國際標準ISO9001(2008年版)改版技術通報

工作草案版(Working Draft)

時間表

1. 預訂於2008年間核准公佈新版。
2. 轉換過度期間尚未決定；因改變幅度不大，預計約1年半時間。

主要修訂重點(草案)

- 參照名詞解釋標準由ISO9000:2000改為ISO9000:2005。

4.1〈一般要求〉

- 對外包過程的鑑別要求，修正為：應在品質管理系統中對這些外包過程的管制方式加以定義。
- 增加一項備考：7.4 款要求可應用於對外包過程的管制。

Where an organization chooses to outsource any process that affects product conformity ~~with~~ to requirements, the organization shall ensure control over such processes. The controls to be applied to these outsourced processes shall be defined within the quality management system.

Note 2：The requirements of Clause 7.4 of this international standard may also apply to outsourced processes.

4.2.1〈文件化要求– 概述〉

- 將原品質紀錄要求項目(e項)拆散併入程序及其他文件要求項目中。
- 備考中強調：一份文件可包含多個程序；一項程序也可能需要不只一份文件來對應。

e) documented procedures and records required by this International Standard, and

f) documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes~~, and~~

~~g) records required by this International Standard (see 4.2.4).~~

Note 1：Where the term “documented procedure“ appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

4.2.3〈文件管制〉

- 應管制之「外來文件」範圍有明確之界定。

f) to ensure that documents of external origin necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

4.2.4〈紀錄管制〉

- 文字敘述方式調整；內容未變。

Records ~~shall be~~ established ~~and maintained~~ to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. ~~Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.~~

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.
Records shall be remain legible, readily identifiable and retrievable.

5.5.2〈管理代表〉

- 強調管理代表應為「組織的」管理階層成員(即不允許外聘)。

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes.

6.2.1〈人力資源– 概述 〉

- 原適用範圍〈執行會影響『產品品質』工作的人員〉修改為〈執行會影響『產品要求之符合性』工作的人員〉。

Personnel performing work affecting ~~product quality~~ conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2〈能力、認知及訓練〉

- 承續6.2.1 的修訂；a)將【產品品質】改為【產品要求之符合性】。
- 更強調本條款之要求在「定義、一致、及確保人員能力」上。

6.2.2 Competence, training and awareness

The organization shall

e). determine the necessary competence for personnel performing work affecting ~~product quality~~ conformity to product requirements,

e). where applicable, provide training or take other actions to ~~satisfy these needs~~ achieve the necessary competence,

c) ~~ensure the effectiveness of the actions taken,~~ ensure that the necessary competence has been achieved,

6.4〈工作環境〉

- 增加備考：舉例：如無塵室、ESD(抗靜電措施)、衛生條件....等。

Note: The term work environment relates to conditions necessary to achieve conformity to product requirements such as clean rooms, anti-static precautions and hygiene controls.

7.2.1〈產品有關要求之決定〉

- c)項「與產品有關之法令與法規要求」修訂為「適用之法令與法規要求」。
- d)項「組織所決定之任何附加的要求」修訂為「組織所需要之要求」。
- 增加備考：舉例解釋何謂「交貨後活動」。

e). statutory and regulatory requirements ~~related~~ applicable to the product, and

e). any additional requirements as needed ~~determined~~ by the organization.

Note：Post delivery activities may include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.3.1〈設計及開發規劃〉

- 增加備考：設計審查、查證與確認各有其明確目的，可依組織及其產品之特性做適當的組合配置。

Note：Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.

7.3.3〈設計及開發輸出〉

- 增加備考：所支援「生產和服務提供」包括「產品之保存」

Note：Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.Design and development outputs shall….

Note：Production and service provision includes preservation of the product.

7.5.2〈生產及服務提供過程之確認〉

增加備考：

- 無法提供先前完全查證符合性的服務過程應屬該確認之範圍。
- 列舉可能需事先確認的各種過程。

Note 1：For many service organizations, the service provided does not readily allow the verification before the delivery of the service. These types of processes should be considered and identified during the planning stage (see 7.1)

Note 2：Processes such as welding, sterilization, training, heat treatment, call center service, or emergency response may need validation

7.6監督及量測裝置之管制

增加備考：

- 監督及量測裝置包含用於量測設備(用於監督或量測)及裝置，不僅限於用在監督其是否符合要求之設備。
- 確認電腦軟體能力以滿足預期之要求應包含其驗證及形態管理。

Note 2：Monitoring and measurement devices, include measuring equipment (whether used for monitoring or measurement) and devices other than measuring equipment that are used for monitoring conformity to requirements.

Note 3：Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8.2.2〈內部稽核〉

- 明確規定必須保存內部稽核的紀錄。(現行版本對內稽紀錄之維持，隱含在4.2.4節以及內稽文件化程序要求中)

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

~~The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.~~

Records of the audit and its results shall be maintained (see 4.2.4).

8.2.3〈過程之監督及量測〉

- 強調當過程未達成所規劃之結果時，所採行的改正與矯正措施，其目的不僅限於確保產品滿足要求。
- 增加備考：因監督及量測結果採行措施的考量重點。

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate~~, to ensure conformity of the product~~.

Note：When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4〈產品之監督及量測〉

- 文字敘述方式調整；內容未變。

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

~~Evidence of conformity with the acceptance criteria shall be maintained~~. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product ~~release~~ and service delivery to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Note：Evidence of conformity with acceptance criteria can be a record or as otherwise specified in the planned arrangements.

8.3〈不符合產品之管制〉

- 對處理不符合產品一節的規定，增加「當適用時」彈性語詞。
- 重新安排原條款各項要求的排列順序。

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define ~~T~~the controls and related responsibilities and authorities for dealing with nonconforming product. ~~shall be defined in a documented procedure.~~

Where practicable, the organization shall deal with nonconforming product by one or more of the following ways:

e). by taking action to eliminate the detected nonconformity;

e). by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

e). by taking action to preclude its original intended use or application.

e). when nonconforming product is detected after delivery or use has started, by taking action appropriate to the effects, or potential effects, of the nonconformity

~~Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).~~

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

8.5.2〈矯正措施〉與 8.5.3〈預防措施〉

- 兩條款之最末項『審查所採行之矯正/預防措施』之要求外，更要求「審查措施之有效性」。

8.5.2 f) reviewing the effectiveness of the corrective action taken.
8.5.3 e) reviewing the effectiveness of the preventive action taken