，人日按照相应的标准具体计算说明，必须重新计算。

可以根据标准的具体计算说明减少的人日数。

组织将收到一份修改后的报价，修改每一项标准和每一次审核人日数。

11.1.4 Adding of new company locations 增加新场所

The calculation for the addition of new company locations is described in the “099 VA multi-site certification procedure” (“099 VA Zertifizierungsverfahren Verbund”).

增加新组织场所的计算在程序“099VA 多场所认证程序” “099 VA Zertifizierungsverfahren Verbund”中加以说明。

11.2 Audit planning and performance of the extension audit 扩大审核的策划和实施

After the confirmation of order the lead-auditor or the audit team get with the subcontract the updated audit programme and changes to the contract.

By the lead auditor / audit team all through the extension relevant management system documents will be examined and all relevant standard requirements for the extension will be audited. The extension is documented in the audit report. Like in the certification audit, the entire audit documentation has to be handed in to the certification body for checking, approval and issue of certificates – see 5.3.3.

A change to contract has to be signed by the client and the certification body.

After approval of the extension of the certification procedure the client receives from the certification body the audit report, the change to contract on certification and the certificates. The validity of the certificate does not change.

With integration of branch offices, the documents are sent to the branch offices for provable transmission to the clients, see the specific arrangements for branch offices.

在订单确认后，审核组长或审核小组将获得更新的审核方案和变更合同。

由审核组长/审核组对扩展的相关管理体系文件进行审核，并对所有相关的扩展标准要求进行审核。审核报告中将记录之一扩大。和初次审核类似，整个审核的文件应提交给认证机构进行检查、批准及签发证书– 详见 5.3.3。

变更的合同须由客户和认证机构签署。

在扩大审核的认证程序批准后，认证委托人将从认证机构收到审核报告、变更合同和新证书。证书的有效性没有改变。

通过分支机构派发的，将文件发送到各分支机构，以便向客户传递，详见分支机构的具体安排。

11.3 Short-term and unannounced audits 短通知期和非事先通知的审核

Short-term and unannounced audits can be necessary amongst other things in order to

- investigate complaints
- audit significant changes of the MS and of the processes
- define the certification capability after a suspension

In the case of audits announced at short notice, the certification body requires necessary documents from the company and fixes the audit expenditure and the elements to be audited. The company is informed on the audit team. The audit at short notice is documented in the audit report.

In the event that the certification body decides to carry out an unannounced audit in the company for serious reasons, the audit will be determined by the management of the certification body. The audited elements are determined by the reasons. The Auditteam is determined by the management of the certification body, with particular care being taken in the selection of the auditors:

There is always an audit team, at least 2 auditors. The required competency is covered in the audit and a senior auditor with a long-term audit experience is included in the auditorium, since the customer can not speak against this auditor. The unannounced audit is documented in an audit report.

In both cases, the management of the certification body of the audit report and, where appropriate, the deviation reports, the checklist of the standard requirements for examination and approval are submitted.

Where necessary, a contract amendment must be signed by the contracting entity and the certification body.

The customer gets from the certification body after the approval of the procedure his audit report and if applicable, the change to the contract and changed certificates.

With integration of branch offices, the documents are sent to the branch offices for provable transmission to the clients, see the specific arrangements for branch offices.

短期和未经事先通知的审核是必要的，以便与

- 投诉调查
- 审核管理体系和过程的重大变化
- 在暂停后确认认证的能力

在短期通知的审核计划中，认证机构要求组织提供必要的文件，并确定审核费用和需要审核的内容。组织受到审核组的通知。该审核应记录在审核报告记录。

如果认证机构因重要原因决定对组织进行未经通知的审核，则审核应由认证机构管理者来决定。审核要素应基于该原因。审核组由认证机构管理者决定，选择审核组需特别关注与：

一个审核小组，至少有 2 名审核员。一位具备审核专业能力的具有长期审核经验的资深审核员应包含在审核组内，因为组织无法和审核组对话。未经事先通知的审核将记录在审核报告中。

在这两种情况下，认证机构需要对审核报告，适当时，偏差报告，标准检查表的检查和批准应该进行管理。必要时，须由合同主体和认证机构签署变更的合同。

客户将在审核后获得审核报告，如适用，从认证机构获得变更的合同和变更的证书。

通过分支机构分发的，将文件发送到各分支机构，以便向客户传递，查看分支机构的具体安排。

11.4 Audit in case of change of the companies address 组织地址变更的审核

The company must inform in its change note according to contract § 2, subparagraph 5 whether the certified management system is affected by this change. It must be confirmed by the company, if applicable, that the management system is still be effective.

When the company changed its address it must be verified and documented in the on-stage audit (preferably a regular SA or RA, so that the additional effort remains low), whether the management system still functions at a new location effectively.

If an unscheduled audit must be carried out, following priorities must be checked:

- Documentation of the management system
- Infrastructure and working environment,
- Site-specific conditions and
- Further norm-specific aspects that may be affected by the change of address.

It is preferred, that the auditor who audited the company earlier, performs the audit. The participation of technical experts is not necessary for this audit. If another auditor, who does not know the company, will perform the unscheduled audit, so this auditor must have at least the competence in the business field or in risk class.

The documentation follows in general "099 F Audit report" ("099 F Auditbericht") without standard-specific annex.

When only the company name or legal form were changed, no on-stage audit is necessary. It must be confirmed by the company, if applicable, that the management system is still be effective.

A new certificate with the changed company name or legal form can be issued after signing the changes to the contract and after confirmation of the effectiveness of the management system by the company.

Changed certificates will be issued with the actual date without changing the previous duration.

The certificates, which got invalid with the changes in the company, must be returned back to the certification body after the customer got his new issued certificates.

组织必须通知根据合同第 2 章第 5 项通知认证机构这一变更，包括管理体系是否受此影响。如有必要，组织必须确认该管理制度仍然有效。

当组织改变其地址时，必须分阶段审核（最好是正规的 SA 或再认证，额外的审核人日少）进行验证并记录在新地址上管理体系是否仍然有效地运行。

如果必须进行非计划的审核，必须检查以下优先事项：

- 管理体系的文档
- 基础设施和工作环境，
- 具体情况和
- 可能因地址变更而影响的进一步规范具体方面。

由之前进行审核的审核员进行审核，那么本次审核不需要技术专家的参与。如果另一个不了解该组织的审核员执行非计划的审核，那么审核员必须至少具备该业务领域或风险大类的能力。

文件总体上遵循“099 F 的审核报告”（“099 F auditbericht”）没有特定附件。

有更改公司名称或法律形式时，才有必要进行分阶段审核。如有必要，公司必须确认管理制度仍然有效。

变更公司名称或法律形式的新证书，可以在签订合同变更后，经公司管理制度有效性确认后签发。

更改的证书将以实际签发日期发出，不会改变之前审核周期。

由于公司的变更而失效的证书必须在客户获得新颁发的证书后退回证书机构。

12. Public information 公共信息

The geographical area of the activities of the certification body is presented on the homepage of TÜV Thüringen. Furthermore, the certification body can check the validity of issued certificates. Details of the certificate holder, certificate number, certification standard(s) and the scope of the certificate are given. Further information can be provided by request from the certification body.

认证机构的活动的地理区域在 TÜV Thüringen 公司主页进行介绍。此外，认证机构可以检查颁发证书的有效性。证书持有人的详细资料，证书号码，认证标准和证书的范围。可以通过认证机构的要求提供进一步的信息。

13. Spot check verification of procedure of certification and surveillance 核查和监督程序的抽查核实

The spot check verification of the certification and surveillance procedures is performed in the internal audits of the certification body. The procedure is described in the management manual of TÜV Thüringen e.V.

认证和监督程序的抽查和核实在认证机构的内部审核中进行。该程序是在 TÜV Thüringen 公司管理手册中加以规定。

14. Archiving 档案管理

The archiving of certification documents and records is regulated in the management manual of the of TÜV Thüringen e.V.

认证文件和记录的归档在 TÜV Thüringen 管理手册中加以规定

15. Other applicable documents 其他适用文件

- Annex 1 to 099 VA Certification procedure (standard specific regulations)
- 099 VA Transfer of accredited certification
- 099 VA **certification organization multi-site**
- 099 VA Certification IMS (Integrated Management Systems)
- 099 AA **Checking approval procedure**
- 099 AA Deadline monitoring
- 099 AA **Remote-Audit**
- 001 AA Certificate preparation
- **Quality Management Criteria (by CNCA)**
- **Others if applicable**

-附件 1 至 099 认证程序 (标准具体规定)

- 099VA 转机构认证

- 099 VA 多场所认证程序

- 099 VA 整合体系的认证 (综合管理系统)

- 099AA 认证批准程序

- 099AA 期限监控

- 099 AA 远程审核程序

- 001AA 证书准备

- 质量认证规则 (由中国国家认证认可监督管理委员会发布)

-其他如适用