



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
修订日期 Date	版 Versions	次 No.				
2018年 6月1日	A	0	新发行 New Issue	马兵兵	薛庄.	薛庄.
2023年2月 1日	A	1	增加 MD-QMS 信息 Add MD-QMS information	汪红	高礼伟	高礼伟
2025年12月 1日	A	2	按照新认证规则修改相关内容 Modify relevant content according to the new certification rules	汪红	高礼伟	高礼伟
2026年2月 25日	A	3	按照 ES 新规修改相关内容 Revise relevant content according to the new ES regulations	汪红	高礼伟	高礼伟

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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）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) 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)
≤15	2.5	876-1175	13
16-25	3	1176-1550	14
26-45	4	1551-2025	15
46-65	5	2026-2675	16
66-85	6	2676-3450	17
86-125	7	3451-4350	18
126-175	8	4351-5450	19
176-275	9	5451-6800	20
276-425	10	6801-8500	21
426-625	11	8501-10700	22
626-875	12	>10700	依照上述级数 According to front level

高风险指的是产品或服务失效将引起巨大经济损失或引起生命危险。包括但不限于：食

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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。High risk refers to the situation where the failure of a product or service will result in significant economic losses or pose a threat to life. Including but not limited to: food, medicine, aircraft, shipbuilding, load-bearing components and structures, complex construction activities, electrical and gas equipment, medical and health services, fishing, nuclear fuel, chemicals, chemical products, and fibers.

中风险指的是产品或服务失效可能引起伤害或疾病。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。Medium risk refers to the possibility of injury or illness caused by the failure of a product or service. Including but not limited to: non load bearing components and structures, simple construction activities, base metals and products, non-metallic products, furniture, optical instruments, leisure and personal services.

低风险指的是产品或服务失效不太可能引起伤害或疾病。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。Low risk refers to a product or service failure that is unlikely to cause injury or illness. Including but not limited to: textiles and clothing, pulp, paper and paper products, publishing, office services, education, retail, hotels and restaurants.

注Note: 1. 有效人数包括认证范围内涉及的所有人员（含每个班次的人员）。认证范围内覆盖的非固定人员（如承包商人员）和兼职人员也应包括在有效人数内。The effective number includes all personnel involved within the certification scope (including personnel for each shift). Non fixed personnel (such as contractor personnel) and part-time personnel covered within the scope of certification should also be included in the valid number.

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确定，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。The effective number of non fixed personnel (including seasonal personnel, temporary personnel, and subcontractor personnel) and part-time personnel can be appropriately reduced or converted into equivalent full-time personnel based on their actual working hours.

3. 申请组织正常工作期间（包括轮班）安排的审核时间可以计入有效的管理体系认证审核时间，但往返多个审核场所之间所花费的路途时间不计入有效的管理体系认证审核时间。The audit time arranged during the normal working period (including shifts) of the application

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organization can be counted as valid management system certification audit time, but the travel time between multiple audit sites is not counted as valid management system certification audit time.

4. 被确定为低风险认证业务类别的，认证审核活动可根据需要在按照以上表格计算所得审核时间的基础上，最多减少10%；被确定为中风险认证业务类别的，认证审核活动应按照以上表格计算审核时间；被确定为高风险认证业务类别的，认证审核活动应在按照以上表格计算所得审核时间的基础上，至少增加10%。For those identified as low-risk certification business categories, the certification audit activities may be reduced by up to 10% based on the audit time calculated according to the above table as needed; For those identified as medium risk certification business categories, the certification audit activities should calculate the audit time according to the above table; For those identified as high-risk certification business categories, the certification audit activities should increase by at least 10% based on the audit time calculated according to the above table.

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	审核时间(人日) 第一阶段+第二阶段 Audit time (person-day) Stage 1 + Stage 2				有效人数 Effective Number of Personnel	审核时间(人日) 第一阶段+第二阶段 Audit time (person-day) Stage 1 + Stage 2			
	高 High	中 Medium	低 Low	有限 limited		高 High	中 Medium	低 Low	有限 limited
≤15	4.5	3.5	3	3	876—1175	19	15	11	7
16—25	5.5	4.5	3.5	3	1176—1550	20	16	12	7.5
26—45	7	5.5	4	3	1551—2025	21	17	12	8
46—65	8	6	4.5	3.5	2026—2675	23	18	13	8.5
66—85	9	7	5	3.5	2676—3450	25	19	14	9
86—125	11	8	5.5	4	3451—4350	27	20	15	10
126—175	12	9	6	4.5	4351—5450	28	21	16	11
176—275	13	10	7	5	5451—6800	30	23	17	12
276—425	15	11	8	5.5	6801—8500	32	25	19	13
426—625	16	12	9	6	8501—10700	34	27	20	14
626—875	17	13	10	6.5	>10700	遵循上述递进规律 Follow the aforementioned progressive pattern			

注 Note:

1. 有效人数包括认证范围内涉及的所有人员（含每个班次的人员）。认证范围内覆盖的非固定人员（包括季节性人员、临时人员和分包商人员）和兼职人员也应包括在有效人数内。

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The effective number of personnel includes all personnel involved within the scope of certification (including personnel from each shift). Non-permanent personnel (including seasonal personnel, temporary personnel, and subcontractor personnel) and part-time personnel covered within the scope of certification should also be included in the effective number of personnel.

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确定，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。For determining the effective number of non-permanent staff (including seasonal staff, temporary staff, and subcontractor staff) and part-time staff, the number can be appropriately reduced or converted into an equivalent number of full-time staff based on their actual working hours.

3. 认证委托人正常工作期间（包括轮班）安排的审核时间可以计入有效的管理体系认证审核时间，但往返多个审核场所之间所花费的路途时间不计入有效的管理体系认证审核时间。The audit time arranged by the certification client during normal working hours (including shifts) can be counted as effective management system certification audit time, but the travel time spent commuting between multiple audit locations is not included in the effective management system certification audit time.

4. 审核时间与 EMS 有效人数和环境因素复杂程度类型有关。The audit time is related to the effective number of EMS personnel and the complexity type of environmental factors.

5. 本表没有涉及“特殊复杂程度”。在这种情况下，CCATS 根据认证委托人具体情况，合理地确定审核时间，审核时间应不低于高环境因素复杂程度的审核时间。This table does not cover "special complexity". In such cases, CCATS will reasonably determine the audit time based on the specific situation of the certification client, and the audit time should not be less than that for high environmental aspect complexity.

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	审核时间(人日) 第一阶段+第二阶段 Audit time (person-day) Stage 1 + Stage 2			有效人数 Effective Number of Personnel	审核时间(人日) 第一阶段+第二阶段 Audit time (person-day) Stage 1 + Stage 2		
	高 High	中 Medium	低 Low		高 High	中 Medium	低 Low
≤15	4.5	3.5	3	876—1175	19	15	11
16—25	5.5	4.5	3.5	1176—1550	20	16	12
26—45	7	5.5	4	1551—2025	21	17	12
46—65	8	6	4.5	2026—2675	23	18	13

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66—85	9	7	5	2676—3450	25	19	14
86—125	11	8	5.5	3451—4350	27	20	15
126—175	12	9	6	4351—5450	28	21	16
176—275	13	10	7	5451—6800	30	23	17
276—425	15	11	8	6801—8500	32	25	19
426—625	16	12	9	8501—10700	34	27	20
626—875	17	13	10	>10700	遵循上述递进规律 Follow the aforementioned progressive pattern		

注Note:

1.有效人数包括认证范围内涉及的所有人员（含每个班次的人员）。认证范围内覆盖的非固定人员（包括季节性人员、临时人员、承包商人员和次级承包商）和兼职人员也应包括在有效人数内。The effective number of personnel includes all personnel involved within the scope of certification (including personnel from each shift). Non-permanent personnel (including seasonal personnel, temporary personnel, contractor personnel, and subcontractor personnel) and part-time personnel covered within the scope of certification should also be included in the effective number of personnel.

2.对非固定人员（包括季节性人员、临时人员、承包商人员和次级承包商）和兼职人员的有效人数确定，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。For the determination of effective personnel numbers for non-permanent staff (including seasonal staff, temporary staff, contractor staff, and subcontractor staff) and part-time staff, the numbers can be appropriately reduced or converted into equivalent full-time staff numbers based on their actual working hours.

3.认证委托人正常工作期间（包括轮班）安排的审核时间可以计入有效的管理体系认证审核时间，但往返多个审核场所之间所花费的路途时间不计入有效的管理体系认证审核时间。The audit time arranged by the certification client during normal working hours (including shifts) can be counted as effective management system certification audit time, but the travel time spent commuting between multiple audit locations is not included in the effective management system certification audit time.

4.审核时间与OHSMS有效人数和OH&S风险类型有关。The audit duration is related to the effective number of personnel covered by the OHSMS and the type of occupational health and safety (OH&S) risks.

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

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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 %.