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审核程序 Audit Procedure

1.0 目的 Purpose

1.1 本程序规定管理体系审核的审核策划、实施、报告过程。To define the procedure for planning, conducting and reporting audits.

2.0 范围 Scope

2.1 本程序适用于 AKA 所有管理体系审核及相关的活动。This procedure applies to all management system audits conducted by AKA.

3.0 定义 Definition

无 None

4.0 引用文件 Reference Document

ISO 17021-1-合格评定-对管理系统进行审核和认证的机构的要求 Conformity assessment — Requirements for bodies providing audit and certification of management systems

ISO/IEC TS 17021-10 合格评定 管理体系审核认证机构要求 第 10 部分：职业健康安全管理体系审核和认证能力要求 Conformity assessment- Requirements for the organization that audits and certifies management systems

ISO 19011 审核管理系统准则 Review management system guidelines

ISO27006 信息技术 安全技术 信息安全管理体系统审核认证机构的要求 Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems

IAF 强制性文件 Mandatory document

5.0 职责 Responsibility

5.1 审核部负责确保该程序的实施。


Assessment Dept. shall be responsible for ensuring this procedure is implemented.

6.0 程序 Procedure

6.1 申请与报价 Application and Quotation

6.1.1 申请组织的授权代表提出申请，完成相应的申请表（AKA-M-F04）；申请表（AKA-M-F04）应包括认证标准、公司名称及其所在地的地址、过程和运作、申请的认证范围、人力资源和技术资源、职能、关系、任何相关的法律义务、所有影响符合性的外包过程、是否接受过咨询（如果接受过，由谁提供咨询）。

The authorized representative of the applicant organization shall submit the application and complete the corresponding application form （AKA-M-F04）；The application form （AKA-M-F04）shall the standards, company name and the address(es) of its site(s), its processes and operations, desired scope, human and technical resources, functions, relationships , any relevant legal obligations, outsourced processes used by the organization that will affect conformity to requirements, consultancy relating to the management system(If yes, who provide

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the consultation).

6.1.1.1 对于 OH&SMS 的客户，申请组织的授权代表向 AKA 提供的有关其工艺和活动的信息还应包括识别与工艺相关的关键危险和职业健康安全风险，工艺中使用的主要危险材料，以及适用的职业健康安全法规规定的任何相关法律义务。OH&SMS 客户应填写 AKA-R-F13 《ISO45001 风险表》。申请书应包括在本组织场所工作的人员的详细情况，以及在本组织场所以外工作的人员的详细情况。For OH&SMS client, the information provided to AKA by the authorized representative of the applicant organization on its processes and activities shall also include the identification of the key hazards and OH&S risks associated with processes, the main hazardous materials used in the processes, and any relevant legal obligations coming from the applicable OH&S legislation. OH&SMS client shall fill the form of<AKA-R-F13 Risk Complexity ISO45001>. The application shall contain details of personnel working on, as well as working away from the organization's premises.

6.1.1.2 申请 ISMS 的组织应具有一个已文件化且已实施的 ISMS。客户的 ISMS 应符合 ISO/IEC 27001 和认证所要求的其他文件。For ISMS client, the client shall have a documented and implemented ISMS which conforms to ISO/IEC 27001 and other documents required for certification.

6.1.2 合同评审会对提交的信息及补充信息进行评审。至少，评审将确认：

The contract review will review the submitted information and supplementary information. At least, the review will confirm:

6.1.2.1 任何涉及范围的问题（例如尚未实施的活动，访问限制，安全性等）

Any scope issues (such as unimplemented activities, access restrictions, security, etc.)


6.1.2.2 申请组织的运作场所、活动区域、完成审核需要的时间和任何其他影响认证活动的因素（语言、安全条件、对公正性的威胁等）。对于 ITSMS，也应评审以确保清晰地了解了 SMS 和服务的可能风险。Apply for the organization's place of operation, the areas of activity of the client、the time required to complete the audit, and any other factors affecting the certification activities (Language, security conditions, threats to justice, etc.). For ITSMS, the contract review also shall review the application from the client to ensure a clear understanding of the likely risks to the SMS and the services.

6.1.2.3 组织人数-注册范围内的人员总数-包括兼职或临时人员。（请参阅服务报价程序）

Number of members of the organization - total number of persons registered - including part-time or temporary staff. (Please refer to service Quote Procedure)

6.1.2.4 访问限制-如果在不审核所识别的机密或敏感信息的情况下无法对管理系统进行充分审核，则营销中心应告知客户无法提供报价，并且除非进行适当的访问安排，否则无法进行认证审核。

Access restrictions - If the management system cannot be adequately audited without auditing the identified confidential or sensitive information, the marketing center should inform the customer that the quotation cannot be provided and the certification audit cannot be

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conducted unless appropriate access arrangements are made.

6.1.2.5 申请组织及其管理体系的信息足以建立审核方案

Information about the application organization and its management system is sufficient to establish an audit program

6.1.2.6 AKA 与申请组织之间任何已知的理解差异

Any known understanding differences between AKA and the applicant organization

6.1.2.7 AKA 有能力并能够实施认证活动; AKA 有能力的审核组及认证决定。

AKA has the competence and ability to perform the certification activity. AKA has competent audit team and certification decisions

6.1.2.8 对于 ISO13485, 如果申请组织使用外包过程, 应确定并记录审核团队中是否需要特定能力来评估外包过程的控制。If the applicant organization uses outsourced processes, the contract review shall determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced process.

6.1.3 合同评审后, AKA 应接受或拒绝认证申请。当 AKA 因申请评审的结果拒绝认证申请时, 应记录拒绝申请的原因, 并使客户清楚拒绝的原因。若接受认证申请, 以上信息用于人天评审和报价。

Following the review of the application, the AKA shall either accept or decline an application for certification. When the AKA declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client. If AKA accept the application, the above information will be used for manday caculation and quotation.

6.1.4 报价单连同合同/条款和条件一起发送给客户以供考虑。

The quotation is sent to the customer for consideration along with the contract/terms and conditions


6.1.5 一旦客户签署了合同, 并在可能的情况下签署了报价单, 则营销中心将信息添加到 ERP 中。 Once the customer has signed the contract and, where possible, signed the quotation, the marketing center adds the information to the ERP.

6.2 审核方案 Audit programme

6.2.1 制定整个认证周期的审核方案, 清晰地识别所需的审核活动, 这些审核活动用以证实客户的管理体系符合认证所依据标准或其他规范性文件的要求。认证周期的审核方案应覆盖全部的管理体系要求。

Develop an audit plan for the entire certification cycle, clearly identify the audit activities required, These audit activities are used to verify that the customer's management system meets the requirements of the certification standards or other normative documents. The audit scheme for the certification cycle shall cover all management system requirements.

6.2.2 对于初次审核: 包括两阶段的初次审核, 循环“始于认证决定”, 该周期包括在认证决定后的第一年和第二年进行监督审核, 以及在认证到期前的第三年进行再认证审核。(初始 - 监督 1 - 监督 2 - 再认证)

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For initial audits: includes a two-stage initial audit, the cycle "begins with the certification decision", which includes a supervisory audit in the first and second years after the certification decision, and a recertification audit in the third year before the certification expires. (Initial -- Supervision 1 -- Supervision 2 -- Recertification)

6.2.3 随后的周期以再认证决定开始, 包括第一年和第二年的监视审核以及重新认证审核 (以重新认证确认决定结束)。(监督 1 - 监督 2 - 再认证)。监督审核应至少每个日历年(应进行再认证的年份除外) 进行一次。初次认证后的第一次监督审核应在认证决定日期起 12 个月内进行。

The subsequent cycle begins with a recertification decision, including a first and second year monitoring audit and a recertification audit (which ends with a recertification confirmation decision). (Surveillance 1 - Surveillance 2 - Recertification). Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The first Surveillance audit after the initial certification shall be conducted within 12 months from the date of certification decision.

6.2.4 审核周期不能超过三年, 并且取决于证书的签发日期和有效期。The audit period cannot exceed three years and depends on the date and validity of the certificate

6.2.5 按上述审核周期策划审核方案, 建立审核矩阵表 (AKA-R-F07), 用于识别审核活动或已执行的活动, 以及用于证明客户的管理系统已在审核周期中得到充分评估的活动。矩阵用于说明在每次审核中完成了哪些过程和要求以及计划在三年周期的剩余时间内进行哪些审核。


Plan the audit plan according to the audit cycle, and establish audit matrix () for identifying audit activities or activities performed, and activities for demonstrating that the customer's management system has been adequately evaluated during the audit cycle. The matrix is used to indicate which processes and requirements have been completed in each audit and which audits are planned for the remainder of the three-year cycle.

6.2.6 标识组织的所有过程, 并在矩阵表上指定“关键范围过程”。如果未在表格中指定, 需收集证据以证实该过程。当指定为关键范围审核程序时, 在表单上, 审核员收集的证据将用于验证范围的适用性。关键范围流程: 审核过程以确认注册范围是最新, 有效和适当的。这通常保留给实现活动所涉及的过程, 在此过程中将确认范围列出的活动。

Identify all the processes of the organization and specify "critical scope processes" on the matrix table. If not specified in the form, evidence is collected to verify the procedure. When specified as a critical scope audit procedure, on the form, evidence gathered by the auditor is used to verify the applicability of the scope. Critical scope process: An audit process to verify that the scope of registration is up to date, valid and appropriate. This is usually reserved for the processes involved in the implementation activities, where scoped activities are identified.

6.2.7 对于客户已获的认证或由另一认证机构实施的审核, 应获取并保留充足的证据, 例如报告和对不符合采取的纠正措施的文件。所获取的文件应为 满足本文件要求提供支持。根据获取的信息证明对审核方案的任何调整的合理性, 并予以记录, 并对以前不符合的纠正措施的实施进行跟踪。

For a client's certification or an audit conducted by another certification body, Such as reports and documentation of corrective actions taken for nonconformance. The documents

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obtained shall provide support for meeting the requirements of this document. Justifies and records any adjustments to the audit protocol based on the information obtained, and tracks the implementation of previously non-conforming corrective actions.

6.2.8 如果客户采用轮班作业,在建立审核方案和编制审核计划时考虑在轮班工作中发生的活动。

If the client uses shift work, consider the activities that occur during the shift work when establishing the audit plan and preparing the audit plan.

6.2.9 以后的周期从再认证决定算起。审核方案的确定和任何后续调整应考虑客户的规模,其管理体系、产品和过程的范围与复杂程度,以及经过证实的管理体系有效性水平和以前审核的结果。

The subsequent cycles start with the recertification decision. The determination of the audit proposal and any subsequent adjustments shall take into account the size of the customer, the scope and complexity of its management system, products and processes, as well as the proven level of effectiveness of the management system and the results of previous audits.

6.2.10 ISMS 审核方案特殊要求 ISMS special requirement for Audit program

6.2.10.1 总则 General

ISMS 审核的审核方案应考虑所确定的信息安全控制 The audit program for ISMS audits shall take the determined information security controls into account.。

6.2.10.2 审核方法 Audit Methodology

AKA 的程序不应预先假定 ISMS 实施的特殊方式或文件和记录的特殊格式,应将重点放在确定客户的 ISMS 满足 ISO/IEC 27001 的要求和客户的策略与目标 AKA's procedures Shall not presuppose a particular manner of implementation of an ISMS or a particular format for documentation and records, shall focus on establishing that a client's ISMS meets the requirements specified in ISO/IEC 27001 and the policies and objectives of the client.。

6.2.10.3 初次审核的总体准备 General preparations for the initial audit

要求客户为调阅内部审核报告和信息安全独立评审报告做出所有必要的安排。在认证审核的一阶段,客户应至少提供以下信息 Require that a client makes all necessary arrangements for the access to internal audit reports and reports of independent reviews of information security. At least the following information shall be provided by the client during stage 1 of the certification audit:


a) ISMS 和其所覆盖活动的一般信息 General information concerning the ISMS and the activities it covers;

b) ISO/IEC 27001 所规定的、必要的 ISMS 文件的副本,及必要的相关文件 A copy of the required ISMS documentation specified in ISO/IEC 27001 and, where required, associated documentation.

6.2.10.4 评审周期 Review periods

如果一个 ISMS 没有至少实施过一次覆盖认证范围的管理评审和内部审核,不应对该 ISMS 实施认证 Shall not certify an ISMS unless it has been operated through at least one management review and one internal ISMS audit covering the scope of certification.

6.2.10.5 认证范围 Scope of certification

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- a) 审核组应根据所有适用的认证要求，对包含在确定范围内的客户 ISMS 进行审核 The audit team shall audit the ISMS of the client covered by the defined scope against all applicable certification requirements.
- b) 应确认客户在其 ISMS 范围内满足了 ISO/IEC 27001 中 4.3 的要求。Shall confirm, in the scope of the client ISMS, that clients address the requirements stated in ISO/IEC 27001, 4.3.
- c) 应确保：客户的信息安全风险评估和风险处置准确地体现了认证范围所界定的活动并扩展到活动的边界 shall ensure that the client's information security risk assessment and risk treatment properly reflects its activities and extends to the boundaries of its activities as defined in the scope of certification。
- d) 应确认这在客户的 ISMS 范围和适用性声明中得到了体现 shall confirm that this is reflected in the client's scope of their ISMS and Statement of Applicability.
- e) 应验证每个认证范围至少有一个适用性声明 shall verify that there is at least one Statement of Applicability per scope of certification。
- f) 应确保：与不完全包含在 ISMS 范围内的服务或活动的接口，已在寻求认证的 ISMS 中得到说明，并已包括在客户的信息安全风险评估中。与其他机构共享设施（如：IT 系统、数据库和通讯系统或外包一项业务职能），是这类情形的一个示例 shall ensure that interfaces with services or activities that are not completely within the scope of the ISMS are addressed within the ISMS subject to certification and are included in the client's information security risk assessment. An example of such a situation is the sharing of facilities (e.g. IT systems, databases and telecommunication systems or the outsourcing of a business function) with other organizations.。

6.2.10.6 认证审核准则 Certification audit criteria

客户 ISMS 接受审核的准则应是 ISMS 标准 ISO/IEC 27001。与所实施的业务相关的其他文件，可以作为认证要求 The criteria against which the ISMS of a client is audited shall be the ISMS standard ISO/IEC 27001. Other documents may be required for certification relevant to the function performed。

6.2.11 ISO13485 审核方案特殊要求 ISO13485special requirement for Audit program


当根据包含或超出 ISO 13485 要求的审核方案对客户进行审核时，如果能够证明已遵守 IAF MD9 的所有要求，则无需重复审核是否符合先前涵盖的 ISO 13485 要素。When AKA has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, providing the AKA can demonstrate that all of the requirements of IAF MD9 have been complied with.

6.3 确定审核时间、策划审核、选择和指派审核组 Determine audit time, plan audit, select and assign audit team

6.3.1 确定审核时间见以下文件 Determine the audit time, please see :

AKA-P-004 Quoting & Contract Review Procedure 报价与合同评审程序

AKA-DCN-001 Quoting Guideline 报价指南

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6.3.1.1 营销中心，客服部，技术质量部负责针对每个客户确定策划和完成对其管理体系的完整有效审核所需的时间。给予审核员足够的时间来开展与初次审核、监督审核或再认证审核相关的所有活动。总审核时间的计算，应包括报告审核情况所需的充足时间。并记录管理体系审核的时间及其合理性。For each client the Sales Center、Customer Service. Dept. and Tech Quality Dept shall determine the time needed to plan and accomplish a complete and effective audit of the client's management system, shall allow auditors sufficient time to undertake all activities relating to an initial audit, surveillance audit or re-certification audit. The calculation of overall audit time shall include sufficient time for audit reporting. And record the duration of the management system audit and its justification.

6.3.1.2 在确定审核时间时，应考虑（但不限于）以下方面： a) 相关管理体系标准的要求； b) 客户及其管理体系的复杂程度； c) 技术和法规环境； d) 管理体系范围内活动的分包情况； e) 以前审核的结果； f) 场所的数量和规模、地理位置以及对多场所的考虑； g) 与组织的产品、过程或活动相关联的风险； h) 是否是结合审核、联合审核或一体化审核。 In determining the audit time, the following aspects shall be considered: a) the requirements of the relevant management system standard; b) complexity of the client and its management system; c) technological and regulatory context; d) any outsourcing of any activities included in the scope of the management system; e) the results of any prior audits; f) size and number of sites, their geographical locations and multi-site considerations; g) the risks associated with the products, processes or activities of the organization; h) whether audits are combined, joint or integrated.

6.3.2 策划审核

Planning the audit


6.3.2.1 确定审核范围和准则，包括任何更改，应在与客户商讨后确定。

Determine the scope and criteria of the audit, including any changes, which shall be determined after consultation with the customer.

6.3.2.2 审核目的由 AKA 确定。确定审核目的说明审核要完成什么，并应包括下列内容

The audit purpose is determined by AKA. Determine the purpose of the audit. State what should be completed and include the following

- 确定客户管理体系或其部分与审核准则的符合性； Determine the compliance of the Customer management system or parts thereof with the audit criteria
- 确定管理体系确保客户满足适用的法律、法规及合同要求的能力； Determine the ability of the management system to ensure that the customer meets the applicable laws, regulations and contractual requirements
- 确定管理体系在确保客户可以合理预期实现其规定目标方面的有效性； Determine the effectiveness of the management system in ensuring that customers can reasonably expect to achieve their stated objectives

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- d) 适用时，识别管理体系的潜在改进区域。Identify potential improvement areas of the management system where applicable.
- e) SM 确定审核目的 SM Determining audit objectives: 审核目的应包括检查客户识别和控制了其参与 SMS 活动的其他方在 SMS 边界内的接口。还应确保客户知晓并管理了来自于这些接口的、对 SMS 和服务的风险。The audit objectives shall include checking that interfaces at the boundaries of the SMS with other parties participating in the activities of the SMS, are identified and controlled. Make sure that the client is aware of and managing any risks to the SMS and the services arising from the interfaces.
- f) ISMS 确定审核目的 ISMS Determining audit objectives: 审核目的应包括确定管理体系的有效性，以确保客户已根据风险评估实施了适用的控制并实现了所设立的信息安全目标 The audit objectives shall include the determination of the effectiveness of the management system to ensure that the client, based on the risk assessment, has implemented applicable controls and achieved the established information security objectives.。

6.3.2.3 审核准则应被用作确定符合性的依据，并应包括：

Audit criteria shall be used as a basis for determining compliance and shall include:

- 所确定的管理体系规范性文件的要求； The requirements for regulatory documents of the established management system
- 所确定的由客户制定的管理体系的过程和文件。The process and documentation of the management system as determined by the customer

6.3.3 选择和指派审核组是由计划员在 ERP 中进行安排，具体见计划安排作业指导书。在 ERP 任务安排模块正式任命审核组，明确地规定审核组的任务，并为其提供相应的审核文件。审核员在审核之前约 1 周发出审核计划通知客户具体的计划安排。


The selection and assignment of the audit group is arranged by the planner in the ERP, as detailed in the work instruction of plan arrangement. In the ERP task arrangement module, the audit team is formally appointed, the tasks of the audit team are clearly defined, and the corresponding audit documents are provided. The auditor will send out the audit plan about 1 week before the audit to inform the customer of the detailed plan arrangement.

6.3.4 在所有情况下，审核组成员必须具有必要的能力代码，否则将使用技术专家。对于 ISO27001、ISO20000、ISO13485 审核，审核组应具有必要的能力代码，不能使用技术专家代替。

In all cases, audit group members must have the necessary capability code, otherwise technical experts will be used. For ISO27001、ISO20000、ISO13485 audit, the auditor team shall has the necessary capability code, technical experts cannot be used instead.

6.3.4.1 ISMS 审核组能力，特殊要求 Special requirements of Audit team competence:

1) 对于监督和特殊审核活动，仅那些与所安排的监督活动和特殊审核活动相关的要求适用 For surveillance and special audit activities, only those requirements which are relevant to the scheduled surveillance activity and special audit activity apply。

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2) 当为特定认证审核选择审核组时, 审核部应确保每次委派时审核组的能力是适宜的 When selecting and managing the audit team to be appointed for a specific certification audit, Assessment department shall ensure that the competences brought to each assignment are appropriate. 审核组应 The team shall:

- a) 对拟认证 ISMS 范围内的特定活动具备适当的技术知识, 以及相关时, 对这些活动的相关规程和其潜在信息安全风险具备适当的技术知识 (技术专家可以履行此项职责) have appropriate technical knowledge of the specific activities within the scope of the ISMS for which certification is sought and, where relevant, with associated procedures and their potential information security risks (technical experts may fulfill this function);
- b) 理解客户, 足以基于客户 ISMS 范围和组织环境对 ISMS (该体系管理着客户活动、产品和服务的信息安全) 进行可靠的认证审核 have understanding of the client sufficient to conduct a reliable certification audit of its ISMS given the ISMS' scope and context within the organization in managing the information security aspects of its activities, products and services;
- c) 适当地理解适用于客户 ISMS 的法律法规要求 have appropriate understanding of the legal and regulatory requirements applicable to the client's ISMS。

6.3.4.2 ISO13485 审核组能力, 特殊要求 Special requirements of Audit team competence:

- a) 审核组应具备审核范围的技术领域 (AKA-DCN-002 行业分类) 的能力 The audit team shall have the competence for the Technical Area (AKA-DCN-002-Industrial Classification) for the scope of audit.
- b) 如果对仅提供零件和服务的组织进行审核, 则审核组不必证明与生产医疗器械的制造商具有相同水平的技术能力 If the audit is performed for an organization that only parts and services, the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer producing medical devices.
- c) AKA 目前尚不为包括无菌或拟用于最终用户灭菌的设备的企业提供认证服务。AKA does not currently provide certification services for businesses that include sterile or intended for end-user sterilization.

6.3.5 审核员应适合其角色 (例如, 组长与组员), 并符合公正性要求。如果仅有一名审核员, 该审核员应有能力代码, 并履行适用于该审核的审核组长职责。


Auditors should be appropriate for their roles (e.g., team leader and team members) and meet the requirements of impartiality. If there is only one auditor, the auditor shall have necessary capability code and perform the duties of an audit team leader applicable for that audit.

6.3.6 将考虑其在 AKA 中的状态 (例如, 有效, 应进行的见证), 以确保对交付的审核不存在不适当的风险。

Its status in THE AKA (i.e., validity, witness to be performed) will be considered to ensure that there is no undue risk to the audit of the delivery.

6.3.7 客户可以随时请求审核员更换, 但决定完全取决于 AKA。

The customer may request a replacement auditor at any time, but the decision is entirely up to the AKA.

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6.3.8 与客户在实施审核前就审核活动中观察员、技术专家的到场达成一致。审核组应确保观察员不对审核过程或审核结果造成不当影响或干预。观察员可以是客户组织的成员、咨询人员、实施见证的认可机构人员、监管人员或其他有合理理由的人员。技术专家不应担任审核组中的审核员。技术专家应由审核员陪同。技术专家可就审核准备、策划或审核向审核组提出建议。

Agree with customer on the presence of observers and technical experts in audit activities prior to audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of the audit. The observer may be a member of the client's organization, a consultant, an AB assessor carrying out the witness, a supervisor or any other person with reasonable reasons. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor. Technical experts can make suggestions to the audit team on audit preparation, planning or audit.

6.3.9 对于职业健康和安全管理体系统，术语“技术领域”是指过程或服务的共性及其相关危害，这些共性可能使工人暴露于职业健康安全风险中。For Occupational Health and Safety management systems, the term “technical area” is related to commonalities of processes or services and their associated hazards which can expose workers to OH&S risks.

6.3.10 ISO/IEC 20000-1 阐明了所有的要求是通用的且是适用于所有的客户，不论其类型、规模和所交付服务的性质。对于 ISO/IEC 20000-1 审核来说，术语“技术领域”是与 SMS 相关的，包括服务管理过程和 SMS 范围中的服务。“技术领域”与服务交付时所用的任何潜在技术无关。ISO/IEC 20000-1 states that all requirements are generic and are intended to be applicable to all clients, regardless of type, size and the nature of the services delivered. For ISO/IEC 20000-1 audits, the term “technical area” relates to the SMS, including service management processes and the services within the scope of the SMS. “Technical area” does not relate to any underlying technology used to enable service delivery.

6.4 审核计划

6.4.1 为审核方案中的每次审核都编制审核计划，计划审核前约 1 周，审核组长将与客户联系并确认： Prepare an audit plan for each audit according to audit program. About 1 week before the audit plan, the audit team leader will contact the customer for confirmation:

6.4.1.1 审核日期是否可以接受

Is the audit date acceptable


6.4.1.2 没有任何会影响审核持续时间的更改（例如，人员数量更改，场所更改，范围更改等）There are no changes that will affect the duration of the audit (e.g., change of staff, change of venue, change of scope, etc.)

6.4.1.3 组织的过程

Organizational process

6.4.1.4 任何可能需要通过审核进行跟进的新客户要求或关键客户反馈。

Any new customer requests or key customer feedback that may need to be followed up through audits.

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6.4.2 审核组长将基于客户提供的信息，审核矩阵和以前的审核报告,进行审核策划。审核计划应与审核目的和范围相适应。

The audit leader will plan the audit based on the information provided by the customer, the audit matrix and the previous audit report. The audit plan shall be appropriate to the objectives and the scope of the audit.

6.4.3 在审核之前约 1 周，审核组长将准备审核计划/议程，并返回给客户。审核计划至少应包括或引用： a) 审核目的； b) 审核准则； c) 审核范围，包括识别拟审核的组织和职能单元或过程； d) 拟实施现场审核活动（适用时，包括对临时场所的访问和远程审核活动）的日期和场所； e) 预计的现场审核活动持续时间； f) 审核组成员及与审核组同行的人员（例如观察员或翻译）的角色和职责。g) 向客户提供审核组每位成员的姓名，并在客户请求时使其能够了解每位成员的背景情况。


Approximately 1 week prior to the audit, the audit leader will prepare the audit plan/agenda and return it to the client. The audit plan shall include or reference at least: a) the purpose of the audit; b) Audit criteria; c) Scope of audit, including identification of organizational and functional units or processes to be audited; d) The date and place on which on-site audit activities (including access to temporary sites and remote audit activities, where applicable) are to be carried out; e) The estimated duration of on-site audit activities; f) The roles and responsibilities of members of the audit Team and those who travel with the audit team, such as observers or translators. g) Provide the customer with the name of each member of the audit group and enable the customer to know the background of each member upon request.

6.4.4 审核计划将明确定义要审核的流程，执行审核的相关审核组成员，进行审核的场所（包括临时站点和 ICT /远程审核）以及现场活动的预期持续时间。如果适用，审核计划将包括对先前 NCR 有效性的验证。注意：审核员将注明审核计划提供给客户的日期。The audit plan will clearly define the process to be audited, the relevant audit team members to perform the audit, where the audit will be conducted (including temporary sites and ICT/remote audits), and the expected duration of on-site activities. If applicable, the audit plan will include validation of previous NCR's effectiveness. Note: The auditor will date when the audit plan is provided to the client.

6.4.5 审核组长应促进和协调审核组的差旅安排，以最大程度地降低成本并促进更协调的沟通。The audit team leader shall facilitate and coordinate the travel arrangements of the audit team to minimize costs and facilitate more coordinated communication.

6.4.6 审核组长在与审核组商议后，应向每个审核组成员分配对特定过程、职能、场所、区域或活动实施审核的职责。所进行的分配应考虑到所需的能力、有效并高效地使用审核组以及审核员、实习审核员和技术专家的不同作用和职责。在审核进程中，为确保实现审核目的，可以改变工作分配。如果在最初的审核计划制定之后进行了任何更改，则更新的审核计划将被上传到系统中。此外，如果更新后的计划影响审核信息（例如审核持续时间，申请表上的信息），审核员将通知客户。

The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use

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of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives. If any changes have been made since the initial audit plan was developed, the updated audit plan will be uploaded to the system. In addition, the auditor will notify the client if the updated plan affects audit information (e.g. duration of audit, information on the application form)

6.4.7 审核组任务的沟通, 要求审核组: a) 检查和验证客户与管理体系标准相关的结构、方针、过程、程序、记录及相关文件; b) 确定上述方面满足与拟认证范围相关的所有要求; c) 确定客户组织有效地建立、实施并保持了管理体系过程和程序, 以便为建立对客户管理体系的信任提供基础; d) 告知客户其方针、目标及指标的任何不一致, 以使其采取措施。

The task communication of the audit team requires the audit team to: a) check and verify the client's structure, policies, processes, procedures, records and related documents related to the management system standards; b) Ensure that the above aspects meet all requirements related to the scope of the proposed certification; c) Determine that the customer organization has effectively established, implemented and maintained management system processes and procedures to provide a basis for trust in the customer management system; d) Inform the customer of any inconsistencies in its policies, objectives and indicators so that the customer may take measures.

6.4.8 审核组长和审核员所需的知识和技能可以通过技术专家和翻译人员补充。 技术专家和翻译人员应在审核员的指导下工作。使用翻译人员时, 翻译人员的选择要避免他们对审核产生不正当影响。技术专家的选择准则根据每次审核的审核组和审核范围的需要为基础确定。


The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit. The selection criteria of technical experts are determined based on the needs of audit team and audit scope of each audit.

6.4.9 实习审核员可以参与审核, 此时要指派一名审核员作为评价人员。 评价人员应有能力接管实习审核员的任务, 并对实习审核员的活动和审核发现最终负责。Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.

6.4.10 SM 审核计划抽样准确度 Sampling accuracy of Audit plan

6.4.10.1 通过识别以下方面的差异, 在初始合同评审和后续审核活动时应确定适当的抽样水平: An adequate level of sampling shall be determined at initial contract review, and subsequent audit activities, identifying differences between the following:

- 1) 地点, 例如: 场所规模, 或在 SMS 内但不在认证范围内的临时场所的使用 Locations, e.g. site sizes or use of temporary sites which are covered by the SMS but are not in the scope of certification;
- 2) 服务 services;
- 3) 顾客 customers;

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4) 参与服务提供的其他方（例如：内部团体、供方、作为供方的顾客）other parties (internal groups, suppliers, customers acting as a supplier) involved in the provision of services;

5) 语言 languages;

6) 所有班次之间工作方式的一致性。如果每个班次的运行方式相同时，审核有大量人员倒班的客户所需的时间可以少些。这要有记录审查，以证实所有班次之间工作方式的一致性。如果各班次之间是一致的，所有班次可被视为是一组活动且一个班次可作为审核样本 Consistency of approach across all shifts. A client with a high proportion of personnel working in shifts can be audited in less time if each shift operates in the same way. This involves a review of records to confirm the consistency of approach across all shifts. If shifts are consistent, all shifts can be treated as one set of activities and one shift can be used as the sample for audit。

7) SMS 的局部变化 local variations of the SMS;

8) 法律法规要求 legal and regulatory requirements;

6.4.10.2 应从客户 SMS 范围中选择有代表性的样本。该选择应基于认证机构的决定，并体现了 6.4.10.1 中所述的因素和随机因素 A representative sample shall be selected from the scope of the client's SMS. The selection shall be based upon the judgement of the certification body, reflecting the factors presented in 6.4.10.1, as well as a random element。

6.4.10.3 审核计划的策划应考虑 6.4.10.1 和 6.4.10.2 中的要求。计划应在认证审核间的 3 年周期内覆盖 SMS 全部范围内有代表性的样本 The design of the audit plan shall take into consideration the requirements in 6.4.10.1 and 6.4.10.2. The plan shall cover representative samples of the full scope of the SMS within the three-year period between certification audits。

6.4.11 ISMS 审核计划特殊要求 Special Requirement of ISMS Audit plan


1) ISMS 审核计划应考虑所确定的信息安全控制措施 The audit plan for ISMS audits shall take the determined information security controls into account.。

2) 如适宜，审核计划应识别在审核中使用的网络支持的审核技术 The audit plan shall identify the network-assisted auditing techniques that will be utilized during the audit, as appropriate。

注：网络支持的审核技术可包括：例如，电话会议、网络会议、基于网络的交互式通信和远程电子访问 ISMS 文件和（或）ISMS 过程。对这些技术的关注，将提高审核的有效性和效率，并支持审核过程的完整性 Network assisted auditing techniques may include, for example, teleconferencing, web meeting, interactive web-based communications and remote electronic access to the ISMS documentation or ISMS processes. The focus of such techniques should be to enhance audit effectiveness and efficiency and should support the integrity of the audit process.。

3) 审核时间的选择 Timing of audit

沟通并与拟审核的组织就选择一个能最有效地证实其整个 ISMS 范围的审核时间达成一致意见。适当时，可考虑季度、月份、日期和班次 Communicate and get the agree with the organization to be audited the timing of the audit which will best demonstrate the full scope of the organization. The consideration could include season, month, day/dates and shift as appropriate.。

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6.4.12 OHS 审核计划特殊要求 Special Requirement of OHS Audit plan

1) 对 OHSMS，若产品或服务实现过程是倒班运行时，认证机构对每个班次的审核程度取决于每个班次从事的过程，这些过程必须考虑其伴随的 OHS 风险，以及客户证实的对每个班次的控制水平。为了审核的有效实施，在第一个认证周期内，应至少对正常办公时间内的一个班次和正常办公时间以外的一个班次进行审核。对于后续周期的监督审核，认证机构可根据组织的 OHSMS 的成熟度决定是否对第二个班次进行审核。若可能，建议推迟审核开始时间以在审核工作日内覆盖两个班次。考虑不审核第二班次的风险，应记录不审核第二个班次的正当理由在审核报告中。For OH&SMS, where product or service realization processes operate on a shift basis, the extent of auditing of each shift by the CAB depends on the processes done on each shift, taking into consideration the associated OH&S risks, and the level of control of each shift that is demonstrated by the client. To audit effective implementation, at least one of the shifts inside and one outside of regular office hours shall be audited during the first cycle of certification. During surveillance audits of the subsequent cycles, the CB may decide not to audit the second shift based on the recognised maturity of the organization's OH&SMS. Adjustments for delaying the starting time of audit are recommended whenever possible, in order to cover both shifts within the audit day. The justification for not auditing the other shifts shall be documented taking into account the risk for not doing so in the audit report.。

6.5 现场审核 – 在每个现场审核活动中，执行以下流程 Site audit - During each site audit activity, perform the following procedures

6.5.1 如有可能，审核组长将与审核小组开会（例如在酒店早餐时），以确保在进行现场活动之前明确期望并解决了疑虑。

If possible, the audit team leader will meet with the audit team (For example, at a hotel breakfast) to ensure that expectations and concerns are clearly addressed prior to the field activities.


6.5.2 举行首次会议，涵盖首次会议清单的所有要求，注意：尽管讨论的深度可以根据组织的成熟程度进行调整，但必须讨论所有列出的项目。

Hold the first meeting to cover all requirements of the first meeting list, Note: Although the depth of the discussion can be adjusted to the maturity of the organization, all listed items must be discussed.

6.5.3 对申请表信息进行了核对，以确保准确性和任何必要的更改。如果发现可能影响审核时间的任何更改，审核员将紧急联系办公室人员。所有更改，包括与办公室讨论的更改，都将记录在提交的审核报告中。此评审至少包括：

The application form information is collated to ensure accuracy and any necessary changes. If any changes are detected that may affect the audit time, the auditor will contact the office personnel as a matter of urgency. All changes, including those discussed with the office, will be recorded in the audit report submitted. This review shall at least include:

1. 评审范围内的措词 Wording within the scope of review
2. 审核范围应说明审核的内容和界限，例如拟审核的场所、组织单元、活动及 过程。


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当初次认证或再认证过程包含一次以上审核（例如覆盖不同场所的审核）时，单次审核的范围可能并不覆盖整个认证范围，但整个审核所覆盖的范围应与认证文件中的范围一致。The scope of the audit shall state the content and boundaries of the audit, such as the site, organizational unit, activities and process to be audited. When the initial certification or recertification process involves more than one audit (such as an audit covering different locations), the scope of a single audit may not cover the entire scope of the certification, but the scope of the entire audit shall be the same as that in the certification document.

3. 被定义为不适用/排除的条款（必须适合其范围的性质，并且要有用于证实该条款的证据来证明，而不仅仅是客户文档参考） A clause that is defined as not applicable/excluded ((must be appropriate to the nature of its scope and supported by evidence to support the clause, not just customer documentation reference)
 4. 员工人数（全职，兼职和临时） Number of employees (full-time, part-time and temporary)
 5. 班次（按班次计算的小时数和人员数） Shifts (number of hours and personnel on shifts)
 6. 列出场所的地址和联系信息 List the address and contact information of the place
 7. 任何新的或更改的场所。 Any new or changed premises
 8. 所列内容的任何更改都可能导致当前/将来审核的持续时间（从原始报价起）发生变化，因此，应及时联系技术质量部进行评审。 Any changes to the listed items may result in a change in the duration of the current/future audit (from the original offer) and therefore should be reviewed in a timely manner by contacting the Technical Quality Department.
 9. 职业健康安全管理体系应包括组织控制或影响范围内可能影响组织职业健康安全管理体系绩效的活动、产品和服务。 The OH&SMS shall include activities, products and services within the organization's control or influence that can impact the organization's OH&SMS performance.
 10. 组织的职业健康安全管理体系覆盖的临时场所应进行抽样审核，以提供管理体系运行和有效性的证据。(见 IAF MD5 条款 9) Temporary sites covered by the organization's OH&SMS are subject to audit on a sample basis to provide evidence of the operation and effectiveness of the management system (see clause 9 of IAF MD5).
- 6.5.4 应当进行工厂巡视，客户和与各个管理系统标准有关的关键领域均应接受审核。这将使审核员能够：

Factory inspections shall be conducted and customer and key areas related to each MIS standard shall be reviewed. This will enable the auditor:

1. 衡量设施的规模。 Measure the size of the facility.
2. 确定客户是否有任何明显的重大问题，例如处理/存储不良，文档不受控制等。 Determine if the customer has any significant apparent problems, such as poor handling/storage, uncontrolled documentation, etc.
3. 确定对过程输入，环境因素，质量目标，ISMS 或 45001 风险和危害的识别是否全

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面且适合于注册范围。Determine whether the identification of process inputs, environmental factors, quality objectives, ISMS or 45001 risks and hazards is comprehensive and appropriate to the scope of registration.

4. 讨论多个轮班范围并讨论轮班开始和停止时间 Discuss multiple shift ranges and shift start and stop times.
5. 为审核小组的活动确定适当的着装（例如安全鞋，安全眼镜，防护服等）。Determine appropriate clothing (e.g. safety shoes, safety glasses, protective clothing, etc.) for audit team activities.


6.5.5 AKA 标记，认可标记和其他认证声明的使用将受到审核，以确保符合 AKA 程序。这将包括通过审核观察到的文件化信息（例如表格，证书，装箱单等）和客户的营销资料（例如网站，小册子，标牌等）。

The use of AKA marks, accreditation marks and other certification declarations will be reviewed to ensure compliance with AKA procedures. This will include documented information observed through audits (e.g. forms, certificates, packing lists, etc.) and customer marketing materials (e.g. websites, brochures, signage, etc.)

6.5.6 审核方法将包括直接访谈，流程审核，文档信息（保持和保留的信息）的审核以及验证与预期一致的结果领域。除极少数情况外，审核应使用 PDCA（计划，执行，检查，行动）方法进行。这样就可以验证所审核样本的期望，联系，结果和改进。

The audit methodology will include direct interviews, process reviews, reviews of document information (retained and retained information), and validation of expected results areas. Except in rare cases, the audit shall be conducted using the PDCA (Plan, execute, inspect, act) method. This allows you to validate the expectations, contacts, results, and improvements of the audited samples.

1. 计划 - 首先确定计划的目标，过程输入，目标和分配给过程的资源（例如人员，基础设施，环境等）。识别支持交互（例如合同/订单，物料，采购，生产计划等）非常重要。
2. Planning - First identify the objectives of the plan, process inputs, objectives and resources allocated to the process (such as people, infrastructure, environment, etc.). It is important to identify supporting interactions (such as contracts/orders, materials, procurement, production plans, etc.).
3. 执行 - 观察操作过程并采访执行活动的人员（不仅是主管），以验证是否遵守程序的要求。Execution - Observe the operation process and interview the person (not just the supervisor) performing the activity to verify compliance with the requirements of the procedure.
4. 检查 - 根据既定的目标检查过程记录。在适当情况下，这应包括人员能力，设备维护，产品产量/报废，交付绩效等。Check - Check process records against established goals. Where appropriate, this should include personnel capacity, equipment maintenance, product yield/scrap, delivery performance, etc.
5. 行动 - 审核在卓越绩效水平上所采取的行动（确定如何利用它并推动系统的改进）和非目标水平（确定需要采取哪些适当措施来改善绩效）。审核员将需要确定所采

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采取的措施是否适当，并与组织和/或客户的期望相一致。Action - Review actions taken at the level of performance excellence (determine how to use it and drive system improvement) and non-target levels (determine what appropriate actions need to be taken to improve performance). The auditor will need to determine whether the action taken is appropriate and in line with the organization and/or customer expectations.

- 6.5.7 审核活动将基于抽样，审核组负责选择自己的样本。应该选择这些样本以偏向观察到的组织风险（例如，大型/复杂客户，客户投诉历史等）


Audit activities will be based on sampling, with the audit team responsible for selecting its own samples. These samples should be selected to bias observed organizational risks (e.g., large/complex customers, customer complaint history, etc.)

1. 为了提高审核的效率，审核组应选择一个接近实现活动即将结束的样本，查看客户合同中的特定要求，然后查看组织过程以确保在实现活动中传达需求。To improve the effectiveness of the audit, the audit team should select a sample near the end of the implementation activity, look at specific requirements in the customer contract, and then look at the organizational processes to ensure that requirements are communicated in the implementation activity.

- 6.5.8 审核员应始终尝试与被访者/被审核者建立融洽的关系，并尝试使他们放心。希望通过询问的方法来使用对话式审核，因此被审核方更愿意回答问题。以下是可用于执行流程的 PDCA 审核的问题示例：

The auditor should always try to establish rapport with the respondent/auditee and try to reassure them. The moderated party is more willing to answer questions because it wants to use conversational auditing by asking questions. The following is an example of a problem that can be used to perform a PDCA audit of the process:

1. 您需要做什么工作？（输入）What kind of work do you need to do? (input)
2. 这些物品从哪里来？（接口）Where did these things come from (interface)
3. 您的工作的预期结果是什么？您如何知道自己做得好？（目标/ KPI）What are the expected outcomes of your work? How do you know when you're doing well? (Target/KPI)
4. 您执行什么步骤？您如何知道它们是什么？（做，能力，记录的信息）What steps do you take? How do you know what they are? (Ability to do, record information)
5. 出问题了怎么办？（不合格和纠正措施）What if something goes wrong? (Nonconformance and corrective action)
6. 别人怎么知道您所处理工作的状态及其进度？（通讯，状态，配置）How will others know the status and progress of the work you are working on? (Communication, status, configuration)
7. 您的工作或活动如何帮助实现目标？（意识，目标，政策）How does your work or activity help you achieve your goals? (Awareness, goals, policies)
8. 您填写什么文书来表明已完成计划？（结果，不适用）What documents do you fill in to show that you have completed the project? (Results, not applicable)
9. 在结束审核之前，审核员将确保收集足够的证据来证明符合性，评估标准的所有要

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求。注意：请确保验证支持过程（例如，如果检查外部提供商处的采购订单，则有必要检查这些提供商的资格及其持续的维护。）Before completing the audit, the auditor will ensure that sufficient evidence has been collected to demonstrate compliance and evaluate all requirements of the standard. Note: Make sure that the validation support process is in place (for example, if you check purchase orders from external providers, it is necessary to check the eligibility of those providers and their ongoing maintenance).

- 6.5.9 审核员将使用“给我展示哲学”来审核足够的证据 – 不要相信客户的话，而是让他们展示客观的证据来证实所提出的主张和所遵循的流程。确保记录了所审核的证据，以便可以证明范围的支持和与审核标准（内部程序，客户要求以及标准的要求-最低）的一致性。应注意包括足够的证据，但不要捕获专有或受控制/受管制的信息（例如，出口受管制的技术数据，价格，利润等）。

The auditor will use "show me the philosophy" to review sufficient evidence - do not take the client at his word, but let them present objective evidence to substantiate the claims made and the process followed. Ensure that the audited evidence is documented to demonstrate scope support and conformance to audit standards (internal procedures, customer requirements and standards requirements - minimum). Care should be taken to include sufficient evidence, but not to capture proprietary or controlled/controlled information (e.g., export controlled technical data, prices, profits, etc.).

- 6.5.10 尽管计划可能会强制规定以下要求，但每年必须涵盖以下要求：


The following requirements must be covered annually, although the plan may mandate them:

1. 内部审核和管理评审 Internal audit and management review
2. 审核对先前审核中发现的不符合项采取的措施 Audit actions to be taken in response to non-conformance identified in previous audits
3. 投诉处理 Complaint handling
4. 管理系统在实现认证客户目标和相应管理系统预期结果方面的有效性
5. 旨在持续改进的计划活动的过程 Effectiveness of the management system in achieving the goals of the certified customer and the expected results of the corresponding management system
6. 持续运营控制 Continuous operation control
7. 审核任何更改 Review any changes
8. 标志的使用和/或任何其他参考证明 Use of the mark and/or any other reference
9. 在此过程中识别的任何特定于计划的要求，支持过程或计划文件。Any program-specific requirements identified in this process support the process or program document.

- 6.5.11 对认证范围/场所子范围进行了审核，以证明范围是适当的

The certification scope/site sub-scope is reviewed to demonstrate that the scope is appropriate

1. 为执行/观察到的可验证活动授予范围，并以证据为依据。在范围内包含未实施或

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未验证的活动是不可接受的, 并且当发现范围内容与审核期间观察到的活动之间存在差异时, 审核员将通知技术质量部 (例如, 通过变更表)。Grant scope for verifiable activities performed/observed and based on evidence. It is not acceptable to include unimplemented or unverified activities within the scope, and the auditor will notify technical Quality when a discrepancy is found between the scope content and the activities observed during the audit (for example, through the change sheet).

2. 每次审核都需要有足够的证据来证明范围是如何通过审核进行验证的, 以及哪些证据是与审核产品 (活动, 产品, 过程, 服务等) 相关联。Each audit shall have sufficient evidence to prove how the scope is verified through the audit and what evidence is associated with the audit products (activities, products, processes, services, etc.).
3. 从审核矩阵中定义为关键范围过程的组织过程将包括为支持注册范围而审核的证据。Organizational processes defined as critical scope processes from the audit matrix will include evidence of evidence audited to support the registration scope.
4. 组织的外包过程, 对管理体系的有效性的影响 Influence of organization's outsourcing process on the effectiveness of management system

1) 如果组织外包其部分职能或过程, 应获得如下证据: 组织已经有效地确定了其采用的控制方式和控制范围, 以确保外部提供的职能或过程不会对管理体系有效性 (包括组织向其顾客稳定提供合格产品和服务的能力、或控制其环境影响因素/控制其 OHS 风险, 并承诺满足法规要求方面) 产生负面影响。If an organization outsources part of its functions or processes, shall obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently deliver conforming products and services to its customers or to control its environmental aspects and commitments to compliance with legal requirements.

2) 对 QMS 和 EMS, 应审核并评估客户管理体系的有效性, 包括对任何外部提供活动及其引起有关目标交付、顾客和满足要求方面的风险进行的管理。这可以包括收集对供方有效性水平的反馈。考虑到组织的管理体系范围仅包括对供应活动的控制, 而且并非由组织自身执行这些 (外部供应) 活动, 因此并未要求审核供方的管理体系。根据对风险的这一理解, 应确定任何附加的审核时间。For QMS and EMS, AKA will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

3) 对 OHSMS, 应将审核和评价组织的 OHSMS 对外包活动管理的有效性, 以及外包活动对其自身活动和过程的 OHS 绩效和符合性要求所带来的风险。For

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OH&SMS the CAB will audit and evaluate the effectiveness of the organization's OH&SMS in managing any supplied activity and the risk this poses to OH&S performance of its own activities and processes and conformity requirements.

a) 这可能包括收集对供方有效性水平的反馈，基于以下内容：This may include gathering feedback on the level of effectiveness from suppliers, based

组织对这些外部供方的评价、选择、绩效监视和再评价的应用准则，这些准则是以他们按照特定要求提供职能或过程的能力为基础，并与法律要求一致，和 On the criteria applied by the organization for the evaluation, selection, monitoring of performance, and re-evaluation of these external providers based on their ability to provide functions or processes in accordance with specified requirements, in compliance with the legal requirements

外部供方可能对组织控制其自身 OHS 风险的能力产生不利影响的风险。On the risk that the external providers can adversely affect the organization's ability to control its own OH&S risks.


b) 虽然不要求对外部供方的管理体系实施审核，为了策划并完成一项有效的审核，应就组织 OHSMS 范围内对外包给外部供方的过程或职能的控制进行审核。包含于组织 OHSMS 范围的过程中，在组织场地作业的承包商人员应被访谈到，以评价他们的 OHS 意识。Although the provider's management system is not required to be audited, the CAB shall audit those controls that the organization has implemented for the processes or functions included within the scope of the organization's OH&SMS, which have been outsourced to external providers to plan and complete an effective audit. The contractor's personnel who operate at the organization's premises, on processes included in the scope of the organization's OH&SMS, shall be interviewed to evaluate their OH&S awareness.

c) AKA 应能够在审核方案准备的过程中确定，并且在后续初次认证审核中、以及在每次监督及再认证审核前对其核实。Should establish this during the preparation of the certification programme and further verify it during the initial audit, and before every surveillance and recertification audit.

6.5.12 在整个审核活动中，与客户的持续沟通是关键。这应该包括与客户人员进行的每日状态审核会议，以审核已发现的任何不合格和/或审核线索。鉴于在整个审核过程中都会与客户公开交流结果，因此客户应该不会感到意外。

In the whole audit activity, continuous communication with customers is the key. This should include a daily status audit meeting with customer personnel to review any nonconformance and/or audit leads that have been identified. Customers should not be surprised, given that results are communicated publicly throughout the audit process.

1. 当发现紧急问题时（例如不安全状况/安全问题，产品逃逸等），审核员应立即通知客户组织联系人以减少发生事故的风险。即使客户已经在内部处理该问题，也会酌情考虑不符合项。When an urgent problem is discovered (e.g. unsafe conditions/safety issues, product escapes, etc.), the auditor should immediately notify the customer to

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organize contacts to reduce the risk of an accident. Nonconformance will be considered as appropriate even if the customer has addressed the issue internally.

2. 审核组长将协调审核小组的时间，以便在向客户展示之前审核和审核发现。The audit team leader will coordinate the audit team's time to review and audit findings before presenting them to the client.
3. 如果发生冲突，审核组长有责任解决。审核组成员在客户面前相互争辩或不尊重对方是绝对不能接受的。注意：如果事情朝着这个方向发展，请考虑“超时”，在此情况下，审核员可以借口进行私人对话以解决问题。In case of conflict, the audit team leader shall have the responsibility to resolve it. It is never acceptable for audit team members to argue or disrespect each other in front of clients. Note: If things go this way, consider a "timeout", in which case the auditor can engage in a private dialogue to resolve the issue.

6.5.13 在末次会议之前，审核组应：

Prior to the last meeting, the audit team shall :

1. 确保认证申请信息保持准确。Ensure that the certification application information is accurate
2. 根据审核结果更新审核矩阵/程序。这应该考虑风险，不符合和其他即将发生的变化，这些变化可能需要调整审核矩阵/计划以进行后续审核。Update the audit matrix/procedures according to the audit results. This should take into account risks, nonconformities and other upcoming changes that may require adjustments to the audit matrix/plan for subsequent audits.
3. 对照审核目的和审核准则，审查审核发现和审核中获得的任何其他适用的信息，并对不符合分级； review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities
4. 考虑审核过程中内在的不确定性，就审核结论达成一致 agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process;
5. 就任何必要的跟踪活动达成一致； agree any necessary follow-up actions
6. 确认审核方案的适宜性，或识别任何为将来的审核所需要的修改（例如认证范围、审核时间或日期、监督频次、审核组能力）。confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

6.5.14 举行了末次会议，涵盖了“末次会议”部分的所有要求。


The last meeting was held, covering all the requirements of the "Last Meeting" section.

6.5.15 尝试基于人天表中确定的暂定持续时间安排后续审核事件。

Try to arrange follow-up audit events based on the tentative duration determined in the day chart.

6.5.16 审核报告：


Audit report:

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1. 审核组长完成审核报告的编制，并对审核报告的内容负责，审核报告提供对审核的准确、简明和清晰的记录。需要提交到 ERP 系统中。The audit team leader finish the writing of audit report, and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record. It shall be submitted to the ERP system
2. 该报告应在末次会议后的七（7）个日历日内提交，并将书面报告提供给客。AKA 享有对审核报告的所有权。The report shall be submitted within 7 calendar days after the last meeting and a written report shall be sent to the client. Ownership of the audit report shall be maintained by AKA.
3. 将捕获对客户，关联的 FRS 或其认证/认证状态的任何更改。Any changes to the customer, associated FRS or its authentication/authentication status will be captured.
4. 根据审核结果将包括审核员的建议：更改增加/减少持续时间的合理性，进行特殊审核等。Based on the audit results, it will include the auditor's recommendations: change the reasonableness of the increase/decrease duration, conduct special audits, etc.
5. 报告应包括：Reports should include:
 - a) 关于管理体系符合性与有效性的声明以及对下列方面相关证据的总结 A statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to:
 - 1 管理体系满足适用要求和实现预期结果的能力 the capability of the management system to meet applicable requirements and expected outcomes
 - 2 内部审核和管理评审的过程 the internal audit and management review process
 - b) 对认证范围适宜性的结论 a conclusion on the appropriateness of the certification scope
 - c) 确认是否达到审核目的。Confirmation that the audit objectives have been fulfilled
 - d) 审核了所有不适用条款的正当性证据（注：证据包括审核时的审核员确认/观察结果，而不仅仅是对客户的正当性陈述）Reviewed all evidence of legitimacy for the non-applicability of the provisions(Note: Evidence includes the auditor's confirmation/observations at the time of the audit and is not merely a statement of justification to the client)
 - e) 审核组可以识别改进机会，但不应提出具体解决办法的建议。The audit team may identify opportunities for improvement but shall not recommend specific solutions.

- 6.5.17 当审核的任何部分以电子手段(电子化场所的远程访问)实施时，或拟审核的场所为虚拟场所时，审核部应确保选择具备适宜能力的人员实施此类活动。在此类审核活动中获取的证据应足以让审核员对相关要求的符合性做出有根据的决定。

Where any part of the audit is made by electronic means or where the site to be audited is virtual, Assessment Dept. shall ensure that such activities are conducted by personnel with

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appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question.

6.5.18 SM 审核报告 SM Audit report

审核报告应足够详细，以支持认证决定。审核报告应包含认证范围的界定，提及范围的任何变更，并描述所遵循的重要审核路线和所使用的审核方法。报告应包括审核组对客户 SMS 认证的推荐意见，以及证实该推荐意见的信息。这种证实应包括对与 SMS 的实施和有效性相关的不符合和改进机会的总结。The audit report shall be of sufficient detail to support the certification decision. It shall contain the certification scope definition with a reference to any changes in scope and descriptions of significant audit trails followed and audit methodologies used. The report shall include the audit team's recommendation on certification of the client's SMS, within formation to substantiate this recommendation. The substantiation shall include a summary of nonconformities and opportunities for improvement regarding the implementation and effectiveness of the SMS.

6.5.19 ISMS 审核报告特殊要求 Special requirement of ISMS Audit report


6.5.19.1 审核报告除包含 6.5.16 的要求，还应提供以下信息或对这些信息的引用 In addition to the requirements for reporting in 6.5.16, the audit report shall provide the following information or a reference to it::

- a) 审核的说明，其中包括了文件评审摘要 an account of the audit including a summary of the document review;
- b) 对客户信息安全风险分析进行认证审核的说明 an account of the certification audit of the client's information security risk analysis;
- c) 与审核计划的偏离（例如：在某一预定的活动上花费更多或更少的时间）deviations from the audit plan (e.g. more or less time spent on certain scheduled activities);
- d) ISMS 的范围 the ISMS' scope。

6.5.19.2 审核报告应足够详细，以帮助和支持认证决定。审核报告应包括 The audit report shall be of sufficient detail to facilitate and support the certification decision. It shall contain:

- a) 所采用的主要审核路线和所使用的审核方法 significant audit trails followed and audit methodologies utilized;
- b) 形成的观察结果，包括正面的（例如，值得注意的特征）和负面的（例如，潜在的不符合）observations made, both positive (e.g. noteworthy features) and negative (e.g. potential nonconformities);
- c) 对客户 ISMS 与认证要求的符合性的评价意见、对不符合的清楚说明、所引用的适用性声明的版本，以及适用时，与客户以往认证审核结果的任何有用的对照 comments on the conformity of the client's ISMS with the certification requirements with a clear statement of nonconformity, a reference to the version of the Statement of Applicability and, where applicable, any useful comparison with the results of previous certification audits of the client.。

6.5.19.3 完成的问卷、检查清单、观察结果、日志或审核员笔记可以构成完整的审核报

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告的一部分。如果使用这些方法，这些文件应作为支持认证决定的证据提供给技术委员会。在审核过程中，有关被评价的样本的信息应包含在审核报告或其他认证资料中 Completed questionnaires, checklists, observations, logs, or auditor notes may form an integral part of the audit report. If these methods are used, these documents shall be submitted to the technical Committee as evidence to support the certification decision. Information about the samples evaluated during the audit shall be included in the audit report, or in other certification documentation.

6.5.19.4 报告应考虑客户所采用的内部组织和规程的充分性，以便对其 ISMS 建立信心 The report shall consider the adequacy of the internal organization and procedures adopted by the client to give confidence in the ISMS.。

6.5.19.5 审核报告还应包括 the report also shall cover:

a) 关于 ISMS 要求和信息安全控制的实施与有效性的、最重要的观察（正面的和负面的）的摘要 a summary of the most important observations, positive as well as negative, regarding the implementation and effectiveness of the ISMS requirements and IS controls;

b) 审核组关于客户的 ISMS 是否获得认证的建议，以及支持该建议的信息 the audit team's recommendation as to whether the client's ISMS should be certified or not, with information to substantiate this recommendation。

6.6 NC 管理 NC management

6.6.1 编写不符合项，过程描述说明哪些过程为部分无效，并使用了哪些证据来证实该陈述。为不符合的选定等级说明理由。

Write nonconformities, process descriptions that indicate which procedures are partially invalid, and what evidence is used to substantiate the statement. Give reasons for selected levels of nonconformity

举个例子：要求：ISO 9001 的 9.2.2c 节要求选择内部审核员，以确保所执行审核的客观性和公正性。For example: Requirements: Section 9.2.2 C of ISO 9001 requires the selection of internal auditors to ensure the objectivity and impartiality of audits performed.

不合格描述：选择审核员以确保公正和客观的过程并不完全有效。Nonconformance description: The process of selecting auditors to ensure impartiality and objectivity is not fully effective.


客观证据：负责采购流程的采购经理对采购流程进行了内部审核。Objective evidence: The purchasing manager responsible for the purchasing process conducted an internal audit of the purchasing process.

这不是严重不符合，因为在两年的内部审核记录抽样中，此问题似乎仅与单个审核事件有关。This is not a Major nonconformance, as in the two-year sample of internal audit records, the issue appears to be related to only a single audit event.

6.6.2 如不符合项被识别了，它将被书面化，并清晰的被陈述。

If the nonconformance is identified, it will be written clearly.

1 一般不符合项是指通过判断和经验表明不太可能导致体系失效。The Minor

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nonconformance means that it is unlikely, through judgment and experience, to cause system failure.

- 2 严重不符合项是指系统缺失或整体瘫痪，从而无法满足要求。针对某项要求的多个一般不符合可能显示系统的整体瘫痪，进而被认定为一个严重不符合。The Major nonconformance term refers to the absence or overall paralysis of the system, so that the requirements cannot be met. Multiple general nonconformities to a requirement may indicate an overall breakdown of the system and thus be determined as a major nonconformance.

- 6.6.3 改进机会可能会在审核期间被识别。它将被形成记录，但不会以不符合开出，也不要求回复。

Improvement opportunities may be identified during the audit. It will be logged by the itinerary, but will not be left with a non-conformance, nor will it require a response.

- 6.6.4 在某些情况下，可以提前终止审核。这种情况的原因可能包括：大量的不符合项（轻微性和严重性）直接反应出质量管理体系的失效性，决定终止审核必须在跟组织管理者协商后执行。终止的分歧可能包括暂停证书。

Under certain circumstances the audit may be terminated prematurely. Reasons for this may include: A large number of nonconformities (minor and serious) directly reflect the failure of the quality management system, and the decision to terminate the audit must be made in consultation with the management of the organization. Terminated differences may include suspension of certificates.

- 6.6.5 客户针对不符合项的申诉将按照 AKA 申诉程序中定义的流程进行处理；

Customer complaints against non conformances will be handled in accordance with the process defined in the AKA appeal procedure.


- 6.6.6 在所有情况下，都需要纠正（针对问题的措施），根本原因和纠正措施（针对根本原因采取的措施，以防止再次发生）。注意：鉴于纠正和纠正措施的目的不同，所执行的活动应不相同。

In all cases, correction (action against problem), root cause and corrective action (action against root cause to prevent recurrence) is required. Note: due to the different purposes of correction and corrective measures, the activities to be performed should be different.

- 6.6.7 对于所有具有证书决定的审核（例如，阶段 2，范围的重新认证更改，地址更改等），在进入证书决定阶段之前，必须正确解决已发布的不符合项。

For all audits with certificate decisions (e.g., phase 2, re certification changes of scope, address changes, etc.), the released non conformances must be properly resolved before entering the certificate determination stage.

- 6.6.8 提交客户措施报告后，审核组长应在收到后 5 天内进行评审并记录评审结果。审核员组长将评审所提供的措施证据，并确保已实施措施，解决所描述的不符合之处，并能够消除不合格原因。审核组长应记录对所评审证据，以证明这一点。关闭严重不符合，要求安排现场特殊审核验证其措施的实施。评审的结果，审核组长应告知客户。

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After submitting the customer action report, the audit team leader shall review and record the review results within 5 days after receiving the report. The team leader of the auditor will review the evidence of the measures provided and ensure that the measures have been implemented to solve the described non conformity and to eliminate the causes of the non conformity. The audit team leader shall record the evidence reviewed to prove this. Close the serious non conformity, and arrange special on-site audit to verify the implementation of the measures. The audit team leader shall inform the results of the review to the clients.

- 6.6.9 通常在下一现场审核（例如，下一次监视，再认证等）下对持续有效性进行验证。要求检查以前审查过的证据以评审实施的措施，审核员将评审以前的不符合是否再发生。如果发现有再次发生的情况，审核员将在适当的级别上重新发布不符合项，并针对无效的纠正措施（无效的实据）考虑其他不符合项。

Continuous effectiveness is usually verified at the next on-site audit (e.g., next monitoring, recertification, etc.). It is required to check the previously reviewed evidence to review the implemented measures, and the auditor will review whether the previous non conformance occurs again. If a recurrence is found, the auditor will reissue the non conformance at the appropriate level and consider other non conformance items for the invalid corrective action (invalid implementation evidence).

6.7 认证决定

Certification decisions

6.7.1 认证决定将包括：

Certification decisions will include:

- 1) 适用方案要求

Applicable program requirements

- 2) 根据审核员的信息，评审进行的审核是适当的。审核组提供的信息足以确定认证要求的满足情况。除 ISO/IEC 17021-1 的要求外，认证决定基于审核报告中审核组对客户管理体系是否通过认证的建议。

Based on the auditor's information, the audit conducted by the review is appropriate. The information provided by the audit team is sufficient with respect to the certification requirements. The certification decision shall be based, additionally to the requirements of ISO/IEC 17021-1, on the certification recommendation of the audit team as provided in their certification audit report.


- 3) 如果适用，所发布的不符合应具有所提供信息的适当等级，并且 OFI 不能用于“软等级化”不符合。

If applicable, the issued non conformance shall have the appropriate level of information provided, and OFI cannot be used to "soft grade" non conformance.

- 4) 书面的 OFI 措辞适当。

The wording of the written OFI is appropriate.

- 5) 审核报告/计划等证明了所需的审核时间已实现，并且审核目标已实现，并有证据证明过程的有效性。

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Audit Reports / plans demonstrate that the required audit time has been achieved, audit objectives have been achieved, and there is evidence to demonstrate the effectiveness of the process.

6) 提供的证据表明符合范围/子范围。

The evidence provided indicates compliance with the scope / sub scope.

7) 对于所有严重不符合，已审查、接受和验证了纠正和纠正措施。对于所有轻微不符合，已审查和接受了客户对纠正和纠正措施的计划。对于第二阶段审核，严重不符合需要在末次会议的六个月内完成，否则需要另一次第二阶段审核。

For any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions. For any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action. For the second stage audit, serious non-compliance needs to be completed within six months of the final meeting, otherwise another phase II audit is required.

6.7.2 认证决定人员应该是具备能力的人员，详见《技术委员会章程》。

The certification decision-making personnel should be competent personnel. See the regulations of the Technical Committee for details.

6.7.3 通常情况下，对授予认证做出决定的人员或委员会不宜推翻审核组的负面建议。如果发生这种情况，AKA 应记录其作出推翻建议的决定的依据，并说明其合理性 The persons or committees that take the decision on granting certification should not normally overturn a negative recommendation of the audit team. If such a situation does arise, AKA shall document and justify the basis for the decision to overturn the recommendation.

只有具备充分的证据证实管理评审和内部审核的安排已经实施，且是有效的并将得到保持，才可向客户授予认证 Certification shall not be granted to the client until there is sufficient evidence to demonstrate that arrangements for management reviews and internal audits have been implemented, are effective and will be maintained.

注：在第 2 阶段开始之前，必须对第 1 阶段进行评审，以确保指定的 QMS 处于就绪状态，这一点很重要。如果计划允许，则可以执行“背对背”一二阶段，并获得技术委员会批准。

Note: it is important to review stage 1 before stage 2 begins to ensure that the designated QMS is in place. If the plan permits, the "back-to-back" stage I or II can be implemented and approved by the technical committee.

6.8 证书颁发 certificate issuance


6.8.1 证书决定完成后，将签发证书。详见《证书管理作业指导书》。

When the certificate decision is completed, the certificate will be issued. For details please refer to the 《certificate management instruction》

6.8.2 证书信息在认证决定后的 10 个日历日内上报 CNCA。

The certificate information shall be reported to CNCA within 10 calendar days after the certification decision.

6.9 保持认证 Maintaining certification

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6.9.1 在证实获证客户持续满足管理体系标准要求后保持对其的认证。技术委员会（未实施该审核的人员）对每次审核进行独立复核和决定。Maintain certification based on demonstration that the client continues to satisfy the requirements of the management system standard. The technical committee (the personnel who have not carried out the audit) independently review and decide on each audit.

6.9.2 对于任何严重不符合或其他可能导致暂停或撤销认证的情况，审核部要求审核组长向审核部经理或分管副总报告，该案卷由具备适宜能力且未实施该审核的人员进行复核，以确定能否保持认证；For any major nonconformity or other situation that may lead to suspension or withdrawal of certification. The Assessment Dept requires the audit team leader to report to the audit department manager or Vice GM. The audit package shall be reviewed by the competent technical committee who have not carried out the audit to determine whether the certification can be maintained.

6.9.3 由具备能力的技术委员会人员对监督审核报告进行评审，以确认证活动在有效地运作。The competent technical committees do the monitoring of its surveillance activities, including monitoring the reporting by auditors, to confirm that the certification activity is operating effectively

7.0 审核类型和要求 Audit types and requirements

7.1 第一阶段：The first stage

7.1.1 第一阶段审核的审核目标是通过充分了解客户的管理体系，来确认客户是否可以继续注册过程，并为审核员提供第二阶段计划的重点。

The audit objective of the first stage audit is to confirm whether the customer can continue the registration process by fully understanding the customer's management system, and provide the auditor with the focus of the second stage plan.

7.1.2 可以执行单独的“书面审核”，重点是查看管理系统文档。可以在阶段 1 之前在现场完成，目的是确保管理系统文档信息的一致性。这可以作为现场阶段 1 的一部分来执行。

A separate "written audit" can be performed, focusing on viewing management system documentation. It can be done on site before phase 1 to ensure consistency of management system documentation information. This can be performed as part of stage 1.

7.1.3 第一阶段审核通常在一天或几天内进行，但通常不超过所引用审核时间的 50%。

The first stage audit is usually carried out in one or several days, but it usually does not exceed 50% of the cited audit time.

7.1.4 通过审核，审核员将：

Through the audit, the auditor will:


7.1.4.1 执行“现场审核”部分的要求

Implement the requirements of the "site audit" section

7.1.4.2 查看程序的详细信息

View program details

7.1.4.3 查看客户的管理系统手册和/或书面信息，以确认这些文件充分满足了标准和适用

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的法律/法规要求。

Review the customer's management system manuals and / or written information to confirm that these documents fully meet the standards and applicable legal / regulatory requirements.

7.1.4.4 评估客户的位置和现场条件，并与客户人员进行面谈，以确定第二阶段审核的准备情况。这将包括对管理系统资源分配的审查。

Evaluate the customer's location and site conditions and interview customer personnel to determine the readiness for stage II audit. This will include a review of management system resource allocation

7.1.4.5 通过充分了解客户的管理系统，为计划阶段 2 提供重点。

Provide focus for planning stage 2 by fully understanding the customer's management system.

7.1.4.6 确保已执行一次完整的内部审核和完整的管理审核，包括审核结果的审核，并且已针对发现的缺陷采取了措施。

Ensure that a complete internal audit and a complete management audit have been carried out, including the audit of audit results, and measures have been taken for the defects found.

7.1.4.7 如果客户有结合的管理体系标准，审核员将验证所达到的结合水平，并在报告中说明。

If the client has a combined management system standard, the auditor will verify the level of integration achieved and explain it in the report.

7.1.4.8 在时间允许的情况下，第一阶段审核可能会开始涵盖第二阶段的要求，尽管这不会减少第二阶段事件的持续时间。

As time permits, phase I audits may begin to cover stage 2 requirements, although this does not reduce the duration of phase II events.

7.1.4.8.1 在第 1 阶段完成的要求不需要在现场第 2 阶段/注册审核期间重新审核；但是，审核员可以在第 2 阶段审核期间抽取额外的审核样本。

Requirements completed in phase 1 do not require re audit during site stage 2 / registration audit; however, auditors may take additional audit samples during stage 2 audit.

7.1.4.8.2 部分审核的需求需要在第二阶段审核中完成。

Part of the audit needs to be completed in the second phase of the audit

7.1.4.8.3 当发现问题时，将提出关注点


When problems are identified, concerns are raised

7.1.5 该报告包将包括：

The report package will include:

7.1.5.1 通过审核确定的关注领域。这是根据已检查的信息列出的有问题/可能不合格的问题的列表，预计在第二阶段审核之前应采取行动。注意：客户应该清楚，在第 2 阶段审核之前未对任何已确定的关注领域采取行动，可能会导致在第 2 阶段发出正式不符合项。

Areas of concern identified through audit. This is a list of problematic / potentially

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non-conforming issues based on the information that has been checked, and action is expected to be taken before the second stage audit. Note: customers should be aware that failure to take action on any identified areas of concern prior to the stage 2 audit may result in a formal non conformance being issued in stage 2.

7.1.5.2 审核员基于已审查的证据作出推荐结论:

The auditor makes a recommendation based on the reviewed evidence

7.1.5.2.1 进入第二阶段

Entering the stage 2

7.1.5.2.2 不进入第 2 阶段, 需要进行第 1 阶段的再一次访问。

Do not enter stage 2, need to visit again in stage 1.

7.1.6 对于非现场进行的一阶段,也应形成以上 7.1.5 要求的报告;

For the off-site stage, the report required in 7.1.5 above shall also be formed;

7.2 第二阶段 - 注册审核 Stage 2 - Registration Review

7.2.1 第 2 阶段审核的审核目标是根据已定义的注册范围(包括子范围)并根据审核标准,对管理系统的有效实施进行确认,以进行认证。

The audit objective of stage 2 audit is to confirm the effective implementation of the management system according to the defined registration scope (including sub scope) and audit standards for certification.

7.2.2 通过审核, 审核员将:

Through the audit, the auditor will:

7.2.2.1 执行“现场审核”的要求

Implement the requirements of "on site audit"

7.2.2.2 确保通过第一阶段审核确定的所有“关注领域”均已解决或写为不合格项

Ensure that all "areas of concern" identified through stage I audit have been resolved or written as non-conforming items


7.2.2.3 查看申请的详细信息并确认根据审核标准的要求, 确认组织的流程及其有效执行。这将包括所有过程, 并且将收集符合/不符合的证据, 以证明已有效解决了标准的所有条款。

View the details of the application and confirm that the organization's processes and their effective implementation are confirmed in accordance with the requirements of the audit standards. This will cover all processes and evidence of compliance / non-compliance will be collected to demonstrate that all terms of the standard have been effectively resolved.

7.2.2.4 确保已执行一次完整的内部审核和完整的管理审核, 并且已针对发现的缺陷采取了措施。注意: 如果未完成, 则将其视为不合格条件, 并进行相应处理。

Ensure that a complete internal audit and a complete management audit have been carried out and actions have been taken to address the identified deficiencies. Note: if it is not completed, it will be regarded as unqualified condition and treated accordingly.

7.2.2.5 如果客户具有已结合的管理系统, 则审核员将验证已实现的系统集成程度, 并在报告中说明。

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If the customer has a combined management system, the auditor will verify the level of system aggregation that has been achieved and describe it in the report.

7.2.3 在第二阶段审核中，审核员将向客户通报任何可能妨碍认证/注册的潜在问题，并且（在计划允许的情况下）为客户提供中止审核事件或继续进行审核的机会。客户可以选择继续审核并通过不符合项解决问题。无论哪种方式，让 AKA 办公室和客户了解这一点都是至关重要的。

In the second phase of the audit, the auditor will inform the client of any potential problems that may hinder the certification / registration and (where the plan permits) provide the client with the opportunity to suspend the audit event or continue the audit. The customer can choose to continue the audit and resolve the problem through the non conformance. Either way, it is crucial that AKA offices and customers understand this.

7.2.4 第二阶段报告包将包括：

The stage 2 package will include:

7.2.4.1 本程序“审核报告”部分的定义要求（6.5.16）

Definition requirements of "audit report" part of this procedure (6.5.16)

7.2.4.2 在适当情况下已解决或将第 1 阶段关注的领域写成不符合项的证据

Where appropriate, areas of concern in phase 1 have been addressed or documented as evidence of non conformance

7.2.4.3 审核员基于已评审的证据：

Based on the reviewed evidence:

7.2.4.3.1 推荐注册

recommended registration

7.2.4.3.2 基于识别不符合的关闭，推荐注册

Registration is recommended based on the closure of identifying non-compliance

7.2.4.3.3 目前尚未准备好注册（再次开始该过程）


Not ready to register (start the process again)

7.3 监督审核

Surveillance audit

7.3.1 监督审核的审核目的是根据定义的审核计划/矩阵和根据审核标准，针对已定义的注册范围（包括子范围），对管理体系的持续有效实施进行持续确认，以确保持续认证的目的。并应考虑获证客户及其管理体系的变更情况。The audit objective of the Surveillance audit is to continuously confirm the continuous and effective implementation of the management system according to the defined audit plan / matrix and audit standards according to the defined registration scope (including sub scope), so as to ensure the purpose of continuous certification. And take into account changes to its certified client and its management system.

7.3.2 监督活动包括对获证客户管理体系满足认证标准规定要求情况的现场审核。监督活动还可以包括： a)就认证的有关方面询问获证客户； b) 审查获证客户对其运作的说明（如宣传材料、网页）； c) 要求获证客户提供文件化信息（纸质或电子介质）； d) 其他监视获

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证客户绩效的方法。Surveillance activities shall include onsite auditing of the certified client's management system's fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities may include: a) enquiries the certified client on aspects of certification; b) reviewing any certified client's statements with respect to its operations (e.g. promotional material, website); c) requests to the certified client to provide documented information (on paper or electronic media); d) other means of monitoring the certified client's performance.

7.3.3 根据审核矩阵/程序的定义，监视周期为~6、9 或 12 个月，并期望每个日历年进行一次审核。

According to the definition of audit matrix / procedure, the monitoring period is ~ 6, 9 or 12 months, and the audit is expected to be conducted once every calendar year.

7.3.4 通过审核，审核员将：

Through the audit, the auditor will:

7.3.4.1 执行“现场审核”部分的要求；

Implement the requirements of the "site audit" section

7.3.5 审核的推荐结论将包括：


The Recommendation of the audit will include

- a) 维持证书有效 Keep the certificate effective
- b) 基于识别不符合的关闭，推荐维持证书有效 It is recommended to keep the certificate valid based on the closure of identifying non conformance
- c) 暂停 suspend
- d) 撤销 Withdrawal

7.4 再认证审核 Recertification audit

7.4.1 再认证审核的审核目的是根据定义的审核计划/矩阵和审核标准，针对已定义的注册范围（包括子范围），对管理体系的持续有效实施进行持续的重新确认。再认证活动应考虑管理体系在最近一个认证周期内的绩效，包括调阅以前的监督审核报告。当管理体系、组织或管理体系的运作环境（如法律的变更）有重大变更时，再认证审核活动可能需要有第一阶段。

The audit objective of recertification audit is to continuously re confirm the continuous and effective implementation of the management system according to the defined audit plan / matrix and audit standards according to the defined registration scope (including sub scope). The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle. Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g. changes to legislation).

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7.4.2 再认证审核应包括针对下列方面的现场审核：The recertification audit shall include an on-site audit that addresses the following

- 结合内部和外部变更来看的整个管理体系的有效性，以及认证范围的持续相关性和适宜性；The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification
- 经证实的对保持管理体系有效性并改进管理体系，以提高整体绩效的承诺；Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance
- 管理体系在实现获证客户目标和管理体系预期结果方面的有效性。The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s)

7.4.3 对再认证审核中发现的严重不符合，企业应采取纠正与纠正措施，并在原认证证书到期前完成对纠正和纠正措施的实施和验证。For Major found in the recertification audit, the client shall take corrective and corrective actions, and complete the implementation and verification of the correction and corrective measures before the expiration of the previous certification certificate. ISMS 严重不符合项，允许采取纠正措施的时间，还应考虑相关的信息安全风险，与信息安全风险相一致，在审核结束后 20 天完成遏制。The time allowed to implement corrective action of ISMS Major shall be associated information security risk, consistent with the information security risk, the containment shall be completed within 20 days after the audit.

7.4.4 审核的推荐结论将包括:

The Recommendation of the audit will include

- 重新颁发证书 Reissue certificate
- 基于识别不符合的关闭，推荐注册 Registration is recommended based on the closure of identifying non-compliance
- 目前尚未准备好注册（再次开始该过程）Not ready to register (start the process again)

7.5 现场验证 On site verification

7.5.1 验证审核的审核目标是审核已定义的纠正措施计划的有效实施。


The audit objective of verification audit is to audit the effective implementation of the defined corrective action plan.

7.5.2 该审核应在发布不符合项的审核结束会议的 60-90 天内进行。


The audit shall be conducted within 60-90 days of the audit closing meeting where the non conformance was issued.

7.5.3 审核计划是必需的，应在活动开始前 1 周提供给客户。

The audit plan is required and should be provided to the customer one week before the start of the activity

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- 7.5.4 根据此程序的要求举行首次会议。
Hold the first meeting in accordance with the requirements of this procedure
- 7.5.5 执行此过程中描述的“现场活动”，但目的是验证所发布的不符合项的实施情况。
Perform the "field activities" described in this process, but the purpose is to verify the implementation of the issued non conformance.
- 7.5.5.1 如现场活动部分所述，仍然希望审核员能够审核申请信息内容，标记的使用，更改和更新矩阵。
As described in the field activities section, it is still expected that auditors will be able to review the content of the application information, the use of markers, and change and update the matrix.
- 7.5.6 根据此过程的要求，举行了末次会议。
In accordance with the requirements of this process, a final meeting was held.
- 7.5.7 验证审核的报告期望将包括：
The report expectation of verification audit will include:
- 7.5.7.1 审核证据记录在审核报告上，并证明接受是合理的。
The audit evidence is recorded in the audit report and the acceptance is justified.
- 7.5.7.2 根据观察到的情况，对摘要的进行书面报告。
According to the observed situation, make a written report on the summary.
- 7.5.6 如果在认证证书到期日期前，未能完成再认证审核或不能验证对严重不符合实施的纠正和纠正措施，则不推荐再认证，并告知客户解释后果。If AKA has not completed the recertification audit or the AKA is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended. The client shall be informed and the consequences shall be explained.
- 7.5.7 在认证到期后，如果能够在 6 个月内完成未尽的再认证活动，则可以恢复认证，否则应至少进行一次第二阶段才能恢复认证。证书的生效日期应不早于再认证决定日期，终止日期应基于上一个认证周期。Following expiration of certification, the AKA can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.
- 7.6 转移 Transfer
- 7.6.1 详见《AKA 程序转换注册控制程序》。
For details, please refer to 《AKA-P-021 Transfer Procedure》
- 7.7 特殊审核 Special audit
- 7.7.1 扩大认证范围
Expand the scope of certification

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对于已授予的认证，应对扩大认证范围的申请进行评审，并确定任何必要的审核活动，以做出是否可予扩大的决定。这类审核活动可以和监督审核同时进行。

For the granted certification, the application for expanding the scope of certification shall be reviewed, and any necessary audit activities shall be determined to make a decision on whether the extension can be made. Such audit activities can be carried out simultaneously with supervisory audit.

7.7.2 提前较短时间通知的审核

Audit with short notice in advance

为调查投诉、对变更做出回应或对被暂停的客户进行追踪，可能需要在提前较短时间通知获证客户后或不通知获证客户就对其进行审核。

In order to investigate complaints, respond to changes, or track suspended customers, it may be necessary to review licensed customers with or without notice.


a) 审核部应使获证客户提前了解将在何种条件下进行此类审核；Assessment Dept. shall describe and make known in advance to the certified clients the conditions under which such audits will be conducted;

b) 由于客户缺乏对审核组成员的任命表示反对的机会，审核部应在指派审核组时给予更多的关注。Assessment Dept. shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

c) 如果企业发生了与职业健康安全有关的严重事件，应要求企业及时通知客服部，例如发生严重事故或严重违反规定，则可能需要安排特殊审核，为了调查管理系统是否未被破坏，是否有效运行。技术质量部应当将调查结果记录在案。In case of serious incidents related to occupational health and safety, the client shall be required to inform the customer service department in time. For example, in case of serious accident or serious violation of regulations, special audit may be arranged to investigate whether the management system is not damaged and whether it operates effectively. The technology and quality department shall record the investigation results.

d) 引起 ISO13485 较短时间通知的审核的外部因素如 The external factors that cause the short notice audit of ISO13485, such as:

1. 可获取的售后市场监督数据表明质量管理体系可能存在重大缺陷 available post-market surveillance data known on the subject devices indicate a possible significant deficiency in the quality management system
2. AKA 获取的重要的安全相关信息 significant safety related information becoming known to AKA
3. 发生重大变化，这些变化已按照法规要求提交或 AKA 已知，并可能影响客户对法规要求遵守状态的决定 significant changes occur which have been submitted as required by the regulations or become known to the CAB, and which could affect the decision on the client's state of compliance with the regulatory requirements
4. 如果有疑虑纠正措施的实施或是否符合标准和法规要求，也可能需要进行突击或短期通知审核。An unannounced or short-notice audit may also be necessary if AKA has justifiable concerns about implementation of corrective actions or compliance with

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standard and regulatory requirements.

7.7.3 ISMS 特殊情况 ISMS Special audit

如果已经通过 ISMS 认证的客户对其管理体系做重大修改，或者发生影响其获证基础的其他变更，须进行特殊审核。The activities necessary to perform special audits shall be subject to special provision if a client with a certified ISMS makes major modifications to its system or if other changes take place which could affect the basis of its certification.。

7.7.3 按上述 6.4 现场审核要求实施。

According to the above 6.4 site audit requirements to implement

7.8 多现场和临时场所审核

Multi site and temporary site audit

7.8.1 详见《多现场认证控制程序》

See the control procedure for multi site certification for details

7.9 结合和一体系统审核

Combined audit and integrated audit

7.9.1 详见《结合审核控制程序》

For details, please refer to control procedure for combined audit

8 OH&SMS 特殊要求 OH&SMS special requirements.


8.1 职业健康安全管理体系认证的法律合规性 Legal Compliance Of OH&SMS Certification

8.1.1 通过认证审核过程，审核组应评估组织是否符合职业健康安全管理体系标准中与法律合规相关的要求，并且 AKA 在证明符合这些要求之前不得授予认证。Through the certification assessment process, audit team shall evaluate an organisation's conformity with the requirements of an OH&SMS standard as they relate to legal compliance, AKA shall not grant certification until conformity with these requirements can be demonstrated.

8.1.2 认证后，在进行的续监督和再认证审核应与上述审核方法一致。After certification, the subsequent surveillance and reassessment audits conducted by the AKA shall be consistent with the above audit methodology.

8.1.3 对于文件和记录的评审与运行活动（如工厂参观和其他工厂现场）期间职业健康安全管理体系实施情况的评价之间的平衡，审核部应确保对职业健康安全管理体系的有效性进行充分的审核。With respect to the balance between review of documents and records and the evaluation of the OH&SMS implementation during operational activities (e.g. tour of facilities and other work sites), assessment department shall ensure that an adequate audit of the effectiveness of the OH&SMS is undertaken.

8.1.4 过多的审核时间专门在会议室进行这可能导致对职业健康安全管理体系（OH&SMS）在法律合规性问题方面的有效性评估不足，并可能导致绩效不佳被忽视，从而导致利益

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相关者对认证过程失去信心。审核要在过程的发生地进行审核过程。这个不仅意味着在生产区域审核生产，但是要在他们各自的区域来审核非制造过程。例如，当设计过程没有在办公室发生时，不能在办公室审核设计。假如设计过程发生在工程部门，审核员必须在工程部门面谈相关在此工作的人员以及审核该过程。Too much of the audit time being dedicated to an office-based review, this could lead to an inadequate assessment of the effectiveness of the OH&SMS with respect to legal compliance issues, and potentially to poor performance being overlooked, leading to a loss of stakeholder confidence in the certification process. Processes are examined where they physically occur. This not only means auditing production in the production area, but auditing non-manufacturing processes in their respective areas. For example, do not audit design from the conference room when the design process does not occur in the conference room. If the design process occurs in the engineering department, then the auditor must examine the process by going to the engineering department and interviewing relevant personnel where they work.

8.1.5 The auditors shall verify the management of legal compliance based on the demonstrated implementation of the system and not rely only on planned or expected results, and make sure the conformity is being maintained during the certification cycle, normally three years. 审核员应根据体系实施情况关于法律合规性的管理进行验证，而不仅仅依赖于计划的或预期的结果，通过周期监督程序，确保在认证周期内（通常为三年）保持一致性。

8.1.6 Any organization failing to demonstrate their initial or ongoing commitment to legal compliance, shall not be certified or continued to be certified as meeting the requirements of an OH&SMS standard by the Certification Body. 任何未能证明初始或持续满足法律合规性承诺的组织，不得被认证或继续保持认证为符合职业健康安全管理体系标准的要求。

8.1.7 Deliberate or consistent non-compliance shall be considered a serious failure to support the policy commitment to achieving legal compliance and shall preclude certification or cause an existing OH&SMS standard certificate to be suspended, or withdrawn. 故意或一贯的不合规应被视为对满足法律法规符合性承诺的严重失效，应阻止认证或导致现有的职业健康安全管理体系标准证书被暂停或撤销。

8.1.8 If the facilities and work areas are subject to closure the OH&S risks change, as there may no longer be the same risks to employees, but there may be new risks applicable to members of the public (e.g. in case of lack of suitable maintenance and surveillance activities). The audit team shall verify that the management system continues to meet the OH&SMS standard and to be effectively implemented in respect of the closed facilities and work areas, and, if not, suspend the certificate. 如果设施和工作区域被关闭，职业健康安全风险会发生变化，因为对员工可能不再存在相同的风险，但可能会有新的风险适用于公众（例如，在缺乏适当的维护和监督活动的情况下）。审核组应验证管理体系持续符合职业健康安全管理体系标准，对于关闭设施和工作区域是否得到有效实施，如不符合，暂停证书。

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8.2 Compliance Criteria For The Certification Decision 认证决定的合规性准则

8.2.1 Full legal compliance is expected by stakeholders and interested parties of an organization claiming conformity with an OH&SMS standard. The perceived worth of accredited certification in this field is closely related to the achieved satisfaction of the interested parties in relation to legal compliance. 声明符合职业健康安全管理体系标准的组织的合法权益关系者和利益相关方应完全遵守法律法规。认可认证在这一领域的感知价值与利益相关方对法律合规性的满意程度密切相关。


8.2.2 The organization shall be able to demonstrate that it has achieved compliance with the legal OH&S requirements that are applicable to it through its own evaluation of compliance prior to the granting certification. 组织应能够在授予认证之前，通过对其合规性的评估，证明其已达到满足适用于其的职业健康安全法律法规要求。

8.2.3 Where the organization may not be in legal compliance, it shall be able to demonstrate it has activated an implementation plan to achieve full compliance within a declared date, supported by a documented agreement with the regulator, wherever possible for the different national conditions. The successful implementation of this plan shall be considered as a priority within the OH&SMS. 如果组织可能不符合法律法规，则应能够证明其已启动实施计划，以便在宣布的日期内实现完全合规，并在可能的情况下，根据不同的国情与监管机构达成书面协议。本计划的成功实施应被视为职业健康安全管理体系的优先事项。

8.2.4 Exceptionally AKA may still grant certification but shall seek objective evidence to confirm that the organization's OH&SMS: 例外情况下，AKA 仍可授予认证，但应寻求客观证据，以确认组织的职业健康安全管理体系：

- a) Is capable of achieving the required compliance through full implementation of the above implementation plan within the due date, 能够在到期日内全面实施上述实施计划，达到所要求的合规性，
- b) Has addressed all hazards and OH&S risks to workers and other exposed personnel and that there are no activities, processes or situations that can or will lead to a serious injury and/or ill-health, 已经解决了工人和其他暴露人员的所有危险和职业健康安全风险，并且没有任何活动、过程或情况会导致严重伤害和/或健康不良，
- c) During the transitional period has put in place the necessary actions to ensure that the OH&S risk is reduced and controlled. 在过渡期间，已采取必要措施，以确保降低和控制职业健康安全风险。

8.2.5 The audit reports contain a statement on the conformity and the effectiveness of the organization's OH&SMS together with a summary of the evidence with regards to the capability of the OH&SMS to meet its compliance obligations. 审核报告包含对组织的职业健康安全管理体系

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体系的合规性和有效性的陈述, 以及有关职业健康安全管理体系履行合规义务能力的证据摘要。

8.3 Summary 总结

8.3.1 Accredited certification of an organization's OH&SMS indicates conformity with the requirements of the applicable OH&SMS standard and includes a demonstrated and effective commitment to compliance with applicable legal requirements. 组织的职业健康安全管理体系认证表明符合适用职业健康安全管理体系标准的要求, 并包括对遵守适用法律要求的有效承诺。

8.3.2 The control of legal compliance by the organization is an important component of the OH&SMS assessment and remains the responsibility of the organization. 组织对法律合规性的控制是职业健康安全管理体系评估的重要组成部分, 也是组织的责任。


8.3.3 It should be stressed that Certification Body auditors are not inspectors of the OH&S regulator. They should not provide "statements" or "declarations" of legal compliance. Nevertheless, they can "verify the evaluation of legal compliance" in order to assess conformity with the applicable OH&SMS standard. 值得强调的是, 审核员不是职业健康安全监管机构的检查员。审核员不应提供遵守法律的“声明”或“宣告”。然而, 他们可以“验证法律法规的合规性”, 以评估是否符合适用的职业健康安全管理体系标准。

8.3.4 Accredited certification of an OH&SMS as fulfilling the requirements in an OH&SMS standard cannot be an absolute and continuous guarantee of legal compliance but neither can any certification or legal scheme guarantee ongoing legal compliance. However, an OH&SMS is a proven and effective tool to achieve and maintain legal compliance and provides top management with relevant and timely information on the organization's compliance status. 职业健康安全管理体系符合职业健康安全管理体系标准要求的认证不能绝对和持续地保证法律合规, 但任何认证或法律方案都不能保证持续的法律合规性。然而, 职业健康安全管理体系是实现和维护法律法规合规性的有效工具, 并向最高管理层提供有关组织合规状态的及时相关信息。

8.3.5 An OH&SMS standard requires a commitment to comply with legal requirements. The organization shall be able to demonstrate it has achieved compliance with its applicable legal requirements through its own evaluation of compliance prior to the Certification Body granting certification. 职业健康安全管理体系标准要求承诺遵守法律要求。在认证机构授予认证之前, 组织应能够通过其对合规性的评估, 证明其已经达到了对适用法律要求的遵守。

8.3.6 Certification of an OH&SMS as fulfilling the requirements in an OH&SMS standard confirms that the OH&SMS has been shown to be effective in achieving its policy commitments including fulfilment of legal compliance obligations and provides the foundation and support for an organization's continued legal compliance. OH&SMS 的认证符合 OH&SMS 标准的要求, 确认 OH&SMS 已被证明是有效的实现其方针承诺, 包括履行合规性义务, 并为组织持续的法律合规性提供了基础和支持。


8.3.7 In order to maintain the confidence of interested parties and stakeholders in the above attributes of the accredited certification of an OH&SMS, AKA shall ensure that the system has demonstrated effectiveness before granting, maintaining or continuing certification. 为了保持相

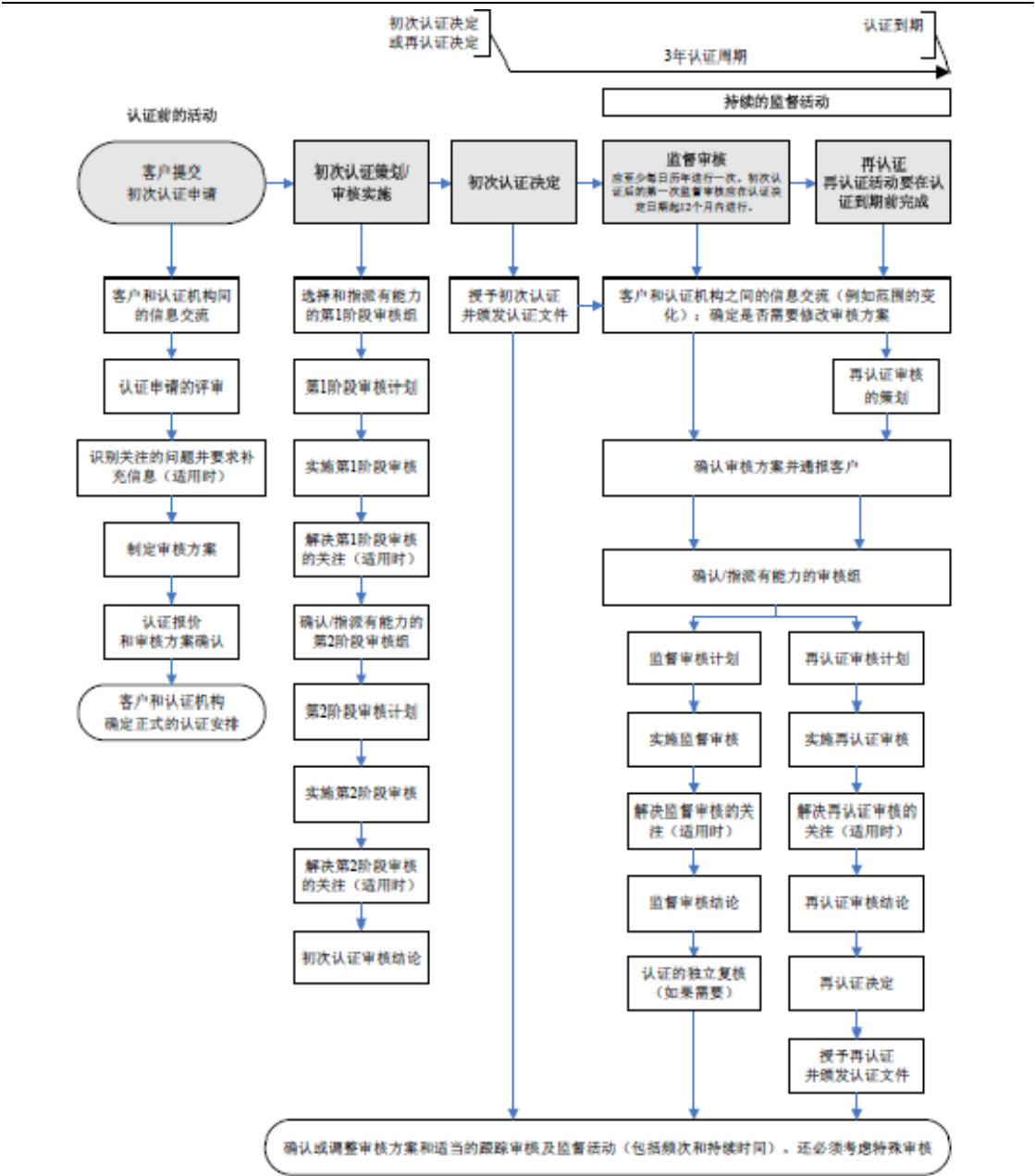
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关方和利益相关方对职业健康安全管理体系认证的上述属性的信心，AKA 应确保体系在授予、维持或持续认证前已证明其有效性。

8.3.8 The OH&SMS can act as a tool for dialogue between the organization and its OH&S regulators and form the basis for a trusting partnership, replacing historical adversarial "them and us" relationships. OH&S regulators and the public should have confidence in organizations with an accredited OH&SMS standard certificate and be able to perceive them as being able to constantly and consistently manage their legal compliance. 职业健康安全管理体系可作为组织与其职业健康安全监管机构之间对话的工具，并构成信任伙伴关系的基础，取代历史上敌对的“他们和我们”关系。职业健康安全监管机构和公众应该对拥有经认证的职业健康安全管理体系标准证书的组织充满信心，并能够认为他们能够持续不断地管理其法律合规性。


9 审核流程图 Audit flow chart

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8 记录 Records

- AKA-S-F01 注册申请表 Customer application form
- AKA-S-F02 人天表 Justification Worksheet
- AKA-R-F01 审核跟踪笔记表单 Audit Trail Note Form
- AKA-R-F02 审核计划 Audit Agenda
- AKA-R-F03 审核资料检查表 Audit File Checklist
- AKA-R-F04 证书确认函 Certificate Confirmation Letter
- AKA-R-F05 审核员报销费用情况表 Auditor Travel Expense List

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- AKA-R-F06 顾客信息变更表 Client Change Request
- AKA-R-F07 审核策划和总结矩阵表 Audit Planning and Summary matrix
- AKA-R-F09 审核矩阵 ISO 27001 Audit Matrix
- AKA-R-F10 首次末次会议记录 Opening Closing Meeting Attendance
- AKA-R-F11 审核报告 Audit report template
- AKA-R-F12 8D 报告 8D Form
- AKA-R-F13 ISO45001 风险验证 Risk complexity
- AKA-R-F14 CB 评审检查表 CB Review Checklist
- AKA-R-F15 初评检查表 Package Reviewer Checklist

历史更改记录表 Revision History Sheet

日期 Date	变更简述 Description of Change	发起人 Originator
03/01/2020	初始建立 Initial establishment	赵改花
02/8/2021	6.2.10.2 更新 updated	赵改花
8/9/2021	6.3.4 更新 updated	赵改花
7/12/2023	公司简称更新, LOGO 更新, 表单号更新 Company abbreviation update, logo update, form number update	赵改花