认证收费标准及审核人日

Certification Charge standard and audit days

1 目的与使用范围

Purpose and scope of use

为加强对认证组织收费的管理，规范认证收费行为，保护双方的利益，促进认证工作的发展，特制订本办法。

These measures are formulated in order to strengthen the management of certification organization fees, standardize certification fees, protect the interests of both parties, and promote the development of certification work.

本办法适用于 CMD 所开展管理体系认证、服务认证和产品认证的服务收费。

These measures are applicable to the service charges for management system certification, service certification and product certification carried out by CMD.

2 基本原则

Basic Principles

收费项目和标准按照国家主管部门的规定制订。（产品认证见国家计委、国家质量技术监督局计价格【1999】1610 号文；管理体系认证、服务认证见国家计委、国家技术监督局计价格【1999】212 号文）。

Charge items and standards shall be formulated in accordance with the provisions of the competent authorities of the State. (Product certification see the State Planning Commission, the State Bureau of Quality and Technical Supervision Price [1999] No. 1610, Management system certification, service certification see the State Planning Commission, the State Bureau of Technical Supervision price [1999] No. 212).

认证审核的工作量（审核人日）按照 CNAS-CC01《管理体系认证机构认可要求》、CNAS-CC02《产品、过程和服务认证机构要求》、CNAS-CC105《管理体系审核时间（QMS、EMS、OHSMS）》、CNAS-CC106《CNAS-CC01 在一体化管理体系审核中的应用》、CNAS-CC170《信息安全管理体系认证机构要求》、IAF MD9《强制性文件 ISO/IEC 17021-1 在医疗器械质量管理体系领域（ISO 13485）的应用》的规定执行，综合考虑客户组织的规模、产品风险程度、审核使用语言、产品种类和数量、其他认证机构的认证结果等因素制定，

总体收费水平执行 CCAA 中认协监〔2013〕102 号《认证机构公平竞争规范——认证价格自律规定》。

The workload of certification audit (audit days) shall be carried out in accordance with CNAS-CC01 Requirements for Bodies Providing Audit and Certification of Management Systems, CNAS-CC02 Requirements for Bodies Certifying Products, Processes and Services, CNAS-CC105 Determination Audit Time of Management Systems (QMS, EMS, OHSMS) and CNAS-CC106 The Application of ISO/IEC 17021 for Audits of Integrated Management System, CNAS-CC170 Requirements for Information Security Management System Certification Bodies, IAF MD9 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management System (ISO 13485), taking into account factors such as the scale of the clients, the degree of product risk, the language used in the audit, the type and quantity of products, and the certification results of other certification bodies. The overall fee level is implemented in accordance with the CCAA ZRXJ (2013) No. 102 *Certification Body Fair Competition norms - Certification Price self-discipline Regulations.*

3 定义

Definitions

3.1 审核时间

Audit time

为客户组织策划并完成一次完整且有效的管理体系/产品认证/服务认证审核所需要时间。

Time needed to plan and accomplish a complete and effective audit of the client organization’s management system/product certification/service certification.

3.2 管理体系认证审核时间

Duration of management system certification audits

审核时间的一部分，包括从首次会议到末次会议之间实施审核活动所有时间。

Part of audit time spent conducting audit activities from the opening meeting to the closing meeting.

3.3 审核人日

Audit days

一个审核人日通常为 8 小时，不包括旅途时间或午饭时间。在策划阶段不应通过增加每个工作日的工作小时数来减少审核人日数.

The duration of an audit day is normally 8 hours, excluding travel time or lunch break. In planning stage, the number of audit days should not be reduced by increasing the number of working hours per working day.

3.4 有效人数

Effective number of personnel

有效人数包括认证范围内涉及的所有人员（固定人员、临时人员和兼职人员，含每个班次的人员）。覆盖于认证范围内的非固定人员（如：承包商人员）也应包括在有效人数内。

The effective number of personnel consists all personnel (permanent, temporary, and part-time) involved within the scope of certification including those working on each shift. When included within the scope certification, it shall also include non-permanent (e.g. contractors) personnel.

对OHSMS，也应包括可能影响到组织的OHSMS绩效，在组织控制下或受组织影响下，来自承包商或次级承包商的工作人员或开展工作相关活动的人员。

For OHSMS, it shall also include personnels from contractors and subcontractors performing work or work- related activities that under the control or influence of the organization, that can have impact on the organization’s OH&SMS performance.

3.5 临时场所

Temporary sites

客户组织为在有限的时期内进行特定工作或服务设立的场所（有形的或虚拟的），且该场所不准备作为常设场所。

Places (physical or virtual) where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site.

3.6 风险类型（仅适用 QMS）

Risk category (QMS only)

对于质量管理体系，根据对客户组织的产品或服务失效带来的风险。风险类型按照高风险、中风险和低风险分为三类。高风险活动（如：有关核、医疗、制药、食品、建筑）通常需要更多的审核时间。中风险活动（如：简单制造业）可能需要平均水平的审核时间来实施一次有效的审核，而低风险活动需用较少的审核时间。

For QMS, according to the risk posed by failure of the product or service the client organization, the risk category is divided into high, medium and low risk. High-risk activities (e.g., nuclear, medical, pharmaceutical, food, construction) normally require more audit time. Medium risk activities (e.g., simple manufacturing) are likely to require the average audit time to carry out an effective audit and low risk activities less time.

3.7 复杂程度类型（仅适用于 EMS）

Complexity category (EMS only)

对于环境管理体系，组织环境因素的性质、数量和严重程度对审核时间有根本影响，基于按照组织环境因素的性质、数量和严重程度划分的五种基本的环境因素复杂程度类型。

For EMS, the provisions specified in this document are based on five primary complexity categories of the nature, number and gravity of the environmental aspect of an organization that fundamentally affect the audit time.

3.8 复杂程度类型（仅适用于 OHSMS）

Complexity Category (OHSMS only)

对于OHSMS，以三个主要的复杂程度类型为基础，这些类型是根据影响组织审核时间的OHS风险的性质、数量和严重程度来划分的。

For OHSMS, the provisions specified in this document are based on three primary complexity categories based on the nature, number and severity of the OH&S risks of an organization that fundamentally affect the audit time.

3.9 一体化管理体系审核

Audit of integrated management system

在同一时间段里，依据两个或以上审核准则/标准，对组织的管理体系所实施的审核。

An audit of an organization’s management system against two or more sets of

audit criteria/standards conducted at the same time.

3.10 一体化管理体系（简称IMS）

Integrated Management System (IMS)

对组织绩效的多方面进行管理，以满足两个或多个管理体系标准要求的、具有一定一体化程度的单一管理体系。管理体系可以是分别按照每一审核准则／标准建立的单个管理体系组合而成的结合体系，也可以是共享单一体系文件、管理体系要素和职责的一体化管理体系，有时也称为“整合的管理体系”。

A single management system managing multiple aspects of organizational performance to meet the requirements of more than one management standard, at a given level of integration. A management system may range from a combined system adding separate management systems for each set of audit criteria/standard, to an Integrated Management System, sharing in single system documentation, management system elements, and responsibilities., sometimes referred to as a "Consolidated management system".

3.11 一体化程度

Level of integration

组织运用单一的管理体系来实现组织绩效的多方面管理，以满足一个以上管理体系标准要求的程度。一体化针对的是能够将涉及两个或以上审核准则/标准的文件、适宜的管理要素和职能加以整合的管理体系。

The level to which an organization uses one single management system to manage multiple aspects of organizational performance to meet the requirements of more than one management system standard. Integration relates to the management system being able to integrate documentation, appropriate management system elements and responsibilities in relation to two or more sets of audit criteria/standards.

4 认证收费

Certification charge

4.1 产品认证收费

Product certification charge

产品认证收费标准

Product certification charge standard

序号 No.	收费项目 Charge Items	收费标准（单位：元） Charge standards（Unit: Yuan）	备注 Remarks
1	申请费 Application fee	1000	初次、复评认证收取 Initial audit, re- certification
2	初次审查费 Initial audit fee	3000×审核人日 3000×audit day	按 CMD 规定的审核人日执行 According to the audit day specified by CMD
3	审定与注册费（含证书费） Approval and registration fee (including certificate fee)	单独申请 2000 Apply separately 2000	加印证书副本，另收费 200 元/套 Additional copy of certificate is charged at ¥200 /set
		与体系同时申请 1000 Apply at the same time as the management system 1000	
4	监督审查费 Surveillance Audit fee	3000×审核人日 3000×audit day	按 CMD 规定的审核人日执行 According to the audit day specified by CMD
5	年金（不含标志使用费） Annuity (excluding mark using fee)	2000	第二年开始交纳，每年一次 From the second year, once a year
6	再认证审查费 Re-certification audit fee	3000×审核人日 3000×audit day	按 CMD 规定的审核人日执行 According to the audit day specified by CMD
7	产品检测费 Product testing fee	按国家规定收取 Charge according to state regulations	由检测机构收取 Collected by the testing institution

4.2 管理体系/服务认证认证收费

Management system/Service certification charge

管理体系/服务认证认证收费标准

Management system/Service certification charge standard

序号 No.	收费项目 Charge Items	收费标准（单位：元） Charge standards （Unit: Yuan）	备注 Remarks
1	申请费 Application fee	1000	初次、再认证收取 Initial audit, re- certification
2	初次审核费 Initial audit fee	3000×审核人日 3000×audit day	按 CMD 规定的审核人日执行
3	审定与注册费（含证书费） Approval and registration fee (including certificate	2000	加印证书副本，另收费 200 元/套 Additional copy of certificate is charged at ¥200 /set

	fee)		
4	监督审核费 Surveillance Audit fee	3000×审核人日 3000×audit day	现场审核时间不少于初次审核人日的 1/2 The on-site audit time is not less than 1/2 of the initial audit day
5	年金 Annuity	2000	第二年开始交纳，每年一次 From the second year, once a year
6	再认证审核费 Re-certification audit fee	3000×审核人日 3000×audit day	现场审核时间不少于初次审核人日的 70%。 The on-site audit time is not less than 70% of the initial audit day.

4.3 各项费用说明

Description of charges

4.3.1 申请费、审定与注册费、年金为固定费用；

Application fees, approval and registration fees, and annuities are fixed fees.

4.3.2 初次审核费、监督审核费、再认证审核费按审核人日计算；

The initial audit fee, Surveillance audit fee and re-certification audit fee shall be calculated according to the audit days.

4.3.3 初次、再认证时免费提供中英文证书 1 套，证书副本或换证每套收取 200 元工本费。如果组织需要其他国家文字证书，则加收翻译费和证书工本费；

One set of Chinese and English certificates will be provided free of charge during the initial and re-certification, copy of certificate or renewal certificate fee of $200 per set. If the organization requires a certificate in a foreign language, a translation fee and the cost of the certificate will be charged.

4.3.4 各种费用的付款时间和具体金额可根据成本及市场变化情况适时调整，具体见双方签订的《认证合同》或《认证协议》；

The payment time and specific amount of various fees can be adjusted according to the cost and market changes. For details, see the *Certification Contract* or *Certification Agreement* signed by both parties

4.3.5 现场审核的交通、食宿费由申请方承担。

Transportation, accommodation expenses for on-site audit shall be borne by

the applicant.

5 审核时间的确定方法

Methodology for determining audit time

5.1 审核时间

Audit time

5.1.1 所有类型审核的审核时间包括在审核客户场所现场的时间（有形的或虚拟的）、使用现场、远程或审核方法的组合，以及进行策划、文件审查、与客户人员之间的相互活动和编写报告等活动的时间。它不包含设计档案审查、型式检验、上市前批准审核和其他类似活动所需的时间。

The audit time for all types of audits includes the total time on-site at a client's location (physical or virtual) and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. It does not include the time required for design dossier review, type inspection, premarket approval review and other similar activities.

5.1.2 管理体系认证/服务认证现场审核时间通常不宜少于合同评审计算出审核时间的 80%。现场审核时间不包括第一阶段在现场实施的文件审查所用时间。适用于初次审核、监督审核和再认证审核。

The duration of a management system certification/service certification audit should typically not be less than 80% of the audit time calculated by the contract review. The on- site audit time does not include the time spent on the document review performed on- site in the stage 1. This applies to initial, surveillance and recertification audits.

5.1.3 旅途（往返途中或在场所之间的途中）以及其他任何中断休息及午餐休息时间不能计入现场的管理体系认证审核时间。

Travel (on-route or between sites) and any breaks and lunch breaks are not included in the on-site duration of management system certification audits.

5.2 审核人日

Audit Day(s)

5.2.1 在策划阶段，不应通过增加每个工作日的工作小时数来减少审核人日数。考

虑允许对倒班活动进行高效的审核，可能需要在一个工作日中增加小时数。

The number of audit days allocated shall not be reduced at the planning stages by programming longer hours per working day. Consideration can be made to allow efficient auditing of shift activities which may require additional hours in a working day.

5.2.2 在计算后结果包括小数，宜将其调整为最接近的半人日数（如：将 5.3 个审核人日调整为 5.5 个审核人日，5.2 个审核人日调整为 5 个审核人日）。

If after the calculation, the result is a decimal number, the number of days should be adjusted to the nearest half day (e.g.: 5.3 audit days becomes 5.5 audit days, 5.2 audit days becomes 5 audit days).

5.2.3 为了确保审核的有效性，宜同时考虑审核组的构成以及审核组的规模（如：2 个审核员 0.5 天的有效性可能不如 1 个审核人日由 1 个审核员领导 1 个技术专家在 1 天完成，而后种情况的有效性强于 1 个审核员不带技术专家的情况）。

To help ensure the effectiveness of the audit, it is appropriate to also consider the composition and size of the audit team (e.g. ½ day with 2 auditors may not be as effective as a one day audit with 1 auditor or 1 audit day with one lead auditor and one technical expert is more effective than 1 auditor day without the technical expert).

5.3 有效人数的计算

Calculation of the effective number of personnel

5.3.1 有效人数是用以计算管理体系审核时间的基础。确定有效人数时，包括考虑兼职人员和部分处于范围中的雇员，倒班工作，行政工作和全部类别的办公室职员，相似或重复过程以及雇佣大量非熟练人员的情况。

The effective number of personnel is used as a basis for the calculation of audit time of management system. In determining the effective number of personnel, Considerations for determining the effective number of employees include part-time personnel and employees partially in scope, those working on shifts, administrative and all categories of office staff, similar or repetitive processes and the employment of large numbers of unskilled personnel.

如果是季节性运营的情况（例如收获活动、度假村或度假旅馆等），计算有效人数应以典型生产季节高峰的人员为计算基础。

In the case of seasonal operations (e.g. harvesting activities, holiday villages and hotels, etc.), the calculation of the effective number of personnel shall be based on the personnel typically present in peak season operations.

对于 OHSMS，应考虑雇用大量非熟练人员而带来相关 OHS 风险的情况，不能忽略带来的相关风险而减少审核时间。

Reductions due to employment of large numbers of unskilled personnel shall not be made without consideration of the associated OHS risk.

5.3.2 若客户组织、认可机构在评审中以及认可机构有要求时，必要时，应记录确定有效人数的正当理由。

The justification to determine the effective number of personnel shall be available to the client organization and to the Accreditation Body for review during their assessments and on request from the Accreditation Body.

5.3.3 兼职人员和部分处于范围中的雇员

Part time personnel and employees partially in scope

根据实际工作的小时数，兼职人员的数量和部分处于范围中的雇员数可以减少或增加并换算成等效的全职人员数量（如：30 名每天工作 4 小时的兼职人员，相当于 15 名全职人员）。

Dependent upon the hours worked, part time personnel numbers and employees partially in scope may be reduced or increased and converted to an equivalent number of full-time personnel. (e.g. 30 part time personnel working 4 hours/day equates to 15 full time personnel.)

5.3.4 范围内相似或重复过程

Similar or repetitive process within scope

对 QMS 和 EMS：当人员中有较高比例从事某项被认定为重复活动/工作时（如：保洁、安保、运送、销售、呼叫中心等），允许在清晰合理并对每个企业应用一致的基础上，减少认证范围内的人员数量。含有人员减少的计算方法，包括任何有关活动/工作风险的考虑应形成文件。

For QMS and EMS: When a high percentage of personnel perform certain

activities/positions that are considered repetitive (e.g. cleaners, security, transport, sales, call centers, etc.) a reduction to the number of personnel which is coherent and consistently applied on a company to company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.

对 OHSMS：

For OHSMS:

a) 当人员中有较高比例从事被认为相似或相同的活动/工作时（如清洁、保安、销售、呼叫中心等），因为人员暴露于相似的 OHS 风险中，可允许在清晰合理并对每个企业应用一致的基础上，减少认证范围内人员数量。应记录该减少所采用的方法，包括对活动/工作风险的任何考虑。

When a high percentage of personnel perform certain activities/positions that are considered similar or identical because they expose personnel to similar OH&S risks (e.g. cleaners, security, sales, call centers, etc.) a reduction in the number of personnel which is coherent and consistently applied on a company to company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.

b) 大量的工作人员从事可降低注意力并增加 OHS 风险程度的重复性工作时（如安装、组装、包装、分类等），应记录可能减少审核时间而采用的方法，包括对工作人员的活动/工作的 OHS 风险的评估。

For groups of workers performing repetitive jobs which can reduce attention and raise the associated level of OHS risk (e.g. mounting, assembling, packaging, sorting, etc.), the methods incorporated for possible reductions shall be documented to include the assessment of the OHS risk of any activities/positions of workers.

5.3.5 倒班雇员

Shift work employees

应确定审核的持续时间和时机，以对有关客户全部活动范围的管理体系实施最为有效的评价，包括需要对正常工作时间之外的、以及各种倒班模式的审核。应与客户就此达成一致。应确保任何审核时间的变化都不影响审核的有效性。

CMD shall determine the duration and timing of the audit which will best assess the effective implementation of the management system for the full scope of the client activities, including the need to audit outside normal working hours and various shift patterns. This shall be agreed with the client, to ensure that any variation in audit time does not compromise the effectiveness of audits.

5.3.6 临时性非熟练人员

Temporary unskilled personnel

通常这种情况仅适用于一些技术水平较低的组织，可以雇佣大量临时的非熟练人员来代替自动化过程。

This issue normally only applies for organizations with a low level of technology where temporary unskilled personnel may be employed in considerable numbers to replace automated processes.

对 QMS 和 EMS，在这种情况下可以减少有效人数。对过程的考虑比对雇员数量的考虑更重要，这种减少不是经常发生的，应记录减少有效人数的正当理由。

For QMS and EMS, under these circumstances, a reduction in effective personnel may be made. Being the consideration of processes more important than employee number, this reduction is unusual and the justification for doing so shall be recorded.

对 OHSMS，原则上认为这种减少不适用，因为雇用临时的非熟练工是 OHS 风险的一个源头。特殊情况下，若为此而减少有效人数，应记录理由。

For OHSMS this reduction is in principle to be regarded as not applicable since the employment of temporary unskilled personnel can be a source of OH&S risks. If, in exceptional cases, a reduction is made, the justification for doing so shall be recorded.

5.4 管理体系审核时间的确定方法

Methodology for determining the audit time of the management systems

5.4.1 对于质量管理体系：

For the quality management system:

5.4.1.1 仅申请 GB/T42061（未认可）或 GB/T19001 以及同时申请 GB/T42061 和 GB/T19001 的客户，初次认证审核基于客户的有效人数和组织的风险类型为基础按照表 QMS1 、表 QMS2 确定质量管理体系审核时间起始点，并考虑组织分布状态和复杂程度关系（图 QMS1）考虑的相关因素进行调整。当存在不同风险程度的混合业务活动时，应对每项活动的有效人数予以考虑，确定适宜的审核时间，并记录理由。产品认证的审核时间基于质量管理体系的基础上确定。

For clients who only apply for GB/T42061/ISO13485 (not accredited) or GB/T19001 (ISO9001) or apply for GB/T42061/ISO13485 and GB/T19001 /ISO9001 at the same time, the initial certification audit shall be based on effective number of personnel of clients and the risk category of the organization, and the starting point of the quality management system audit shall be determined according to Table QMS1 and Table QMS2. The relevant factors considered in the relationship between organization distribution and complexity (Figure QMS1) were also taken into account for adjustment. Where there are mixed business activities with different risk categories, the effective number of personnel for each activity should be taken into account, the appropriate time for audit should be determined and the rationale documented. The audit time of product certification is determined on the basis of the quality management system.

表 QMS1：QMS+P 有效人数与审核时间的关系

Table QMS1：QMS+P Relationship between Effective Number of Personnel and Audit Time

<table>
<tr><td rowspan="2">认证种类
certification types
有效人数
Effective number of personnel</td><td colspan="2">管理体系认证初次审核人日
（第 1 阶段+第 2 阶段）
Audit days of Initial audit of management system certification
（Stage 1+ Stage 2）</td><td>产品认证
初次审核人日
（适用 1 个产品认证单元）
Audit days of Initial audit of product certification
（Applicable to one product certification unit）</td></tr>
<tr><td>GB/T42061（未认可）或 GB/T19001</td><td>GB/T42061（未认可）和 GB/T19001 ISO13485（not</td><td>体系+产品
System + Product</td></tr>
</table>

	GB/T42061（not accredited）or ISO9001	accredited）& ISO9001	
	A	B	C
0-25	4	5	见注 2 说明 See note 2 for instructions
26-45	5	6	
46-65	6	7	
66-85	7	8	
86-125	8	9	
126-175	9	10	
176-275	10	11	
276-425	11	12	
426-625	12	13	
>626	**以此类推 the same applies to above**		

注 1：表中 A 指申请 GB/T42061/ISO13485（未认可）或 GB/T19001/ISO9001 标准认证；B 指申请 GB/T42061/ISO13485（未认可）和 GB/T19001/ISO9001 两个标准认证；C 指在体系认证基础上申请医疗器械产品认证。

Note 1: A in the table refers to the application for GB/T42061/ISO13485 (not accredited) or GB/T19001/ISO9001 certification; B refers to the application for GB/T42061/ISO13485 (not recognized) and GB/T19001/ISO9001 two standard certification; C refers to the application for medical device product certification on the basis of system certification.

注 2： 在体系认证基础上申请医疗器械产品认证的，以 1 个产品认证单元为例，在体系认证的基础上增加 1 个审核人日；再增加产品认证单元，则每个产品单元增加 0.5 审核人日；累计计算。现场审核人日为体系认证审核时间与产品认证审核时间分开计算后的合计时间。

Note 2: Apply for medical device product certification on the basis of system certification, take 1 product certification unit as an example, add 1 audit day on the basis of system certification. If the product certification unit is added, 0.5 audit days will be added for each product unit, cumulative calculation.

The on-site audit day is the total time after system certification audit time and product certification audit time are separately calculated.

注 3：标准转换的质量管理体系审核时间及收费：

——监督换版：审核人日按原认证合同再认证审核人日（最小规模企业监督总审核时间不少于 3 人日），审核费以此人日计收。

——再认证(含单独换版申请)：审核人日在原认证合同再认证审核人日基础上增加1-2人日（具体视企业规模、产品复杂程度、场地分布等决定），审核费以此人日计收。

Note 3: Quality management system audit time and fee for standard conversion:

------ Standard conversion during Surveillance audit: the audit day shall be based on the re-certification audit day of the original certification contract (the total surveillance audit time of the smallest enterprise shall be no less than 3 days), and the audit fee shall be charged on this audit day.

------ Recertification (including a separate application for standard conversion): the number of auditors will increase by 1-2 people per day on the basis of the number of re-certification auditors of the original certification contract (depending on the size of the enterprise, the complexity of the product, the distribution of the site, etc.), and the audit fee will be charged on this audit day.

5.4.1.2 申请 ISO13485（认可）的客户，初次认证审核基于客户的有效人数和组织的风险类型（如审核范围、目标和要审核的具体法规要求等因素，以及医疗器械的范围、类别和复杂程度，以及组织的规模和复杂程度）为基础按照表 QMS3 确定质量管理体系审核时间起始点，并考虑组织分布状态和复杂程度关系（图 QMS1）考虑的相关因素进行调整。当存在不同风险程度的混合业务活动时，应对每项活动的有效人数予以考虑，确定适宜的审核时间，并记录理由。CMD 策划审核时，应给予审核组足够的时间来确定客户组织的 ISO13485 质量管理体系是否符合相关法规要求。审核国家或地区法规要求和档案审查所需的时间应是额外的和合理的，以不减少对质量管理体系的审核。产品认证的审核时间基于质量管理体系的基础上确定。

For clients applying for ISO13485 (accredited), the initial certification audit is based on the effective number of personnel of the clients and the risk category of the organization (such as the scope of the audit, objectives and specific regulatory requirements to be audited and other factors, as well as the scope, category and complexity of the medical device). The starting point of the audit time of the quality management system was determined according to Table QMS3, and the relevant factors considered in the relationship between the distribution state of the

organization and the complexity (Figure QMS1) were adjusted. Where there are mixed business activities with different levels of risk, the effective number of personnel for each activity should be taken into account, the appropriate time for review should be determined and the rationale documented. When CMD plans an audit, the audit team should be given sufficient time to determine whether the client organization's ISO13485 quality management system complies with relevant regulatory requirements. The time required to review national or regional regulatory requirements and file reviews should be additional and reasonable so as not to reduce the audit of the quality management system. The audit time of product certification is determined on the basis of the quality management system.

表 QMS3：QMS（认可）+P 有效人数与审核时间的关系

Table QMS3：QMS（accredited）+P The Relationship Between the Effective Number of Personnel and the Audit Time

认证种类 certification types / 有效人数 the effective number of personnel	管理体系认证初次审核人日（第 1 阶段+第 2 阶段） Audit days of Initial audit of management system certification（phase 1+ phase 2）		产品认证 初次审核人日（适用 1 个产品认证单元） Audit days of Initial audit of product certification（Applicable to one product certification unit）
	ISO13485（认可） ISO13485 (accredited)	同时认证 GB/T19001 和 ISO13485（认可） Integrated certification of GB/T 19001 and ISO 13485 (accredited)	体系+产品 System + Product
	A	B	C
1-5	3	B=A*1.25	见注 3 说明 See note 3 for instructions
6-10	4		
11-15	4.5		
16-25	5		
26-45	6		

46-65	7		
66-85	8		
86-125	10		
126-175	11		
176-275	12		
276-425	13		
426-625	14		
>626	以此类推 **the same applies to above**		

注 1：表中 B 指申请 ISO13485 标准认证（认可）；B 指同时认证 GB/T19001 和 ISO13485（认可）；C 指在体系认证基础上申请医疗器械产品认证。

Note 1: In the table, B refers to the application for ISO 13485 standard certification (accredited); B refers to the integrated certification of GB/T 19001 and ISO 13485 (accredited); C refers to the application for medical device product certification based on the management system certification.

注 2：该表适用于申请 ISO13485 标准认证（认可）（如单独申请 ISO9001 标准认证或申请 ISO13485 标准认证（非认可）时适用表 QMS1）。

Note 2: This table is applicable to the application for ISO13485 standard certification (accredited) (Table QMS1 is applicable when ISO9001 standard certification or ISO13485 standard certification (non-accredited) applied separately).

注 3： ISO13485 标准体系认证基础上申请医疗器械产品认证的，以 1 个产品认证单元为例，在体系认证的基础上增加 1 个审核人日；再增加产品认证单元，则每个产品单元增加 0.5 审核人日；累计计算。现场审核人日为体系认证审核时间与产品认证审核时间分开计算后的合计时间。

Note 3: For medical device product certification based on ISO13485 system certification, take 1 product certification unit as an example, add 1 audit day on the basis of system certification. If the product certification unit is added, 0.5 audit days will be added for each product unit, cumulative calculation. The on-site audit day is the total time after system certification audit time and product certification audit time are separately calculated.

注 4：如果同时申请 GB/T19001 和 ISO13485（认可）的客户，初次认证审核基于客户的有效人数和组织的风险类型为基础按照表 QMS3 确定质量管理体系审核时间起始点，并考虑组织分布状态和复杂程度关系（图 QMS1）考虑的相关因素进行调整。当存在不同风险程度的混合业务活动时，应对每项活动的有效人数予以考虑，确定适宜的审核时间，并记录理由。

Note 4: If both GB/T19001 and ISO13485 (accredited) are applied, the initial certification audit shall be based on the effective number of personnel of the clients and the risk category of the organization, and the starting point of the quality management system audit shall be determined in accordance with Table QMS3. The relevant factors considered in the relationship between organization distribution and complexity (Figure QMS1) were also taken into account for adjustment. Where there are mixed business activities with different levels of risk, the effective number of personnel for each activity should be taken into account, the appropriate time for review should be determined and the rationale documented.

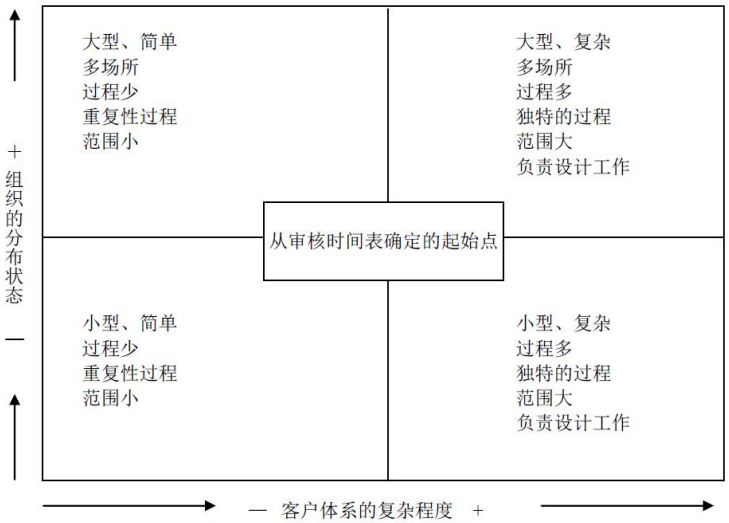


图 QMS1——复杂程度与审核时间的关系

Figure QMS 1 – Relationship between Complexity and Audit Time

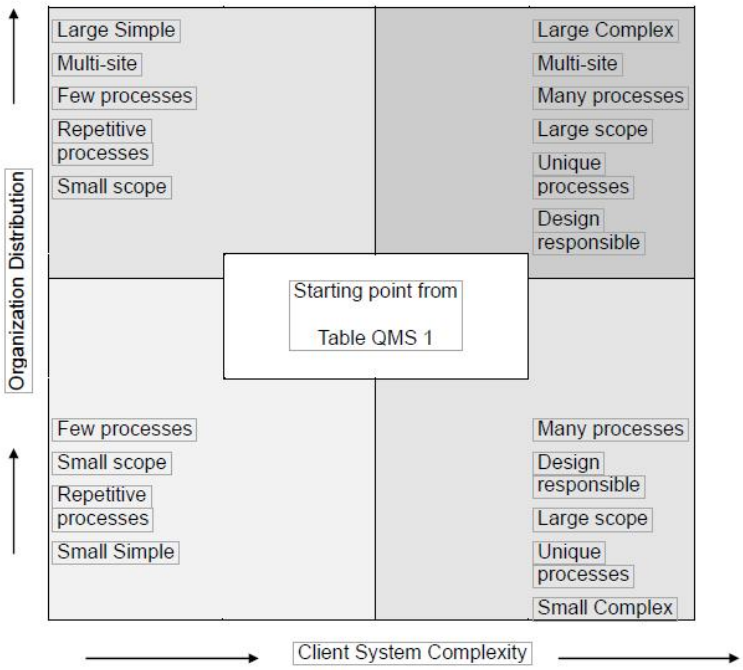


表 QMS2——风险类型示例

这里的风险类型并非固定不可变的，仅作为示例可供认证机构在确定某审核的风险类型时采用。

高风险：	产品或服务失效将引起巨大经济损失或引起生命危险。示例包括但不限于： 食品，药品，飞机，造船，承重部件和结构，复杂的施工活动，电力和燃气设备，医疗卫生服务，捕鱼，核燃料，化学品，化学制品及纤维。
中风险：	产品或服务失效可能引起伤害或疾病。示例包括但不限于： 非承重部件和结构，简单的施工活动，基础金属及制品，非金属制品，家具，光学仪器，休闲和个人服务。
低风险：	产品或服务失效不太可能引起伤害或疾病。示例包括但不限于： 纺织品和服装，纸浆、纸及纸制品，出版，办公服务，教育，零售，酒店和餐馆。

Table QMS 2 – Examples of Risk Categories

These risk categories are not definitive, they are examples only that could be used by a CB when determining the risk category of an audit.

High Risk

Where failure of the product or service causes economic catastrophe, or puts life at risk. Examples include but are not limited to:

Food; pharmaceuticals; aircraft; shipbuilding; load bearing components and structures; complex construction activity; electrical and gas equipment; medical and health services; fishing; nuclear fuel; chemicals, chemical products and fibres.

Medium Risk

Where failure of the product or service could cause injury or illness. Examples include but are not limited to:

Non load bearing components and structures; simple construction activities; basic metals and fabricated products; non-metallic products; furniture; optical equipment; leisure and personal services.

Low Risk

Where failure of the product or service is unlikely to cause injury or illness. Examples include but are not limited to:

Textiles and clothing; pulp, paper and paper products; publishing; office services; education; retailing, hotels and restaurants.

5.4.2 对于 EMS，初次认证审核基于客户的有效人数和行业典型组织的环境因素的性质、数量、严重程度为基础按照表 EMS1 和表 EMS2 确定环境管理体系审核时间。

For EMS, it is appropriate to base audit time on the effective number of personnel of the organization and the nature, number and gravity of the environmental aspects of the typical organization in that industry sector. Tables EMS 1 and EMS 2 provide the framework for the process that should be used for Audit planning.

表 **EMS1**——有效人数、复杂程度与审核时间的关系

（仅适用于初次审核，第一阶段+第二阶段）

有效人数	审核时间 第 1 阶段＋第 2 阶段 （天）				有效人数	审核时间 第 1 阶段＋第 2 阶段 （天）			
	高	中	低	有限		高	中	低	有限
1-5	3	2.5	2.5	2.5	626-875	17	13	10	6.5
6-10	3.5	3	3	3	876-1175	19	15	11	7
11-15	4.5	3.5	3	3	1176-1550	20	16	12	7.5
16-25	5.5	4.5	3.5	3	1551-2025	21	17	12	8
26-45	7	5.5	4	3	2026-2675	23	18	13	8.5
46-65	8	6	4.5	3.5	2676-3450	25	19	14	9
66-85	9	7	5	3.5	3451-4350	27	20	15	10
86-125	11	8	5.5	4	4351-5450	28	21	16	11
126-175	12	9	6	4.5	5451-6800	30	23	17	12
176-275	13	10	7	5	6801-8500	32	25	19	13
276-425	15	11	8	5.5	8501-10700	34	27	20	14
426-625	16	12	9	6	>10700	遵循上述递进规律			

Table EMS 1 – Relationship between Effective Number of Personnel, Complexity and Audit Time
(Initial Audit only- Stage 1 + Stage 2)

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)				Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)			
	High	Med	Low	Lim		High	Med	Low	Lim
1-5	3	2.5	2.5	2.5	626-875	17	13	10	6.5
6-10	3.5	3	3	3	876-1175	19	15	11	7
11-15	4.5	3.5	3	3	1176-1550	20	16	12	7.5
16-25	5.5	4.5	3.5	3	1551-2025	21	17	12	8
26-45	7	5.5	4	3	2026-2675	23	18	13	8.5
46-65	8	6	4.5	3.5	2676-3450	25	19	14	9
66-85	9	7	5	3.5	3451-4350	27	20	15	10
86-125	11	8	5.5	4	4351-5450	28	21	16	11
126-175	12	9	6	4.5	5451-6800	30	23	17	12
176-275	13	10	7	5	6801-8500	32	25	19	13
276-425	15	11	8	5.5	8501-10700	34	27	20	14
426-625	16	12	9	6	>10700	Follow progression above			

表 EMS 2——业务类别与环境因素复杂程度类型的联系示例

复杂程度类型	业务类别
高	● 采矿与采石 ● 油和气的开采 ● 纺织品与服装的染色 ● 纸张生产的纸浆生产部分，包括纸张的再生过程 ● 炼油 ● 化学品与药品 ● 基础生产—金属 ● 包含陶瓷、水泥的非金属加工过程与产品 ● 煤电 ● 民用建筑的建设与拆除 ● 有害与无害的废物处理，如焚烧 ● 污水处理
中	● 渔/农/林 ● 纺织品与服装，不包括染色 ● 板的制造，木材和木制品的处理/填充 ● 纸张制造与印刷，不包括纸浆生产 ● 包含玻璃、黏土、石灰等的非金属加工过程与产品 ● 金属合成产品的表面处理与其他化学处理，不包括基础生产 ● 一般机械加工的表面处理与其他化学处理 ● 电子工业用印刷线路板的生产 ● 交通设备的制造—陆上、铁路、航空和水运设备 ● 非煤的发电与电的输送 ● 气的生产、贮存与输送（注：气的开采属高风险） ● 水的汲取、净化与供给，包括河流管理（注：商业污水处理属高风险） ● 化石燃料的批发与零售 ● 食品与烟草—加工 ● 交通与运输—海运、空运、陆地运输 ● 房地产公司、房地产管理和作为一般服务一部分的工业清洗、卫生清洗与干洗 ● （无害废物的）回收、堆肥与填埋 ● 技术试验与试验室 ● 医疗/医院/兽医 ● 不包括宾馆/饭店的娱乐服务和个人服务
低	● 宾馆/饭店 ● 不包括板的制造、木材的加工与填充的木材与木制品 ● 不包括印刷、纸浆的生产与纸张制造的纸制品 ● 橡胶和塑料的注塑、成型和组装—不包括橡胶和塑料原材料的生产（该生产属化学品范畴） ● 合成金属的冷/热成型，不包括表面处理、其他化学处理与初次生产 ● 一般机械加工组装，不包括表面处理和其他化学处理 ● 批发与零售 ● 电子、电工设备的组装，不包括印刷线路板的生产
有限	● 社团活动与管理，总部和股份公司的管理 ● 交通与运输—不含运输设备管理的管理服务 ● 电子通讯 ● 不包括房地产公司、房地产管理和工业清洗、卫生清洗与干洗的一般商业服务 ● 教育服务
特殊	● 核 ● 核发电 ● 大量有毒材料的贮存 ● 公共行政管理 ● 地方政府 ● 提供环境敏感产品或服务的组织，金融机构

Table EMS 2 – Examples of Linkage between Business Sectors and Complexity Categories of Environmental Aspects

Complexity Category	Business Sector
High	– mining and quarrying – oil and gas extraction – tanning of textiles and clothing – pulping part of paper manufacturing, including paper recycling processing – oil refining – chemicals and pharmaceuticals – primary productions – metals – non-metallics processing and products covering ceramics and cement – coal-based electricity generation – civil construction and demolition – hazardous and non-hazardous waste processing, e.g. incineration, etc. – effluent and sewerage processing
Medium	– fishing/farming/forestry – textiles and clothing except for tanning – manufacturing of boards, treatment/impregnation of wood and wooden products – paper production and printing, excluding pulping – non-metallics processing and products covering glass, clay, lime, etc. – surface and other chemically-based treatment for metal fabricated products, excluding primary production
	– surface and other chemically-based treatment for general mechanical engineering – production of bare printed circuit boards for electronics industry – manufacturing of transport equipment – road, rail, air, ships – non-coal-based electricity generation and distribution – gas production, storage and distribution *(note: extraction is graded high)* – water abstraction, purification and distribution, including river management *(note: commercial effluent treatment is graded as high)* – fossil fuel wholesale and retail – food and tobacco processing – transport and distribution by sea, air, land – commercial estate agency, estate management, industrial cleaning, hygiene cleaning, dry cleaning normally part of general business services – recycling, composting, landfill (of non-hazardous waste) – technical testing and laboratories – healthcare/hospitals/veterinary – leisure services and personal services, excluding hotels/restaurants

Low	– hotels/restaurants – wood and wooden products, excluding manufacturing of boards, treatment and impregnation of wood – paper products, excluding printing, pulping, and paper making – rubber and plastic injection moulding, forming and assembly, excluding manufacturing of rubber and plastic raw materials that are part of chemicals
	– hot and cold forming and metal fabrication, excluding surface treatment and other chemical-based treatments and primary production – general mechanical engineering assembly, excluding surface treatment and other chemical-based treatments – wholesale and retail – electrical and electronic equipment assembly, excluding manufacturing of bare printed circuit boards
Limited	– corporate activities and management, HQ and management of holding companies – transport and distribution management services with no actual fleet to manage – telecommunications – general business services, except commercial estate agency, estate management, industrial cleaning, hygiene cleaning, dry cleaning – education services
Special Cases	– nuclear – nuclear electricity generation – storage of large quantities of hazardous material – public administration – local authorities – organizations with environmental sensitive products or services, financial institutions

环境因素的复杂程度

本文件根据组织环境因素的性质和严重程度定义了五种主要的对审核时间有根本影响的环境因素复杂程度类型，据此来阐述本文件的规定。这五种类型是：

- **高**——环境因素的性质与严重程度重大（典型的有：多个环境因素有重大影响的生产或加工型组织）；
- **中**——环境因素的性质与严重程度中等（典型的有：某些环境因素有重大影响的生产型组织）；
- **低**——环境因素的性质与严重程度低（典型的有：几乎没有重要环境因素的装配型组织）；
- **有限**——环境因素的性质与严重程度有限（典型的有：办公室环境中的组织）；
- **特殊**——在审核策划阶段需要给予另外的特殊考虑。

Complexity Categories of Environmental Aspects

The provisions specified in this document are based on five primary complexity categories of the nature and gravity of the environmental aspects of an organization that fundamentally affect the audit time. These are:

High – environmental aspects with significant nature and gravity (typically manufacturing or processing type organizations with significant impacts in several of the environmental aspects);

Medium – environmental aspects with medium nature and gravity (typically manufacturing organizations with significant impacts in some of the environmental aspects);

Low – environmental aspects with low nature and gravity (typically organizations of an assembly type environment with few significant aspects);

Limited – environmental aspects with limited nature and gravity (typically organizations of an office type environment);

Special – these require additional and unique consideration at the audit planning stage.

5.4.3 对于 OHSMS，初次认证审核基于客户的有效人数和行业中典型组织的 OHS 风险性质、数量和严重程度来按照表 OHSMS1 和表 OHSMS2 确定职业健康安全管理体系审核时间。

For OHSMS, it is appropriate to base audit time on the effective number of personnel of the organization and nature, number and severity of the OH&S risks of the typical organization in that industry sector. Tables OH&SMS 1 and OH&SMS 2 provide a framework for the process that should be used for planning.

表 **OHSMS1——OHSMS** 有效人数、**OHS** 风险复杂程度与审核时间的关系

（仅适用于初次审核，第一阶段+第二阶段）

有效人数	审核时间 第 1 阶段＋第 2 阶段（天）			有效人数	审核时间 第 1 阶段＋第 2 阶段（天）		
	高	中	低		高	中	低
1-5	3	2.5	2.5	626-875	17	13	10
6-10	3.5	3	3	876-1175	19	15	11
11-15	4.5	3.5	3	1176-1550	20	16	12
16-25	5.5	4.5	3.5	1551-2025	21	17	12
26-45	7	5.5	4	2026-2675	23	18	13
46-65	8	6	4.5	2676-3450	25	19	14
66-85	9	7	5	3451-4350	27	20	15
86-125	11	8	5.5	4351-5450	28	21	16
126-175	12	9	6	5451-6800	30	23	17
176-275	13	10	7	6801-8500	32	25	19
276-425	15	11	8	8501-10700	34	27	20
426-625	16	12	9	>10700	遵循上述递进规律		

Table OH&SMS 1 – Occupational Health and Safety Management Systems

Relationship between Effective Number of Personnel, Complexity Category of OH&S Risk and Audit Time (Initial Audit only – Stage 1 + Stage 2)

Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)			Effective Number of Personnel	Audit Time Stage 1 + Stage 2 (days)		
	High	Med	Low		High	Med	Low
1-5	3	2.5	2.5	626-875	17	13	10
6-10	3.5	3	3	876-1175	19	15	11
11-15	4.5	3.5	3	1176-1550	20	16	12
16-25	5.5	4.5	3.5	1551-2025	21	17	12
26-45	7	5.5	4	2026-2675	23	18	13
46-65	8	6	4.5	2676-3450	25	19	14
66-85	9	7	5	3451-4350	27	20	15
86-125	11	8	5.5	4351-5450	28	21	16
126-175	12	9	6	5451-6800	30	23	17
176-275	13	10	7	6801-8500	32	25	19
276-425	15	11	8	8501-10700	34	27	20
426-625	16	12	9	>10700	Follow progression above		

表 OHSMS 2——业务类别与 OHS 风险复杂程度类型的联系示例

OHS 风险复杂程度类型	业务类别
高	● 捕鱼（近海、沿海捕捞和潜水捕捞） ● 采矿与采石 ● 焦炭和精炼石油产品的制造 ● 石油和天然气开采 ● 皮革及皮革制品的鞣制 ● 纺织品和服装的染色 ● 纸张生产的纸浆生产部分，包括纸张的再生过程炼油 ● 化学品（包括杀虫剂，电池和蓄电池的制造），和药品 ● 玻璃纤维制造 ● 天然气生产，储存和分配 ● 发电和配电 ● 核 ● 储存大量有害物质 ● 包含陶瓷，混凝土，水泥，石灰，石膏的等非金属加工过程和产品 ● 金属的初级生产 ● 冷热成型和金属制造 ● 金属结构的制造和组装 ● 造船厂（取决于活动可能会是中风险） ● 航天工业 ● 汽车工业 ● 制造武器和爆炸物 ● 回收危险废物 ● 有害和无害的废物处理，例如焚化等 ● 污水处理 ● 工业和民用建筑和拆除（包括水电和空调安装活动的完整建筑） ● 屠宰场 ● 运输和分配危险物品（通过陆地，空中和水上） ● 国防活动/危机管理 ● 医疗/医院/兽医/社会工作
中	● 水产养殖（在各种水环境中繁殖，饲养和收获植物和动物） ● 捕鱼（近海捕鱼时高风险） ● 农业/林业（取决于活动可能是高风险） ● 食品，饮料和烟草加工 ● 纺织品和服装，除了染色 ● 皮革和皮革制品，除了鞣制 ● 制造木材和木制品，包括制造木板，处理/浸渍木材 ● 造纸和纸制品，不包括制浆 ● 包含玻璃，陶瓷，粘土的非金属加工过程和产品 ● 通用机械工程装配 ● 金属制品的制造 ● 除金属初级生产和一般机械工程外的金属加工产品的表面和其他化学处理（取决于处理方法和部件尺寸，可能是高风险） ● 为电子行业生产印刷电路裸板 ● 橡胶和塑料注塑，成型和组装 ● 电气和电子设备组装

OHS 风险复杂程度类型	业务类别
	● 运输设备的制造及其修理 – 公路，铁路和航空（取决于设备的大小，可能是高风险） ● （无害垃圾的）回收，堆肥，填埋 ● 取水，净化和分配，包括河流管理（注意商业污水处理被评为高风险） ● 化石燃料的批发和零售（取决于燃料的数量，可能是高风险） ● 旅客运输（空运、陆运、海运） ● 一般货物运输和分配（陆运、空运、水运） ● 通常是一般商业服务的一部分的工业清洁、卫生清洁、干洗 ● 自然科学和技术科学的研究和开发（取决于业务类别，可能是高风险）。技术测试和实验室 ● 酒店，休闲服务和个人服务不包括餐馆 ● 教育服务（取决于教学活动的对象，可能是高风险或低风险）
低	● 公司活动和管理，总部和控股公司的管理 ● 批发和零售（取决于产品，可能是中风险或高风险，如，燃料） ● 除工业清洁、卫生清洁、干洗和教育服务以外的一般商业服务 ● 运输和分配 – 管理服务，没有实际的船队/车队管理 ● 工程服务（根据服务类型，可能是中风险） ● 电信和邮政服务 ● 餐馆和露营 ● 商业地产代理，物业管理 ● 社会科学和人文科学研究与开发 ● 公共行政，地方政府 ● 金融机构，广告代理

TABLE OH&SMS 2 - Examples of Linkage between Business Sectors and Complexity Categories of OH&S Risks

Complexity category of OH&S risk	Business Sector
High	• fishing (offshore, coastal dredging and diving) • mining and quarrying • manufacture of coke and refined petroleum products • oil and gas extraction • tanning of leather and leather products • dyeing of textiles and clothing • pulping part of paper manufacturing including paper recycling processing • oil refining • chemicals (including pesticides, fabrication of batteries and accumulators), and pharmaceuticals • manufacturing of fibreglass • gas production, storage and distribution • electricity generation and distribution • nuclear • storage of large quantities of hazardous material • non-metallic processing and products covering ceramics, concrete, cement, lime, plaster, etc. • primary productions of metals • hot and cold forming and metal fabrication • manufacturing and assembly of metal structures • shipyards (depending on the activities could be medium) • aerospace industry • automotive industry • manufacturing of weapons and explosives • recycling of hazardous waste • hazardous and non-hazardous waste processing e.g. incineration etc. • effluent and sewerage processing • industrial and civil construction and demolition (including building completion with electrical, hydraulic and air conditioning installation activities) • slaughter houses • transport and distribution of dangerous goods (by land, air and water) • defence activities/crisis management • healthcare/hospitals/veterinary/social works

Medium	• aquaculture (breeding, rearing, and harvesting of plants and animals in all types of water environments) • fishing (offshore fishing is high) • farming/forestry (depending on the activities could be high) • food, beverage and tobacco – processing • textiles and clothing except for dyeing • leather and leather product except for tanning • manufacturing of wood and wooden products including manufacturing of boards, treatment/impregnation of wood • paper production and paper products excluding pulping • non-metallic processing and products covering glass, ceramics, clay, etc. • general mechanical engineering assembly • manufacturing of metallic products • surface and other chemically based treatment for metal fabricated products excluding primary production and for general mechanical engineering (depending on the treatment and the size of the component could be high) • production of bare printed circuit boards for electronics industry • rubber and plastic injection moulding, forming and assembly • electrical and electronic equipment assembly • manufacturing of transport equipment and their repairs - road, rail and air (depending on the size of the equipment, could be high) • recycling, composting, landfill (of non-hazardous waste) • water abstraction, purification and distribution including river management (note commercial effluent treatment is graded as high) • fossil fuel wholesale and retail (depending on the amount of fuel, could be high) • transport of passengers (by air, land and sea) • transport and distribution of non-dangerous goods (by land, air and water) • industrial cleaning, hygiene cleaning, dry cleaning normally part of general business services • research & development in natural and technical sciences (depending on the business sector could be high). Technical testing and laboratories • hotels, leisure services and personal services excludes restaurants • education services (depending on the object of teaching activities could be high or low)

Low	• corporate activities and management, HQ and management of holding companies • wholesale and retail (depending on the product, could be medium or high, e.g. fuel) • general business services except industrial cleaning, hygiene cleaning, dry cleaning and education services). • transport and distribution - management services with no actual fleet to manage • engineering services (could be medium depending on type of services) • telecommunications and post office services • restaurants and campings • commercial estate agency, estate management • research & development on social sciences and humanities • public administration, local authorities • financial institutions, advertising agency

OHS 风险复杂程度类型

本文件中的条款规定是根据 OHS 风险的三个主要复杂程度类型，这些类型基于从根本上影响组织审核时间的 OHS 风险的性质和严重程度。这三种类型是：

- 高风险——OHS 风险具有重大程度和严重性（通常是建筑业，重型制造或加工型组织）；
- 中风险——OHS 风险具有中等程度和严重性（通常是有一些重大风险的轻型制造组织）；和
- 低风险——OHS 风险具有低等程度和严重性（通常是基于办公室的组织）。

Complexity Categories of OHS Risks

The provisions specified in this document are based on three primary complexity categories of OH&S risks based on the nature and severity of the OH&S risks of an organization that fundamentally affect the auditor time. These are:

High – OH&S risks with significant nature and severity (typically the construction industry, heavy manufacturing or processing type organizations),

Medium – OH&S risks with medium nature and severity (typically light manufacturing organizations with some significant risks), and

Low – OH&S risks with low nature and severity (typically office based organizations).

5.4.4 上述表 QMS1、表 EMS1、表 OHSMS1 中人数视为连续变化的，QMS1 有效人数 2026-10700 审核时间具体见 CNAS-CC105 附件 A 的 QMS1 表描述（在 CNAS-CC105 附件 A 的 QMS1 表对应人日基础上增加 1 人日），QMS3 中 IS09001 标准有效人数 626-10700 审核时间具体见 CNAS-CC105 附件 A 的 QMS1 表描述，ISO13485 标准有效人数 626-10700 审核时间具体见 IAF MD9 附件 D 中表 D.1 描述，各表人数超过 10700 人时的审核时间遵循上表递进规律，保持一致。

The number of persons in the above tables QMS1, EMS1 and OHSMS1 shall be regarded as continuously changing. The audit time is specifically described in the QMS1 table in Annex A of CNAS-CC105 (1 audit day is added on the basis of the corresponding audit day in QMS1 table in Annex A of CNAS-CC105). The audit time of IS09001 effective number of personnel 626-10700 in QMS3 is described in Table QMS1 of Annex A of CNAS-CC105, and the audit time of 626-10700 effective number of personnel of ISO13485 is described in Table D.1 of Annex D of IAF MD9. The audit time of each table with more than 10,700

persons shall follow the progressive rule of the above table and be consistent.

5.4.5 对于 EMS，并非所有特定行业的组织都会处于相同的复杂程度类型。在合同评审确定审核时间时，在确定组织复杂程度类型时考虑该组织的具体活动，当将特定行业中的组织归入较低复杂程度类型时，应记录理由。如遇“特殊复杂程度”应根据具体情况分析，合理调整管理体系审核时间。

For EMS, not all industry-specific organizations will be at the same level of complexity. When the contract review determines the timing of the review, the specific activities of the organization are considered in determining the type of complexity of the organization, and the reasons should be documented when the organization in a particular industry is classified as a lower type of complexity. In case of "special complexity", the management system audit time should be reasonably adjusted according to the specific situation.

5.4.6 对于 OHSMS，并非所有特定行业的组织都会处于相同的 OHS 风险类型。在合同评审确定审核时间时，在确定组织 OHS 风险复杂程度类型时考虑该组织的具体活动，当降低特定行业中的组织的 OHS 风险复杂程度类型时，应记录理由。必要时确定 OHS 风险的复杂程度也可能考虑与 OHSMS 控制风险失效的后果相关。

For OHSMS, not all industry-specific organizations will be at the same type of OH&S risk. When the contract review determines the timing of the audit, the specific activities of the organization are considered in determining the type of complexity of the OHS risk of the organization, and the reasons should be documented when reducing the type of complexity of the OHS risk of the organization in a particular industry. Where necessary, determining the complexity of OH&S risk may also be considered in relation to the consequences of failure of OHSMS control risk.

注：组织OHS风险的复杂程度程度型也可能与OHSMS控制风险失败的后果相关：

高——风险管理失败可能会危及生命或导致严重伤害或疾病；
中——风险管理失败可能会导致伤害或疾病；及
低——风险管理失败可以导致轻微伤害或疾病。

Note: The *complexity category of OH&S risk of an organization may also be associated with the consequences of a failure of the OH&SMS to control the risk:*

- High – where failure to manage the risk could put life at risk or result in serious injury or illness,
- Medium – where failure to manage the risk could result in injury or illness, and
- Low – where failure to manage the risk may result in minor injury or illness.

5.4.7 在合同评审时，应按照上述表 QMS1、表 QMS3、表 EMS1、表 OHSMS1 中拟审核客户的有效人数确定基准审核时间，作为计算审核时间的起始点，然后根据该客户的每个重要因素赋予一个对基准审核时间的增加量或减少量，根据这些因素对基准审核时间进行调整。应记录确定审核时间（包括审核时间的调整）的依据。审核时间的任何减少应确保不能影响审核的有效性。审核时间应覆盖所有的业务范围，包括正常工作时间之外的审核或者是和倒班的工作模式。

During contract review, the benchmark audit time shall be determined according to the effective number of personnel of the client to be audited in table QMS1, Table QMS3, Table EMS1 and Table OHSMS1 as the starting point for calculating the audit time, and then an increase or decrease of the benchmark audit time shall be assigned according to each important factor of the client. The benchmark audit time is adjusted according to these factors. The basis for determining the audit time (including the adjustment of the audit time) shall be documented. Any reduction in audit time should ensure that the effectiveness of the audit is not affected. Audit time should cover all business areas, including audits outside normal working hours or in and out of shift work patterns.

对 QMS 和 EMS，若产品或服务的实现过程是倒班运行时，应对每个班次的审核程度取决于每个班次完成的过程以及客户所证实的对每个班次的控制水平。为了审核有效实施，至少对其中的一个班次进行审核。如果不对其他班次（如：那些在正常工作时间之外的班次）进行审核，则应记录这样做的理由。

For QMS and EMS, where the implementation of a product or service is run in shifts, the degree of audit that should be conducted for each shift depends on the process completed for each shift and the level of control demonstrated by the client for each shift. Audit at least one of these shifts in order to audit effective implementation. If other shifts (e.g., those outside normal working hours) are not audited, the reasons for doing so should be recorded.

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，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。

For OHSMS, where the product or service realization process is run in shifts, The degree to which the certification body audits each shift depends on the processes that each shift is engaged in, which must take into account their associated OH&S risks and the level of control that the client has demonstrated over each shift. For the effective implementation of the audit, at least one shift during normal office hours and one shift outside normal office hours should be audited during the first certification cycle. For surveillance audits of subsequent cycles, a second shift may be audited based on the maturity of the organization's OH&SMS. If possible, it is recommended that the audit start time be delayed to cover two shifts within the audit working day. To consider the risk of not reviewing the second shift, a valid reason for not reviewing the second shift should be documented.

5.4.8 在使用上述图表确定管理体系审核时间时，不应计入实习审核员、观察员或技术专家的工作时间。

When using the above chart to determine the duration of management system audits, the working hours of trainee auditors, observers or technical experts should not be taken into account.

5.4.9 在一体化管理体系中，如果暂停、缩小或撤销其中一个或多个管理体系标准/规范认证时，策划审核时间时应考虑调查由此产生的对于其他管理体系标准/规范认证的影响。

In an integrated management system, if one or more management system standard/specification certifications are suspended, reduced or revoked, the timing of the audit should be planned with consideration to investigating the resulting impact on other management system standard/specification certifications.

5.4.10 在对表 QMS1、表 EMS1 和表 OHSMS1 所列管理体系审核时间进行调整时，减少量不应超过 30%，对表 QMS3 所列管理体系审核时间进行调整时，ISO9001 标准对应人日减少量不应超过 30%，IS013485 标准对应人日减少量不应超过 20%。

When adjusting the management system audit time listed in Table QMS1, Table EMS1 and Table OHSMS1, the reduction shall not exceed 30%; when adjusting the management system audit time listed in table QMS3, the reduction of the corresponding audit days of ISO9001 standard shall not exceed 30%. The IS013485 standard should not reduce the number of audit days by more than 20%.

5.4.11 对管理体系运行覆盖多个场所的情况，有必要确定是否允许抽样。应记录抽样的理由，并应满足 CNAS-CC11《多场所组织的管理体系审核与认证》中规定。

In cases where the operation of the management system covers multiple sites, it is necessary to determine whether sampling is allowed. The reasons for sampling should be recorded and should meet the requirements of CNAS-CC11(IAF MD1) *The audit and certification of a management system operated by a Multi-Sites organizations*.

如果认证申请方或获证客户在临时场所提供其产品或服务，该临时场所应被纳入审核方案。临时场所可以是较大的项目管理现场，也可以是较小的服务/安装现场。应评估与客户运行相关的管理体系运行失效的风险（对 QMS 为产品或服务输出的控制失效、对 EMS 为环境因素及影响的控制失效、对 OHSMS 为 OHS 风险控制失效），根据该风险评估的结果来确定是否需要访问这些临时场所以及抽样的范围与程度。

If a certification applicant or a certified client provides its products or services in a temporary site, that temporary site shall be incorporated into the audit programs. Temporary sites could range from major project management sites to minor service/installation sites. The need to visit such sites and the extent of sampling should be based on an evaluation of the risk of operational failure of the management system associated with the client's operation (Failure of control for product or service output of QMS, failure of control for environmental factors and effects of EMS, failure of OHS risk control for OHSMS) , and determine based on the results of this risk assessment.

对QMS和EMS，所选取的临时场所样本宜代表客户的认证范围、能力需求和不同服务的范围，并已考虑了活动的规模和类型、 进行中的项目不同阶段以及相关的环境因素及影响。

For QMS and EMS, the sample of sites selected should represent the range of the client's scope of certification, competency needs and service variations having given consideration to sizes and types of activities, and the various stages of projects in progress and associated environmental aspects and impacts.

对于 OHSMS 认证覆盖多个场所的情况，应基于与活动和过程的性质相关的 OHS 风险程度的评价，确定认证范围内的每个场所可否抽样，即使一个场所与其他场所有类似的过程或制造类似的产品，也应考虑每个场所的业务活动（技术、设备、使用和存储的危险材料的数量、工作环境、场所等）之间的差异。所选取的临时场样本宜代表客户认证范围、活动和过程的规模和类型、所涉及的危险源相关 OHS 风险类型、以及项目进行的不同阶段。通过外部执行职能和过程活动相关的 OHS 风险、合同协议、被另一认证机构认证、内部审核制度、事故统计和未遂事件统计等影响因素来确定是否对所有外包场所都必须进行抽样。

For OHSMS, the sites included in sampling should represent the client's scope of certification, sizes and types of activities and processes, type of hazards involved and associated OHS risks, and stages of projects in progress, even if one site has similar processes or manufactures similar products to other sites. The differences between the business activities of each site (technology, equipment, amount of hazardous materials used and stored, working environment, premises, etc.) should also be taken into account. The sample of temporary sites selected should be representative of the scope of client certification, the size and type of activities and processes, the type of hazard related OHS risk involved, and the different stages of the project. Factors such as OHS risks associated with external executive functions and process activities, contractual agreements, certification by another certification body, internal audit systems, accident statistics and near missed statistics are used to determine whether all outsourcing sites must be sampled.

5.4.12 如果客户外包其部分职能和过程，由另一个组织的场所提供产品或服务，CMD 应确定客户对外包方所采用的控制方式和控制范围，以确保外部提供的职能和过程不会对管理体系有效性（包括外包方向其客户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, it is the responsibility of CMD to 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 clients or to control its environmental aspects or to control its OH&S risks, and commitments to comply with legal requirements.

对QMS和EMS，CMD应评估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，甚至还可包括收集对供方有效性水平的反馈进行风险评估，确定对客户管理体系的有效性的影响。必要时，对外包方进行审核，考虑到客户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。 应确定任何附加的审核时间。

For QMS and EMS, CMD 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, client 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.

对 OHSMS，CMD 应验证客户的 OHSMS 是否涵盖这些场所外的活动（尽管另一个组织具有其 OHSMS 的责任）。应策划客户 OHSMS 范围内对外包给外部供方的过程或职能的控制以及收集对供方有效性水平的反馈等进行风险评估，确定客户的 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 绩效和符合性影响。

包含于客户 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。在确定审核时间时，应考虑初次认证审核中、以及每次监督和再认证审核前对其进行核实，定期审核这些员工工作的场所。

For OHSMS, CMD should verify that the client's OHSMS covers activities outside of these premises (although another organization has responsibility for its OHSMS). Risk assessment shall be conducted by planning the control of processes or functions outsourced to external suppliers within the scope of the Client's OHSMS and collecting feedback on the supplier's effectiveness level to determine the effectiveness of the client's OHSMS in managing outsourcing activities and the impact of outsourcing activities on the OHS performance and compliance of its own activities and processes. Contractor personnel working on the organization's site shall be interviewed to assess their OHS awareness as part of the process included in the Client's OHSMS scope. When determining the timing of the audit, consider verifying them during the initial certification audit, as well as before each supervision and recertification audit, and periodically audit the premises where these employees work.

5.5 管理体系认证初次审核（第一阶段+第二阶段）

Initial Audit of Management system Certification (Stage1 + Stage2)

5.5.1 确定用于管理体系非现场组合活动的审核时间，不宜使现场总的管理体系认证 审核时间少于上文 5.4 条款计算出合同评审时间的 80%。需要更多的时间来进行策划和（或）编写报告不是减少现场管理体系认证审核时间的理由。

To determine the audit time for off-site management system portfolio activities, it is not appropriate to make the total on-site management system certification audit time less than 80% of the time calculated in stage of contract review in according with Article 5.4 above. The need for more time to plan and/or prepare reports is not a reason to reduce the time required for a site management system certification audit.

5.5.2 上述表 QMS1、表 EMS1 和表 OHSMS1 所列管理体系审核时间分别为 QMS、EMS、OHSMS 初次审核（第一阶段+第二阶段）时间的确定提供了起始点。

The management system audit time listed in Table QMS1, Table EMS1 and Table OHSMS1 above provides the starting point for determining the initial audit

time (stage 1 + stage 2) of QMS, EMS and OHSMS respectively.

5.5.3 在确定的审核范围内，为对组织的管理体系实施完整而有效的审核分配足够的时间。合同评审时确定的审核时间以及其理由应保留记录。应明确覆盖整个认证范围而分配时间的详细信息。

Allocate sufficient time to conduct a complete and effective audit of the organization's management system within the defined scope of the audit. Records shall be kept of the time and reasons for the audit as determined during the contract review. Details of the time allocation covering the entire scope of certification should be clear.

5.5.4 合同评审中确定的审核时间及其理由，应作为认证合同的一部分项向客户组织提供。

The timing of the audit and the reasons for it as determined in the contract review shall be provided to the Client organization as part of the certification contract.

5.5.5 认证审核中可以包括使用远程审核的技术，例如基于网络的交互式协作，网络会议，电视电话会议和（或）通过电子化方式验证客户的过程。在策划一项审核中采用远程审核活动，应适用 CNAS-CC14 中规定的要求。这些活动应在审核计划中得到标识，并可以考虑将用于这些活动的时间计入总的管理体系认证审核时间。

Certification audits may include techniques that use remote audits, such as web-based interactive collaboration, web conferencing, teleconferencing and/or the process of verifying the client electronically. The use of remote audit activities in planning an audit shall apply the requirements set out in CNAS-CC14. These activities should be identified in the audit plan and consideration may be given to counting the time spent on these activities towards the overall management system certification audit.

对 OHSMS，应用远程审核的活动仅限于对文件/记录的评审、对员工及工作人员访谈。此外对现场活动及 OHS 风险控制不能采取远程审核技术。

For OHSMS, the activities for which remote auditing is applied are limited to the review of documents/records and interviews with employees and staff. In addition, remote audit technology cannot be adopted for on-site activities and OHS risk

control.

在审核中采用远程审核或 ICT 技术，需要在策划审核方案、制定审核计划时予以考虑，并确定采用远程审核及 ICT 的限制（包括所采用形式、所涉及的内容、所占审核时间比例等方面的限制）以保证审核活动的充分性与策划的合理性；除特定认证方案另有规定，初次认证、以及通常每年度监督保持与再认证的审核活动需包括访问组织现场的现场审核。

The use of remote auditing or ICT technology in auditing should be taken into account when planning auditing programs and formulating auditing plans, and the restrictions on the use of remote auditing and ICT (including restrictions on the form adopted, the content involved, the proportion of auditing time, etc.) should be determined to ensure the adequacy of auditing activities and the rationality of planning. Unless otherwise specified by the specific certification program, the initial certification, as well as the audit activities that typically involve annual surveillance maintenance and recertification, shall include an on-site audit visit to the organization's site.

5.6 监督与再认证审核时间的确定

Determine the audit time of supervision and recertification

5.6.1 监督审核的总时间应不少于初次认证审核（第 1 阶段+第 2 阶段）时间的 1/2。CMD 将策划每次监督审核时间，包括收集客户与认证有关的更新信息，以便考虑客户的组织、体系成熟度等方面的变化，以确定监督审核时间是否需要调整。

The total surveillance audit time should not be less than 1/2 of the time of the initial certification audit (Stage 1 + Stage 2). CMD will plan the time of each surveillance audit, including collecting the updated information related to the certification of the client, in order to consider the changes in the client's organization, system maturity, etc., to determine whether the surveillance audit time needs to be adjusted.

5.6.2 再认证/复评的总时间应根据更新的客户信息考虑。如果再认证/复评组织的基本信息（如：场所、有效人数、覆盖产品、认证标准等）不变，则再认证/复评的总时间约为初次认证审核（第 1 阶段+第 2 阶段）时间的 70%。管理体系审核时间应考虑管理体系绩效评价的结果。对管理体系绩效评价本身并不作为再认证审核时间的一

部分。

The total time for recertification/re-evaluation should be considered based on updated client information. If the basic information of the recertification/re-evaluation organization (e.g., location, effective number of personnel, covered products, certification criteria, etc.) is unchanged, the total time for recertification/re-evaluation is approximately 70% of the time of the initial certification audit (stage 1 + stage 2). Management system audit time should take into account the results of management system performance evaluation. The evaluation of management system performance itself is not part of the recertification audit time.

5.6.3 监督和再认证时应确认组织 IMS 的一体化程度变化，以确保审核时间适宜性。

Surveillance and recertification should identify changes in the level of integration of the organization's IMS to ensure appropriate audit timing.

5.6.4 监督、再认证/复评审核时间通常情况下不能少于 1 个审核人日，否则可能影响审核有效性。

Surveillance, recertification/re-evaluation audit time is usually not less than 1 auditor day, otherwise it may affect the effectiveness of the audit.

5.7 调整管理体系审核时间考虑的因素

Factors to consider when adjusting the management system audit time

在调整审核时间时，需要考虑下列因素（但不限于这些因素）：

The following factors need to be taken into account (but are not limited to) when adjusting the audit time:

5.7.1 所有管理体系增加审核时间的考虑因素：

Factors to be considered to increase the audit time of all management systems

a) 多场所或需要访问临时场所（如安装现场）；

Multiple sites or need to visit temporary sites (such as installation sites).

b) 审核需要使用汉语以外的语言；

The audit shall be conducted in languages other than Chinese.

c） 人员数量大、现场大的大型组织；

Large organizations with large numbers of personnel and large sites.

d） 覆盖着高度复杂的、特殊的过程或数量较多的互不相同的活动（一个技术领域以上的）；

Covering highly complex, specialized processes or a large number of distinct activities (more than one technical area).

e） 受法规管制的程度较高（例如食品、医疗器械、医院等领域）。

High degree of regulatory control (e.g. food, medical devices, hospitals, etc.).

5.7.2 仅适用于 QMS 增加审核时间的考虑因素：

Considerations for increasing audit time (QMS only):

a）被划为高风险的活动（见附录A的表QMS2）；

Activities classified as high-risk (see Table QMS2 in Appendix A).

b）外包职能或过程。

Outsourced functions or processes.

c）制造商使用供应商提供对医疗器械功能和/或用户安全或成品（包括自有标签产品）至关重要的工艺或零件。当制造商不能提供足够的证据证明符合审核标准时，可以允许每个供应商有额外的时间接受审核；（ISO13485标准MDQMS认证适用）.

Manufacturers use suppliers to provide processes or parts that are critical to the function and/or safety of the user or the finished product (including private label products). Where the manufacturer cannot provide sufficient evidence of compliance with the audit criteria, each supplier may be allowed additional time to be audited; (ISO13485 MDQMS certification applicable).

d）制造商的法规遵从性差；（ISO13485标准MDQMS认证适用）.

Poor regulatory compliance by manufacturers (ISO13485 MDQMS certification applicable).

e）多班次、生产线数量等可能会增加审核时间；（ISO13485标准MDQMS认证适用）

Multiple shifts, number of production lines, etc., may increase the audit time

(ISO13485 MDQMS certification applicable).

5.7.3 仅适用于 EMS 增加审核时间的考虑因素：

Considerations for increasing audit time (EMS only):

a）同行业典型情况相比，受纳环境的敏感度较高；

Higher sensitivity to the receiving environment than is typical in the industry.

b）相关方的意见；

Views of interested parties.

c）有必要增加审核时间的间接因素；

Indirect factors that necessitate an increase in audit time.

d）组织所属行业的附加的或特殊的环境因素或法规要求；

Additional or special environmental factors or regulatory requirements of the industry to which the organization belongs.

e）环境事故的风险，以及作为事件后果产生的或可能发生的影响，事故和潜在的紧急情况，之前由于组织原因发生过的环境问题；

The risk of environmental accidents, as well as the effects arising or likely to occur as a consequence of the event, accidents and potential emergencies.

Environmental problems that have occurred before due to organizational reasons.

f）外包职能或过程。

Outsourced functions or processes.

5.7.4 仅适用于 OHSMS 增加审核时间的考虑因素：

Considerations for increasing audit time (OHSMS only):

a）相关方的意见；

Views of interested parties.

b）事故和职业病发生率高于行业平均水平；

The incidence of accidents and occupational diseases is higher than the industry average.

c）组织的场所存在公众人员（如：医院、学校、机场、火车站、港口、公共交通运输）；

Public persons are present in the organization's premises (e.g. hospitals,

schools, airports, railway stations, ports, public transport).

d）组织正面临与OHS相关的法律诉讼（取决于所涉及风险的严重程度和影响）；

The organization is facing legal action related to OHS (depending on the severity and impact of the risks involved).

e）承包商公司（次级承包商公司）及其雇员临时性地大量出现，导致复杂程度或OHS风险增加（如：定期启停的炼油厂、化工厂、钢铁厂和其他大型工业联合体）；

Contractor companies (subcontractor companies) and their employees are present in large numbers on a temporary basis, resulting in increased complexity or OHS risk (e.g., refineries, chemical plants, steel mills and other large industrial complexes that start and stop regularly).

f）根据适用的国家法规和/或风险评估文件，危险物质存在的数量使工厂面临重大工业事故的风险；

According to applicable national regulations and/or risk assessment documents, the amount of hazardous substances present exposes the plant to the risk of a major industrial accident.

g）认证范围内包含境外场所的组织（如果不熟悉法律法规和语言）。

Organizations that include foreign sites within the scope of certification (if unfamiliar with laws, regulations and language).

5.7.5 减少审核时间的考虑因素：

Considerations for reducing audit time:

a) （仅适用于QMS）客户不负责设计工作,或体系删减了标准的其它要素;

The client is not responsible for the design work, or the management system cuts out other elements of the standard (QMS only).

b) 与人员数量相比，现场很小且简单；

The site is small and simple compared to the number of personnel.

c) 体系成熟；

The management system has matured.

d) 对客户的管理体系已有的了解，如已对另一标准进行认证，对OHSMS这意味着

在其他自愿性OHSMS方案中已经认证；

Existing knowledge of the client's management system. Such as certification to another standard. For OHSMS, this means that certification has been made in other voluntary OHSMS programme.

e) 客户为认证所做的准备，如已取得了CNAS认可的相同认证标准的认证；对OHSMS意味着已经接受国家主管部门定期对其进行强制性政府OHSMS方案的审核；

The client's preparation for certification. Such as having obtained certification of the same certification standards accredited by CNAS. For OHSMS, it means that it has been regularly audited by the national authorities for the mandatory government OHSMS programme.

f) 覆盖过程的复杂程度低，如：过程仅包含单一的一般性

The complexity of the coverage process is low. for example, the process contains only a single generality.

g) 活动（例如仅包含服务）；所有班次都实施相同的活动,且有适当证据表明所有班次的表现相同（对OHSMS不适用）；

Activities (such as services only). All shifts implement the same activities and there is appropriate evidence that all shifts perform the same (not applicable to OHSMS).

h) 重复性过程；

A repetitive process.

i) 产品风险很低（对OHSMS不适用）；

Low product risk (not applicable to OHSMS).

j) 自动化程度高（对OHSMS不适用）；

High degree of automation (not applicable to OHSMS).

k) 有一部分员工在组织的场所外工作,如销售人员、司机、服务人员等，可通过记录审查来对其活动是否符合体系要求充分地审核（对OHSMS不适用）；

Some employees work outside the organization's premises. For example, sales personnel, drivers, service personnel, etc., can fully audit whether their activities meet the requirements of the system through record review (not applicable to OHSMS).

l） 申请认证企业的范围不包括制造，而是批发、零售、运输或设备维修活动的（ISO13485标准MDQMS认证适用）；

The scope of the application for certification does not include manufacturing, but wholesale, retail, transportation or equipment maintenance activities (ISO13485 MDQMS certification applies).

m） 自上次审核以来制造商产品范围的缩减（ISO13485标准MDQMS认证适用）；

Reduction in the manufacturer's product scope since the last audit (ISO13485 MDQMS certification applies).

n） 自上次审计以来设计/生产过程的减少（ISO13485标准MDQMS认证适用）；

Reduction in design/production processes since the last audit (ISO13485 MDQMS certification applies).

o） 仅针对“分销或运输服务”的认证范围执行的审核时间“可从表QMS3中ISO13485标准对应人日最多减少50%（ISO13485标准MDQMS认证适用）。

The audit time performed only for the certification scope of "distribution or transportation services" can be reduced by up to 50% from the ISO13485 audit days in Table QMS3 (applicable to the ISO13485 MDQMS certification).

5.7.6 在确定审核时间时，宜考虑客户的体系、过程和产品或服务的所有属性，并根据上述因素合理调整审核时间，增加审核时间的因素与减少审核时间的因素对审核时间的影响可以相互抵消，审核时间的调整应合理并确保审核的有效性，应记录任何调整的理由并保留记录。

When determining the audit time, it is advisable to take into account all attributes of the client's system, process and product or service, and adjust the audit time reasonably according to the above factors. The impact of factors increasing the audit time and reducing the audit time can offset each other. The adjustment of the audit time should be reasonable and ensure the effectiveness of the audit, and the reasons for any adjustment should be recorded and kept.

5.7.7 多管理体系标准一体化审核时间影响

Impact of multi-management system standard integrated audit time.

5.7.7.1为涵盖了两个或以上管理体系标准的 IMS 审核确定审核时间，应：

To determine the audit time of an IMS that covers two or more management system standards, you should:

a）按照上述要求分别针对每一个管理体系标准计算所要求的审核时间；

Calculate the required audit time for each management system standard in accordance with the above requirements.

b）将分别计算出的每个管理体系标准的审核时间相加，计算出IMS 审核时间的起始点T（例如T=A+B+C）；

Add the calculated audit time of each management system standard to calculate the starting point T of the IMS audit time (e.g. T=A+B+C).

c）考虑可以增加或减少所需审核时间的影响因素，并在确定的起始点(T)基础上调整审核时间（见图A.1）；

Consider influencing factors that can increase or decrease the required audit time and adjust the audit time based on the identified starting point (T) (see Figure A.1)

增加审核时间的因素应包括但不限于：

Factors for increasing audit time shall include, but are not limited to:

- IMS 审核较单一的管理体系审核的复杂性。

  IMS audits are more complex than a single management system audit.

减少审核时间的因素应包括但不限于：

Factors that reduce audit time should include, but are not limited to:

- 组织管理体系的一体化程度，应从以下方面进行考虑，但不限于：

  The level of integration of the organizational management system should be considered from the following aspects, but is not limited to:

  （1） 一套整合的文件，适宜时，包括适度融合的作业文件；

  An integrated set of documents, including, where appropriate, moderately integrated operational documents.

（2） 考虑总体经营战略和计划的管理评审；

Management reviews that consider overall business strategies and plans.

（3） 对内部审核采用的一体化方法；

An integrated approach to internal audits.

（4） 对方针和目标采用的一体化方法；

An integrated approach to policies and objectives.

（5） 对体系过程采用的一体化方法；

An integrated approach to the system process.

（6） 对改进机制（纠正和预防措施、测量和持续改进）采用的一体化方法；

An integrated approach to improvement mechanisms (corrective and preventive measures, measurement and continuous improvement).

（7） 一体化的管理支持和管理职责。

Integrated management support and management responsibilities.

客户的申请信息应包括与一体化程度有关的信息，包括文件、管理体系要素和职责整合的信息，根据客户管理体系满足上述规定的程度，来确定其一体化程度的百分率。如下图A.1中纵坐标为组织管理体系的一体化程度

The client's application information shall include information related to the level of integration, including information on the integration of documents, elements of the management system and responsibilities, and determine the percentage of the level of integration according to the degree to which the client's management system meets the above requirements. In Figure A.1 below, the ordinate is the degree of integration of the organization's management system.

- 组织的人员应对涉及多个管理体系标准问题的能力；

The ability of the organization's personnel to respond to issues

involving multiple management system standards.

- 具有审核多个管理体系标准/规范能力的审核员的可用性。
  Availability of auditors with the ability to audit multiple management system standards/specifications.

下图 A.1 中横坐标为审核组具有的能力程度，按给出的比例乘百分数得到能力程度的百分率：

$$\frac{[(X_1-1)+(X_2-1)+(X_3-1)+\ldots(X_n-1)]}{Z\times(Y-1)}\times 100\%$$

式中：

X_1、X_2、X_3…X_n 为与 IMS 审核范围相关的、审核员具有的标准审核能力的数量。

Y 为 IMS 审核所涵盖的管理体系标准数量。

Z 为审核员的数量。

示例：

一个涵盖了三个不同管理体系标准的 IMS 审核项目，其 IMS 审核组由三名审核员组成，其中一名审核员具备了所有三个标准的审核能力，另一名审核员具备了其中两个标准的审核能力，第三名审核员则具备一个标准的审核能力。

按图 A.1，其横坐标为：

$$\frac{[(3-1)+(2-1)+(1-1)]}{3\times(3-1)}\times 100\%=50\%$$

鉴于组内每个审核员具有至少一个以上审核准则/标准的审核能力，可将由此获得的效率计入上述公式中，以计算可能减少的审核时间。这些包括了：

1）由于首次、末次会议所节省的时间；

2）编制一体化审核报告所节省的时间；

3）优化的后勤所节省的时间；

4）审核组会议所节省的时间；

5）同时审核通用要素所节省的时间，如文件控制。

In figure A.1 below：

Horizontal axis: The extent, given as a ratio to be multiplied by a factor of 100 in order to achieve the extent given as percentage, to which individual audit team members are qualified:

$$\frac{100\ ((X1-1) + (X2-1) + (X3-1) + (Xn-1))}{Z(Y-1)}$$

Where

X1, 2, 3…n is the number of standards for which an auditor is qualified relevant for the scope of the integrated audit;
Y is the number of management system standards to be covered by integrated audit;
Z is the number of auditors.

Example:

An integrated audit team of three auditors covering three different management system standards. One auditor is qualified for all three standards; one auditor is qualified for two of the standards and the other auditor is qualified for one standard.

The percentage figure to be used for the horizontal axis is:

$$100\ \frac{((3-1) + (2-1) + (1-1))}{3(3-1)} = 50\ \%$$

Due to available competence of each auditor to more than one set of audit criteria/standards, efficiencies are gained and go into the calculation of the possible reduction of time in the formula above. These include:

1. Time saved due to one opening and one closing meeting.
2. Time saved as one integrated audit report is produced.
3. Time saved in optimized logistics.
4. Time saved in auditor team meetings.
5. Time saved auditing common elements simultaneously, e.g. document control.

图 A.1 说明了 IMS 审核时间的减少量（%）及其与 IMS 的一体化程度和审核组执行 IMS 审核能力之间的关系：

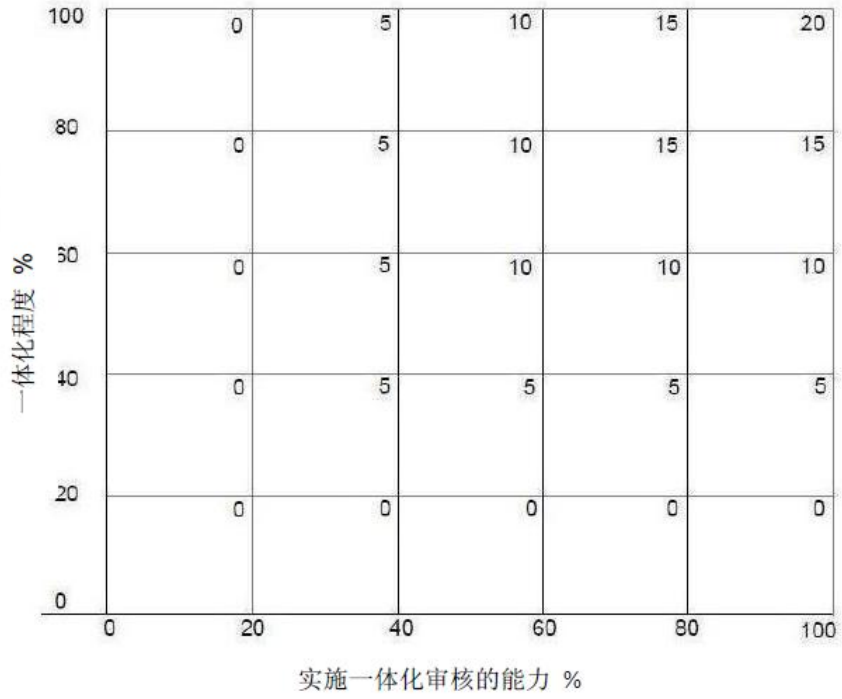
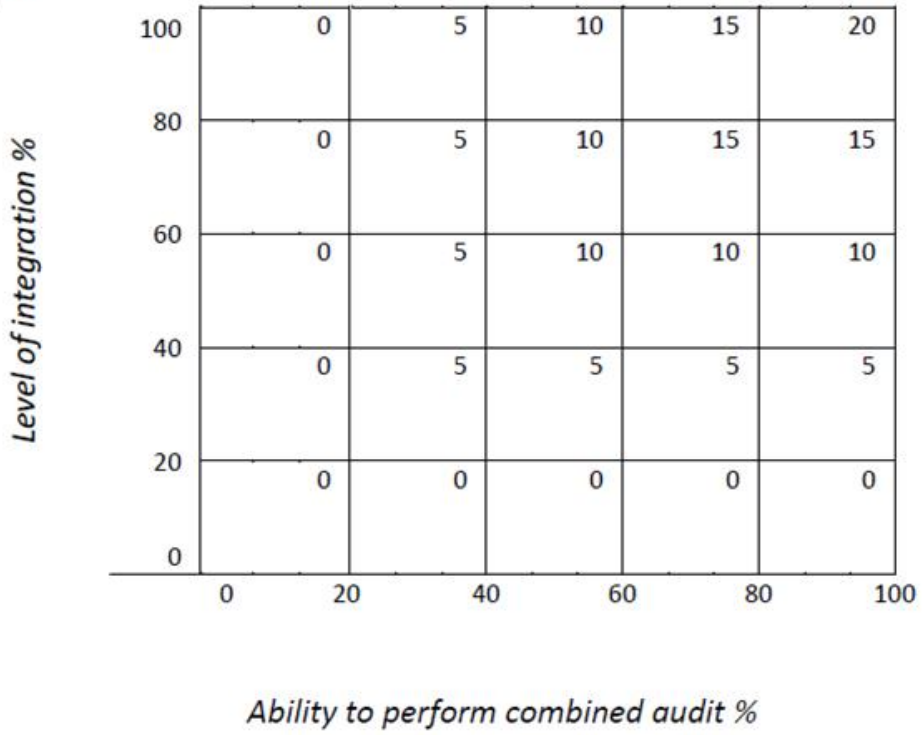


图 A.1

Figure A.1 Illustrates the reduction (%) in integrated audit duration and its relationship to the level of integration and the audit team's ability to perform combined audit %

Figure A.1



5.7.7.2 基于组织所声明的管理体系的一体化程度来确定的 IMS 审核时间，可在一阶段和后续的审核中，根据所确认的组织管理体系的一体化程度来做出调整，并告知顾客。

IMS audit timings can be adjusted in stage1, or in surveillance audits, basing on the confirmed level of integration of the organization's management system and communicated to the client.

5.7.7.3 IMS 审核可能会导致审核时间的增加，但在减少审核时间的情况下，其减少量不应超过起始点 T 的 20%。

IMS audits may result in an increase in audit time, but in the case of a reduction in audit time, the reduction should not exceed 20% of the starting point T.

5.7.7.4 当确定同时进行 ISO 9001 和 ISO 13485（认可）审核所需的时间时，根据表 QMS3 计算的最小审核天数将在 ISO13485 标准对应人日基础上至少增加 25%的时间或按照表 QMS3 中 ISO9001 标准对应人日和 ISO13485 标准对应人日分别核算后求和后，两者中取大者。需要考虑可能需要额外时间的情况，包括范围、有效人员数量等方面的差异。

When determining the required time for conducting an ISO 9001 and ISO 13485 audit together, a minimum of 25% will be added to the minimum number of ISO 13485

audit days calculated as per table QMS3, or summed the ISO9001 audit days and ISO13485 audit days calculated separately in Table QMS3, whichever is greater. Circumstances that may require additional time need to be considered, including differences in scope, effective number of personnel, etc.

5.7.7.5 起始点的计算以 QU 及增加或减少审核时间的合理性应给予记录。

注：减少后不应违反CCAA中认协监〔2013〕102 号《认证机构公平竞争规范——认证价格自律规定》。

The calculation of the starting point and the rationality of increasing or decreasing the audit time shall be recorded.

Note: The reduction should not violate the *CNCA- [2013] No. 102* "*Certification Body Fair competition norms - Certification Price self-discipline Regulations*".

5.8 服务认证审核时间的确定方法

Methodology for determining the audit time of service certification

5.8.1 对于服务认证，初次认证审核基于客户的有效人数按照表 SC1 确定服务认证审核时间起始点，并考虑服务组织的行业特点、规模和运作的复杂程度等相关因素进行调整。

For service certification, the starting point of the initial certification audit is determined according to Table SC1 based on the effective number of personnels, and adjusted considering relevant factors such as the industry characteristics, scale and complexity of operation of the service organization.

表 SC1：服务认证有效人数与审核时间的关系

Table SC1: The relationship between the effective number of personnels and audit time of the service certification

有效人数 Effective number of personnels	审核时间（天） Audit time (days)	有效人数 Effective number of personnels	审核时间（天） Audit time (days)
1-5	1.5	626-875	12
6-10	2	876-1175	13
11-15	2.5	1176-1550	14
16-25	3	1551-2025	15
26-45	4	2026-2675	16

46-65	5	2676-3450	17
66-85	6	3451-4350	18
86-125	7	4351-5450	19
126-175	8	5451-6800	20
176-275	9	6801-8500	21
276-425	10	8501-10700	22
426-625	11	>10700	遵循上述递进规律 Follow progression above

5.8.2 在合同评审时，应按照表 SC1 中拟审核客户的有效人数确定基准审核时间，作为计算审核时间的起始点，然后根据该客户的每个重要因素赋予一个对基准审核时间的增加量或减少量，根据这些因素对基准审核时间进行调整。应记录确定审核时间（包括审核时间的调整）的依据。审核时间的任何减少应确保不能影响审核的有效性。审核时间应覆盖所有的业务范围。

In the contract review, the benchmark audit time shall be determined according to the effective number of personnels to be audited in Table SC1 as the starting point for the calculation of the audit time, and then an increase or decrease in the benchmark audit time shall be assigned to each important factor of the client, and the benchmark audit time shall be adjusted according to these factors. The basis for determining the audit time (including the adjustment of the audit time) shall be documented. Any reduction in audit time should ensure that the effectiveness of the audit is not affected. Audit time should cover all business scopes.

5.8.3 在使用表 SC1 确定服务认证审核时间时，不应计入实习审核员、观察员或技术专家的工作时间。

When using Table SC1 to determine the duration of a service certification audit, the working hours of trainee auditors, observers or technical experts should not be taken into account.

5.8.4 在对表 SC1 所列服务认证审核时间进行调整时，减少量不应超过 30%。

When adjusting the audit time for services certification listed in Table SC1, the reduction should not exceed 30%.

5.8.5 对服务活动覆盖多个场所的情况，有必要确定是否允许抽样，应记录抽样的

理由，并应满足 CNAS-SC25:2017《服务认证机构认可方案》中规定。

In the case of service activities covering multiple sites, it is necessary to determine whether sampling is allowed, the reasons for sampling should be recorded, and should meet the requirements of *CNAS-SC25:2017 Accreditation Scheme for Bodies Providing Certification of Service*.

5.8.6 如果客户外包其部分职能和过程，由另一个组织的场所提供产品或服务，CMD 应确定客户对外包方所采用的控制方式和控制范围，以确保外部提供的职能和过程不会对服务活动产生负面影响。必要时，对外包方进行审核，应确定任何附加的审核时间。

If the client outsources some of its functions and processes to provide products or services from the premises of another organization, CMD shall determine the type and scope of control that the Client employs to the outsourcing party to ensure that externally provided functions and processes do not negatively affect the service activities. If necessary, the contractor shall conduct an audit and determine any additional audit time.

5.9 服务认证初次审核

Initial audit of service certification

5.9.1 确定用于服务认证非现场组合活动的审核时间，不宜使现场总的审核时间少于合同评审时间的 80%。需要更多的时间来进行策划和（或）编写报告不是减少现场管理体系认证审核时间的理由。

Determine the audit time for off-site portfolio activities for service certification, so that the total audit time on site should not be less than 80% of the contract review time. The need for more time to plan and/or prepare reports is not a reason to reduce the time required for a site management system certification audit.

5.9.2 在确定的审核范围内，为对组织的服务活动实施完整而有效的审核分配足够的时间。合同评审时确定的审核时间以及其理由应保留记录。应明确覆盖整个认证范围而分配时间的详细信息。

Allocate sufficient time to conduct a complete and effective audit of the organization's service activities within the defined scope of the audit. Records shall be kept of the time and reasons for the review as determined during the contract

review. Details of the time allocation covering the entire scope of certification should be clear.

5.9.3 认证审核中可以包括使用远程审核的技术，例如基于网络的交互式协作，网络会议，电视电话会议和（或）通过电子化方式验证客户的过程。在策划一项审核中采用远程审核活动，应适用 CNAS-CC14 中规定的要求。这些活动应在审核计划中得到标识，并可以考虑将用于这些活动的时间计入总的管理体系认证审核时间。

Certification audits may include techniques that use remote audits, such as web-based interactive collaboration, web conferencing, teleconferencing and/or the process of verifying the customer electronically. The use of remote audit activities in planning an audit shall apply the requirements set out in CNAS-CC14. These activities should be identified in the audit plan and consideration may be given to counting the time spent on these activities towards the overall management system certification audit.

在审核中采用远程审核或 ICT 技术，需要在策划审核方案、制定审核计划时予以考虑，并确定采用远程审核及 ICT 的限制（包括所采用形式、所涉及的内容、所占审核时间比例等方面的限制）以保证审核活动的充分性与策划的合理性；除特定认证方案另有规定，初次认证以及通常每年度监督保持与再认证的审核活动需包括访问组织现场的现场审核。

The use of remote audit or ICT technology in audit should be taken into account when planning audit programs and formulating audit plans, and the restrictions on the use of remote audit and ICT (including restrictions on the form adopted, the content involved, the proportion of audit time, etc.) should be determined to ensure the adequacy of audit activities and the rationality of planning. Unless otherwise specified by the specific certification program, the initial certification and, typically, the annual surveillance and recertification audit activities shall include an on-site audit visit to the organization's site.

5.10 服务认证监督与再认证审核时间的确定

Service certification surveillance and re-certification audit time determination

5.10.1 监督审核的总时间应不少于初次认证审核时间的 1/2。CMD 将策划每次监督

审核时间，包括收集客户与认证有关的更新信息，以便考虑客户的组织、体系成熟度等方面的变化，以确定监督审核时间是否需要调整。

The total time of surveillance and audit shall not be less than 1/2 of the time of the initial certification audit. CMD will plan the time of each surveillance audit, including collecting the updated information related to the certification of the client, in order to consider the changes in the client's organization, system maturity, etc., to determine whether the surveillance audit time needs to be adjusted.

5.10.2 再认证的总时间应根据更新的客户信息考虑。如果再认证组织的基本信息（如：场所、有效人数、覆盖产品、认证标准等）不变，则再认证的总时间约为初次认证审核时间的 70%。

The total time for recertification should be considered based on updated client information. If the basic information of the recertification organization (such as: location, effective number of personnel, covered products, certification standards, etc.) is unchanged, the total recertification time is about 70% of the initial certification audit time.

5.10.3 监督、再认证审核时间通常情况下不能少于 1 个审核人日，否则可能影响审核有效性。

Surveillance and recertification audit time is usually not less than 1 audit day, otherwise it may affect the effectiveness of the audit.

5.11 调整服务认证审核时间考虑的因素

Factors to be considered in adjusting the service certification audit time

在调整审核时间时，需要考虑下列因素（但不限于这些因素）：

When adjusting the audit time, the following factors need to be considered (but are not limited to these):

a) 服务组织的行业特点、规模和运作的复杂程度；

The industry characteristics, size and operational complexity of the service organization.

b） 服务场所的数量；

Number of service places.

c） 服务类别、评价范围；

Service category and evaluation scope.

d） 技术和规范环境；

Technical and regulatory environment.

e） 服务接触方式；

Service contact mode.

f） 所使用的测评方法和技术；

Assessment methods and techniques used.

g） 服务活动的外包情况；

Outsourcing of service activities.

h） 与服务活动相关联的风险。

Risks associated with service activities.

在确定审核时间时，宜考虑客户服务活动的所有属性，并根据上述因素合理调整审核时间，增加审核时间的因素与减少审核时间的因素对审核时间的影响可以相互抵消，审核时间的调整应合理并确保审核的有效性，应记录任何调整的理由并保留记录。

When determining the audit time, all attributes of client service activities should be taken into account, and the audit time should be reasonably adjusted according to the above factors. The influence of factors increasing and reducing on the audit time can offset each other. The adjustment of the audit time should be reasonable and ensure the effectiveness of the audit.

5.12 对于ISMS认证审核，考到到认证审核的特殊性，可以考虑单独安排审核或者与QES一体化审核组组成联合审核组进行审核，审核时间的确定执行附录A《ISMS认证审核时间确定办法》。

For ISMS certification audit, the particularity of the certification audit can be considered to arrange A separate audit or form a joint audit team with the QES integrated audit team to conduct the audit. The determination of the audit time shall be carried out in Appendix A "Methods for Determining the Time of ISMS Certification Audit".

5.13 管理体系、产品认证、服务认证变更覆盖范围的审核时间

Audit time of Management system, product certification, service certification coverage changes

5.12.1 扩大

Expanding

管理体系、产品认证、服务认证扩大覆盖范围的审核，可分为现场审核和文件审核。扩大的审核时间应考虑所涉及的场所、审核依据标准、过程、产品复杂程度等因素。具体审核费用以双方签订的《认证协议》为准。

The audit of the expanded coverage of management system, product certification and service certification can be divided into on-site audit and document audit. The extended audit time should take into account factors such as the site involved, the criteria against which the audit was conducted, the process, and the complexity of the product. The specific audit fee shall be subject to the *Certification Agreement* signed by both parties.

对于扩大场所、扩大产品生产过程差别较大、包括产品设计且产品结构性能等有变化、审核依据标准有较大变化、服务流程有较大变化等均考虑实施现场扩大审核。现场扩大审核一般不少于1审核人日，并参照本文5.3条款考虑增减审核人日。若现场扩大审核与监督审核或再认证审核一并进行，则现场扩大审核时间可减少0.5审核人日。

For the expanding of the site, the expanding of the product production process, the difference is large, including the product design and product structure performance changes, the audit according to the standard has a greater change, the service process has a greater change are considered to implement the on-site expanding audit. The expanded on-site audit is generally not less than 1 audit day, and consider increasing or decreasing the audit day with reference to article 5.3 of this document. If the site expanding audit is conducted in conjunction with the surveillance audit or recertification audit, the site expanding audit time can be reduced by 0.5 audit days.

对于在已覆盖的范围内同类产品（包括规格型号）扩大，可考虑文件扩大审核。文件扩大审核的时间可参照本文5.3条款考虑增减审核人日，一般为0.5审核人日。

For the expanding of similar products (including specifications and models) in the

covered scope, the document expanding audit can be considered. The time of documents expanding audit can be considered by referring to Article 5.3 of this document to increase or decrease the number of audit days, generally 0.5 audit days.

5.12.2 缩小

Reducing

对于在已覆盖的范围内产品（包括规格型号）缩小，审核人日无变化。

For the reducing of the scope of covered products (including specifications and models), the audit days do not change.

附录A

Appendix A

ISMS 认证审核确定办法

Methods for Determining ISMS Certification Audits

ISMS 的认证收费标准及审核人日管理办法（以下简称本管理办法、或管理办法）仅为信息安全管理体系审核管理之用，为 CMD-CR-010 文件的附件。遵守 CMD-CR-010 的基本规定，如“目的与使用范围”、“基本原则”、“定义”中审核人天等基本规定。

The certification fee standards and audit day management methods for ISMS (hereinafter referred to as this management method or management method) are solely for the management of information security management system audits and serve as an attachment to document CMD-CR-010. Comply with the basic provisions of CMD-CR-010, such as 'Purpose and Scope of Use', 'Basic Principles ', and 'Definitions ', including the basic provisions regarding audit days.

本管理办法的制定工作依据了 CNAS-SC170《信息安全管理体系机构认可方案》、CNAS-CC170/GB/T 25067-2020 《信息技术安全技术信息安全管理体系审核和认证机构要求》规定，以及 GB/T 27021.1-2017《合规评定 管理体系审核认证机构要求》有关的进一步要求。

The formulation of this management method is based on CNAS-SC170 *Accreditation Scheme for ISMS Certification Bodies*, CNAS-CC170/ISO/IEC27006:2015 *Information technology - security techniques - Requirements for bodies providing audit and certification of information security management system*, and further requirements related to ISO/IEC 17021-1 - 2017 *Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements.*

本管理办法为 CMD 制定有关确定 ISMS 的审核时间的程序提供了最低要求和指南，以便其在对组织（或称客户）涉及广泛的活动且具有不同规模和复杂度的 ISMS 范围实施认证时确定所需的时间。针对每一个客户及其被认证的 ISMS, 识别初次认证、监督审核和再认证审核所需花费的审核时间。在审核策划阶段，使用本文件可以确保使用一致的方法来确定适当的审核时间，达到合规性。此外，审核策划管理人员可以根据审核过程(尤其是第一阶段)的发现(如 ISMS 范围的复杂度的不同评价结果，或范围中增加的场所)来调整审核时间。

This management approach provides CMD with the minimum requirements and guidelines for determining the audit time for ISMS, so that it can establish the necessary time when implementing certification for organizations (also referred to as clients) that involve a wide range of activities with varying scales and complexities of ISMS scope. For each client and their certified ISMS, identify the audit time required for initial certification, surveillance audits, and recertification audits. During the audit planning stage, using this document can ensure a consistent approach to determining the appropriate audit time to achieve compliance. In addition, the audit planning manager can adjust the audit time based on findings from the audit process (especially the stage 1), such as varying evaluation results of the complexity of the ISMS scope or additional locations added to the scope.

本管理办法带有附录 A.1。附录 A.1 给出了审核时间计算的示例，对本管理办法的应用做出了说明。该方法的基本假设是，确定审核时间的计算方案宜：

This management method includes Appendix A.1 which provides an example of the calculation of audit time and explains the application of this management method. The basic assumption of this method is that the calculation scheme for determining audit time should:

a) 仅考虑那些能够被确定和证实的属性；

   Only consider attributes that can be identified and verified.

b) 足够简便，以得到认证机构的有效应用；

Be simple enough to allow for effective application by the certification body.

c) 足够复杂，以能够体现充分的差异。

Be complex enough to reflect sufficient differences.

1 ISMS 相关概念

Concepts related to ISMS

1.1 在组织控制下工作的人员的数量

The number of personnel working under the control of the organization

在确定审核时间时，应以认证范围内所有班次中受组织控制的工作人员的总数为起点。在组织控制下工作的兼职人员，按照其工作小时数与在组织控制下工作的全职雇员的工作小时数的比例，计入在组织控制下工作的人员的数量。具体比例的确定，取决于兼职人员工作小时数与一名全职雇员工作小时数的比较。

When determining audit time, the starting point should be the total number of staff under the control of the organization across all shifts within the certification scope.
The number of personnel working under the organization's control is calculated based on the ratio of their working hours to the working hours of full-time employees under the organization's control. The specific ratio is determined by comparing the working hours of part-time personnel to those of a full-time employee.

1.2 临时场所

Temporary location

临时场所是认证文件所注明的场所之外的位置，其活动在认证范围内并在规定的时间周期内实施。此类场所的范围可从大项目管理场所到较小的服务或安装场所。在确定对这些场所的访问需求及其抽样范围时，宜基于对在临时场所发生的不符合而导致没能满足信息安全目标的风险的评价。所选择的场所样本宜考虑活动的规模与类型和实施中的项目的不同阶段，并体现组织的能力需求和服务变化的范围。对于一般的抽样机构考虑使用基于抽样的方法进行多场所认证审核：

A temporary location is a site outside of the locations specified in the certification documents, where activities are carried out within the certification scope and implemented within a specified time period. The scope of such locations can range from large project management sites to smaller service or installation sites. When determining the access requirements for these locations and their sampling scope, it is advisable to base this on an assessment of the risks

associated with non-conformities occurring at temporary locations that could lead to the failure to meet information security objectives. The selected sample of locations should consider the scale and type of activities and the different stages of implementation, reflecting the organization's capability requirements and the scope of service changes. For general sampling, organizations should consider using a sampling-based approach for multi-site certification audits:

a）所有的场所在同一个 ISMS 下运行且该 ISMS 实行集中统一管理、审核和管理评审；

All locations operate under the same ISMS, and this ISMS is managed, audited, and reviewed centrally

b）所有的场所都包含在客户的 ISMS 内部审核方案中；

All locations are included in the client's ISMS internal audit program.

c）所有的场所都包含在客户的 ISMS 管理评审方案中。

All locations are included in the client's ISMS management review program.

2 确定初次认证审核时间的程序

Procedure for determining the timing of the initial certification audit

2.1 总则

General principles

审核时间的计算，应遵从本文件规定的程序。

The calculation of audit time should follow the procedures specified in this document.

2.2 远程审核

Remote audit

如果使用了远程审核技术(例如：基于网络的交互式协作、网络会议、电话会议和/或电子验证组织 的过程)与组织接触，这些活动宜在审核计划中加以识别,可以考虑将其作为总的“现场审核时间”的一部分。

If remote audit technologies (e.g., web-based interactive collaboration, web conferencing, teleconferencing, and/or electronic verification processes) are used to engage with the organization, these activities should be identified in the audit plan and may be considered as part of the overall on-site audit time.

如果认证机构制定的审核计划中远程审核活动占据了大于 30%的现场审核时间，认证机构宜证实审核计划的合理性，并在审核计划实施前得到认可机构的专门批准。

If remote audit activities account for more than 30% of the on-site audit time in the audit plan

established by the certification body, the certification body should confirm the rationality of the audit plan and obtain special approval from the accreditation body before implementing the audit plan.

注：现场审核时间是指分配给单个场所的现场审核时间。对远程场所的电子审核被视为远程审核，即使电子审核是在组织的物理场所进行。

Note: On-site audit time refers to the time allocated for on-site audits at a single location. Electronic audits of remote locations are considered remote audits, even if the electronic audit is conducted at the client's physical location.

2.3 审核时间的计算

Calculation of audit time

表 1 给出了初次审核天数平均值的起点[这个数值包括初次审核 (第一阶段和第二阶段)的天数]。对于覆盖了给定数量的（在组织控制下工作人员）情况下，对于相似规模的 ISMS 范围，有些需要较多的审核时间，有些需要较少的审核时间。

Table 1 provides the starting point for the average number of days for the initial audit [this value includes the days for the initial audit (stage 1 and stage 2)]. For cases under a given number of personnel (in the organization-controlled workforce), for ISMS scopes of similar size, some require more audit time while others require less audit time.

计算审核时间时，首先基于在组织控制下工作的、所有班次的人员的总数来确定审核时间的起点；然后根据适用于所审核的ISMS范围的重要因素来调整它，通过对每一个因素赋予增、减权重来修正基数；需要明确是使用表1 时应考虑调整的促成因素和最大偏离的限制(见本章2.4和2.5)。

When calculating audit time, first determine the starting point for audit time based on the total number of personnel working in all shifts under the organization's control. Then adjust it according to the significant factors applicable to the audited ISMS scope, by assigning weights to each factor to modify the baseline. When using Table 1, It is necessary to clarify the facilitating factors to be considered for adjustments and the limits of maximum deviation (see sections 2.4 and 2.5 of this chapter).

2.4 调整审核时间的因素

Factors Affecting Audit Time

不能孤立地使用表 1 所安排的时间，还应考虑以下因素。

The time arranged in Table 1 should not be used in isolation, the following factors should

also be considered.

2.4.1 这些因素与 ISMS 复杂程度相关，并因此与 ISMS 审核工作量相关

These factors are related to the complexity of the ISMS and therefore are related to the workload of the ISMS audit.

a) ISMS 的复杂程度(例如，信息的关键程度、ISMS 的风险状况)；

The complexity of the ISMS (e.g., the criticality of the information, the risk status of the ISMS).

b) ISMS 范围内所开展的业务的类型；

The types of business activities conducted within the scope of the ISMS.

c) 以往已证实的 ISMS 绩效；

The previously confirmed performance of the ISMS.

d) 在 ISMS 各部分的实施过程中，所应用的技术水平和多样性[例如，不同 IT 平台的数量、隔离网络的数量；

The level and diversity of technology applied during the implementation of various parts of the ISMS, e.g., the number of different IT platforms, the number of isolated networks.

e) ISMS 范围内所使用的外包和第三方安排的程度；

The extent of outsourcing and third-party arrangements used within the scope of the ISMS.

f) 信息系统开发的程度；

The degree of information system development.

g) 场所的数量和灾难恢复场所的数量；

The number of locations and the number of disaster recovery sites.

h) 对于监督或再认证审核：与 ISMS 相关的变更的数量和程度，具体针对获证客户的变更通知，认证机构做出在法律上具有强制实施力的安排,以确保获证客户即时将可能影响管理体系持续满足认证标准要求的能力的事宜通知认证机构，包括（不限于）符合 GB/T27021.1—2017 中 8.5.3 要求的 5 个方面的变更，认证机构应采取适当的行动：

For surveillance or re-certification audits: the number and extent of changes related to the ISMS, specifically regarding change notifications for certified clients, the certification body shall make legally enforceable arrangements to ensure that certified clients promptly notify the certification body of any matters that may affect the management system's ongoing ability to meet certification standard requirements, including (but not limited to)

changes in the five aspects required by ISO/IEC 17021.1-2015 section 8.5.3. The certification body should take appropriate actions:

① 法律地位、经营状况、组织状态或所有权；

The legal, commercial, organizational status or ownership;

② 组织和管理层(如关键的管理、决策或技术人员)；

Organization and management (e.g. key managerial, decision-making or technical staff);

③ 联系地址和场所；

Contact address and sites;

④ 获证管理体系覆盖的运作范围；

Scope of operations under the certified management system;

⑤ 管理体系和过程的重大变更。

Major changes to the management system and processes.

在计算审核时间时如何考虑这些不同因素的示例见本管理办法的**附录 A.1**。

An example of how to consider these different factors when calculating audit time see Appendix A.1 of this management measure.

表 1 审核时间表

Table 1 Audit Schedule

在组织控制下工作的人员的数量 Number of personnel Working under the control of the organization	ISMS初次审核时间（审核人日） ISMS Initial Audit Time (Audit days)	在组织控制下工作的人员的数量 Number of personnel Working under the control of the organization	ISMS初次审核时间（审核人日） ISMS Initial Audit Time (Audit days)
1 ~ 10	5	876 ~ 1175	18.5
11 ~ 15	6	1176 ~ 1550	19.5
16 ~ 25	7	1551 ~ 2025	21
26 ~ 45	8.5	2026 ~ 2675	22
46 ~ 65	10	2676 ~ 3450	23
66 ~ 85	11	3451 ~ 4350	24
86 ~ 125	12	4351 ~ 5450	25
126 ~ 175	13	5451 ~ 6800	26
176 ~ 275	14	6801 ~ 8500	27
276 ~ 425	15	8501 ~ 10700	28
426 ~ 625	16.5	>10700	沿用以上规律

			Follow progression above
626 ~ 875	17.5		

2.4.2 需要增加审核时间的其他因，例如：

Other factors that require additional audit time, example:

a) 复杂的后勤，在 ISMS 范围中涉及不止一处建筑物或地点；

Complex logistics involving more than one building or location within the ISMS scope;

b) 员工的语言超过一种(需要翻译或审核员个人无法独立工作),提供的文件使用了一种以上的语言；

Employees speak more than one language (requiring translation or the auditor cannot work independently), and the provided documents are in more than one language;

c) 为了确认管理体系认证范围内永久场所的活动，需要访问临时场所的活动；

To confirm the activities at the permanent locations within the scope of the management system certification, it is necessary to access the activities at temporary locations;

d) 适用于 ISMS 的标准和法规数量很多。

There are many standards and regulations applicable to ISMS.

2.4.3 允许减少审核时间的因素，例如：

Factors that allow for a reduction in audit time, example:

a) 没有风险或者低风险的产品/过程；

Products/processes with no risk or low risk;

b) 过程只涉及单一的常规活动(例如，只有服务)；

The process only involves a single routine activity (for example, only services);

c) 在组织控制下工作的雇员大部分是从事相同的任务；

Most employees working under the organization's control are engaged in the same tasks;

d) 对组织已经有些了解(例如，如果组织获得了同一个认证机构的、另一个标准的认证)；

Some understanding of the organization already exists (for example, if the organization has obtained certification for another standard from the same certification body);

e) 客户的认证准备情况较好(例如已经获得了另一个第三方认证方案的认证或承认)；

The client's certification preparation is relatively good (for example, they have already obtained certification or recognition from another third-party certification scheme);

f) 高度成熟的管理体系。

A highly mature management system.

当认证客户或获证组织在临时场所提供其产品或服务时，将对这类场所的评价纳入到认证审核和监督方案中是十分重要的。

When the certified client or certified organization provides its products or services at a temporary location, it is very important to include the evaluation of such locations in the certification audit and surveillance program.

宜考虑上述因素，并根据这些因素对审核时间做出调整。这些因素可证实一次有效审核所需更多或更少的审核时间的合理性。增加时间的因素可被减少时间的因素冲抵。在任何情况下，对审核时间表中的时间调整，应保持足够的证据和记录来证实其变化的合理性。

The above factors should be considered, and adjustments to the audit time should be made based on these factors. These factors can justify the rationality of requiring more or less audit time for an effective audit. Factors that increase time can be offset by factors that reduce time. Under no circumstances should adjustments to the audit schedule be made without sufficient evidence and records to substantiate the rationality of the changes.

2.5 对审核时间偏离的限制

Limitations on deviations from audit time

为了确保能够实施有效的审核并确保可靠和可比较的结果，对表 1 中审核时间的减少不应超过 **30%** 。应确定偏离审核时间表的适当理由，并形成文件。

To ensure that effective audits can be conducted and reliable and comparable results are achieved, reductions in audit time as outlined in Table 1 should not exceed **30%**. Appropriate justifications for deviations from the audit schedule should be determined and documented.

2.6 现场审核时间

On-site audit time

预计策划和报告编写所需的时间总和通常不应使现场“审核时间”少于根据**上述 2.3 和 2.4 节计算的时间的 70%**。如需额外时间用于策划和/或报告编写，这不应成为减少现场审核时间的理由。审计员的旅行时间不包括在此计算中，而是附加于图表中引用的审核时间。

The total time expected for planning and report writing should generally not result in the on-site 'audit time' being less than 70% **of the time calculated according to** Sections 2.3 and 2.4 above. If additional time is needed for planning and/or report writing, this should not be a justification for reducing on-site audit time. The travel time of the auditor is not included in this

calculation, but is added to the audit time referenced in the chart.

注：70%是基于 ISMS 审核经验所得出的系数。

Note: 70% is the coefficient derived from ISMS audit experience.

3 监督审核的审核时间

Audit time for surveillance audits

在初次认证审核周期，对一个组织的监督时间宜与初次审核时间成比例，每年用于监督审核的时间总量大约是初次审核时间的 1/3。宜时常评审所策划的监督审核时间，以考虑影响审核时间的变更。 为审核 ISMS 的变更(例如，审核新的或发生变更的控制),应增加监督审核的时间。

During the initial certification audit cycle, the surveillance time for an organization should be proportional to the initial audit time, with the total time allocated for surveillance audits each year being approximately 1/3 of the initial audit time. The planned surveillance audit time should be regularly reviewed to account for changes that may affect the audit time. For changes in the ISMS being audited (e.g., auditing new or modified controls), additional surveillance audit time should be allocated.

4 再认证审核的审核时间

Audit time for re-certification audits

用于再认证审核的全部时间，再认证审核所需的时间，宜与同一组织的初次认证审核所用的时间成比例，宜至少是同一组织初次认证审核时间的 **2/3**。

The total time allocated for re-certification audits should be proportional to the time used for the initial certification audit of the same organization, and should be at least **2/3** of the initial certification audit time for the same organization.

5 多场所的审核时间

Audit time for multiple locations

根据本管理办法 2.3 节所述程序计算得出的总现场审核员天数应基于管理体系的相关性和已识别的风险，在各不同现场之间进行分配。认证机构应记录分配的理由。初次审核和监督审核所花费的总时间，应为在每个分场所、总部所花费的时间的总和，且绝不应少于如果所有工作都在一个现场进行（即公司所有员工都在同一现场）时，根据操作的规模和复杂性所计算出的时间。

The total on-site auditor days calculated according to the procedures described in Section 2.3 of this management measure should be allocated among different sites based on the relevance of the management system and the identified risks. The certification body should

document the reasons for the allocation. The total time spent on the initial audit and surveillance audit should be the sum of the time spent at each sub-site and headquarters, and it should never be less than the time calculated based on the scale and complexity of operations if all work were conducted at a single site (i.e., all employees of the company at the same site).

可以考虑因部分审核与总部或分场所无关而减少审核时间。认证机构应记录这类减少的合理理由。

Consideration may be given to reducing audit time for partial audits that are unrelated to headquarters or sub-sites. The certification body should document reasonable justifications for such reductions.

附录 A.1

Appendix A.1

审核时间计算方法示例

Example of Audit Time Calculation Method

A.1 总则

General Principles

本附录为推导出审核时间计算公式提供了进一步的指南。表 A.1 给出了对因数进行分类的示例，它可用作审核时间计算的基础；表 A.2 给出了业务与组织（非 IT）相关的因数；表 A.3 给出了与 IT 环境相关的因数；表 A.4 提供了因数对审核时间的影响。最后给出了 2 个审核时间计算的示例。

This appendix provides further guidance for deriving the audit time calculation formula. Table A. 1 gives examples of classifying factors that can serve as the basis for audit time calculations; Table A.2 provides factors related to business and organization (non-IT); Table A.3 provides factors related to the IT environment; Table A.4 provides the impact of factors on audit time. Finally, two examples of audit time calculations are given.

A.2 审核时间计算因数的分类

Classification of Audit Time Calculation Factors

如本管理办法2.4.1 中 a)～h)所列举的，表 A.1 给出了对主要的审核时间计算因数进行分类的示例。认证机构可以使用该分类来制定一个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。

As listed in this management measure 2.4.1 items a) to h), Table A.1 provides examples of classifying the main audit time calculation factors. Certification bodies can use this classification to allocate sufficient time for auditors to carry out all activities related to initial audits, surveillance audits, or re-certification audits. The total audit time calculation should include adequate time for reporting the audit findings.

表A.1 审核时间计算因数的分类

Table A.1 Classification of Audit Time Calculation Factors

因数Factor (见本管理办法2.4 See this management measure 2.4)	对工作量的影响		
	减少工作量 Reduce Workload	正常工作量 Normal Workload	增加工作量 Increase Workload
a) ISMS的复杂性： Complexity of ISMS: ● 信息安全要求[保密性、完整性和可用性，(CIA)] Information Security Requirements [Confidentiality, Integrity, and availability (CIA)] ● 关键资产的数量 Number of critical assets ● 过程和服务的数量 Number of Processes and Services	● 只有少量的敏感信息或保密信息，可用性要求低； Only a small amount of sensitive or confidential information, with low availability requirements ● 很少的关键资产(根据CIA)； Very few critical assets (according to CIA); ● 只有一个关键业务过程，该过程的接口和涉及的业务单元很少； Only one critical business process, with few interfaces and involved business units	● 较高的可用性要求或若干敏感/保密信息； Higher availability requirements or several sensitive/confidential information. ● 若干关键资产； Several critical assets ● 2个～3个简单的业务过程，这些过程的接口和涉及的业务单元很少； 2 to 3 simple business processes, with few interfaces and involved business units;	● 比较多的保密信息或敏感信息(例如，健康、个人可识别信息、保险、银　行)，或可用性要求高； Relatively more confidential or sensitive information (e.g., health, personally identifiable information, insurance, banking), or high availability requirements; ● 很多关键资产； Many critical assets; ● 超过2个复杂的过程，这些过程的接口和涉及的业务单元很多； More than 2 complex processes, with many interfaces and involved business units;
b) ISMS范围内所开展的业务的类型 Types of business	● 低风险的业务，没有法规要求； Low-risk business, with no regulatory	● 法规要求高； High regulatory requirements;	● 高风险的业务，有(仅有)有限的法规要求； High-risk business, with (only) limited regulatory

conducted within the scope of the ISMS	requirements;		requirements;
c)以往已证实的ISMS绩效 Previously confirmed ISMS performance	● 最近刚获得认证; Recently passed the supervisory audit; ● 没有获得认证，但ISMS已充分实施了多个审核与改进周期，包括文件化的内部审核、管理评审和有效的持续改进体系; Not certified, but ISMS has fully implemented multiple audit and improvement cycles, including documented internal audits, management reviews, and an effective continuous improvement system;	● 最近刚通过监督审核; Recently passed the supervisory audit; ● 没有获得认证，但部分实施了ISMS:获得并实施了一些管理体系工具，一些持续改进过程是适宜的但未全部文件化; Not certified, but partially implemented ISMS: obtained and implemented some management system tools, some continuous improvement processes are appropriate but not fully documented;	● 未获得认证且最近未接受审核; Not certified and has not undergone an audit recently; ● ISMS是新的且没有完全建立(例如：缺少管理体系的特定控制机制，不成熟的持续改进过程，灵活的过程执行); ISMS is new and not fully established (e.g., lack of specific control mechanisms for the management system, immature continuous improvement processes, flexible process execution);
d)在ISMS各部分的实施过程中，所应用的技术的水平和多样性(例如，不同IT平台的数量、隔离网络的数量); The level and diversity of technologies applied in the implementation of various parts of ISMS (e.g., the number of different IT platforms, the number of isolated networks);	● 高标准化、低多样性的环境(很少的IT平台、服务器、操作系统、数据库、网络等); A highly standardized and low-diversity environment (with few IT platforms, servers, operating systems, databases, networks, etc.);	● 标准化且多样性的IT平台、服务器、操作系统、数据库和网络; Standardized yet diverse IT platforms, servers, operating systems, databases, and networks;	● 高多样性或复杂的IT环境(例如，很多不同的网 段、服务器或数据库的类型、关键应用的数量); A highly diverse or complex IT environment (for example, many different types of networks, servers, or databases, and a large number of critical applications);
e)ISMS范围内所使用的外包和第三方安排的程度; The extent of outsourcing and third-party arrangements used within the ISMS scope;	● 没有外包且对供应商的依赖较小；或对外包协议进行了明确的规定、良好的管理与监视 ; No outsourcing and minimal reliance on suppliers; Or clear specifications, good management, and monitoring of outsourcing agreements; ● 外包方获得了ISMS认证; The outsourcing party has obtained ISMS certification; ● 可获得相关的独立担保报告; Relevant independent assurance reports are available;	● 多个管理不充分的外包协议; Multiple poorly managed outsourcing agreements	● 高度依赖外包或供应商，它们对重要业务活动有很大影响；或对外部的数量或程度不清楚 ; High dependence on outsourcing or suppliers, which have a significant impact on critical business activities; or unclear quantity or extent of outsourcing; ● 多个未得到管理的外包协议; Multiple unmanaged outsourcing agreements;

f)信息系统开发的程度； The extent of information system development;	● 没有内部的系统开发； No internal system development; ● 使用标准化的软件平台 Use of standardized software platforms;	● 使用标准化的、具有复杂配置/参数化的平台； Use of standardized platforms with complex configurations/parameterizations; ● (高度)定制软件； (Highly) customized software; ● 若干开发活动(内部的或外包的) Several development activities (internal or outsourced)	● 大量的内部软件开发活动，有若干针对重大业务目的的、持续进行的项目. A large number of internal software development activities, with several ongoing projects aimed at significant business purposes.
g)场所的数量和灾难恢复场所的数量； The number of locations and the number of disaster recovery sites;	● 较低的可用性要求，且没有或有一个可选的灾难恢复场所 Lower availability requirements, with no or one optional disaster recovery site	● 中等或高的可用性要求，且没有或有一个可选的灾难恢复场所； Medium or high availability requirements, with no or one optional disaster recovery site;	● 高可用性要求，例如7×24服务； High availability requirements, such as 7×24 service; ● 若干个可选的灾难恢复场所 ； Several optional disaster recovery sites; ● 若干个数据中心； Several data centers;
h)对于监督或再认证审核：符合GB/T27021.1-2017中8.5,3、与ISMS相关的变更的数量和程度 For surveillance or re-certification audits: Compliance with ISO/IEC17021.1-2015 section 8.5.3.regarding the quantity and extent of changes related to ISMS	● 自上次再认证审核后未发生变化 No changes have occurred since the last re-certification audit	● ISMS的范围或适用性声明有微小的变化，例如：策略、文件发生变化 There are minor changes in the scope or applicability statement of the ISMS, for example: changes in policies or documents; ● 以上因素有微小变化； The above factors have slight changes;	● ISMS的范围或适用性声明有重大变化，例如，新的过程、新的业务单元、区域、风险评估管理方法、策略、文件、风险处置 ； There are significant changes in the scope or applicability statement of ISMS, such as new processes, new business units, regions, risk assessment management methods, strategies, documents, and risk treatment; ● 以上因素有重大变化； The above factors have significant changes;

A.3 审核时间计算的示例

Example of Audit Time Calculation

以下示例阐述了认证机构使用本管理办法第 1 章中的因数来计算审核时间。该示例中的审核时间计算，是按照以下方法进行的：

The following example illustrates how the certification body uses Chapter 1 of this management measure to calculate audit time. The audit time calculation in this example is conducted as follows:

第一步：确定与业务和组织相关的(非 IT)因数：识别表 A.2 中每个类别的适宜分值，并对结果

求和；

Step 1: Identify the (non-IT) factors related to business and organization: determine the appropriate score for each category in Table A.2 and sum the results;

第二步：确定与 IT 环境相关的因数：识别表 A.3 中每个类别的适宜分值，并对结果求和；

Step 2: Identify the factors related to the IT environment: determine the appropriate score for each category in Table A.3 and sum the results;

第三步：基于以上第一步和第二步的结果，通过选择表 A.4 中的适宜条目，识别这些因数对审核时间的影响；

Step 3: Based on the results of the first and second steps above, identify the impact of these factors on audit time by selecting appropriate entries from Table A.4;

第四步：最终计算。用审核时间表(表 1) 所确定审核人天数乘以第三步中得出的系数。当利用多场所抽样时，要根据执行多场所抽样计划所需的工作量增加所计算出的审核人天。

Step 4: Finally calculate. Multiply the number of auditor days determined by the audit time table (Table 1) by the coefficient obtained in Step Three. When using multi-site sampling, increase the calculated auditor days based on the workload required to execute the multi-site sampling plan.

这个结果是最终的审核人天数。

This result is the final number of auditor days.

表 A.2 与业务和组织(非 IT)相关的因数

Table A.2 Factors related to business and organization (non -IT)

类别Category	分值Score
业务类型和法规要求 Business type and regulatory requirements	1． 组织所处的是一个非关键业务领域，且不受管制的领域a; The organization is in a non-critical business area and is in an unregulated areas [a] 2． 组织的客户处于关键业务领域[a]; The organization's clients are in critical business areas [a] 3． 组织处于关键业务领域[a]。 The organization is in critical business areas [a]
过程与任务 Processes and tasks	1．一般的过程，涉及一般的且重复的任务；大量在组织控制下工作的人员从事相同的任务；很少的产品或服务； General processes involving common and repetitive tasks; a large number of personnel working under the organization's control performing the same tasks; few products or services; 2．一般的但不重复的过程，涉及大量的产品或服务； General but non-repetitive processes involving a large number of products or services; 3．复杂的过程，大量的产品和服务，许多业务单元包含在认证范围内(ISMS有复杂性高的过程，或数量相对较多的活动，或独特的活动)。 Complex processes, a large number of products and services, with many business units included within the certification scope (ISMS has highly complex processes, or a relatively large number of activities, or unique activities).
管理体系的建立水平 Level of establishment of the management system	1． 已经很好地建立了ISMS，和(或)存在其他管理体系； ISMS has been well established, and/or there are other management systems present; 2．其他管理体系的要素，有些已经实施，有些没有实施； Elements of other management systems, some have been implemented, while others have not; 3．根本没有实施其他管理体系，ISMS是新的且没有建立。

	There has been no implementation of other management systems; ISMS is new and has not been established.

[a]注：关键业务领域是可以影响关键公共服务的领域，这些公共服务将引起健康、安全、经济、形象和政府履职能力的风险，从而可能对国家造成非常重大的负面影响。

[a]Note: Key business areas are those that can affect critical public services, which may pose risks to health, safety, economy, reputation, and government performance capabilities, potentially leading to significant negative impacts on the nation.

表 A.3 与 IT 环境相关的因数

Table A.3 Factors Related to the IT Environment

类别Category	分值Score
IT基础设施的复杂程度 Complexity of IT Infrastructure	1． 很少的或高度标准化的IT平台、服务器、操作系统、数据库、网络等； Few or highly standardized IT platforms, servers, operating systems, databases, networks, etc.; 2． 多个不同的IT平台，服务器、操作系统、数据库、网络； Multiple different IT platforms, servers, operating systems, databases, networks; 3． 很多不同的IT平台、服务器、操作系统、数据库、网络。 Many different IT platforms, servers, operating systems, databases, and networks.
对外包和供应商（包括云服务）的依赖程度 Degree of reliance on outsourcing and suppliers (including cloud services)	1． 很少或不依赖外包或供应商； Little or no reliance on outsourcing or suppliers; 2． 有些依赖外包或供应商，这些外包或供应商与某些重要业务活动相关，但不是与所有的重要业务活动相关； Some reliance on outsourcing or suppliers, which are related to certain important business activities, but not all important business activities; 3． 高度依赖外包或供应商，外包或供应商对重要业务活动有着很大影响 Highly reliant on outsourcing or suppliers, with a significant impact on important business activities.
信息系统开发 Information system development	1． 没有或非常有限的内部系统/应用开发； No or very limited internal system/application development; 2． 有一些服务于某些重要业务目的的、内部的或外包的系统/应用开发； Some internal or outsourced system/application development serving certain important business purposes; 3． 有大量服务于重要业务目的的、内部的或外包的系统/应用开发。 A large amount of internal or outsourced system/application development serving important business purposes.

表 A.4 因数对审核时间的影响

Table A.4 Impact of Factors on Audit Time

业务复杂性 Business Complexity	IT复杂性 IT Complexity		
	低 Low（3~4）	中 Medium（5~6）	高 High（7~9）
高 **High**（7～9）	+5%～+20%	+10%～+50%	+20%～+100%
中 **Medium**（5～6）	−5%～−10%	0%	+10%～+50%
低 **Low**（3～4）	−10%～—30%	−5%～−10%	+5%～+20%

示例 1：

Example 1:

受审核的组织有 700 人，因此根据表 1，其初次认证审核需要 17.5 人天。该组织不属于关键业务领域，从事高度标准化和重复性的任务且刚建立 ISMS 。根据表 A.2，可以得出与业务和组织相关的因子为 1+1+3=5。该组织具有非常少的 IT 平台和数据库，但大量地使用外包。该组织没有内部的或外包的开发活动。根据表 A.3，可以得出与 IT 环境 相关的因子为 1+3+1=5。利用表 A.4，可以得出该审核时间无需调整。

The audited organization has 700 people, therefore according to Table 1, its initial certification audit requires 17.5 audit days. The organization does not belong to critical business areas, engages in highly standardized and repetitive tasks, and has just established an ISMS. According to Table A.2, the factors related to business and organization can be calculated as 1+1+3=5. The organization has very few IT platforms and databases, but extensively uses outsourcing. The organization has no internal or outsourced development activities. According to Table A.3, the factors related to the IT environment can be derived as 1+3+1=5. Using Table A.4, it can be concluded that the audit time does not need to be adjusted.

示例 2:

Example 2:

还是示例 1 中的这个组织，但其已有多个管理体系且已较好地建立 ISMS 。根据表 A.2，与业务和组织相关的因子将变为：1+1+1=3。根据表 A.4，将得出需要减少 5%～10%的审核时间，即：审核时间将减少 1 到 1.5 人天，变为 16 到 16.5 人天。

This is still the organization from Example 1, but it has multiple management systems and has established the ISMS quite well. According to Table A.2, the factors related to business and organization will change to: 1+1+1=3. According to Table A.4, it will be concluded that the audit time needs to be reduced by 5% to 10%, which means the audit time will be reduced by 1 to 1.5 audit days, changing to 16 to 16.5 audit days.