

099 F Description of certification procedure 认证程序

适用于 TUV Thuringen e.V.以及分支机构特灵顿（上海）检查认证服务有限公司

ISO22716: 2007 化妆品良好生产规范认证程序

Certification Procedure-ISO22716: 2007 Cosmetics- Good Manufacturing Practices

The certification procedure for the examination of ISO22716: 2007 Cosmetics- Good Manufacturing Practices and Guideline for Good Manufacture Practice of Cosmetic Products management system is divided into 3 phases. The auditors are selected by the head of the certification body in accordance with the authorization for the particular sector and qualification.

ISO 22716:2007 《化妆品——良好生产规范》以及化妆品产品良好生产规范管理体系的认证审核程序分为三个阶段。审核员由认证机构负责人根据特定领域的授权和资质进行选派。

The subsequently described audit and certification activities have basically as objective to determine the conformity of the management system of the client to be certified with the requirements of the underlying normative documents and with the defined processes and documentation of the management system developed by the client. Furthermore it will be evaluated both the ability of the management system to ensure the client organization meets applicable statutory, regulatory and contractual requirements and the effectiveness of the management system to ensure the client organization is continually meeting its specified objectives. In result of the audit and certification activities areas for potential improvement of the management system will be identified or, if applicable, critical and non-critical nonconformities will be given. The audit extent necessary for these audit and certification activities can be taken from the particular audit program (see offer) and the audit plan.

文件按描述的审核与认证活动，其基本目标是确定认证客户的管理体系是否符合基础规范文件的要求，以及是否符合客户开发的管理体系所定义的流程和文件。此外，还将评估管理体系确保客户组织满足适用的法定、法规和合同要求的能力，以及管理体系确保客户组织持续实现其既定目标的有效性。通过审核与认证活动，识别出管理体系潜在的改进领域，或者在适用情况下，指出关键和非关键的不符合项。这些审核与认证活动所需的审核范围可以从特定的审核计划（见报价）和审核计划中获取。

1. Application examination 申请评价

The company interested in ISO22716: 2007 Cosmetics- Good Manufacturing Practices Guideline for Good Manufacture Practice of Cosmetic Products certification is asked to provide all the data which are necessary in the customer questionnaire for preparation a tender, so that the certification body can assess and calculate the extent of certification according to recognized rules. The applicant organization will receive a non-binding offer for the certification and if agreed with the certification conditions send an order for certification to the certification body.

希望获得 ISO 22716:2007 《化妆品——良好生产规范》以及化妆品产品良好生产规范认证的公司，需提供客户调查问卷中所需的所有数据，以便认证机构根据既定规则评估和计算认证范围。申请组织将收到一份认证的非约束性报价，如果同意认证条件，则向认证机构发送认证订单。

If the certification body cannot fulfil the certification extent or scope of the certification requested by the company in the customer questionnaire thus no offer for certification will be sent to the applicant organization and the company will be informed of the reasons for the rejection by the certification body.

如果认证机构无法满足公司在客户调查问卷中所请求的认证范围或认证范围，则不会向申请组织发送认证报价，并且认证机构将告知公司拒绝的原因。

2. Audit stage-1 and evaluation of submitted management system documents 审核第一阶段和管理体系文件的评估

The certification audit begins with a stage-1 audit and the review of the submitted management system documents (e.g. manual, if available; organization chart, work and procedure instructions, reports to the internal audits and last management review).

认证审核从第一阶段审核和提交的管理体系文件的审查开始（例如，手册（如有）；组织架构图、工作和程序指导书、内部审核和最近一次管理层评审的报告）。

The applicant submits the management system documents in their current version to the lead auditor in reasonable time prior to the certification audit. The management system documents will be evaluated by the lead auditor on the basis of the specific standard requirements.

Parts of the review of the management system documentation can take made on-site during the stage-1 audit.

申请方应在认证审核前的合理时间内将管理体系文件的当前版本提交给审核组长。审核组长将根据特定标准要求对管理体系文件进行评估。

管理体系文件的审查部分可以在第一阶段审核现场进行。

In good time prior to the stage-1 audit the applicant receives an audit plan for the stage-1 audit. The content of the audit plan will be agreed with the applicant during the introductory meeting before the beginning of the stage-1 audit. The purpose of the stage-1 audit is to check the management documentation, to evaluate the client's location and the site-specific conditions, to communicate adequately with the client in order to evaluate the client's understanding regarding the requirements of the standards. Necessary information on the scope or scope of application of the management system, processes and the location as well as applicable legal and official aspects and their implementation will be collected. Furthermore it will be evaluated if the internal audits and management reviews were performed and if the degree of the implementation of the management system shows that the stage-2 audit can be performed.

在第一阶段审核前，申请方将收到第一阶段审核的审核计划。审核计划的内容将在第一阶段审核开始前的介绍性会议中与申请方协商一致。第一阶段审核的目的是检查管理体系文件，评估客户场所及现场特定条件，与客户进行充分沟通，以评估客户对标准要求的理解。将收集有关管理体系范围或适用范围、流程、场所以及适用的法律和官方要求及其实施的必要信息。此外，还将评估是否进行了内部审核和评审管理层，以及管理体系的实施程度是否表明可以进行第二阶段审核。

The applicant receives a report for the stage-1 audit including the evaluation of the management system documents. Detected critical or non-critical nonconformities must be corrected demonstrably before the beginning of the stage-2 audit. Maximum 6 months can lie between stage-1 and stage-2 audits. If significant changes occur with the applicant's management system which to be certified thus it may be necessary to repeat the entire stage-1 or parts thereof. If appropriate the applicant will be informed if the results of the stage-1 audits result in a postponement or cancellation of the stage-2 audit.

After clarification of all nonconformities and/or uncertainties the stage-2 audit can take place. After the expiration of 6 months a new stage-1 audit must be performed.

申请方将收到一份第一阶段审核报告，其中包括对管理体系文件的评估。发现的关键或非关键不符合项必须在第二阶段审核开始前明显地纠正。第一阶段和第二阶段审核之间最多可以有 6 个月的时间。如果申请方的待认证管理体系发生了重大变化，则可能需要重新进行整个第一阶段审核或其部分。如有必要，申请方将被告知第一阶段审核的结果是否导致第二阶段审核的推迟或取消。

在澄清所有不符合项和/或不确定性之后，可以进行第二阶段审核。如果 6 个月期限已过，则必须重新进行第一阶段审核。

3. Audit stage-2 审核第二阶段

Prior to the beginning of the stage-2 audit the client receives an audit plan for stage-2 audit. During the stage-2 audit the effectiveness of the management system conforming to specific standard requirements as well as the determinations of the implemented management system based on specific examples of procedures and sampling procedures will be checked.

It is the task of the company to demonstrate the practical application of its documented management system in the stage-2 audit. Upon completion of the audit the client will be informed during a final discussion about the audit results.

Nonconformities will be documented in nonconformity reports. The lead auditor decides about the classification of nonconformities in critical or non-critical. The result of the audit will be documented in a report.

在第二阶段审核开始之前，客户将收到第二阶段审核的审核计划。在第二阶段审核中，将检查管理体系的有效性，以符合特定标准要求，并根据具体流程示例和抽样程序来确定已实施的管理体系。

被审核方有责任在第二阶段审核中展示其文件化管理体系的实际应用。审核完成后，客户将在最终讨论中被告知审核结果。

不符合项将记录在不符合项报告中。审核组长将决定不符合项的分类，是关键的还是非关键的。审核结果将记录在报告中。

Procedure in case of identified critical nonconformities 发现关键不符合项的处理程序

A critical nonconformity exists when standard points or process elements as a whole are not described in a required extent and/or when they are not implemented which can lead probably to the delivery of faulty products/services.

当标准条款或流程要素整体未按要求描述和/或未得到实施，可能导致交付有缺陷的产品/服务时，即存在关键不符合项。

The client must analyse the cause of this nonconformity and determine both corrections and corrective actions within 2 weeks after the audit was performed. The implementation of corrections and corrective actions must be made within maximum 3 months (differing from this: for certification audit: within maximum 6 months from the last day of stage-2, otherwise a new stage-2 audit must be carried out).

客户必须在审核完成后 2 周内分析该不符合项的原因，并确定纠正措施和纠正措施。纠正措施和纠正措施的实施必须在最多 3 个月内完成（与之不同的是：对于认证审核，必须在第二阶段审核最后一天起最多 6 个月内完成，否则必须重新进行第二阶段审核）。

A critical nonconformity leads either to a re-audit, which means a new on-site examination, or to a submission of new documents and evidences. The lead auditor decides about the extent of a re-audit, however only the management system processes affected by the critical nonconformity will be audited. The re-audit will be calculated according to the necessary complexity.

The issue of the certificate or the continuity of the certification can only be recommended by the lead-auditor after the confirmation of implementation of the corrections and corrective actions.

关键不符合项可能导致重新审核，即新的现场检查，或者提交新的文件和证据。审核组长决定重新审核的范围，但只有受关键不符合项影响的管理体系流程将被审核。重新审核将根据必要的复杂程度进行计算。

只有在确认纠正措施和纠正措施已实施后，审核组长才能推荐颁发证书或维持认证。

Procedure in case of identified non-critical nonconformities 发现非关键不符合项的处理程序

A non-critical nonconformity exists when an inadequacy was determined in the description or realization in one part of a standard point or process element.

The client must analyse the cause of this nonconformity and determine both corrections and corrective actions within 2 weeks after the audit was performed. If the lead auditor evaluates the corrections and corrective actions as adequate in order to correct the inadequacy then he can recommend the issue of the certificate or the continuation of the certification. The implementation of the determined corrections and corrective actions will be checked and evaluated at the latest by the lead auditor during the next scheduled surveillance audit.

当在标准条款或流程要素的某一部分中发现描述或实施存在不足时，即存在非关键不符合项。

客户必须在审核完成后 2 周内分析该不符合项的原因，并确定纠正措施和纠正措施。如果审核组长评估这些纠正措施和纠正措施足以纠正不足之处，则他可以推荐颁发证书或继续认证。所确定的纠正措施和纠正措施的实施情况最迟将在审核组长下一次计划的监督审核中进行检查和评估。

4. Issue of the certificate and maintenance of the certification 签发证书和维持认证

The issue of the certificate follows after the approval of the certification procedure by the head of the certification body. In the framework of the approval of the certification process the certification body can evaluate the fulfilment of the standard requirement differently from the lead auditor.

When the signed contract for the certification is present, the certificates (if desired, in several languages) including the contract and audit report, will be delivered to the client. The certificate is valid for 3 years as long as annual surveillance audits will be performed in the company with the purpose of maintenance of the certification.

If there are significant changes in the scope or in company data during the validity period of the certificate, then these changes must be checked in the next surveillance audit or in the extension audit. If necessary, a change of contract according to the points which changed will be signed by both sides.

证书的颁发是在认证机构负责人批准认证程序之后进行的。在批准认证程序的过程中，认证机构可能会与审核组长的评估不同地评价对标准要求的符合性。

当认证合同签署后，证书（如需，可提供多种语言版本）连同合同和审核报告将交付给客户。只要公司每年进行监督审核以维持认证，证书有效期为 3 年。

如果在证书有效期内公司的认证范围或公司信息发生重大变化，则这些变化必须在下一次监督审核或扩展审核中进行核查。如有必要，双方将根据变化的内容签署合同变更。

Surveillance audits: 监督审核

Within the 3 years of certificate validity annual surveillance audits will be performed. During the surveillance audit it will be checked on a sample basis whether the certified management system is still fulfilling the requirements.

在证书有效期的 3 年内，将每年进行监督审核。在监督审核过程中，将通过抽样的方式检查认证的管理体系是否仍然符合要求。

The 1st surveillance audit after the first certification must be performed within one year after the approval of the certification procedure. A postponement of the audit date after the due date leads to a suspension (Immediate suspension by exceeded the due date) or withdrawal of the certificate (6 months after the due date).

首次认证后的第一次监督审核必须在认证程序批准后的三年内完成。如果审核日期在截止日期之后推迟，将导致证书暂停（超出截止日期立即暂停）或撤销证书（截止日期后 6 个月撤销）。

The 2nd surveillance audit must be performed analogous no later than 2 years after approval of the certification procedure. The suspension will be made 3 months after the due date, the withdrawal 6 months after the due date.

第二次监督审核必须在认证程序批准后不超过 2 年的时间内按照类似要求进行。如果逾期 3 个月未进行审核，则证书将被暂停；逾期 6 个月未进行审核，则证书将被撤销。

In the log term before the scheduled surveillance audit the applicant will be informed by the certification body about the upcoming audit and the planned audit team. Simultaneously the applicant will be asked to inform the certification body about the changes in the company e.g. changed number of employees or changed scope. The audit date will be coordinated between the applicant and the lead auditor.

在计划的监督审核前的较长时间内，认证机构将通知申请方即将进行的审核以及计划的审核团队。同时，认证机构将要求申请方告知认证机构公司方面的变化，例如员工人数的变化或认证范围的变化。审核日期将由申请方和主审核员协商确定。

For the audit preparation the applicant receives the audit plan with the standard specific requirements that need to be checked. It is not necessary to check all standard requirements in every surveillance audit.

为准备审核，申请方将收到审核计划，其中包含需要检查的特定标准要求。在每次监督审核中，并非需要检查所有标准要求。

In case of critical and non-critical nonconformities the process is the same as in the certification audit. The certificate can be withdrawn in case of serious critical nonconformities. The applicant receives a report with the audit results after the surveillance audit.

如果发现关键或非关键不符合项，处理程序与认证审核相同。如果存在严重的不符合项，可能会撤销证书。监督审核完成后，申请方将收到一份包含审核结果的报告。

Suspension and restoration after a suspension: 暂停与暂停后的恢复：

In case of a declared suspension the certification will be temporary invalid. The certified company is not authorized during this period to advertise with the certification, including the certificate and certification mark. 如果宣布暂停认证，则认证将暂时失效。在此期间，获得认证的公司无权使用认证进行宣传，包括使用证书和认证标志。

A successful audit and subsequent approval of the certification procedure may lead to the renewal of the certification and to the recovery of the certificate.

如果通过成功的审核并随后获得认证程序的批准，则可以恢复认证并重新获得证书。

The validity of the certification can be regained by a successfully performed audit. Additional regulations can be found in the certification contract.

认证的有效性可以通过成功完成的审核重新获得。更多相关规定可以在认证合同中找到。

Withdrawal: 证书撤销

A withdrawal of the certificate must be performed by the certification body 6 months after the exceeded due date. With completion of withdrawal the allowance of the applicant to advertise with the certificate terminates. The withdrawn certificates must be sent to the certification body. After the completed withdrawal a certification is only possible as a completely new initial certification.

认证机构必须在超出截止日期后的 6 个月内撤销证书。完成撤销后, 申请方使用该证书进行宣传的权利将终止。被撤销的证书必须送回认证机构。完成撤销后, 再次进行认证只能作为全新的初始认证进行。

Refusing of the certification: 拒绝认证:

A refusal of the certification may be concluded if the certification body after submitting the application for certification by the customer establishes that a certification of the relevant customer is not possible by reason f.e. the competence in the certification body is not ensured or the company does not comply with the principles. Furthermore a refusal of the certification can also be determined in following an audit by the certification body. In this case the company must remedy the deficient aspects of the auditor and may then apply for a new certification.

认证机构在收到客户提交的认证申请后, 发现由于某些原因(例如认证机构的资质无法确保, 或者公司不符合相关原则)无法对相关客户进行认证, 则可能会拒绝认证。此外, 认证机构在审核后也可能会拒绝认证。在这种情况下, 公司必须纠正审核员指出的不足之处, 然后可以重新申请认证。

Restriction or extension of the scope of the certification: 认证范围的限制或扩展:

An extension of the scope of the certification can be requested by the certified company for example, if further activities are to be certified or another standard within an integrated audit (auditing several standards at the same time under using synergy effects). An extension may also be done when e.g. new branches/sites shall be included or further production or service processes shall be added. After an order has been issued after receipt of a correspondingly amended offer it will be carry out an audit to check the extended scope and after approval in the certification body the changed certificates will be issued.

If necessary, an adaption of the existing audit program follows for the remaining period of certificate validity. An extension audit may be performed both in the context of the regular surveillance audit or a re-certification audit as well as on a specially scheduled date, during which the extended aspects will be checked.

如果需要认证更多活动, 或者在综合审核中(同时审核多个标准并利用协同效应)增加另一个标准, 获得认证的公司可以申请扩展认证范围。例如, 当需要新增分支机构/场所, 或者增加更多生产或服务流程时, 也可以申请扩展。在收到相应修改后的报价并下达订单后, 将进行审核以检查扩展后的范围。经认证机构批准后, 将颁发修改后的证书。如有必要, 将对现有审核计划进行调整, 以覆盖证书剩余有效期内的内容。扩展审核可以在定期监督审核或再认证审核期间进行, 也可以在特别安排的日期进行, 届时将检查扩展的内容。

A restriction of the scope can be requested by the certified company if parts of the certified scope are no longer to be certified or if the number of standards which were included in the certification have to be reduced. The changed extent of the audit is communicated to the certified company and after an appropriate successful audit the changed certificates will be issued.

如果认证范围的部分内容不再需要认证, 或者需要减少包含在认证中的标准数量, 获得认证的公司可以申请限制认证范围。审核范围的变更将通知给获得认证的公司, 经过适当的审核并成功通过后, 将颁发修改后的证书。

A restriction of the scope must be made if during the audit or during the approval in the certification body will be detected that for some parts of the certified scope not all certification requirements were implemented. Should despite of an anew audit or submitted documents not all evidences for the maintenance of the granted certification be provided, the scope of the certification will be restricted and new certificates will be issued.

如果在审核过程中或在认证机构批准过程中发现认证范围的某些部分未实施所有认证要求, 则必须限制认证范围。如果尽管进行了重新审核或提交了文件, 但仍未提供维持认证的所有证据, 则认证范围将被限制, 并将颁发新的证书。

As a result of the audit for an extension or if necessary for a restriction a new approval of the certification procedure and issue of changed certificates follows. The previously valid certificates must be returned by the applicant to the certification body.

在扩展或必要时限制认证范围的审核之后，将重新批准认证程序并颁发修改后的证书。申请方必须将之前有效的证书退回给认证机构。

5. Renewed certification or re-certification audit;

Renewal of certification 续期认证或再认证审核；认证续期

Prior to the exceeding of validity of the certificate a re-certification audit must be performed in order to a renewal of the certification for another 3 years. A beginning of the re-certification audit is not permitted after expiry of the currently valid certificate with the conditions of a re-certification; in this case a new initial certification must be carried out with stage-1 and stage-2.

在证书有效期届满之前，必须进行再认证审核，以便将认证续期再延长 3 年。不允许在当前有效证书到期后以再认证的条件开始再认证审核；在这种情况下，必须重新进行初始认证，包括第一阶段和第二阶段。

Information about the existing management system or about the changes in the existing certification must be handed in in advance by the applicant together with the customer questionnaire to the certification body. In the re-certification offer to the applicant the audit program for the next three years of the certification cycle will be specified.

申请方应提前将现有管理体系的信息或现有认证的变更信息，连同客户调查问卷一起提交给认证机构。在提交给申请方的再认证报价中，将明确未来三年认证周期的审核计划。

During the re-certification audit the efficiency of the whole management system will be checked by random samples. The audit procedure will be implemented according to point 2 in this description.

在再认证审核中，将通过随机抽样的方式检查整个管理体系的效率。审核程序将按照本说明第 2 点实施。

Activities for re-certification audits may require a stage-1 if there are significant changes in the management system, in the organization or in the context with function of the management system (e.g. changes in legislation).

如果管理体系、组织结构或与管理体系功能相关的方面（例如法规变更）发生了重大变化，则再认证审核活动可能需要进行第一阶段审核。

The new certification cycle begins with the release of the re-certification process. The re-certification procedure including the approval by the head of the certification body should be completed during the validity period of the current certificate to ensure an uninterrupted connecting certification to the existing certificate.

新的认证周期从再认证程序的批准开始。再认证程序，包括认证机构负责人的批准，应在当前证书有效期内完成，以确保与现有证书无缝衔接。

If the re-certification (including the completion of all deviations and approval by the certification body) could not be completed within 6 months after expiry of the existing certificate a new stage-2 audit shall be carried out in accordance with the audit extent of a first certification.

如果再认证（包括完成所有偏差并获得认证机构的批准）未能在现有证书到期后的 6 个月内完成，则应按照初始认证审核的范围进行新的第二阶段审核。

To continue maintaining the certification must be carried out annual surveillance audits in the 1st and 2nd year after the re-certification. The due date corresponds to the release of the re-certification process + 1 or 2 years.

为了维持认证，必须在再认证后的第 1 年和第 2 年进行年度监督审核。截止日期为再认证程序批准之日起加 1 年或 2 年。

6. Short-notice or unannounced audits 临时通知或不预先通知的审核

If required it could be carry out short-noticed or unannounced audits in the audited company, for example to investigate complaints or to examine changes which have been made or to make void a suspended certification. In the case of short-notice audits the certification body reserves the right to inform the certified

company at least 3 days before the visit date about the main focus of the audit. Unannounced audits are not announced to the certified company.

如有需要，可以在被审核公司进行临时通知或不预先通知的审核，例如用于调查投诉、检查已实施的变更，或者取消暂停的认证。在临时通知审核的情况下，认证机构有权在审核日期前至少 3 天通知获证公司审核的主要关注点。不预先通知的审核则不会告知获证公司。

In both cases the certified company is engaged to grant the employees or the auditors of the certification body of TÜV Thüringen e.V. and its branches access to the relevant locations of the company.

在上述两种情况下，获证公司有义务允许 TÜV Thüringen e.V. 认证机构和分支机构的员工或审核员进入公司相关场所。

7. Multi-site certification 多场所认证

Multi-site certifications are applied to enterprises with several (production) sites or offices. One of these sites must be defined by the certified company as a central office, which plans, steers and controls the defined activities for all sites. The central office must not necessarily be the head office (headquarters) of the company.

多场所认证适用于拥有多个（生产）场所或办公地点的企业。获证公司必须将其中一个场所定义为中心办公室，该办公室负责规划、指导和控制所有场所的既定活动。中心办公室不一定必须是公司的总部（总公司）。

The sites can be separate legal entities, but they must be connected to the central office in a legal or contractual way. The legal access by the central office and the management representative of the top management of the central office to all sites must be ensured (e.g. by contractual regulations).

这些场所可以是独立的法人实体，必须但通过法律或合同方式与中心办公室相连。必须确保中心办公室及其管理层代表对所有场所的法律访问权（例如通过合同规定）。

In case of a multi-site certification and if appropriate requirements are fulfilled the audit will be performed in the defined central office and in further locations according to the sampling procedure. This will be defined in the audit program (see offer) for the certification audit and annual surveillance audits.

如果满足适当的条件，对于多场所认证，审核将在定义的中心办公室以及根据抽样程序选择的其他地点进行。这将在认证审核和年度监督审核的审核计划（见报价）中明确。

The sampling procedure for the multi-site certification is possible, if following requirements are fulfilled:

如果满足以下要求，则可以对多场所认证进行抽样程序：

- Establishment, implementation and maintenance of a management system **which applies to all locations uniformly**. This also applies also for the substantial process descriptions.
- Surveillance of the whole management system under the **central direction** by the management representative of the central office. He is authorized to give instructions to all sites.
- Performance of the **internal audits in all sites** and according to all standard requirements with the evidence of the implementation of the management system before the audit of the certification body will be performed.
- Accomplishment of the **central** management review and complaint management.
- 建立、实施和维护一个适用于所有场所的统一管理体系，这也包括主要流程描述。
- 在中心办公室管理层代表的集中指导下，对整个管理体系进行监督。他有权向所有场所下达指令。
- 在认证机构审核之前，所有场所均需按照所有标准要求完成内部审核，以证明管理体系的实施情况。
- 完成中心管理层评审和投诉管理。

The inclusion or discontinuation of some sites requires an adjustment of the audit program for the existing remaining certification cycle. However it is not possible to separate sites retroactively from the multi-site company after the audit was performed (e.g. if critical nonconformities were detected in one site).

场所的增加或减少需要对现有剩余认证周期的审核计划进行调整。然而，在审核完成后，无法将场所从多场所公司中追溯性地分离出来（例如，如果在一个场所中发现了关键不符合项）。

The audit process and the maintenance of the certification by conducting annual surveillance audits will be performed according to points 2 and 3 of this description.

审核过程以及通过进行年度监督审核来维持认证，将按照本的说明第 2 点和第 3 点执行。

Annex 1: Auditor qualification 附件 1: 审核员资质

The requirements for the auditors: 对审核员的要求:

1. Appointment as auditor in ISO 9001 in EA Scope 3, 12 or 13 or appointment as food safety auditor (eg ISO 22000, HACCP etc.)

ISO 9001 标准被任命为 EA 范围 3、12 或 13 的审核员，或者被任命为食品安全审核员（例如 ISO 22000、HACCP 等）。

2. Participation in training providing knowledge of ISO 22716, HACCP, ISO 22000 for equivalent.

参加过 ISO 22716、HACCP、ISO 22000 或等效知识的培训。

Annex 2: Audit effort 附件 2: 审核工作量

The following table is used to calculate the time required for the audit:

以下表格用于计算审核所需的时间:

Number of employees 雇员人数	total ZA *初审 总审核人 天	minimum on site (ZA) 初审最低现场审核人 天	total ÜA 监督审 核总人天	minimum on site (ÜA) 监督 审核最低 现场审核 人天	total WA 再认 证审核总 人天	minimum on site (WA) 再 认证审核 最低现场 审核人天
1 – 5	1,5	1,2	0,5	0,4	1,0	0,8
6 – 10	2,0	1,6	0,7	0,5	1,3	1,1
11 – 15	2,5	2,0	0,8	0,7	1,7	1,3
16 – 25	3,0	2,4	1,0	0,8	2,0	1,6
26 – 45	4,0	3,2	1,3	1,1	2,7	2,1
46 – 65	5,0	4,0	1,7	1,3	3,3	2,7
66 – 85	6,0	4,8	2,0	1,6	4,0	3,2
86 – 125	7,0	5,6	2,3	1,9	4,7	3,7
126 – 175	8,0	6,4	2,7	2,1	5,3	4,3
176 – 275	9,0	7,2	3,0	2,4	6,0	4,8
276 – 425	10,0	8,0	3,3	2,7	6,7	5,3
426 – 625	11,0	8,8	3,7	2,9	7,3	5,9
626 – 875	12,0	9,6	4,0	3,2	8,0	6,4
876 – 1175	13,0	10,4	4,3	3,5	8,7	6,9
1176 – 1550	14,0	11,2	4,7	3,7	9,3	7,5
1551 – 2025	15,0	12,0	5,0	4,0	10,0	8,0
2026 – 2675	16,0	12,8	5,3	4,3	10,7	8,5
2676 – 3450	17,0	13,6	5,7	4,5	11,3	9,1
3451 – 4350	18,0	14,4	6,0	4,8	12,0	9,6
4351 – 5450	19,0	15,2	6,3	5,1	12,7	10,1
5451 – 6800	20,0	16,0	6,7	5,3	13,3	10,7

6801 – 8500	21,0	16,8	7,0	5,6	14,0	11,2
8501 – 10700	22,0	17,6	7,3	5,9	14,7	11,7

Please take into account that a reduction in time of up to 60% is possible if the customer already has a management system (eg ISO 9001 or ISO 22000 or equivalent) for at least 3 years. 80% of the time must be audited on site.

请注意，如果客户已经拥有一个管理体系（例如 ISO 9001 或 ISO 22000 或等效体系）至少 3 年，则审核时间最多可以减少 60%。审核时间的 80% 必须在现场进行。

注明：以上中英文翻译如有不同，请参考中文。