

	亞瑞仕國際驗證股份有限公司 ARES INTERNATIONAL CERTIFICATION CO., LTD.	編號 No. : ARES-WI-17
	公開文件-管理系統驗證稽核時間 management system certification audit time	頁碼 Page:1

1. 目的 Purpose

為向外界明確本公司稽核時間安排規定特制訂本文件。

This document specifies the assessment time and schedule.

2. 適用範圍.Scope

適用於擬向我機構申請管理系統驗證的各組織。

Applicable to all organizations that intend to apply to our institution for management system verification

3.依據 criteria

3.1 本文件的人數劃分依據：國際認證論壇對決定品質、環境管理及職業安全衛生管理系統 稽核時間之強制文件(IAF MD 5)、IECQ規則、食品安全管理系統驗證機構認證規範 (ISO/TS 22003:2013)、ISO / IEC 17021-1在醫療器械質量管理系統領域的應用(ISO 13485) (IAF MD 9)、資訊安全管理系統驗證機構認證規範(ISO/IEC 27006:2015)、FSSC 22000方案(第5版)、能源管理系統驗證機構認證規範(ISO 50003:2014)。

The number of personnel based on DETERMINATION OF AUDIT TIME OF QUALITY, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEMS (IAF MD 5), Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems (ISO/TS 22003:2013), IECQ Rules of Procedure – Part 5, Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) (IAF MD 9), Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems (ISO/IEC 27006:2015), FSSC 22000 Scheme (Version-5), Energy management systems — Requirements for bodies providing audit and certification of energy management systems (ISO 50003:2014).

4. 管理系統稽核人日標準 The basis for management system assessment assessor

4.1 QMS 品質管理系統有效人數與稽核時間之關係(限初次稽核) The basis for quality management system valid assessor and assess time(for initial assessment)

有效人數 Valid person number of application.	第一階段+第二階段稽核時間 (天)Stage 1+Stage 2 assessment time (day)	有效人數 Valid person number of application.	第一階段+第二階段稽核時間 (天) Stage 1+Stage 2 assessment time (day)
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

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126 - 175	8	5451-6800	20
176 -275	9	6801-8500	21
276 - 425	10	8501-10700	22
426 - 625	11	>10700	依照上述級數 According to front level

註 1：上表中之有效人數須視為連續統計數字而非階段性改變。

Remark1: Valid auditor number of this table shall be regarded as a continuum of statistics rather than periodic change.

註 2：初次稽核第一階段與第二階段稽核人天分配原則為 1/3 與 2/3。

Remark2: the assessor number and time for the first and second assessment in initial assessment shall be 1/3 and 2/3.

註 3：追查稽核人天為初次稽核人天的 1/3;重新驗證稽核人天為初次稽核人天的 2/3

Remark3: the assessor number and time for track assessment shall be 1/3 of initial assessment. the assessor number and time for re-assessment shall be 2/3 of initial assessment.

4.2 EMS 環境管理系統有效人數與稽核時間之關係(限初次稽核)

EMS - Relationship between Effective Number of Personnel, Complexity and Audit Time (Initial Audit)

有效人員數 Effective Number of Personnel	稽核時間 第一階段+第二 階段 (天) Audit Time Stage 1 + Stage 2 (days)				有效人員數 Effective Number of Personnel	稽核時間 第一階段+第二階段 (天) Audit Time Stage 1 + Stage 2 (days)			
	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	依照上述級數 Follow progression above			

註 1：上表有效人數須視為連續統計數字而非階段性改變。

Remark1: Valid auditor number of this table shall be regarded as a continuum of statistics rather than periodic change.

註 2：初次稽核第一階段與第二階段稽核人天分配原則為1/3與2/3。

Remark2: the assessor number and time for the first and second assessment in initial assessment shall be 1/3 and 2/3.

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註 3：追查稽核人天為初次稽核人天的 1/3;重新驗證稽核人天為初次稽核人天的 2/3。

Remark3: the assessor number and time for track assessment shall be 1/3 of initial assessment. the assessor number and time for re-assessment shall be 2/3 of initial assessment.

4.3 OH&SMS 職業安全衛生管理系統有效人數與稽核時間之關係(限初次稽核)

OH&SMS - Relationship between Effective Number of Personnel, Complexity Category of OH&S Risk and Audit Time (Initial Audit)

有效人員數 Effective Number of Personnel	稽核時間 第一階段+第二階段 (天) Audit Time Stage 1 + Stage 2 (days)			有效人員數 Effective Number of Personnel	稽核時間 第一階段+第二階段 (天) Audit Time Stage 1 + Stage 2 (days)		
	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	依照上述級數 Follow progression above		

註 1：上表有效人數須視為連續統計數字而非階段性改變。

Remark1: Valid auditor number of this table shall be regarded as a continuum of statistics rather than periodic change.

註 2：初次稽核第一階段與第二階段稽核人天分配原則為1/3與2/3。

Remark2: the assessor number and time for the first and second assessment in initial assessment shall be 1/3 and 2/3.

註 3：追查稽核人天為初次稽核人天的 1/3;重新驗證稽核人天為初次稽核人天的 2/3。

Remark3: the assessor number and time for track assessment shall be 1/3 of initial assessment. the assessor number and time for re-assessment shall be 2/3 of initial assessment.

4.4 QC080000 有效人數與稽核時間之關係

受稽核方的 員工數 Certified Entity Number of Employees	初次稽核 現場人日數 Initial Assessment On-site Days	重新驗證 現場人日數 Recertification assessments On-site Days	文件評審人日數 (初審及必要時的重新驗證) Initial Assessment Document Review Days. Re-certification Document reviews as necessary	年度追查人 日 Annual Surveillance
1-75	2	1.5	0.5	1
76-150	3	2.5	0.5	2
151-600	4	3	1	3
601-1000	5	4	1	3

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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：上表中時間可根據以下影響因素做出增減，但最多不能超過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 %.

4.5 食品安全衛生管理系統最低初次稽核時間之計算 FSMS Minimum initial audit time calculation

類別或次類別 category or subcategory	基本場區稽核持續時間，以稽核天數表示 Basic site audit duration, expressed in audit days T_D	每一額外 HACCP 審視的稽核天數 Audit days per additional HACCP review T_H	有效之全職相當員工數 Effective number of full-time equivalent employees T_{FTE}	每一需訪視之額外場區 Each of the additional field areas to visit
AI	1.0	0.25	1 to 5 =0 6 to 49=0.5 50 to 99=1.0 100 to 199=1.5 200 to 499=2.0 500 to 999=2.5 >1000=3	最低現場稽核時間之 50% 50% of the minimum on-site audit time
AII	1.0	0.25		
BI	1.0	0.25		
BII	1.0	0.25		
BIII	1.0	0.25		
CO	2.0	0.50		
CI	2.0	0.50		
CII	2.0	0.50		
CIII	2.0	0.50		
CIV	2.0	0.50		
D	1.0	0.50		
E	1.5	0.50		
FI	1.0	0.50		
FII	1.0	0.50		
G	1.5	0.25		
H	1.5	0.25		
I	1.5	0.50		
J	1.5	0.50		
K	2.0	0.50		

※ T_H ：一個 HACCP 不需加人天，兩個 HACCP 加 0.5 人天，三個加 1 人天，四個加 1.5 人天…以此類推。
 T_H : A HACCP does not need to be added, two HACCP plus 0.5 person days, three plus one person day, four plus 1.5 person days... and so on

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注：除主場區外，每一場區之稽核時間依上表計算出，每個場區至少 1 稽核天。如已適當文件化並有正當理由，對於較不複雜的組織，可依員工數、組織規模及/或產品量，或在各類別範圍內之 T_s 時間少於 1.5 稽核天，則可縮減稽核時間。

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 醫療器材品質管理系統最低初次稽核時間之計算 MDQMS minimum initial audit time calculation

Effective Number of Personnel 企業有效人數	Audit Duration Stage 1 + Stage 2 (days) 稽核人日數 1 階段+2 階段 (天)	Effective Number of Personnel 企業有效人數	Audit Duration Stage 1 + Stage 2 (days) 稽核人日數 1 階段+2 階段 (天)
1-5	3	626-875	15
6-10	4	876-1175	16
11-15	4.5	1176-1550	17
16-25	5	1554-2025	18
26-45	6	2026-2675	19
46-65	7	2676-3450	20
66-85	8	3451-4350	21
86-125	10	4351-5450	22
126-175	11	5451-6800	23
176-275	12	6801-8500	24
276-425	13	8501-10700	25
426-625	14	>10700	按比例增加 Follow progression above

注：稽核人日數減少因素，但是減少的人日數不能多於最低初次稽核時間的 20%。

Note: Factors that may reduce the audit duration, but not by more than 20% in minimum initial audit time.

4.7 資訊安全管理系統最低初次稽核時間之計算 ISMS minimum initial audit time calculation

組織控制下之工作人數 Number of employees under organizational control	ISMS 初次稽核之稽核時間 (稽核員天數) Auditing time of ISMS initial audit (man-day)	組織控制下之工作人數 Number of employees under organizational control	ISMS 初次稽核之稽核時間 (稽核員天數) Auditing time of ISMS initial audit (man-day)
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

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276~425	15	8501~10700	28
426~625	16.5	> 10,700	按照上述進展
626~875	17.5		

注：為了確保執行有效稽核及確保可靠與可比較結果，稽核時間表上所提供的稽核時間不應減少超過 30%。時間差異之正當理由應做成書面紀錄。

Note: To ensure effective audits and ensure reliable and comparable results, the audit time provided on the audit schedule should not be reduced by more than 30%. The justification for the time difference should be recorded in writing.

4.8 FSSC 22000 最低初次稽核時間之計算 FSSC 22000 minimum initial audit time calculation

$T_s + T_{FSSC}$

T_s :

類別或次類別 category or subcategory	基本場區稽核持續時間，以稽核天數表示 Basic site audit duration, expressed in audit days T_D	每一額外 HACCP 審視的稽核天數 Audit days per additional HACCP review T_H	有效之全職相當員工數 Effective number of full-time equivalent employees T_{FTE}	每一需訪視之額外場區 Each of the additional field areas to visit
AI	1.0	0.25	1 to 5 =0 6 to 49=0.5 50 to 99=1.0 100 to 199=1.5 200 to 499=2.0 500 to 999=2.5 >1000=3	最低現場稽核時間之 50% 50% of the minimum on-site audit time
AII	1.0	0.25		
BI	1.0	0.25		
BII	1.0	0.25		
BIII	1.0	0.25		
CO	2.0	0.50		
CI	2.0	0.50		
CII	2.0	0.50		
CIII	2.0	0.50		
CIV	2.0	0.50		
D	1.0	0.50		
E	1.5	0.50		
FI	1.0	0.50		
FII	1.0	0.50		
G	1.5	0.25		
H	1.5	0.25		
I	1.5	0.50		
J	1.5	0.50		
K	2.0	0.50		

※ T_H ：一個 HACCP 不需加人天，兩個 HACCP 加 0.5 人天，三個加 1 人天，四個加 1.5 人天…以此類推。
 T_H : A HACCP does not need to be added, two HACCP plus 0.5 person days, three plus one person day, four plus 1.5 person days... and so on

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T_{FSSC}:

考量因素 Considerations	人天數 auditor day	備註 note
現場稽核準備 Preparation	最少增加 0.25 人天 At least 0.25 auditor day shall be added	
稽核報告 Reporting time	最少增加 0.5 人天 At least 0.5 auditor day additional shall be added	
前提方案 PRP 組織規模與複雜性 Organization size and complexity 包括食品欺詐和食品防護的評估(including food fraud prevention and food defense assessment)	最少增加 0.5 人天 At least 0.5 auditor day additional shall be added	員工人數為 1-249 人 以及 HACCP: 1-2 項 when the company has less than 250 FTE & 3 HACCP studies
	最少增加 1 人天 At least 1 auditor day additional shall be added	員工人數多於 249 人 或 HACCP: 多於 2 項 when the company has 250 FTE or more OR 3 HACCP studies or more.
使用翻譯人員 Use of an interpreter	最少增加 0.5 人天 At least 0.5 auditor day additional on-site audit time shall be added	
場外貯存(外倉) Off-site storage	最少增加 0.25 人天 At least 0.25 auditor day additional on-site audit time shall be added	每一個外倉 for each off-site storage facility.
獨立的總部辦公室, 由不在製造現場的總部控制的組織 Organizations with a separate head office. For organizations where some functions pertinent to the certification are	最少增加 0.5 人天	如果總部辦公室負責人員在現場參加稽核則無額外稽核人天 When the responsible person from the head office attends the audit at manufacturing site, no extra

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controlled by a head office separate to the manufacturing site(s).		audit time is calculated.
如由總部辦公室控制功能並 分享者 where the shared functions are controlled by the (off-site) head office.	每個製造現場 最多可減少 20%的稽核時間 A maximum of 20% audit time reduction can be allowed for each of the single manufacturing sites	ISO 22003:2013 附錄 B 的規 定 as shown in ISO/TS 22003:2013, Annex B.
場外活動 Organizations with off-site activities (即一個或多個流程步驟發 生於第二現場)	每一個第二場地 最多可減少總稽核時間的 50% each secondary site, maximum of 50% audit time reduction	在開展非現場活動的製造企 業中, 基於 Ts 減少 50%的稽 核時間, 適用於每個第二現場 計算的最短總現場稽核時間 In manufacturing organizations with off-site activities where one or more process steps take place at a secondary site, a 50% audit time reduction based on Ts is applied for the minimum calculated total on-site audit time for each secondary site.
過渡 至 FSSC22000 Transition to FSSC 22000	最少的 FSSC22000 現場稽核驗 證時間是初次驗證稽核時間的 2/3, 最少是 1 天(8 小時), 之後 再加上 FSSC 22000 額外的稽核 時間如上所述 the minimum FSSC 22000 certification on-site audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 auditor day (8 working hours) on-site plus the	由 Dutch HACCP、ISO22000 或是 GFSI 同意的驗證過渡至 FSSC 22000 驗證時 when transitioning from Dutch HACCP, ISO 22000 or a GFSI recognized certification to FSSC 22000 certification.

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	FSSC 22000 additional audit time as defined above.	
FSSC 22000-品質驗證 FSSC 22000-Quality	1.對於 ISO 9001 來說，稽核的部分應用 IAF MD5 進行計算 2.稽核期間對於 FSSC 22000 和 ISO 9001 稽核的結合應依據 IAF MD11 2.1.5.1 1. The audit time for the ISO 9001 part of the audit shall be calculated using IAF MD 5. 2. The audit duration for the integrated FSSC 22000 and ISO 9001 audit shall be based on IAF MD 11, section 2.1.5.1.	

4.9 能源管理系統最低初次稽核時間之計算 EnMS minimum initial audit time calculation

能源管理系統有效人員數 Number of effective employees in EnMS	複雜性 Complexity		
	低 Low	中 Medium	高 High
1~15	3	5	6
16~25	4	6	7.5
26~65	5.5	7	8.5
66~85	6.5	8	9.5
86~175	7	9	10
176~275	7.5	9.5	10.5
276~425	8.5	11	12.5
≥ 426	驗證機構可提供超過 425 位的 EnMS 有效人員之稽核時程。此時程宜依照本表中之級數。The certification body can provide an audit schedule for more than 425 effective EnMS personnel. At this time, the schedule should be in accordance with the level in this table.		