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ISO 9001 新版標準及轉版案例說明會

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Welcome! 歡迎!

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稽 核 資 格 / 專 長：

- ISO 9001 Lead Assessor, Tutor
- ISO 14001 Lead Assessor, Tutor
- OHSAS 18001 Assessor
- TOSHMS Assessor
- 溫室氣體 ISO 14064-1 Lead Verifier
- 企業社會責任 Lead Assuror

- 14年以上的工作經驗
- 管理系統已實施超過7年
- 進行了超過1,000次稽核人天
- 具有台灣, 日本, 新加坡, 美國稽核經驗

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新版標準轉版攻略 (一)
風險概念導入新版ISO 9001:2015標準對企業的助益

新版標準轉版攻略 (二)
從BSI稽核多家轉版企業的案例，談轉換新版要點

4

ISO 9001:2015 發展過程

ISO/FDIS 9001:2015 版於2015/07/09發佈。

ISO/IS 9001:2015 正式版於2015/09/15發佈。

There are different stages involved within the development of the international standard: 國際標準的發展包含不同階段:

Working Draft ("WD") 工作草案版

Committee Draft ("CD") 委員會草案版

Draft International Standard ("DIS") 國際標準草案版 (2014/7/10)

Final Draft International Standard ("FDIS") 最終國際標準草案版 (2015/7/9)

International Standard ("IS") 國際標準 (2015/09/15正式發佈)

- Subject to "systematic review" every 5 years 每5年「系統性審查」一次

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ISO 9001:2015 新版標準

ISO 9001:2015 第5 版取消並取代了第4 版(ISO 9001:2008)。相對於上一版本，經由採用了新的條文順序，修訂了 "品質管理原則" ，並增加了一些新的思維新版，進行了技術性修訂。

- 新的條文順序：High Level Structure - 高階結構
  (從 Clause 1 範圍 到 Clause 10 改善)
- 品質管理原則：七大品質管理原則
- 新的思維：以風險導向的思維

ISO 9001:2015

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6

品質管理系統的潛在效益

採用品質管理系統是組織的一項策略性決定，有助於改善組織的整體績效，也為組織的永續發展提供穩固的基礎。

基於此國際標準，組織實施品質管理系統的潛在效益包含：

a) 有能力持續穩定地提供滿足客戶和符合法令與規章要求的產品和服務；

b) 促進提昇客戶滿意的機會；

c) 處理與其組織環境背景和目標相關的風險和機會；

d) 展現滿足特定品質管理系統要求的能力。

Strategic No Changes to Date
到目前為止的不變策略

Quality Management Principles remain the guideline
品質管理原則 (七大管理原則)

Customers remain the primary focus
(客戶焦點)

PDCA remains the methodology
(PDCA 方法)

Process approach remain the recommendation
(流程方法)

Organizations implementing an integrated system achieve benefits.
(整合管理系統的好處)

Strategic Changes to Date 到目前為止的策略轉變

- **Exclusion 排除條款 (A5),** 未明確限定條款。

  shall not affect the organization's ability or responsibility.

  ex: clause 7.1.5 (MM resources) and some clauses in the clause 8 operation, such as 8.3 design and development, 8.5.3 property of customers/providers.

- **No Quality Manual clause 沒有品質手冊條款。(4.2.2)**

  does not include a clause giving specific requirements for 'quality manual', but shall establish its QMS scope (4.3).

- **No Management Representative clause 沒有管理代表條款。(5.5.2)**

  does not include a clause giving specific requirements for 'Management Representative' appointment, but it is in its role/R&A (5.3).

- **No special process clause (752) replaced by 8.5.1.(f).** 特殊製程

  does not include a clause for special process, but incorporated into the clause "Control of product and service provision clause 8.5.1.(f)."

- **No Preventive action clause** 沒有預防措施條款。**(853) replaced by 6.1 risk.**

  doesn't include a clause giving specific requirements for Preventive Action, but replaced by risk management in clauses (6.1) …etc. (風險取代之)

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9

不需要改變的改變
Key changes you do not need to change

組織不需要 (Organizations do not need to)

- 廢除 **MR制度** (Remove their management representatives).
  While there is no requirement in ISO 9001:2015 for a management representative, this does not prevent organizations from choosing to retain this role if they so wish.
- 丟掉 **QM手冊** (Throw out their Quality).
  While ISO 9001:2015 sets out no requirement for organizations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn.
- 丟掉程序書/標準書及其他文件 (Throw out their Documented Procedures).
  While ISO 9001:2015 sets out no requirement for organizations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn
- 重編程序書文件號碼:
  Renumber existing QMS documentation to correspond to the new clause references.

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可以改變的考量 Key changes you can change

組織可以 (Organizations can …)

- 按條款順序重編QM手冊: Restructure their management systems to follow the sequence of requirements as set out in the ISO 9001:2015.
- 按新用術語更新手冊及程序書: Refresh existing documentation to use the new terms and definitions contained within ISO 9001:2015. If organizations are more comfortable using their own terminology, e.g. "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.

ISO 9001 needs to: ISO 9001的考量:

- Provide a consistent foundation for the next 10 years
  *在未來**10**年提供一致的基礎。*
- Integrate with other management systems
  與其他管理系統整合。
- Provide an integrated approach to organizational management
  為組織管理(企業管理)提供整合方法。

11

Different Terms 新用語/術語 (1/3)

ISO 9001:2008	ISO 9001:2015
products	products and services 1 (產品與服務)-intended for or required by a customer. -Internal and external customers
Procedure	Process, no longer use the word, procedure. (流程/過程)
Management representative	**Not used.** **(沒有MR條款) (5.3 roles, R&A)**
Documentation, quality manual, documented procedures, records	Documented information (文件化資訊) (7.5.1, 7.5.2, 7.5.3)
Work environment (6.4)	Environment for the operation of processes (流程作業環境) (7.1.4)
Monitoring and measurement equipment (7.6)	Monitoring and measurement resources (監督量測資源) (7.1.5)
Outsource (41) Purchased product (741)	Externally provided products and services (外部提供的產品及服務) (8.4.1, 8.4.2, 8.4.3)

Different Terms 新用語/術語 (2/3)

ISO 9001:2008	ISO 9001:2015
supplier	External provider: supplier, vendor, partner, subcontractor (外部供應者)
NA	**Issues can include positive and negative factors or conditions for consideration. (議題 Issue) 可能是正面的，也可能是負面的 (4.1 note 1)**
Continual improvement 持續改善	改善： Improvement: activity to enhance performance. ex: correction, corrective action, continual improvement, breakthrough change, innovation, re-organization…etc. 持續改善: continual improvement: recurring activity to enhance performance. ex: analysis & evaluation results, MR outputs …etc.
NA	(創新) Innovation: process resulting in a new or substantiality changed object.
NA	**(知識) Knowledge: available collection of information being a justified belief and having a high certainty to be true.**

b

Different Terms 新用語/術語 (3/3)

ISO 9001:2008	ISO 9001:2015
NA	Strategy: planned activities to achieve an objective (策略)
NA	Strategic direction: the direction for the strategy (策略方針)
NA	**Risk-based thinking (Risk & Opportunity) (風險導向思考模式)** **ISO 9001:2015強調以風險為基礎的思維**
NA	Intended results (預期的結果/輸出)

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Different Terms 新用語/術語

- **預期 vs. 期望:**
  ('intended' outcome vs. 'expected' outcome:
  - ✓'Intended outcome' is that which is 'intended' as a result of the application of the standard, or process etc.
  - ✓'Expected outcome' is that which is 'expected' by interested parties

- 效果: **Process effectiveness – Ability to achieve desired results**
- 效率: **Process efficiency – Results achieved vs. resources used**

- **程序 vs. 流程 (Procedure vs. process!!!)**
  Process has replaced procedure.

- **維持 vs. 保存 (Maintain documents vs. Retain records!!!)**
- **保留 (Keep= Maintain+Retain document information)**

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新的條文順序：ISO 9001:2015 Key Clauses – 主要條款

Clause 1	Scope	範圍
Clause 2	Normative references	參考規範
Clause 3	Terms and definitions	專有名詞與定義
Clause 4	Context of the organization	組織背景
Clause 5	Leadership	領導統御
Clause 6	Planning	規劃
Clause 7	Support	支援
Clause 8	Operation	營運作業
Clause 9	Performance evaluation	績效評估
Clause 10	Improvement	改善

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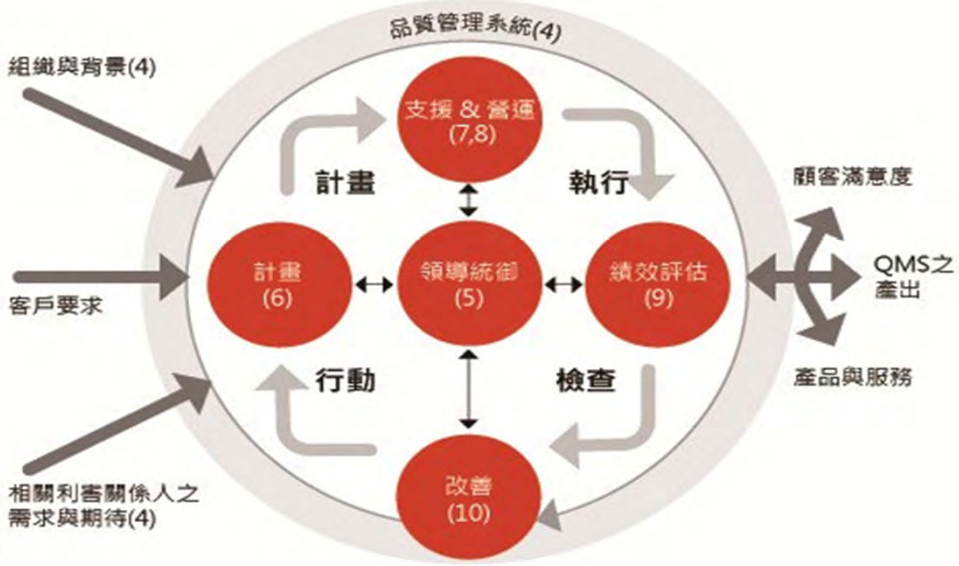
16

新的條文順序：ISO 9001:2015採用新高階結構(HLS)



17

品質管理原則：七大品質管理原則

以前有8項: ISO 9001:2008	現在是7項: ISO 9001:2015
客戶導向 Customer focus	客戶導向 Customer focus
領導統御 Leadership	領導統御 Leadership
全員投入 Involvement of people	全員參與 Engagement of people *
流程方法 Process approach	流程方法 Process approach
對管理的系統方法 System approach to management	(涵蓋在流程方法內) (Included in the process approach)
持續改善 Continual improvement	改善 Improvement (持續改善為改善的一環)
根據事實的決策 Factual approach to decision making	以證據的決策 Evidence-based decision making
互利的供應商關係 Mutually beneficial supplier relationships	關係管理 Relationship management

*現在全員參與意味著，授權和吸引人們增強創造價值的能力
（對於組織效益/目標/標的）。不再是過去僅僅系統相關者的參與！

品質管理原則：流程方法的重申

ISO 9001:2015應用了流程方法，其中包括：規劃-執行-檢查-行動(PDCA) 和風險導向的思維。

流程方法：可以使組織規劃其所需的流程及其流程的相互關係。

PDCA 循環：可使組織確保其流程得到充分的資源和管理，並決定及執行改善的機會。

風險導向的思維：可使組織決定可能導致其流程及其品質管理系統背離該預期結果的因素，並實施預防措施來降低負面影響及當機會出現時，盡可能加以運用。

「在日趨變化和複雜環境中，組織面臨需持續滿足要求以及因應未來需求和期望的挑戰。」

為實現此目標，組織也許會發現除了進行矯正與持續改善外，採取其他各種形式的改善也是必要的，如突破性的改變、創新和組織重整。

品質管理原則：在品質管理系統中運用流程方法可以：

a) 了解和一致地滿足要求;

b) 從附加價值的觀點來考慮流程;

c) 實現有效的流程績效;

d) 基於資料和資訊的評估來改善流程。

圖1 提供了任何一個流程的圖示說明和表示個別要素間的相互關係。基於管控的需要，各流程所需的監督與量測檢查點是特定的，**並且將與其相關的風險程度不同而有所不同。**

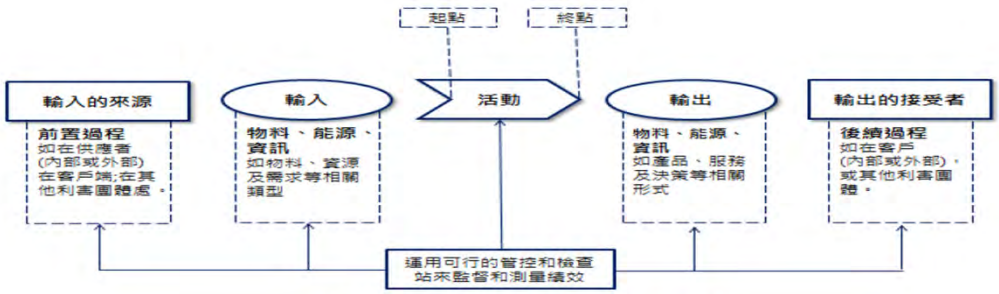


圖 1 單一流程組成要素的圖示說明

品質管理原則：規劃—實施—檢查—行動 循環

規劃: 依照客戶的要求和組織的政策，建立系統及其流程的目標和實現結果所需的資源；

實施: 執行所規劃的事項；

檢查: 依據政策、目標和要求來監督和量測(適用時)流程及其所輸出的產品和服務，並報告其結果；

行動: 必要時，採取相關行動以改善績效。

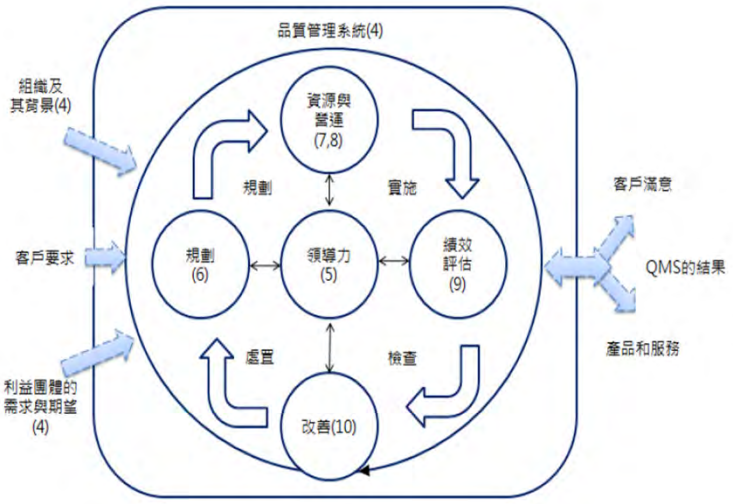
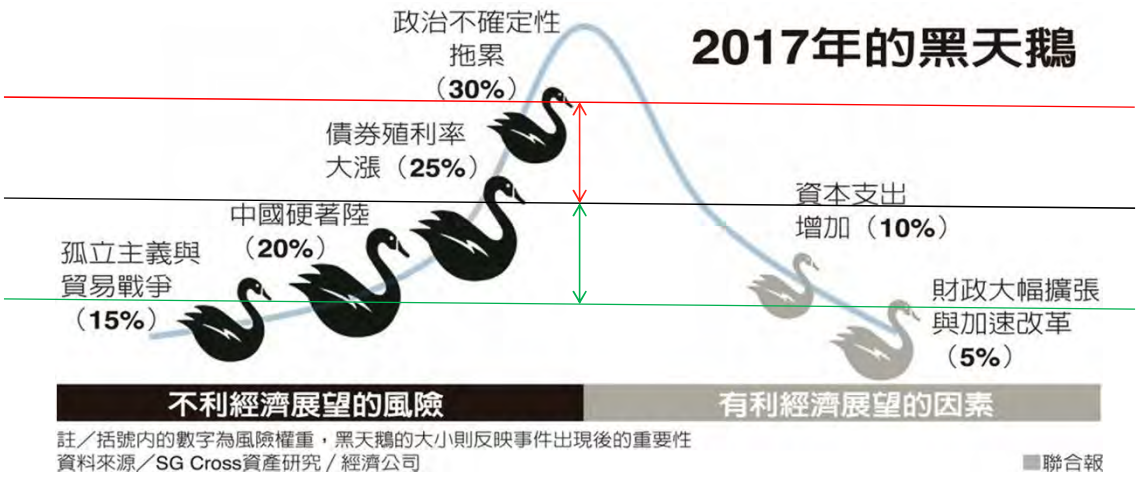


圖 2 - 本國際標準架構的 PDCA 循環圖示

風險導向思維：以一個日常生活為例

風險導向思維：風險是指不確定性對預期結果的影響，此不確定性可以是正面的或負面的影響。



23

風險導向思維：機會可源自於有利實現預期結果的情境

例如，讓組織吸引客戶、開發新產品和服務、降低浪費、或提升生產力的一組環境。

處理機會的措施也可以包括所考慮的相關聯風險。

水資源的風險，所帶來的商業機會。

新加坡濱海灣花園的擎天樹Super Tree，可收集雨水、排熱氣 、觀光，甚至是太陽能發電。

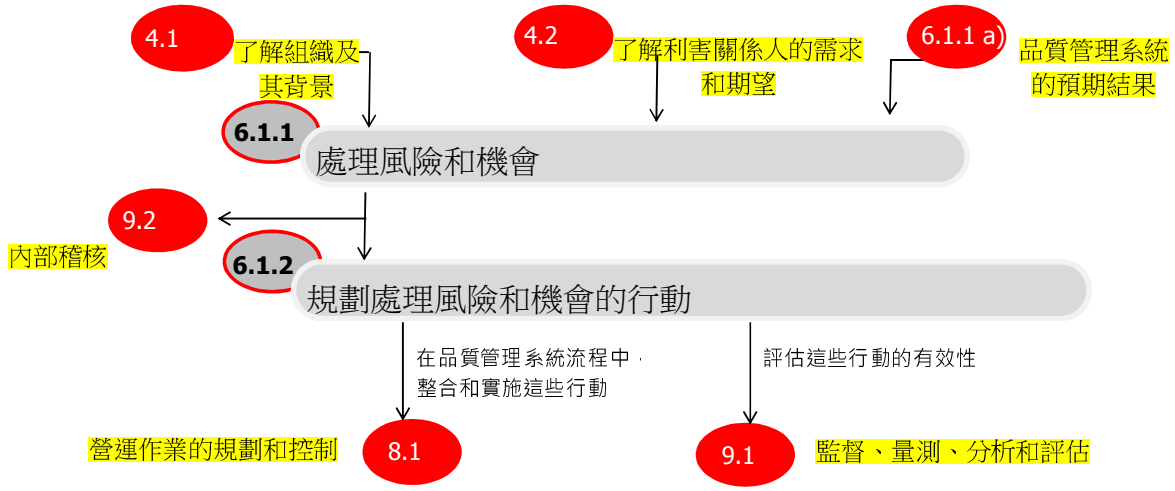
24

Risk-based thinking 風險導向思維

- ISO 9001:2015 條款中提及風險之處:
  - 6.1 – Actions to address risks and opportunities
  - 0.1, 0.3, 0.5 - Intros
  - 4.4. f) – QMS and its Processes
  - 5.1.2. b) – Customer focus
  - 8.5.5.a) – Post-delivery activities
  - 9.3.1.d) – Management Review input
  - A.4,5,7,8 – Annexes

- 可供參考的方法-風險:
  - ISO/IEC Guide 73 – Risk management vocabulary – Guidelines for use in standards
  - ISO 31000-2009 -- Risk management – Principles and guidelines
  - BS 31100 Risk management – Code of practice and guidance for the implementation of ISO 31000
  - ISO 31010, Provides details on risk assessment concepts, process, and selection/comparison of risk assessment tools/techniques
  - ISO 14971:2012 Risk Management for Medical Device

風險導向思維 v.s 流程方法



風險管理方法相關資訊 from ISO 31000

— Risk analysis 風險分析

systematic use of available information to identify hazards and to estimate the risk

系統性地使用可取得的資訊以找出危害，識別風險並估計風險。

— Risk evaluation 風險評估

process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

對照特定的風險標準來比較估計的風險，以決定風險可接受度的過程。

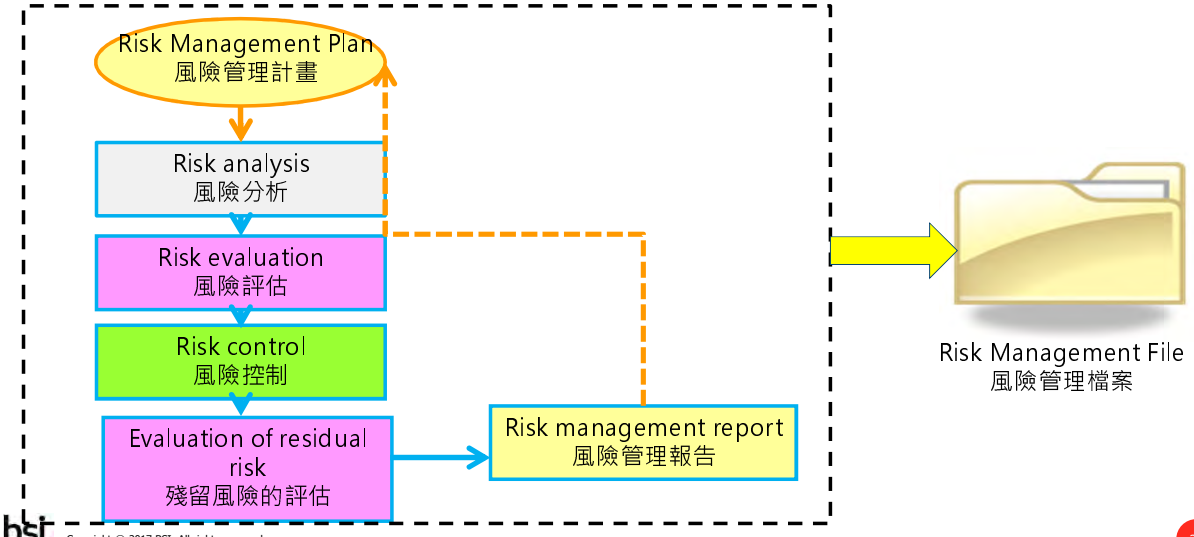
— Risk assessment 風險審查(鑑別)

overall process comprising a risk analysis and a risk evaluation

比較風險分析和風險評估的整體過程

27

Risk management process 風險管理流程



28

Information on risk management techniques
風險管理方法相關資訊

- Failure Mode and Effects Analysis (FMEA)
  失效模式與效應分析（FMEA）
- Multiple Factors Scoring Analysis
  多因子打分評價法: S, f, D, P...etc.
- Brainstorming Analysis (BA)
  腦力激盪分析（BA）
- Fault Tree Analysis (FTA)
  故障樹分析（FTA）
- Hazard and Operability Study (HAZOP)
  危害與可操作性研究（HAZOP）
- Hazard Analysis and Critical Control Point (HACCP)
  危害分析與關鍵控制點（HACCP）...etc.

	Helpful 對達成目標有幫助的 to achieving the objective	Harmful 對達成目標有害的 to achieving the objective
Internal 內部(組織) attributes of the organization	Strengths:優勢	Weaknesses:劣勢
External 外部(環境) attributes of the environment	Opportunities:機會	Threats:威脅

29

一個簡易的風險評估方式

簡易風險估算 = "發生頻率" 相乘 "嚴重程度" 的結果

R= f * s (expected result, uncertainty)

可能性	影響 低	中	高
可能	低風險	中風險	高風險
不可能	低風險	中風險	中風險
高度不可能	低風險	低風險	中風險

30

風險與機會 以一電纜業為例子

No.	課題 (內部)	預期結果	不確定性	風險高/中/低(影響)	行動措施
1	員工多能工	員工可勝任	現有安裝員工不具有電纜測試之能力	中	一組多能安裝隊伍、對安裝時間的影響
2	組織文化	有動力的員工	不可接受的作業品質	高	高層管理領導的機會
3	員工留任	對組織忠心的員工	員工為更好的薪資離去	中	比對競爭對手薪資的機會
No.	**課題 (外部)**	**預期結果**	**不確定**	**風險高/中/低(影響)**	**機會**
4	客戶工作環境-與其他一起合作之夥伴	電纜於安裝後的完整性保護	佈線的損害	高	可建置隔離、與清楚辨識之標誌
5	產業內的標準化和認證	知曉最新的標準	執行守則一直改變	低	讓設計師參加免費貿易組織更新會議的機會
6	客戶端的考慮 - 將專業知識帶到內部(挖角)	員工對於組織忠心	管理現場約合約之員工直接透過客戶端被雇用	高	新合約條款，禁止就業（時限）的機會
7	競爭者(們)-結束營業	我們承擔他們的合約-收入	我們有做到這點的手段嗎?	中	建置可快速擴張之計畫(員工、設施等)

31

Opportunities, objectives and actions 機會, 目標與行動

Opportunities and actions can be turned into measured objectives
機會與行動可被轉換成測量目標

SPECIFIC	特定
MEASURABLE	可量測（定性、定量）
ACCURATE/ACHIEV**A**BLE	正確/可達成
REALISTIC	實行
T IME CONTRAINED	時效性
E VALUATED	已評估
REVISE ACTIONS	更新行動

32

與其他管理系統標準的關係

— ISO 9000 品質管理系統— 基礎和術語，提供了一個重要的依據用來正確的了解和實行此國際標準。此國際標準的原則在ISO 9000 有詳細的描述，並且在此國際標準建立時，就已納入考慮。此原則並非僅是其本身的要求，而是此國際標準基本的要求。ISO 9000 也說明了此國際標準的術語、解釋和概念。

— ISO 9001 (本國際標準)規範要求的主要目的是加強組織對其所提供的產品與服務更具可靠度，進而也可以增強客戶滿意。適當的執行ISO 9001 預期可帶給組織的效益包括：改善組織內部溝通，或對組織流程更加瞭解與管控。

— ISO 9004 組織永續成功的管理，這是一個品質管理方法，目的是提供指導那些想要達成下列目標的組織：不只是符合ISO標準，並實施更廣泛的內容，以達到組織全面績效提升。 ISO 9004 包括了自我評估方式的指引，使組織能評估其品質管理系統的成熟度。

下列的國際標準可以協助組織，當其要建立或尋求改善品質管理系統、流程或活動。

— ISO 10001 品質管理《客戶滿意度– 組織行為準則指南》指導組織決定其客戶滿意度之規範能滿足客戶的需求和期望。使用該標準能夠提升客戶對組織的信任度，推廣客戶瞭解應對組織報以何種期望，進而減少誤解和可能之抱怨。

— ISO 19011《管理系統稽核指南》指導如何管理一個稽核流程，如何計畫和執行管理系統的稽核，如何決定和評估一個稽核人員和稽核小組的能力。該指南適用於稽核人員、執行管理系統的組織，以及需要執行管理系統稽核的組織。

— ISO 31000, 風險管理-原則與指引

關於本國際標準與前一版標準(ISO 9001:2008)條文之間對照關係表，可在ISO/TC 176/SC2 所設立的開放網站：www.iso.org/tc176/sc02/public 中找到。

ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
4 Context of the organization 組織背景	1.0 Scope
4.1 Understanding the organization and its context 了解組織及其背景	1.1 General
4.2 Understanding the needs and expectations of interested parties 了解利害關係人的需 求	1.1 General
4.3 Determining the scope of the quality management system 確定品質管理系統的範圍	1.2 Application 4.2.2 Quality manual
4.4 Quality management system and its processes 品質管理系統及其流程 4.4.1 the organization shall establish … 4.4.2 to the extent necessary …	4 Quality management system 4.1 General requirements 4.2.1 Documented quality management system
5 Leadership 領導統御	5 Management responsibility
5.1 Leadership and commitment 領導和承諾	5.1 Management commitment
5.1.1 General 一般要求	5.1 Management commitment
5.1.2 Customer focus 客戶焦點	5.2 Customer focus
5.2 Quality policy 品質政策	5.3 Quality policy
5.2.1 Developing the quality policy 發展品質政策	5.3 Quality policy
5.2.2 Communicating the quality policy 溝通品質政策	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities 組	5.5.1 Responsibility and authority

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ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
6 Planning 規劃	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities 6.1.1 … 處理風險和機會的行動 6.1.2 …	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them 6.2.1 … 品質目標和實現目標的規劃 6.2.2 …	5.4.1 Quality objectives
6.3 Planning of changes 變更的規劃	5.4.2 Quality management system planning
7 Support 支援	6 Resource management
7.1 Resources 資源	6 Resource management
7.1.1 General 一般要求	6.1 Provision of resources
7.1.2 People 人員	6.1 Provision of resources
7.1.3 Infrastructure 基礎設施	6.3 Infrastructure
7.1.4 Environment for the operation of processes 作業流程的環境	6.4 Work environment
7.1.5 Monitoring and measuring resources 監督和量測的資源	7.6 Control of monitoring and measuring equipment
7.1.5.1 General 一般要求	

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ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
7.1.6 Organizational knowledge 組織的知識	New
7.2 Competence 能力	6.2.1 General 6.2.2 Competence, training and awareness
7.3 Awareness 認知	6.2.2 Competence, training and awareness
7.4 Communication 溝通	5.5.3 Internal communication
7.5 Documented information 文件化資訊	4.2 Documentation requirements
7.5.1 General 一般要求	4.2.1 General
7.5.2 Creating and updating 建立及更新	4.2.3 Control of documents 4.2.4 Control of records
7.5.3 Control of documented Information 7.5.3.1 …. 7.5.3.2 ….	文件化資訊的控制 4.2.3 Control of documents 4.2.4 Control of records
8 Operation 營運作業	7 Product realization
8.1 Operational planning and control 作業規劃和控制	7.1 Planning of product realization
8.2 Determination of requirements for products and services 確定產品和服務的要求	7.2 Customer-related processes
8.2.1 Customer communication 客戶溝通	7.2.3 Customer communication
8.2.2 Determination of requirements related to products and services 確定產品和服務相關的要求	7.2.1 Determination of requirements related to the product

bsi.

ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
8.2.3 Review of requirements related to the products and services 審查產品和服務相關的要求 8.2.3.1 … 8.2.3.2 …	7.2.2 Review of requirements related to the product
8.2.4 Changes to requirements for product and services 產品和服務要求的變更	7.2.2 Review of requirements related to the product
8.3 Design and development of products and services 產品及服務的設計與開發	7.3 Design and development
8.3.1 General 一般要求	New
8.3.2 Design and development planning 設計與開發規劃	7.3.1 Design and development planning
8.3.3 Design and development Inputs 設計與開發輸入	7.3.2 Design and development inputs
8.3.4 Design and development controls 設計與開發控制	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation
8.3.5 Design and development outputs 設計與開發輸出	7.3.3 Design and development outputs
8.3.6 Design and development changes 設計與開發變更	7.3.7 Control of design and development changes
8.4 Control of externally provided products and services 外部提供產品和服務的控制	7.4.1 Purchasing process
8.4.1 General 一般要求	7.4.1 Purchasing process

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ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
8.4.2 Type and extent of control 控制的型式及程度	7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers 給外部供應者之資訊	7.4.2 Purchasing information
8.5 Production and service provision 生產和服務提供	7.5 Production and service provision
8.5.1 Control of production and service provision 生產和服務提供的控制	7.5.1 Control of production and service provision
8.5.2 Identification and traceability 鑑別和追溯	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers 客戶或外部供應者的財產	7.5.4 Customer property
8.5.4 Preservation 防護	7.5.5 Preservation of product
8.5.5 Post-delivery activities 交付後活動	7.5.1 Control of production and service provision
8.5.6 Control of changes 變更的控制	New
8.6 Release of products & services 產品和服務之放行	8.2.4 Monitoring & measurement of processes 7.4.3 Verification of purchased product
8.7 Control of nonconforming process outputs, products and services 8.7.1 ... 不符合之流程輸出,產品和服務的控制 8.7.2 ...	8.3 Control of nonconforming product

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ISO 9001:2008 vs. ISO 9001:2015

ISO 9001:2015	ISO 9001:2008
9 Performance evaluation 績效評估	8 Measurement, analysis and improvement
9.1 Monitoring, measurement, analysis and evaluation 監督,量測,分析和評估	8 Measurement, analysis and improvement
9.1.1 General 一般要求	8.1 General
9.1.2 Customer satisfaction 客戶滿意	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation 分析與評估	8.4 Analysis of data
9.2 Internal audit 內部稽核 9.2.1 ... 9.2.2 ...	8.2.2 Internal audit
9.3 Management review 管理審查	5.6 Management review
9.3.1 General 一般要求	5.6.1 General
9.3.2 Management review inputs 管理審查輸入	5.6.2 Management inputs
9.3.3 Management review outputs 管理審查輸出	5.6.3 Management outputs
10 Improvement 改善	8.5 Improvement
10.1 General 一般要求	8.5.1 Continual improvement
10.2 Nonconformity and corrective action 10.2.1 ... 不符合與矯正措施 10.2.2 ...	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual Improvement 持續改善	8.5.1 Continual improvement

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轉版條文進行差異分析

No.	舊版條文	新版條文	流程/ 文件化資訊	原版內容/ 修改內容	負責單位 (部門/承辦)	修改期限
Eq. 1	7.2.2 產品相關要求的審查	8.2.3 審查產品與服務之要求事項	業務部訂單審查辦法 QP721 A4	7.2.2 當產品要求變更時，組織應確保相關文件已完成修正，且將變更之要求告知相關人員。/ 8.2.4產品與服務要求事項變更時，組織應確保直接相關的文件化資訊得以修訂，且直接相關人員得以瞭解要求事項之變更。	業務部/丁小美	2017/1/E (舊版既有要求但在新版不同的條款) Revise
Eq. 2	7.1 產品實現的規劃	8.1 運作之規劃與管制	品保體系圖	7.1/ 8.1 滿足所提供產品與服務要求事項的過程(參照第4.4節)，並以下列方法實施第6 節所決定之措施：a), b), c), d), e)	設計部/王大明	2017/2/E (舊版沒有要求但在新版進階要求) New
1						
2						
3						

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新版標準轉版攻略 (二)

從BSI稽核多家轉版企業的案例，談轉換新版要點

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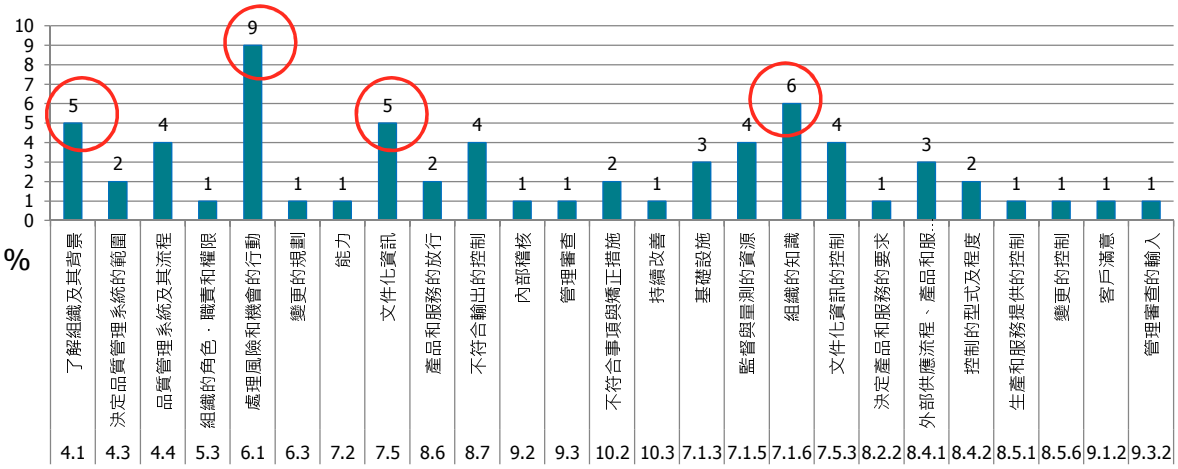
42

轉版的缺失統計



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43

你的組織　打的是哪一場比賽？

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Context of the organization (組織背景)

4.1 了解組織及其所處的環境背景 (Understanding the organization and its context):

- ✓ 確定內外部議題: the organization will need to determine external and internal issues that are relevant to its purpose and strategic direction.
- ✓ 預期的結果: what its intended result(s) are of its management system. Intended result(s) of the QMS have already been covered and were detailed in 1 Scope.
- ✓ 外部議題: External context include: legal, technological, market, cultural, social ...etc.
- ✓ 內部議題: Internal context include: values, culture, knowledge, performance ...etc.
- ✓ 內外部議題更新: Once external and internal issues have been determined, information relating to them must be subject to monitor and review i.e. keep them up to date!
- ✓ **組織應監測和審查關於內部和外部議題的資訊。**

4.2 了解利害關係人的需求及期望 (Understanding the needs and expectations of interested parties):

- ✓ 確定利害關係人所關切的事項: This clause requires an organization to determine those interested parties that are relevant to its QMS (by considering possibly their effects on its purpose, intended result(s) and strategic direction for example).
- ✓ 利害關係人所關切的事項更新: Once interested parties and their requirements have been determined, information relating to these must also be subject to monitor and review i.e. keep it up to date!

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ex: Consumers, Employees, Owners, shareholders, Society, Suppliers and partners ...etc.
股東,客戶,供應商... 等等

4. Context of the organization (組織背景)

4.1 了解組織及其所處的環境背景 (Understanding the organization and its context):

確定內外部議題: the organization will need to determine external and internal issues that are relevant to its purpose and strategic direction.

預期的結果: what its intended result(s) are of its management system. Intended result(s) of the QMS have already been covered and were detailed in 1 Scope.

外部議題: External context include: legal, technological, market, cultural, social ...etc.

內部議題: Internal context include: values, culture, knowledge, performance ...etc.

內外部議題更新: Once external and internal issues have been determined, information relating to them must be subject to monitor and review i.e. keep them up to date!

Clause 4.1 – Understanding the organization and its context – NEW REQUIREMENT

You will need to be able to demonstrate that you have identified external and internal issues, which you monitor and review.

Please provide information:

1) about the internal and external issues relevant to your organization?
2) the process of monitoring the internal and external issues?
3) how you have considered the impact of any changes to the issues?

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08/12/2015

4. Context of the organization (組織背景)

4.2 了解利害關係人的需求及期望 (Understanding the needs and expectations of interested parties):

確定利害關係人所關切的事項: This clause requires an organization to determine those interested parties that are relevant to its QMS (by considering possibly their effects on its purpose, intended result(s) and strategic direction for example).

利害關係人所關切的事項更新: Once interested parties and their requirements have been determined, information relating to these must also be subject to monitor and review i.e. keep it up to date!

ex: Consumers, Employees, Owners, shareholders, Society, Suppliers and partners ...etc.

股東,客戶,供應商... 等等

Clause 4.2 – Understanding the needs and expectations of interested parties – NEW REQUIREMENT

You will need to be able to demonstrate that you have identified, monitor and review all interested parties that are relevant to the QMS and their requirements. Please provide:

1) Information about interested parties who affect or could affect your QMS?
2) Information about their needs and expectations?
3) The process of monitoring and reviewing interested parties and their needs?

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08/12/2015

4. Context of the organization (組織背景)

4.3 組織應決定品質管理系統的邊界和本國際標準要求的適用性，以建立其範圍。 **在決定品質管理系統範圍時，組織應考慮:**

a) 條文4.1中的內部和外部的議題;

b) 條文4.2中的相關利害關係人的要求;

c) 組織的產品及服務。

Clause 4.3 – Determining the scope of the quality management system – ENHANCED REQUIREMENT

There was a requirement in ISO 9001:2008 to document the scope of the QMS.

The new standard now requires you to consider the 'context of the organization'

(Clause 4.1) and 'interested parties' (Clause 4.2).

You'll need to identify any boundaries and applicability of the QMS.

This could include the whole organization or specific functions. Please provide information on:

1) The boundary and applicability information on the scope of your QMS?
2) The products and / or services included in your quality management system?
3) Has the scope of your QMS changed and if so how?

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4. Context of the organization (組織背景)

4.4.1/4.4.2 組織應依照本國際標準之要求建立、實施、維持和持續改善品質管理系統，**包括所需的流程和流程間的相互關係**。

Clause 4.4 – Quality management system and its processes – OTHER CHANGES

The final requirement is for you to establish, implement, maintain and continually improve your QMS. Whilst there was a similar clause (Clause 4.1) in the 2008 version, this now requires the adoption of a process approach.

Although every organization will be different, documented information such as process diagrams or written procedures could support this.

Please provide information on the process-based QMS including:

List of processes, process sequences and interactions, methods to manage the processes, resources to support processes, process responsibilities and authorities, risks and opportunities of each process and how you ensure the system improves the processes and the quality management system.

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08/12/2015

評估組織的外部議題可能包括：

a）社會、文化，政治，法律，監管，財務，科技，經濟，自然和競爭環境，無論是國際，國家，區域或地方;

b）關鍵驅動力與趨勢，可對組織的目標有影響;

c）關係，觀念和外部利益相關者的價值。

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評估組織的內部議題可能包括：
1）治理，組織架構，角色和責任;
2）政策，目標，以及實現這些目標的策略;
3）能力，理解資源和知識和能力（如資金，時間，人員，流程，系統和技術）;
4）資訊系統，資訊流和決策流程（正式和非正式）;
5）關係，觀念和內部利益相關者的價值;
6）組織文化;
7）標準，組織之指導方針和模式;
8）合約關係的形式與程度;

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由於利害相關者對組織一致性地提供符合顧客、適用法令及法規要求事項之產品與服務的能力，有其影響或潛在影響，組織應決定：

a) 與品質管理系統有直接相關的利害相關者；

b) 此等與品質管理系統有直接相關的此等利害相關者之要求事項。

組織應監督與審查此等利害相關者及其直接相關要求事項之資訊。

ex: Consumers, Employees, Owners, shareholders, Society, Suppliers and partners …etc. 股東, 客戶, 供應商... 等等

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確認您的組織背景、利害關係人、 產品及服務

No.	外部與內部議題 (正向/負向)	直接相關利害相關者之要求事項	組織之產品與服務	品質管理系統之範圍
1				
2				
3				
4				
5				
不適用於QMS範圍(條款):				
正當理由:				

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什麼是風險？！

bsi.

08/12/2015

6. Planning (規劃)

6.1.1 組織應考慮條文4.1所提及的議題和條文4.2所提及的要求，並決定需要處理的風險和機會，以:

a) 確保品質管理系統能實現其預期的結果;

b) 提高所希望的效果;

c) 預防或降低不希望的效果;

d) 實現持續改善。

6.1.2 組織應規劃:

a) 措施以處理風險和機會; b) 該如何:

1) 在品質管理系統流程中，整合和實施行動 (見第4.4);

2) 評估這些行動的有效性。

Clause 6.1 – Actions to address risks and opportunities – NEW REQUIREMENT

This clause requires you to identify the risks and opportunities that need to be managed. You need to consider the outputs from 'understanding the context of the organization' (Clause 4.1) and 'interested parties' (Clause 4.2).

The requirements in relation to contingency planning and preventive action from the 2008 version are now addressed within this clause. This is not a risk assessment; it is risk-based thinking. Annex A4 provides more guidance.

Please provide information on how the risks and opportunities have been identified

and how actions to address these have been managed.

bsi.

6. Planning (規劃)

6.2.1/6.2.2 組織應就相關的功能、層級和流程，建立品質管理系統所需要的品質目標。組織應維持品質目標的文件化資訊。

Clause 6.2 – Quality objectives and planning to achieve them – ENHANCED REQUIREMENT

This clause retains some of the requirements contained in Clause 5.4 of the 2008 version but is more specific.

Quality objectives need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhancing customer satisfaction.

Once defined, the objectives need to be monitored, communicated and updated as appropriate.

Whilst this clause is more specific than previous, there is no fundamental change in the approach. Guidance is contained within the clause contents.

Please provide information on how the organization ensures objectives are relevant to the organizations policy, how they are communicated and monitored.

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5W1H的條款要求:

9.1.1 監督，量測，分析，評估

(General of monitoring, measurement, analysis and evaluation)

a) What needs to monitoring and measurement?
b) The methods of monitoring and measurement?
c) When to monitor and measure?
d) When to analyze and evaluate?

6.2.2 品質目標 (objectives): when planning how to achieve…

a) What will be done?
b) What resources required?
c) Who will be responsible?
d) When it completed?
e) How to evaluate results?

7.4 溝通 (communication):

internal and external

a) What to communicate?
b) When to communicate?
c) With whom to communicate?
d) How to communicate?
e) Who communicates?

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6. Planning (規劃)

6.3 變更的規劃 當組織決定品質管理系統需要變更時，這些變更應以計畫的方式完成 (4.4)。組織應考慮:

a) 變更的目的及其潛在的影響;

b) 品質管理系統的完整性;

c) 可用的資源;

d) 責任和權限的指派或再分配。

Clause 6.3 – Planning of changes – ENHANCED REQUIREMENT

There is little change to Clause 5.4.2 of ISO 9001:2008 in that the integrity of the QMS must be maintained when planning changes. However you now need to consider the purpose of change, why it's being made, potential consequences and the resources and (re) allocation of responsibilities.

Please provide information on how the organization manages and implements change.

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Risk-based thinking (風險導向思考模式)

- 風險: 不確定性對預期結果的影響。 R= f (expected result, uncertainty)
- 風險導向思考模式 **(Risk-based thinking):**
  整個 **ISO 9001:2015** 標準內均採納風險導向思考模式，使整個管理系統成為預防性工具，並鼓勵持續改善。

✓ One of the purposes of a QMS is to act as a preventive tool. This Standard does not have a separate clauses/sub-clause titles 'Preventive action'.
✓ This concept is expressed through a risk-based approach to formulating QMS requirements.
✓ The concept of risk based thinking is explicit in this Standard; being incorporated throughout its requirements, especially: Clause 6.1 (Actions to address risks and opportunities) which requires a determination of risks and opportunities .
✓ It does not advocate a risk management approach though, as detailed in ISO 31000 for example.
✓ Risk-based thinking means considering risk qualitatively (and, depending on the organization's context, quantitatively) when defining the rigor and degree of formality needed.

bsi.

Risk-based thinking (風險導向思考模式)

- 風險評估: "發生頻率" 乘以 "嚴重程度" 的結果。
  R= f * s (expected result, uncertainty)
  Risk: effect of uncertainty on an expected result
  Note 1 to entry: An effect is a deviation from the expected — positive or negative

- **本標準 ISO 9001:2015 所稱之風險的 "不確定性" 可能是正面的，也可能是負面的 (0.3.3)。**

  Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity.

  Actions to address opportunities can also include consideration of associated risks.

  Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

bsi.

Risk-based thinking (風險導向思考模式)

- ISO 9001:2015 條款中提及風險之處:
  - 6.1 – Actions to address risks and opportunities
  - 0.1, 0.3, 0.5 - Intros
  - 4.4. f) – QMS and its Processes
  - 5.1.2. b) – Customer focus
  - 8.5.5.a) – Post-delivery activities
  - 9.3.1.d) – Management Review input
  - A.4,5,7,8 – Annexes

- 可供參考的方法-風險:
  - ISO/IEC Guide 73 – Risk management vocabulary – Guidelines for use in standards
  - ISO 31000-2009 -- Risk management – Principles and guidelines
  - BS 31100 Risk management – Code of practice and guidance for the implementation of ISO 31000
  - ISO 31010, Provides details on risk assessment concepts, process, and selection/comparison of risk assessment tools/techniques
  - ISO 14971:2012 Risk Management for Medical Device

bsi.

確認風險、 機會及行動 (1/2)

No.	外部與內部議題 (正向/負向)	直接相關利害相關者之要求事項	對品質管理系統可達成其預期結果	風險評估的結果 (高/中/低度)	決定需加以處理之風險與機會 (Y/N)	處理此等風險與機會之措施
1						
2						
3						

bsi.

規劃處理此等風險與機會之措施 (2/2)

No.	處理此等風險與機會之措施	將措施予以整合並實施各措施於其品質管理系統流程中		所需要的資源	何時完成	如何評估結果	評估此等措施之有效性 (Y/N)
		流程/條款	部門/承辦				
1							
2							
3							

bsi.

CHANGE MANAGEMENT (變更的管理)-1/2

- 變更的管理:
  - 6.3 品質管理系統的變更: 應以有計畫的方式來進行品質管理系統的變更。

    Clause 6.3 (Planning of changes) relates to any changes of the QMS being carried out in a 'planned manner'. This will include considering (1) the purpose of the change and the potential consequences, (2) the integrity of the QMS, (3) the availability of resources , and (4) the allocation of responsibilities and authorities.
  - 7.1.6 首處理變更的需求和趨勢時，組織應考慮其現有的知識，並決定如何獲得或取得任何必要的額外知識，以及必要的更新。(new)
  - 8.1 作業規劃及控制, 含計劃性及非預期變更的控制:

    Clause 8.1 (Operational planning and control) is addressing the control of planned changes . (ex: from addressing risks opportunities of 6.1).

    Requirement to review the consequences of unintended changes, including taking action to mitigate any adverse effects (as necessary).
  - 8.5.6 生產或服務 之 非計劃性變更的審查 & 控制: (new)

    Clause 8.5.6 (Control of changes) is addressing unplanned changes (i.e. review and control) essential to ensure continuing conformity of the product or service to meet specified requirements.

bsi.

CHANGE MANAGEMENT (變更的管理)-2/2

- 變更的管理:
  - 9.2.2 內部稽核時須考量到變更: (new)
    an audit programme(s) … shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - 9.3.2.b 管理審查輸入須考量到內外環境議題的變更: (new)
    changes in external and internal issues that are relevant to the quality management system;
  - 4.4.1.g 流程的變更:
    evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results…
  - 7.5.2 文件的變更:
    Creating and updating: …format (e.g. language, software version, graphics) and media (e.g. paper, electronic)…
  - 8.2.4 合約/訂單的變更:
    Changes to requirements for products and services
    產品和服務要求的變更 ，首產品和服務的要求發生變更時，組織應確保修訂相關的文件化資訊，並確保相關人員了解變更後的要求。
  - 8.3.6 設計開發的變更:
    Design and development changes

bsi.

品質管理系統中的變更管理

No.	流程名稱	變更之目的	可能後果	品質管理系統之完整性 (Y/N)	資源之取得 (Y/N)	責任與職權之配置或重新配置 (Y/N)
1						
2						
3						

bsi.

知識的力量

bsi.

08/12/2015

7. Support (支援)

7.1 資源

7.1.1 一般要求

組織應決定及提供所需的資源，以建立、實施、維持和持續改善品質管理系統。

7.1.2 人員

組織應決定並提供必要的人力以有效實施品質管理系統與其流程的運作與控制。

7.1.3 基礎設施

組織應決定提供和維護其流程運作所必要的基礎設施以實現產品和服務的符合。

7.1.4 流程運作的環境

組織應決定提供和維護其流程運作所必要的環境，以實現產品和服務的符合性。

7.1.5 監督與量測的資源

7.1.5.1 一般要求

7.1.5.2 量測的追溯

7.1.6 組織的知識

組織應決定其流程作業，及實現符合的產品和服務所需要的知識。

維持及便於取得這些知識，應達到所需要的程度。

bsi.

處理變更的需求和趨勢時，組織應考慮其現有的知識，並決定如何獲得或取得任何必要的額外知識，以及必要的更新。

Knowledge management (知識的管理)-1/2

- 組織所必要的知識 (7.1.6 Organizational knowledge): - NEW REQUIREMENT

✓ 知識: Defined as 'available collection of information being a justified belief and having a high certainty to be true' .

✓ 流程及產品服務所須要的知識: The requirement here is to determine, maintain and make available (extent necessary) the knowledge necessary for the operation of its processes, AND to achieve conformity of products and services.

✓ 變動需求及趨勢; 知識更新: Knowledge necessary to address changing needs and trends will also need considering, and how to acquire or access any additional knowledge necessary and required update.

✓ 來源 (Sources):

a) 內部來源: e.g. intellectual property; from experience; from failures and success; the results of improvements in processes, products and services ... etc.
b) 外部來源: e.g. standards; academia; conferences; from customers or external providers ... etc.

bsi.

Knowledge management (知識的管理)-2/2

Example approach:

組織所需要的知識 (7.1.6 Organizational knowledge)

7.1.6 Organizational knowledge	組織所需要的知識
1. What knowledge is necessary here, for process, product, service?	組織所需要的知識是甚麼, 流程及產品服務所需要的?
2. How is this knowledge maintained within the organization?	此知識如何在組織中維持?
3. How is it made available?	此知識要用時如何取得?
4. Are there any changing needs/trends?	是否有需要改變?趨勢?
5. Is any additional knowledge required for 4.? How is this to be acquired or accessed?	為滿足條款4,是否有需要額外的知識? 如何獲得? 如何存取?
6. Required update.	知識更新!

bsi.

1. What knowledge is necessary here?
那些是必要知識？
2. How is this knowledge maintained (updated) within the organization?
該知識將如何在組織裡被維護/更新?
3. How is it made available?
它將如何被提供/應用?
4. Are there any changing needs/trends?
有任何需求/趨勢上的改變嗎?
5. Is any additional knowledge required for (4.1/4.2)? How is this to be acquired/accessed?
是否須額外知識？該如何獲取 / 取用？

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08/12/2015

流程運作與達成產品與服務的符合性所必需之知識

No.	流程名稱	知識名稱	知識來源 (內部/外部)	知識維持 (部門/承辦)	知識取得 (電子/紙本)	最近一版 更新日期
1						
2						
3						

bsi.
08/12/2015

7. Support (支援)

7.2 能力: 組織應:

a) 決定在組織控制下從事會影響績效及效果的人員所必須具備的能力;

b) 依據適當的教育程度、訓練、或經驗，確保人員能勝任其工作;

c) 適用時，採取措施以獲得必要的能力，並評估這些措施的有效性;

d) 保存適當的文件化資訊作為具有能力的證據。

Clause 7.2 – Competence – OTHER CHANGES

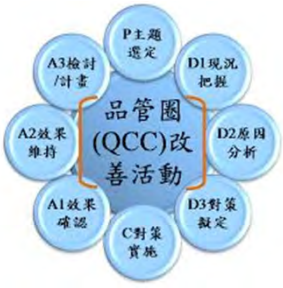
There are no significant changes within this clause; it's a combination of Clauses 6.2.1 and 6.2.2 from 2008. You will need to determine the competency of people and ensure that these are met and maintained. This applies to any person affecting the organizations quality performance including contractors.

Within this clause you are required to retain documented information as evidence of competence.

Please provide information on those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training, or experience, and how the information required for the effective implementation and operation of the QMS have been determined.

bsi.

7. Support (支援)



7.3 認知: 組織應確保在組織控制下工作的人員認知:

a) 品質政策;

b) 相關的品質目標;

c) 他們對品質管理系統有效性的貢獻，包括品質績效改善的益處;

d) 不符合品質管理系統要求的含意。

Clause 7.3 – Awareness – OTHER CHANGES

This clause covers awareness of the quality policy, objectives and the implications of not conforming to the requirements. However there is no fundamental change in approach when taking into account the guidance provided within the clause. Please provide information on how you have raised awareness of the policy and the QMS requirements.

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Audit situation 2: (稽核狀況2)

稽核員正在稽核衝壓部現場, 發現衝壓機台#15, 機台邊有掛示機台作業指導書#TU-WI-019, 作業員小李. 稽核員詢問小李: 為什麼機台每日點檢表這兩天沒記錄呢?! 小李回說: 喔! 對不起! 我忘了. 我才剛來一個月, 我們班長有交待我這張表要每天勾一勾, 說著就接過點檢表, 把這兩天的記錄補齊.... 請您判斷以上情事是否已構成不符合? 違反ISO 9001:2015那一條款要求? 請完成下列不符合報告單. 或者您認為尚不足以構成不符合, 尤需再繼續追查那些證據來佐證----請說明!

bsi.

08/12/2015

7. Support (支援)

7.5 文件化資訊

7.5.1 一般要求

7.5.2 制定及更新

7.5.3 文件化資訊的控制

7.5.3.1 本國際標準和品質管理系統所要求的文件化資訊應管制...

7.5.3.2 適用時，組織應處理以下文件化資訊的控制活動....

Clause 7.5 – Documented information– OTHER CHANGES

Clause 7 replaces 'documented procedures' and 'records' from the 2008 version with 'documented information'. Additional requirements now include the activity to control 'distribution' of necessary documented information, especially with regards to permission to view and authority to change. However there is no fundamental change in approach when taking into account the guidance provided within the clause contents of 7.5.3.

Please provide information on how you control the distribution of necessary documentation.

bsi.

Documented information (文件化) – 1/5

7.5 Documented information – no Quality Manual,
no mandated 6 documented procedures
文件化資訊 - 沒有強制的品質手冊、沒有過去強制的6份文件化程序。

7.5.1 General
7.5.2 Creating and updating – enhanced:
description, format & suitability
建立及更新, 強化: 描述、格式及適用性。

7.5.3 Control of documented information
now includes confidentiality, integrity and access explicitly
文件化資訊的控制 - 包括機密性、完整性和明確地存取。

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Documented information (文件化) – 2/5

Documented information:
文件化資訊 **(7.5.1, 7.5.2, 7.5.3)**。文件化要求更有彈性。組織決定所需的文件化資料及其格式。

- (維持 vs. 保存) maintain vs. retain;
- …no longer use procedures

. 維持 **vs.** 保存
(Maintain documents vs. Retain records!!!)
. **Keep=maintain + retain**

. 程序 **vs.** 流程
(Procedure vs. process!!!)
Process has replaced procedure.

bsi.

Documented information (文件化) – 3/5

4.3 Maintained scope

4.4 Maintained documented information to the extent necessary to support the operation of processes, and retained documented information to the extent necessary to have confidence that the processes are being carried out as planned

5.2 Quality policy (5.2.2)

6.2 Retained quality objectives (6.2.1)

7.2 Appropriate documented information as evidence of competence

7.1 Retained evidence of fitness for its purpose, as a monitoring and measurement resource (7.1.5); Where no such standard exists (measurement), the basis used for calibration or verification (7.1.5); This knowledge shall be maintained, and made available to the extent necessary. (7.1.6)

7.2 Retained appropriate evidence of competence

7.5 Required by this International Standard (7.5.1); Determined by the organization as being necessary for the effectiveness of the QMS (7.5.1); Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS (7.5.3.2)

bsi.

Documented information (文件化) – 4/5

8.1 Retained documented information to the extent necessary to have confidence that the processes have been carried out as planned, and to demonstrate conformity of products and services to requirements

8.2 Retained description of the results of the review, including any new or changed requirements for the products and services, relevant amended documented information. (8.2.3)

8.3 Confirmation that design and development requirements have been met. (8.3.2) Retained documented information resulting from the design and development process. (8.3.5)

Design and development changes – retained (8.3.6)

8.4 Retained results of the evaluations, monitoring of the performance and re- evaluations of the external providers.(8.4.1)

8.5 Defining the characteristics of the products and services, as applicable. (8.5.1 a) Defining the activities to be performed and the results to be achieved, as applicable. (8.5.1 b)

Retained to maintain traceability (where traceability is a requirement). (8.5.2)

Retained description of the results of the review of changes, the personnel authorizing the change, and any necessary actions. (8.5.6)

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Documented information (文件化) – 5/5

8.6 Retained evidence of conformity with the acceptance criteria

Traceability to the person(s) authorizing release of products and services for delivery to the customer.

8.7 Actions taken on nonconforming process outputs, products and services, including on any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity – retained

9.1 Appropriate documented information as evidence of the results of monitoring, measurement, analysis and evaluation.

9.1 Retained evidence of the results of monitoring and measurement activities. (9.1.1)

9.2 Audit programme. (9.2.2)

Retained evidence of the implementation of the audit programme and the audit results. (9.2.2)

9.3 Retained evidence of the results of management reviews. (9.3.2)

10.2 Retained evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action. (10.2.2)

bsi.

鴻海夏普戀

bsi.

08/12/2015

10. Improvement (改善)

10.1 一般要求

組織應決定和選擇改善的機會，及實施任何必要的行動，以滿足客戶 要求，並提升客戶滿意。此些應包括:

a) 改善產品與服務以符合要求，以及處理未來的需求與期望;

b) 改正、預防、或減少不希望的影響;

c) 改善品質管理系統的績效與有效性。

備註:改善的例子可能包括改正、矯正措施,、持續改善、突破性改變、創新、及組織重整

Clause 10.1 – General – OTHER CHANGES

This clause covers the general need for improvement, whether to meet existing and future customer requirements, correcting or reducing undesired effects or improving the performance or effectiveness of the system.

Please provide information on how your organization has addressed these changes.

bsi.

08/12/2015

確認您的組織是否已準備好 ISO 9001:2015轉版?

bsi.

轉版差異分析評審工具

BS EN ISO 9001:2015
管理系統差異分析評審

答案
1-不存在
3-存在但不完整
5-存在且完整

填寫以下確定合規性方面的調查結果和差距出現的地方使用答案為每個適用部分分辨一個分數，必要時，提供發現結果的評語。輸入的數據進入填充圖（標籤卡2）針對ISO 9001每個元素的合規/差異。

評審者: 日期： 評審領域：

計畫	條款	價值	評語
組織已確認、監督與審查外部與內部課題 直接利害相關者之要求	4.1 4.2		
範圍被定義與紀錄	4.3		
範圍包含QMS與所有權覆蓋下的產品/服務(排除辯護?)	4.3		
展現高層管理領導與決心	5.1		
高層主管執行a~j	5.1.1		
適用的政策，提供架構目標，並被記錄	5.2		
已建立可提供給利害關係人的政策溝通機制	5.2.2		
政策有包含滿足申請要求與持續改善的決心	5.2.1		
政策會定期性審查組織目的/背景環境/策略方針	5.2.1		
組織角色、職責、權限被指派、理解與溝通	5.3		

bsi.

轉版差異分析評論審工具

BS EN ISO 9001:2015
管理系統差異分析評論審

答案
1-不存在
3-存在但不完整
5-存在且完整

填寫以下確定合規性方面的調查結果和差距出現的地方使用答案為每個適用部分分辨一個分數，必要時，提供發現結果的評語。輸入的數據進入填充圖（標籤卡2）針對ISO 9001每個元素的合規/差異。

評審者: 日期： 評審領域：

計畫	條款	價值	評語
考量過提出風險與機會的行動	6.1.1		
評估風險/機會/行動的效益	6.1.2		
建立了為達到目標而建立的流程	6.2.1		
在適當時, 記錄與量測目標	6.2.1		
目標與政策及可應用之要求一致	6.2.1		
透過a-e(5W1H)確認目標	6.2.2		
目標與產品/服務相關，被監督及溝通	6.2.1		
擁有規劃QMS變動的方法	6.3		
QMS變動:考量資源、目的、影響、職責與權限的再分配或指定	6.3		
QMS 知識管理流程/內外部/必要的更新	7.1.6		

ISO 9001:2015 驗證轉換時間表

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ISO 9001:2015 Certification transition timeline
ISO 9001:2015 驗證轉版期程

September 15, 2015Publication
2015年9月15日,正式發行

September 2015 start of 3 years transition period to September 2018
2015/09/15開始為期3年至2018/09/14的轉版期

Eq. CAV1: 3 MDs, CAV2: 3 MDs, RA: 6 MDs, IA: 9 MDs

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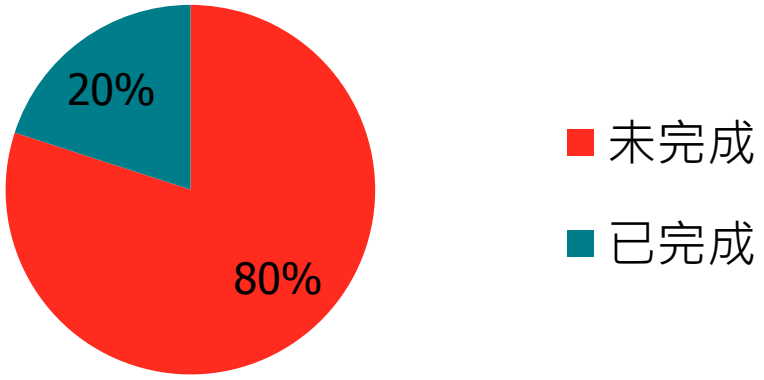
目前轉版的客戶統計 (截至2016年底)



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ISO 9001:2015
品質管理系統條款要求
Q&A

bsi.

ISO 9001:2015 - Q & A

Q1: ISO 9001與ISO 14001 於改版時，需要刻意合併嗎?(程序文件的部分)

A1: ISO 9001:2015 改版時並未強制要求與ISO 14001:2015 合併，但是強烈鼓勵組織合併ISO 9001, ISO 14001及其他管理系統成整合性管理系統。

Q2: BSI 如何針對 ISO 9001:2015及ISO 14001:2015進行整合性驗證稽核?

A2: BSI會安排同時具有 ISO 9001:2015, ISO 14001:2015及/或 ISO 45001:2016資格的稽核員,進行整合性驗證稽核。

Q3: ISO 9001、TS 16949、QC 080000 及OHSAS 18001 稽核員是否同時執行整合驗證稽核?

A3: BSI會安排同時具有 ISO 9001， ISO 14001 及 ISO 45001 資格的稽核員進行整合性Q/E/O驗證稽核。但是 TS 16949或QC 080000 則視情況而定。

Q4: ISO 證書轉換驗證程序為何?

A4:目前所知 ISO 9001 及ISO 14001的證書轉換期為3年。

Q5: 若維持有品質手冊的文件，是否需將內容重新以 ISO 9001:2015 的10個章節的架構進行編排?

A5: 鼓勵組織以 ISO 9001:2015的新架構10個章節 (HLS) 進行編制品質手冊。

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ISO 9001:2015 - Q & A

Q 6: ISO 9001:2015 轉版稽核所須增加的稽核人天為何?

A 6: 轉版稽核所須增加的的稽核人天是依據IAF的規定執行。原則上大型組織須增加的的稽核人天較多，反之，中小型組織 較少。基本上增加一個人天是普遍的case。

Q 7: ISO 9001:2015 轉版教育訓練等資訊或規劃為何? 如: 條文說明課程、內部稽核員轉版課程及主導稽核員轉版課程等資訊或規劃。

A 7: BSI Taiwan 針對 ISO 9001:2015 轉版教育訓練規劃有二：

(1) ISO 9001:2015轉版一天課程: 提供給之前已取得 ISO 9001:2008合格內部稽核員課程證書者。

(2) ISO 9001:2015轉版兩天課程: 分為三類: 2008版主導稽核員升級轉版課程 / 2015版內部稽核員課程 / 2015版轉版及差異建置課程。提供持有ISO 9001:2008主導稽核員五天課程證書者 / 提供一般對於品質管理系統初學及欲取得合格內部稽核員資格者 / 提供組織參與品質管理系統運行規劃者， 可取得相關ISO 9001:2015轉版兩天課程證書。

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ISO 9001:2015 - Q & A

Q 8: ISO 9004 將繼續提供指導嗎？

A 8: 是的，這份ISO 9004 將繼續提供非常有用的訊息，關於怎樣運用品質管理的原則，以應對廣泛的企業管理議題，並且建立一可持續的企業。

Q 9: 多久以後就能開始進行轉版過程？

A 9: ISO 9001的修定已於2015/09/15完成並公告，你可以審查組織的流程是否符合新高層次結構(HLS)? 但是，請記得，你的系統必須保持滿足 ISO 9001:2008的要求 ，直到依新標準要求轉版完成為止。

Q 10: 可以在2016年轉版嗎？

A 10: 是的，可以。只要組織的系統已滿足 ISO 9001:2015 的所有要求。

Q 11: 已取得 ISO 31000 風險管理驗證，因為風險是ISO 9001:2015版所不可缺少的，如此，還需要兩個標準嗎？

A 11: 是的，ISO 31000 著重於整個組織採用風險管理。但是，ISO 9001:2015著重於達成客戶滿意度的系統。故，還需要兩個標準。

Q 12: 有關於醫療器材標準 ISO 13485的改版狀況為何？

A 12: 醫療器材標準 ISO 13485目前正在進行改版作業，不過，與其他 ISO 標準不同，它不能採用高層次架構 (HLS) 。

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Thank you for your Attendance!
感謝您的參與！

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94