华认标准技术服务（苏州）有限公司

CCATS (SuZhou) Co., Ltd

公开文件-管理体系认证审核时间

Management system certification audit time

制定修订 Formulate or modify			修订内容摘要 Revision Summary	制定 Formulated	审核 Checked	核准 Approved
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1.目的 Purpose

为向外界明确本公司审核时间安排规定特制订本文件。This document specifies the assessment time and schedule.

2.适用范围 Scope

适用于拟向我机构管理体系认证的各认证申请组织。This document is applicable to the application which has applied for management system assessment.

3.依据 Criteria

本文件的人数划分依据：(IAF MD 5) 质量管理体系(QMS)和环境管理体系(EMS)审核时间、职业健康安全管理体系（OHSMS）、(IAF MD 9)医疗器械质量管理体系（MD-QMS）、食品安全管理体系(FSMS)及IECQ有害物质过程管理体系（HSPM） 审核时间之强制文件。The division of personnel in this document is based on mandatory documents such as (IAF MD 5) Quality Management System (QMS) and Environmental Management System (EMS) audit time, Occupational Health and Safety Management System (OHSMS), (IAF MD 9) Medical Device Quality Management System (MD-QMS), Food Safety Management System(FSMS) and IECQ Hazardous Substance Process Management System (HSPM) audit time.

4. 管理体系审核人日标准 The basis for management system assessment assessor

4.1 QMS 质量管理体系有效人数与审核时间之关系(限初次审核) QMS Relationship between Effective Number of Personnel and Audit Time (Initial Audit only)

有效人数Effective Numb of Personnel	审核时间 第一阶段＋第二阶段（天）Audit Time Stage 1 + Stage 2(days)	有效人数Effective Numb of Personnel	审核时间 第一阶段＋第二阶段（天）Audit Time Stage 1 + Stage 2(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	依照上述级数 According to front level

注：高风险指的是产品或服务的失效会造成经济上的灾难或致命的风险。以下是范例但不限于：食品、药物、飞行器、造船、承重组件和结构、复杂的建筑活动、电器和使用气体燃料的设备、医疗保健服务、捕捞、核燃料、化学品、化学产品和纤维。Note: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.

中度风险指的是产品或服务的失效可能造成伤害或生病的风险。以下是范例范例但不限于：非承重组件和结构、简单的建筑活动、基本金属与加工产品、非金属产品、家具、光学设备、休闲与个人服务。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.

低风险指的是产品或服务的失效不大可能造成伤害或生病的风险。以下是范例范例但不限于：纺织与成衣制品、纸浆、造纸与纸制品、出版、办公室服务、教育、零售业、酒店业和餐饮业。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.

注Note：预计被确定为低风险的业务活动可需要少于表 QMS1 计算的审核时间，被确定为中风险的业务活动将使用表 QMS1 计算审核时间，被定义为高风险的业务活动将使用多于表 QMS1 计算的审核时间。It is estimated that business activities identified as low risk may require less than the audit time calculated in Table QMS1. Business activities identified as medium risk will use Table QMS1 to calculate the audit time, and business activities defined as high risk will use more than the audit time calculated in Table QMS1.

4.2 EMS 环境管理体系有效人数与审核时间的关系（限初次审核）EMS Relationship between Effective Number of Personnel and Audit Time (Initial Audit only)

有效人数 Effective Number of Personnel	第一阶段+第二阶段审核时间(天) Audit Time Stage 1 + Stage 2(days)			有效人数 Effective Number of Personnel	第一阶段+第二阶段审核时间(天) Audit Time Stage 1 + Stage 2(days)		
	高 High	中 Medium	低 Low		高 High	中 Medium	低 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	依照上述级数 According to front level		

注Note：「特殊复杂度」的类别且必须视个案拟定管理体系的审核时间并于《申请&合同评审表》中说明正当理由。The category of "special complexity" must be clearly defined on a case-by-case basis and justified in the *Application & contract review form.*

4.3 职业健康安全管理系统有效人数与审核时间的关系（限初次审核）OHSMS Relationship between Effective Number of Personnel and Audit Time (Initial Audit only)

有效人数 Effective Number of Personnel	第一阶段+第二阶段审核时间(天) Audit Time Stage 1 + Stage 2(days)			有效人数 Effective Number of Personnel	第一阶段+第二阶段审核时间(天) Audit Time Stage 1 + Stage 2(days)		
	高 High	中 Medium	低 Low		高 High	中 Medium	低 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	依照上述级数 According to front level		

备注Note 1：审核时间是依高、中及低OHSMS风险审核显示。The audit time is based on high, medium and low OHSMSM risk audits.

备注2 Note 2：表OHSMS 1之人员数须视为连续，而非阶段式变化。若绘制成图，线应从

较低层带的值开始。图之起始点须是1人2.5日(如上)。若计算结果有小数点，则日数须调整到最接近之半日(例如：5.3审核日算做5.5审核日；5.2审核日就算5审核日)。 The number of people in table OHSMS 1 must be considered as continuous, not as a phase change. If plotted, the line should start with the value of the lower band. The starting point of the map must be 2.5 persons for 2.5 days (as above). If the calculation result has a decimal point, the number of days must be adjusted to the nearest half day (for example: .5.3 audit date is calculated as 5.5 audit date; 5.2 audit date is calculated as 5 audit days).

备注3Note 3：有效人员数包含在认证范围内参与的所有人员(正式、临时及兼职)，包括在每个班次工作之轮班人员。若包括在认证范围内，亦应包含承揽商/分包商执行工作或与工作有关活动，受组织管制或影响，会影响组织OHSMS绩效之人员。 The number of effective personnel includes all personnel (formal, temporary, and part-time) who participate in the verification scope, including the shift personnel who work in each shift. If included in the scope of verification, it should also include the contractor/subcontractor performing work or work-related activities that are subject to organizational controls or influence that will affect the organization's OHSMS performance.

备注4Note 4：有效人员数是做为计算OHSMS审核时间的基础。决定有效员工数时，考虑的因素包括兼职人员、轮班制员工、行政与各类办公人员，以及类似或重复过程(备注5)。「若是季节性作业(例如收成活动、度假村及旅馆等)，有效人员数之计算应以通常会在旺季到工之人员为基础。」有效人员数不得未经考虑相关风险，即因雇用大量非技术人员而减少(备注7)。The number of valid staff is the basis for calculating the OHSMS audit time. When deciding on the number of effective employees, the factors to be considered include part-time employees, shift-workers, administrative and office workers, and similar or repeated processes (Note 5). "If seasonal operations (such as harvest activities, resorts and hotels, etc.), the calculation of the number of effective staff should be based on the staff who normally go to work during peak season." Decrease in technical staff (Note 7).

备注5Note 5：范围内类似或重复过程 Similar or Repeating Processes in Range

a) 若有高比例人员执行被认为类似或相同之活动/职位时(例如清洁工、保全、销售、电话中心等)，因人员暴露在类似的OHSMS风险，则可能允许在认证范围内，减少公司之间可连贯与一致地应用的人员数。If a high percentage of people perform activities/positions that are

considered similar or identical (such as cleaners, maintenance, sales, call centers, etc.), personnel may be allowed to reduce within the scope of verification due to exposure to similar OHSMS risks. The number of people that can be applied consistently and consistently between companies.

b) 执行重复工作之员工群组会降低注意力，并因而提高相关的OHSMS风险程度(例如，安装、组装、包装、分类等)，则为了可能减少有效人员数而采用之方法应予以文件化，包括员工之任何活动/职位之OHSMS风险之评鉴。The group of employees performing the repetitive work will reduce their attention and thus increase the related OHSMS risk level (for example, installation, assembly, packaging, classification, etc.). The methods adopted in order to reduce the number of effective personnel shall be documented. , including OHSMS risk assessment of any activity/position of the employee.

备注6 Note 6： 轮班制员工Shift employee

CAB应决定最能评鉴客户活动全部范围之OHSMS实施成效的审核时机，包括需要在正常工作时间以外审核及各种轮班模式。此应取得客户同意。The CAB should determine the timing of audits that can best evaluate the effectiveness of OHSMS implementation across the full range of client activities, including the need for audits and various shift patterns outside normal working hours. This should obtain client consent.

CAB须确保审核时间的任何改变均不影响审核之有效性(决定OHSMS审核时间的起始点应基于有效人员数予以鉴别，然后再根据适用于被审核客户的重要因素加以调整，并给予每项因素加减权重，以修订基数。在任何情形下，确立OHSMS审核时间之依据，包括所做之调整，均应予以记录。CAB须确保审核时间之任何变动均不影响审核的有效性。若产品或服务之实现是一班制过程，则CAB对每班之审核程度视每班完成之过程而定，并考虑到相关之OHSMS风险及客户证明的每班管制水平。为使审核有效实施，在第一个认证周期期间，至少应审核正常上班时间内及时间外各一班。后续周期的追查审核期间，CB可基于组织OHSMS之公认成熟度，决定不审核第二班。可能时，建议调整延后审核的开始时间，以便可在8小时的审核时间内涵盖两班。考虑到不审核其他班之风险后，应将正当理由文件化。)。The CAB must ensure that any change in the audit time does not affect the validity of the audit (the starting point for determining the OHSMS audit time should be identified based on the number of effective personnel, and then adjusted according to the important factors applicable to the audited client and given each item Addition and subtraction of weights to the revision of the base In any case, the

basis for establishing the OHSMS audit time, including the adjustments made, should be recorded.CAB must ensure that any change in audit time does not affect the validity of the audit. The implementation of the service is a one-shift process, and the degree of CAB auditing for each shift depends on the completion process of each shift, taking into account the related OHSMS risks and the level of control for each class certified by the client. During a verification cycle, at least one audit shall be performed during the normal working hours and outside of the time. During the follow-up audit of the follow-up cycle, CB may decide not to audit the second shift based on the recognized maturity of the organization's OHSMS. When possible, it is recommended to adjust the delay. The start time of the post-audit so that it can cover two shifts at the eight-hour audit time, taking into account the risk of not auditing other classes. Documents should be justified.)

备注7 Note 7：临时非技术人员 Temporary non-technical staff

此问题通常只在技术水准低，可能雇用相当数量非技术人员，替代自动化过程的国家适用。在此情形下，其他认证方案(QMS、EMS)，可能减少有效人员数。此种减少原则上是被认为不适用于OHSMS，因为非技术人员之雇用可能就是OHSMS风险的来源。若有例外情形，做出减少的原因应予以记录，并在评鉴时提供给AB。This problem is usually only applied at a low technical level and may employ a considerable number of non-technical personnel and countries that replace the automation process. In this case, other verification schemes (QMS, EMS) may reduce the number of effective personnel. This reduction is in principle considered not to be applicable to OHSMS because the employment of non-technical personnel may be the source of OHSMS risk. If there are exceptions, the reasons for the reduction should be recorded and provided to AB during the evaluation.

4.4 医疗器械质量管理体系有效人数与审核时间的关系（限初次审核）MD-QMS Relationship between Effective Number of Personnel and Audit Time (Initial Audit only)

Effective Number of Personnel 有效员工人数	Audit Duration Stage 1 + Stage 2 (days)审核天数（一阶段+二阶段）			Effective Number of Personnel 有效员工人数	Audit Duration Stage 1 + Stage 2 (days) 审核天数（一阶段+二阶段）		
	I 类	II 类	III 类		I 类	II 类	III 类
1-5	1.5	2	3	626-875	12	13.5	15
6-10	2	3	4	876-1175	13	14.5	16

11-15	2.5	3.5	4.5	1176-1550	14	15.5	17
16-25	3	4	5	1551-2025	15	16.5	18
26-45	4	5	6	2026-2675	16	17.5	19
46-65	5	6	7	2676-3450	17	18.5	20
66-85	6	7	8	3451-4350	18	19.5	21
86-125	7	8.5	10	4351-5450	19	20.5	22
126-175	8	9.5	11	5451-6800	20	21.5	23
176-275	9	10.5	12	6801-8500	21	22.5	24
276-425	10	11.5	13	8501-10700	22	23.5	25
426-625	11	12.5	14	>10700	Follow progression above		

注 Note：1.有效人数，包括认证范围内涉及的所有全职人员，原则上以组织的社会保险登记证所附名册等信息为准。The number of valid persons, including all full-time staff involved in the scope of certification, is based on information such as the roster attached to the social insurance registration certificate of the organization in principle.

2.对非固定人员（包括季节性人员、临时人员和分包商人员）和兼职人员的有效人数核定，可根据其实际工作小时数予以适当减少或换算成等效的全职人员数。To approve the effective strength of non-permanent staff (including seasonal staff,temporary staff and subcontractor staff) and part-time staff, which may be reduced or converted to equivalent full-time staff as appropriate in accordance with the actual number of hours worked.

4.5 食品安全管理系统有效人数与审核时间的关系 FSMS Relationship between Effective Number of Personnel and Audit Time

类别 Category	基本现场审核时间(审核天数) Basic site audit time (audit days) ***T*D**	每一类外 HACCP 审视(审核天数) Each type of external HACCP review (audit days) ***T*H**	缺乏已认证之相关管理体系(审核天数) Lack of certified management systems (audit days) ***T*MS**	每批员工数(审核天数) Number of employees per batch (audit days) ***T*FTE**	每一需访视之额外场所 Each of the additional field areas to visit

A 动物畜养 Animal husbandry	0.75	0.25	0.25	1~19=0 20~49=0.5 50~79=1.0 80~199=1.5 200~499=2.0 500~899=2.5 900~1299=3.0 1300~1699=3.5 1700~2999=4.0 3000~5000=4.5 >5000=5.0	最低现场审核时间之50% 50% of the minimum on-site audit time
B 植物耕作 Plant cultivation	0.75	0.25			
C 食品制造 Food manufacturing	1.5	0.5			
D 动物饲料生产 Animal feed production	1.5	0.5			
E 餐饮 Catering	1	0.5			
F 经销 Distribution	1	0.5			
G 提供运输与储存服务 Provide transport and storage services	1	0.25			
H 服务 Service	1	0.25			
I 食品包装与包装材料之生产 Food packaging and packaging materials production	1	0.25			
J 设备之制造 Equipment manufacturing	1	0.25			
K(生物)化学品之生产 (Biological) chemical production	1.5	0.5			
最低审核时间 *T*S，以天数表示: *T*S=(*T*D+*T*H+*T*MS+*T*FTE)					

注：除主场所外，每一场所之审核时间依上表计算出，每个场所至少 1 审核天。如已适当文件化并有正当理由，对于较不复杂的组织，可依员工数、组织规模及/或产品量，或在各类别范围内之 *T*S 时间少于 1.5 审核天，则可缩减审核时间。Note: In addition to the home area, each field of the audit time calculated on the basis of each field at least 1 audit day. If it is properly documented and justified, for less complex organizations, the audit time may be reduced by the number of employees, the size of the organization and / or the quantity of the product, or the time of the *T*S in each category is less than 1.5 audit days.

4.6 QC080000 有效人数与审核时间之关系 QC080000 Relationship between Effective Number of Personnel and Audit Time

受审核方的员工数 Certified Entity Number of Employees	初次审核现场人日数 Initial Assessment On-site Days	再认证现场人日数 Recertification assessments On-site Days	文件评审人日数 (初审及必要时的再认证) Initial Assessment Document Review Days. Re-certification Document reviews as necessary	年度监督审核人日 Annual Surveillance
1-75	2	2	0.5	1.5
76-150	3	2.5	0.5	2
151-600	4	3	1	3
601-1000	5	4	1	3
1001-2000	5	4.5	1	4
2001-3000	6	5	1	4
3001-4000	7	6	1	5
4001-8000	8	6.5	1	5
8001-15000	8	7	1	6
15001-20000	9	8	1	6

注：上表中时间可根据以下影响因素做出增减，但最多不能超过30%。Note: The increase or reduction in the times shown above table may be altered due to the factors described below, but not more than 30 %.