

Product Compliance Program

產品符合計畫

StandardsMark

標準標誌



SAI GLOBAL

SAI全球公司

PRODUCT CERTIFICATION

產品認證

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AMENDMENT HISTORY

修訂歷史

Date 發行日期	Issue 修訂的簡介摘要	Brief Summary of Amendments
1/11/91 1/11/91	01 01	Original Issue as Quality Assurance Program (QAP01/02) 原發行名稱為品質保證計畫 (QAP01/02)
14/12/93 14/12/93	02 02	Minor Editorial Amendments 次要編輯的修訂
12/8/96 12/8/96	03 03	Major revision to incorporate ISO 9002:1994 主要校訂是將ISO 9002:1994併入
1/12/96 1/12/96	04 04	Change of title to Product Compliance Program 產品符合計畫的名稱變更
1/11/98 1/11/98	05 05	Editorial Amendments 編輯的修訂
5/2/04 5/2/04	06 06	Review including alignment with ISO 9001:2000 審閱時應包括ISO 9001:2000
19/8/05 19/8/05	06.02 06.02	Addition of Customer Related Processes, Minor Editorial Amendments 增訂與顧客相關程式，次要編輯修訂

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PREFACE

序言

The aim of the SAI Global Product Certification Program is to deliver to its customers a program that will engender confidence in the various stakeholders (manufacturers, suppliers, regulators and consumers) that products or service bearing the StandardsMark consistently meet the requirements of the relevant Standard or Specification.

SAI全球產品認證計畫的目標是為了傳達給其顧客一項產生信任的方案；各製造商、供應廠商、管制人員和消費者如何才能對標有標準標誌 (StandardsMark) 的產品持續符合相關標準 的要求或規格。

This Product Compliance Program has been designed to include where relevant the following criteria:
本產品符合計畫是為包含下列相關準則而設計的：

- Certification for SAI Global's client at competitive prices.
對SAI全球公司客戶的認證是以最合理價位計算。
- International recognition – based on the criteria in ISO Guide 67 for product certification system 5 and quality system elements of ISO 9001.
國際承認 – 是基於對產品認證體系-5的ISO指引67和ISO 9001的品質系統基本要素。
- Credibility amongst its stakeholders.
在利益各方中的可信度高。
- Accreditation requirements for ISO Type 5 product certification programs - ISO Guide 65.
對iso第5類產品認證計畫的公認要求 - iso指引65。
- An audit process focusing on the product and its conformity with standards and relevant quality system elements to provide confidence of continuing product compliance.
一項審核過程焦點在產品和符合標準及相關品質系統的要素，對產品持續符合性提供信心。
- Specific requirements relating to relevant product or service standard (the Technical Schedule has been designed for this purpose, and in some cases it may vary the general PCP requirements).
特定的要求與有關的產品或服務標準 (技術計畫表是為這一個目的而設計，並在某些情況它可能與一般的PCP要求不同)。

The changes to this document version have been made in line with the above objectives.
對本檔版本的修訂是符合上述的目的。

The official version of this Product Compliance Program is the English version, which is downloadable from our website, at the following hotlink. _
<http://www.saiglobal.com/static/forms/PCP06.02%20StandardsMark%20Product%20Compliance%20Program1.pdf>

1. SCOPE AND GENERAL 範圍和概述

1.1 Scope 範圍

This document sets out the requirements for the Product Compliance Program (PCP) to be implemented by all StandardsMark Licensees. The PCP includes requirements for:

本文獻為所有標準標誌 (StandardsMark) 的持認證許可者須執行的產品符合計畫 (PCP) 的要求。產品符合計畫 (PCP) 包括下列各項要求：

- compliance of the product with Australian, National or International Standards, or other published specification;
產品符合澳大利亞標準，國家標準或國際標準或其他已發表的規格；
- quality plan elements;
品質計畫的要素；
- use of SAI Global's certification trade mark, known as the WaterMark.
SAI全球公司的認證商標的使用，稱為水標誌。

This document shall be read in conjunction with the Technical Schedule issued by SAI Global for the particular product standard, the Rules Governing the WaterMark Scheme and the Terms and Conditions for Certification of Licence as amended from time to time.

本檔必須連同SAI全球公司對特定產品標準的工藝計畫表同時閱讀，並且參閱對認證執照經常修訂的水標誌方案、條款和條件。

Note: StandardsMark applicants should also refer to the guidance document, PCD 30 Guide to Applicants.

備註：標準標誌 (StandardsMark) 申請者還應參閱申請指南檔，PCD- 30申請者指引。

1.2 Application 申請

1.2.1 Licence Requirements 證書的使用

Licensees who use the registered certification trademarks (including the StandardsMark) of SAI Global Limited do so on certain terms and under the Rules Governing the Use of the Certification Trademarks of SAI Global Limited and must comply in all respects with this PCP. SAI Global may at its discretion vary the requirements of the PCP.

使用SAI全球有限公司的註冊認證商標 (包括標準標誌 (StandardsMark) 的持許可證者須在某些規定條件使用，並必須全面遵守本產品符合計畫 (PCP) 的規定。SAI全球公司可自由變更產品符合計畫 (PCP) 的要求。

By granting a StandardsMark licence, SAI Global demonstrates that it is satisfied that the Licensee is capable of consistently producing a product complying with a specified Standard. The Licensee, by applying the StandardsMark to a product, warrants that the product meets all relevant requirements of the specified Standard.

授予標準標誌 (StandardsMark) 給持認證許可者，表示SAI全球公司對持認證許可者有能力使產品持續符合規定的標準達到要求。持認證許可者在產品上使用標準標誌 (StandardsMark) 即是保證該產品符合標準的所有相關要求。

1.2.2 Relationship to ISO 9001-2000 與ISO 9001-2000的關係

In general the Quality Plan requirements within this PCP (Section 4) are based upon the adoption of ISO 9001-2000 Quality Management Systems – Requirements. The principles have been adopted where appropriate to support the basic requirements of the program. Additional requirements have been incorporated where necessary.

概括的說，此產品符合計畫 (第四段) 中的品質計畫要求是依據ISO:9001:2000的品質管制系統

要求為基礎。被採用的適合原則作為支持計畫的基本要求。增加的要求被併入相關的章節中。

1.3 Related Documents

相關文獻

ISO 9001-2000 – Quality Management Systems - Requirements.

ISO 9001-2000 -- 品質管制系統 – 要求。

ISO 9000-2000 - Quality Management Systems – Fundamentals and Vocabulary.

ISO 9000-2000 -- 品質管制系統 -- 基本和辭彙。

ISO 10012 – Measurement management systems – Requirements for measurement processes and measuring equipment.

ISO 10012 – 測量管理系統 – 對測量過程與測量儀器的要求。

PCD 30 – Guide to Applicants – A step-by-step guide through the product certification process.

PCD 30 -- 申請人的指引 - 一項產品認證過程指引。

SMG 03 - Guidelines for Product Certification Testing

SMG 03 -- 產品認證測試指南。

Q100A – The Australian StandardsMark Rules Governing the Product Certification Scheme

Q100A -- 澳大利亞標準標誌 (StandardsMark) 管理產品 認證方案的規則。

QGD17 – Terms & Conditions for Certification and Certification Mark.

QGD17- 為認證和認證標誌的條款與條件。

1.4 Definitions

定義

For the purpose of this PCP, the definitions in ISO 9000 and the following apply:

在本產品符合計畫 (PCP) 中 , **ISO 9000**的定義和下列的定義適用 :

1.4.1 Batch

批量

A clearly identifiable collection of units, manufactured consecutively or continuously under the same conditions.

一批連續在一同樣的情況之下製造並可清楚確認的產品。

1.4.2 Certified Product

經認證的產品

Finished product for which a Licensee may apply the StandardsMark, to demonstrate that the product conforms to the specified Standard and that the licensee has in all other respects complied with SAI Global's Product Compliance Program.

持認證許可者使用標準標誌 (StandardsMark) 的成品表示該產品符合規定的標準 , 並且持認證許可者並已全面符合SAI全球公司的產品符合計畫 (PCP) 的要求。

Note: Certified products models are listed on the Schedule to each StandardsMark Licence issued by SAI Global.

備註 : 經認證的產品型號都列明在SAI全球公司發佈的每種標準標誌(StandardsMark)許可證上。

1.4.3 Critical Defect

嚴重缺點

A defect that analysis, judgment and experience indicates is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product.

產品缺點若根據分析、判斷和經驗的顯示 , 可能導致使用、維修或依靠此產品的個人處於危險或不安全狀況。

1.4.4 Design Freeze

設計凍結

The term applied to the rule that once the final product design has been type tested and certified, none of the aspects of design which might adversely affect compliance of the product with the standard may be changed without the written approval of SAI Global.

該條款指一旦設計的產品通過式樣測試和認證 , 未經SAI全球公司書面同意不得更改設計的任何點 , 以免可能產生影響產品符合標準的要求。

1.4.5 Licensee

持認證許可者

Organisation or individual that has been granted the right to use a registered certification trademark of SAI Global Limited for particular products or services as a demonstration of compliance with a specified Standard.

組織（公司）或個體被授權，對某產品或服務使用SAI全球有限公司註冊認證商標，作為符合指定標準。

Note: Throughout this document Licensee also refers to StandardsMark licence applicants.

備註：本檔中的持認證許可者也指標準標誌（StandardsMark）認證許可申請者。

1.4.6 Major Defect 重大缺陷

A defect other than critical or special, that is likely to result in failure, or to reduce materially the usability of the item for its intended purpose.

除指關鍵性或特殊的缺陷外的缺陷，但可能導致該產品測試不通過或因減少材料份量不能依原規定用途使用。

1.4.7 Product 產品

Result of activities or processes.
活動或流程的結果。

Notes:

備註：

1. A product may include a service, hardware, processed materials, software or a combination thereof.

產品可以包括服務、硬體、經加工的材料、軟體或綜合以上各點。

2. A product can be tangible (eg. assemblies or processed materials) or intangible (eg. knowledge or concepts) or a combination thereof.

產品可以有形的（例如：組裝品或已加工的材料），也可以是無形的（例如：知識或理念），或綜合以上各項。

1.4.8 Quality Plan 品質計畫

A documented system including specific quality practices, resources and sequence of activities implemented and maintained by the Licensee to ensure consistent compliance with the requirements of the product standard and the PCP.

持認證許可者為保證持續符合產品標準和達到產品符合計畫（PCP）的要求所建立的向持認證許可者供應產品的組織（廠商）

。

具體品質實施、資源和行動執行程式的列檔檔。

Note: The quality plan may stand alone, for example in a small company making one simple product. In larger companies it is likely to be a part of the company's quality management system.

備註：品質計畫可以是單獨的，比如在一家生產一項簡單產品的小公司。在較大的公司品質計畫就可能是公司品質管制的一部份。

1.4.9 Standard 標準

Australian Standard, National Standard, International Standard, Specification or other publicly available criteria against which SAI Global may grant certification.

SAI全球公司可授於認證的澳大利亞標準、國家標準、國際標準、規格或其他公認可用的標準。

1.4.10 StandardsMark 標準標誌

A reference to a registered certification Trade Mark of Standards Australia International Limited that has been assigned to SAI Global Limited and which is used on conforming product.

參照澳大利亞標準國際有限公司註冊的認證商標已經被指定給SAI全球有限公司使用於產品的符合性。

1.4.11 StandardsMark Labels 標準標誌的標籤

Serially numbered labels incorporating the StandardsMark, provided by SAI Global for application to certified products.

SAI全球公司為已認證的產品提供有序號的標準標誌（StandardsMark）標籤。

Note: StandardsMark labels are not available for all products.

備註：並不是所有產品都可申請標準標誌（StandardsMark）標籤。

1.4.12 Subcontractor 協力廠商

Organization that supplies a product to the Licensee.

1.4.13 Technical Schedule

技術計畫表

SAI Global document, read in conjunction with the Standard that defines certification requirements and provides guidance for testing and auditing against the Standard.

SAI全球公司的文件，須連同說明認證要求和提供測試指引與依據審核的標準閱讀。

1.4.14 Type Test

式樣測試

A test or series of tests directed towards approval of a design conducted to determine if an item is so designed that it is capable of meeting the requirements of the product standard.

對一種設計進行的測試或一系列的測試以判定該產品設計是否能夠達到產品標準的要求。

2. LICENCE CONDITIONS 認證許可證的條件

2.1 Product Compliance 產品符合

Adequate supervision and control shall be exercised at all stages of process to ensure that the finished product, together with related marking and information, meets all the relevant requirements of the specified Standard.

在生產過程的所有階段採取充分的監督和管制以保證成品和相關的標誌與資訊都符合特定『標準』的所有相關要求。

All necessary action shall be taken to ensure that the StandardsMark is not associated with products which do not comply with the Standard. If a non-conforming Standards-Marked product is identified, the licence may be suspended pending results of investigation. The full cost of such investigation shall be borne by the Licensee.

必須採取所有必要的動作以確保標準標誌

(StandardsMark) 不會與不符合規格的产品相混。如被發現產品帶有標準標誌 (StandardsMark) 而不符合標準要求，許可證將可被暫時取消，並等待調查結果。調查的所有一切費用將由持認證許可者承擔。

The licensee remains responsible at all times for ensuring that the StandardMark is applied and remains on conforming products only.

持認證許可者須負責保證標準標誌 (StandardsMark) 使用在並留在符合要求的產品上。

2.2 Confidentiality 保密性

All proprietary documents, including specifications, quality plans and test reports shall remain confidential between SAI Global and the Licensee unless and to an extent that

所特有的專有檔，包括規格，品質計畫和測試報告都將限於SAI全球公司和持認證許可者之間的機密，除非

- i) the licensee authorizes (expressly or by implication) the release of such information to a third party, such as an agent, a test facility or a government authority.

持認證許可者(不論明白地或有意識地)授權釋放此資料給第三者，如代理人，測試單位或政府當局。

- ii) SAI Global has been served with a subpoena, summons, notice or other legally enforceable order to disclose the information. SAI全球公司被迫於傳票、傳喚、通告或其他法律上的程式必須揭露的資料。
- iii) a relevant accreditation body seeks access to the information as part of accreditation audit or process; or 一家有關的公認團體尋求取得部份稽核或程式的資料；或
- iv) the information is in the public domain 資訊已在登載公眾媒體領域中

2.3 Surveillance Audits 監督審核

Audits focus on the quality plan for the certified product including the mechanisms that the company has in place to ensure continuing compliance of the product. If a company has a certified quality system, elements of the quality system which are identical to those required by the PCP will not normally be audited except in so far as they apply to the quality plan for the certified product. For example, document control procedures will not be audited but it will be verified that documents related to the product (eg specifications, purchasing records, work instructions, test reports etc) are included within the existing document control system, address the appropriate requirements and are current.

審核重點在於被認證的產品的品質計畫，包括公司現有結構制度以確保產品能持續符合規定。如某家公司的品質系統已認證過，而品質系統中的要件與產品符合計畫 (PCP) 雷同的部分一般是不需要審核的，除非該部分運用於認證產品的品質計畫。例如：文件管制將不被審核，只需被驗證，證明與產品相關的文件 (例如：規格、採購記錄、工作指令、測試報告等) 已被包括在現有的控制系統文件中，並滿足適當的要求和不過時即可。

Note: For the purposes of this clause, a certified quality system is a system certified by an independent body accredited for the appropriate scope by JAS-ANZ or an equivalent nationally recognised accreditation body.

備註：僅限於本條款內，認證過的品質系統是指經過JAS- ANZ或同等國家級的機構鑒定合格的獨立機構，在適當範圍內所作的品質系統認證

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2.4 TERMS & CONDITIONS

條款與條件

Refer to Terms & Conditions for Licence for details.

有關認證許可證書的條款與條件的細節。

2.5 Licence Review and Renewal

執照審查與更新

The StandardMark license will normally identify an expiry date, which is calculated on a normal period from initial certification date. The licence will be renewed for a further period subject to confirmation of the status of certification.

標準標誌 (StandardsMark) 執照一般注明有效期限 (依發照日期算起)。執照依認證狀況的確認更新。

3. TESTING 測試

3.1 Type Testing 式樣測試

A type test shall be conducted when:
式樣測試將在以下情況下進行：

- a) a manufacturer completes an application form in respect of a StandardsMark licence; and
生產廠商填妥關於標準標誌(Standards Mark)執照申請表；和
- b) at the discretion of SAI Global when -
SAI全球公司可斟酌處理當下述情況發生時-
 - i) certified product has undergone or may have a design change; or
已通過認證的產品再作設計修改；或
 - ii) testing of certified product indicates a failure to comply with the Standard; or
認證過的產品測試顯示不符合標準；或
 - iii) the Licensee wishes to add another product to the licence.
持認證許可者希望在執照上增加另一項產品。

3.2 Submission of Products for Type Testing 提交產品作式樣測試

Where product is submitted for StandardsMark certification, the Licensee shall provide the following information:

申請標準標誌 (StandardsMark) 認證的產品時，持認證許可者必須提供以下資訊：

- a) full identification of the product;
填寫產品的完整識別；
- b) detailed supportive test data;
支援測試的詳細資料；
- c) an indication of when samples for type tests may be selected;

注明式樣測試的樣品何時可以選取；

- d) samples of packaging and labelling, and
包裝和標籤的樣品，
- e) if the product is resubmitted following a type test failure, details of the nature of the failure and the corrective action taken to enable the re-submission to pass. Re-testing of failed product will normally be conducted by the same test laboratory that performed the original test unless otherwise agreed by SAI Global.
如果在一次式樣測試失敗後，重新提交樣品作測試，則需說明測試失敗的原因及為了能夠通過重新測試已採取的糾正措施。重測樣品一般是由原測試單位執行除非經SAI全球公司同意。

3.3 Test Sample Selection 測試樣品的選取

3.3.1 General 概述

Product test samples will normally be selected by a SAI Global staff member or person authorised by SAI Global. This requirement may be varied as determined by SAI Global to suit circumstances such as required by the IECEE CB scheme.

測試樣品通常由SAI全球公司的人員選取或由SAI全球公司授權的人選取。此要求可由SAI全球公司視情況而有不同。例如IECEE CB方案的要求。

3.3.2 Samples from stabilised production 穩定生產中的取樣

Samples shall be selected when the production process has stabilised. The samples shall be randomly selected from a production lot that is large enough to ensure that they are representative of the processes involved and of the quality that the Licensee intends to present to the market.

樣品將在生產過程已經穩定後才選取，並且從某批量中隨意抽取；該批產品的數量必須大到足以保證能夠代表該產品的製造

過程和品質，並且是持認證許可者準備提供給市場的產品。

3.3.3 Prototypes

原型

For initial assessment purposes a type test may be conducted on laboratory-scale pilot batches or prototype samples incorporating hand-made parts. Such testing may demonstrate the suitability of the product design in terms of the Standard. However, further correlation testing will normally be required once production has stabilised and usually before any product is released.

在初步評估時，式樣測試可在實驗室進行生產的試產批量產品或含有手工製作部份的原型樣品。此類測試可以顯示產品的設計是否適合標準的要求。但是，一旦生產穩定則一般需要進行進一步的相關測試，通常在產品未上市之前。

3.3.4 Condition of Samples

樣品的條件

Samples shall be in the condition in which they are offered for sale and shall be accompanied by all relevant attachments. Applicable instructions for use, care, installation or maintenance, shall also be submitted.

提交樣品的狀態必須和產品出售時的狀態一般的，並附上所有相關附件。有關使用、保養、安裝或維修的說明也必須一併提交。

3.3.5 Test Groups and Worst Case Samples

測試群和最差實例

A range of models with varying characteristics may be grouped together for type testing purposes if the models can be expected to perform similarly during testing. A test group shall only include models of the same style, type or class in terms of the Standard, which are made using the same general production methods. Type test samples shall be selected from the model in the group that can be expected to give the worst results for any given test or group of tests.

一系列具有不同特性的類型可以集成一組作式樣測試，但是這些類型必須可以作相似的測試。該測試的系列組只能包括相同樣式、類型和級別使用一般相同的生產方法或依標準的要求是同級的。

式樣測試的樣品應從測試系列組中選取被認為在任何測試中會產生最差的結果的。

Nominations by the Licensee for test groups and worst case models shall be accompanied by supportive data in the form of calculations, test results and written explanation. The final decision on test groups and worst case models rests with SAI Global.

持認證許可者提出的測試組和最差實例的類型時，必須同時附上資料、測試結果和書面說明的支援資料，再由SAI全球公司作最後的決定。

3.3.6 Delivery of samples

樣品的運送

Delivery of samples to the agreed laboratory shall be the responsibility of the Licensee. Samples shall be preserved and packaged to prevent damage or deterioration in transit.

持認證許可者負責把樣品送到同意的實驗室。樣品務須包裝好以免途中受損壞或變質。

3.4 Test Laboratory

測試實驗室

The test laboratory shall be agreed between SAI Global and the Licensee.

測試實驗室將由SAI全球公司和持認證許可者雙方協商決定。

The contract for testing shall be between the Laboratory and the Licensee, unless otherwise specified and costs for and incidental to testing shall be met by the Licensee.

測試合同由實驗室和持認證許可者之間簽訂。除非對測試明確說明和費用和其他費用，所有測試費用都由持認證許可者承擔。

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Testing must be conducted under the terms of SMG 03 in order for the test results to be accepted by SAI Global for certification purposes.

測試必須按照SMG 03條款的規定進行，以便測試結果被SAI全球公司接受認證。

Note: Laboratories accredited by a nationally recognised body such as NATA or IANZ or under the IECEECB Scheme will generally be preferred.

備註：必須是經過國家承認的實驗室，如：一般來說NATA或IANZ或在LECEECB計畫內的實驗室都會被接受。

在製造業者呈交在申請之前所作的樣式測試報告SAI全球可以考慮如果該報告是目前的，可追溯到製造的批量符合SAI全球公司的指導方針如本產品符合計畫，相關的工藝計畫表和SMG 03。

3.5 Test Results 測試結果

Original Test reports will normally be sent by the laboratory to SAI Global. Evaluation and acceptance of the test results and certification of the product remains the responsibility of SAI Global and SAI Global reserves the right to reject any test result.

測試報告正本一般由實驗室寄給SAI全球公司。再由SAI全球公司負責評估和接受測試結果及產品的認證。SAI全球公司保留不接受測試結果的權利。

A pass test result does not automatically lead to certification. For example if the test report does not cover all aspects of the product standard or if the result is outside the known process capability limits, further testing or information will be required.

測試結果的通過並不表示當然獲得認證通過。例如：當測試報告不包含產品標準的所有重點時，或當測試結果超出已知的製造過程能力，需要進行進一步的測試或提供進一步的資訊。

3.6 Re-Test 重新測試

SAI Global reserves the right to re-test certified products at any time during the currency of a licence. Products may be selected from the licensee's premises or at the point of importation, distribution or sale and the cost of re-testing shall be met by the licensee.

SAI全球公司保留有權在認證許可書有效期中的任何時間重新測試已認證的產品。重新測試的產品可以從持認證許可者的生產地或進口點、批發點或銷售點選取。所有重新測試的費用將由持認證許可者承擔。

3.7 Existing Type Test Reports 現有的樣式測試報告

Where the manufacturer submits type test reports conducted prior to the application, these may be considered by SAI Global provided the reports are current, traceable to a production batch and meet SAI Global guidelines as documented in this PCP, the relevant technical schedule and SMG 03.

4. QUALITY PLAN REQUIREMENTS

品質計畫的要求

4.1 GENERAL

概述

The organization shall establish, document, implement and maintain a quality plan for the certified product, as a means for ensuring conformance to the product standard, and that the requirements of this PCP and any relevant technical schedule are met. The quality plan shall cover each of the elements of the PCP.

組織對已認證的產品需建立,文件化,執行並維持品質計畫作為一種確定產品符合標準和產品符合計畫 (PCP) 需求 與符合相關工藝計畫表。該品質計畫必須包含本產品符合計畫 (PCP) 的每項要素。

Note: Some of the requirements have been taken from ISO 9001-2000 and where these have been directly taken it is shown in italics. The word 'organisation' appearing in italics means the Licensee. Appendix A shows a correlation of the clauses of ISO 9001:2000 and those of the PCP as an overview of the requirements adopted. Differences between PCP 05 are also listed.

備註：一些需求是從 ISO 9001-2000 摘錄的，而且這些被直接摘錄的文字是以斜體字顯示。該字『組織』是斜體的話就是指持認證許可者。附錄A顯示ISO9001: 2000的條款與相互關係，而產品符合計畫 (PCP) 是採用整體性的需求。產品符合計畫-5 (PCP 05) 列出差異之處。

4 Documentation Requirements

檔作業的要求

4 General Requirements

一般的要求

The quality documentation shall include
品質文件須包括：

- a) Quality Plan Summary
品質計畫摘要。
- b) Documented procedures as required by this PCP.
本PCP所要求的書面程序。

- c) Documents required by the organization to ensure the effective planning, organization and control of processes.
組織必需確定有效的計畫，組織結構和程序控制的文章。
- d) Records required by this PCP.
本PCP要求的所需要的記錄。

4.2.2 Quality Plan Summary (QPS)

品質計畫摘要 (QPS)

A summary of the quality plan for the applicable product(s) shall be submitted to SAI Global (in English) for acceptance. The Quality Plan Summary (QPS) may be presented in either of the following ways:

品質計畫摘要 (用英文書寫) 對適用的產品呈交SAI全球公司審核。品質計畫摘要 (QPS) 可在下列任一方式呈現：

- a) For suppliers with a certified quality system, as a process flowchart including references to the manufacturing processes, test method and inspection and test points (including those for sub-contracted services) which ensure continuing compliance of the product with the applicable standard. This document shall be the part of the supplier's quality system; or
對品質系統已被認證過的供應商而言，以一製程流程表包括製造流程，測試方法和檢驗及測試點 (包括協力廠提供的服務) 以確保產品持續符合適用的標準的參考。這份文件將是供應商的品質系統的部份；或
- b) For suppliers who do not have a certified quality system, a document incorporating the following items:
對沒有被認證過的品質系統的供應商而言，須提供一份包含下列各項目的文件：
 - i. Organization Chart;
組織 (公司) 結構圖；
 - ii. Quality Policy;
品質政策

- iii. Responsibilities and authorities of management representative and deputy/s;
管理代表和助理的職責和權責；
- iv. Flow chart referenced with the applicable procedures, methods, work instructions and test points (including sub-contracted processes) in accordance with document PCD 30.
以符合PCD 30文件的適用程序、方法、工作指導和測試點(包括協力廠的流程) 的流程圖。

Note: Guidance on the preparation of a quality plan summary is given in SAI Global document PCD 30.

注意:SAI全球公司的PCD30文件是準備品質計畫摘要的指導。

4.2.3 Control of Documents

文件的控制

Documents required by or referenced within the quality plan shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

在品質計畫裏所需的文件或參考是屬於控制的。記錄是一特別類型的檔而且依照4.2.4條款也是屬於控制的。

A documented procedure shall be established to define the control needed.

建立一份書面程序以界定需要的控制：

- a) *to approve document for adequacy prior to issue;*
文件在公佈之前須獲得批准；
- b) *to review and update as necessary and re-approve documents;*
檢討並作必需的更新後再批准文件；
- c) *to ensure that changes and the current revision status of documents are identified;*
確定所有變更和現有文件的校訂狀態被識別；

d) to ensure that relevant versions of applicable documents are available at points of use;

確定可適用文件的有關版本可在使用點取得的；

e) to ensure that documents remain legible and readily identifiable;

確定文件保持清晰的和可以確認；

f) to ensure that documents of external origin eg. Standards or documents critical to the certification are identified and their distribution controlled, and

確定外來文件例如標準或對認證的關鍵文件的識別，和其分發的控制，和

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

避免作廢的文件被無意中使用，如果被保留為某種目的必須有適當的標示。

4.2.4 Control of Records

記錄的控制

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality plan. 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.

需建立並保持記錄以對符合需求和品質計劃的有效運作提供證據。記錄將保持清晰，不遲疑的和可取出的。需要建立一份被書面程序書與定義所需控制，對記錄的識別、儲存、保護、使用、保存時間和作廢。

The organization shall maintain legible and indelible records of the following:

組織需維持下列各記錄的清晰和不能消除：

- a) Final release eg. Batch release (in English), including serial numbers (where appropriate), date, batch identify and signature of the authorized person for release of the batch;

最後放行例如批量放行（以英文書寫），包括序號（適用之處），日期，批量 識別和授權放行人的簽字。

Notes:
注意

- i. An example of a batch release record is given in Appendix B.
附錄B是一批量放行記錄的例子。
 - ii. The organization's licence signatory is ultimately responsible for the correctness, completeness and validity of the data shown in the record.
組織的執照簽字者是最終負責記錄中顯示的資料的正確性，完整性和有效性。
- b) If serially numbered labels are used, a StandardMark label register is required to be maintained;
如果使用序號標籤，必須保存一份標準標誌(StandardMark) 標籤登錄；

Notes: The StandardMark label register may be combined with batch release records.
注意：標準標誌 (StandardMark) 標籤登錄可以與批量放行記錄合併在一起。

- c) Type test reports;
樣式測試報告；
- d) Inspection and test reports;
核對總和測試報告；
- e) Acceptable sub-contractors;
可接受的協力廠商；
- f) Design changes;
設計變更；
- g) Traceability;
追溯；
- h) Calibration;
校正；
- i) Training;
培訓；
- j) Customer complaints.
客戶投訴。

The organization shall retain records relevant to products released under the scheme for a minimum of 10 years from the date of product release. Such records shall include:

組織（公司）需保存相關產品放行紀錄依規定從放行日期起最少10年。此類記錄包括：

- a) final release test reports;
最後放行測試報告；
- b) final release records; and
最後放行記錄；和

StandardsMark label records (where relevant).
標準標誌 (StandardMark) 標籤記錄 (視需要之處)。

In deciding the retention period of other records, the organization should give consideration to the records required to justify limiting any recall of product and to defend any product liability action that may be taken.

在決定其他的記錄保存期限方面，組織應考慮記錄必需配合任何產品回收規定和法規對產品責任規定所需的時限。

Note: Commonwealth and State laws may require certain records to be kept for a minimum period from the date of sale.

注意：英聯邦國和州法律可能需要某些記錄自銷售日期起保存最低期限。

4.3 Management Responsibility 管理職責

Quality Policy 品質政策

Top management shall ensure that the quality policy

高層管理人員必須確保品質政策

- a) Is appropriate to the purpose of the organization,
對組織目的是適宜的。
- b) Is communicated and understood within the organization, and is reviewed for continuing stability.
確定在組織裏已被檢討過，溝通並且瞭解可持續穩定進行的。

c) Make a statement of commitment to supporting ongoing compliance of the certified product with the appropriate Standard.

宣告一份承諾以支持進行中已認證的產品符合標準。

4.3.2 Responsibility and Authority

職責與職限

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

高層管理層需確保責任與權責已界限及在組織裏溝通。

4.3.3 Management Representative

管理代表

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes :

高層管理層需指定管理層中一位，不論其現有責任，需負責並被授權為管理代表並包刮以下責任：

a) ensuring that processes needed for the quality system or quality plan are established, implemented and maintained;

保證按照本產品符合計畫 (PCP) 建立、執行、維持一套品質計畫，

b) ensuring the planning of the quality system or quality plan is carried out in order to meet the requirements of the PCP (see ISO 9001 clause 5.4.2);

保證品質計畫在產品生產的每個過程中都受到充分的監督和管制作用，以確保成品及相關的標示和資訊都符合產品符合的要求 (參閱ISO 9001第5.4.2條款) 。

c) ensuring that adequate control is exercise at all stages of the processes to ensure that the delivered product, together with related marking and information, meets the relevant requirements of the product Standard, the PCP and relevant Technical Schedule.

保證在所有各階段流程都被控制執行以確保被運送的產品、包含相關標誌與資訊都符合產品符合計畫和相關工藝計畫表。

d) informing SAI Global of changes to: -

下述變更事項需通知SAI全球公司：--

i) Product specifications or production processes that could affect compliance of the product with the Standard; and
有可能影響產品符合標準要求的產品規格或生產過程；

ii) licence conditions such as company ownership, company name, address, key personnel, etc;

執照條件，例如：公司擁有人、公司名稱，地址、主要人員、等等；

iii) subcontracting/outsourcing of parts of the manufacturing process.

外包/外購的零件製造過程。

e) notifying SAI Global of any information or evidence that may indicate that non-conforming StandardsMark product has been released from the place of manufacture; and
任何資訊或證據顯示市場上可能有不符合標準標誌 (StandardsMark) 產品時，必須通知SAI全球公司；

f) notifying SAI Global of corrective action taken in relation to SAI Global audit findings, or non-conforming products and ensuring that action is effective.

通知SAI全球公司有關SAI全球公司審核時發現的缺點或不合格產品後所採取的糾正措施並保證該措施是具體有效的。

The organization shall also establish a mechanism to ensure that there is at least one person appointed to deputise when necessary for the management representative in matters relating to the StandardsMark Licence and PCP requirements.

組織還需建立一套系統以保證在必要時至少有一人被指定為助理給管理代表負責標準標誌 (StandardsMark) 和產品符合計畫事宜。

The responsibilities and authorities of the management representative and deputies shall be documented. SAI Global shall be notified of any changes to the personnel appointed.

管理代表人和其助理人的職責和職權應明文紀錄在案。任何人事變更應及時通知SAI全球公司。

4.3.4 Internal Communication

內部溝通

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the implementation of the quality plan.

高層管理在組織裏面需確定建立適當的溝通过程式，而且溝通關於品質計畫的落實與發生效力。

4.4 Resource Management

資源管理

4.4.1 Human Resources

人力資源

4.4.1.1 General

概述

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

會影響品質的操作員工必須接受適當的教育、培訓、技能和經驗為基礎才能勝任的。

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4.4.1.2 Competence, Awareness and Training. The Organisation Shall

勝任，認知和訓練。組織必須

a) Determine the necessary competence for personnel performing work affecting product quality.

員工從事的工作對產品品質具影響的程度確定所需的勝任性。

b) Provide training or take other actions to satisfy these needs.

提供訓練或採取其他的行動以使達到這些需求。

c) Evaluate the effectiveness of the actions taken.

評估執行的行動效力。

d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of finished product conformity with the relevant product standard.

確定其人員知道他們對他們的活動的重要性和對達到完成符合相關產品標準產品的貢獻。

e) maintain appropriate records of education, training skills and experience (see 4.2.4).

維持適當教育、技能培訓和經驗的記錄（參見 4.2.4）。

4.4.2 Infrastructure

環境設施

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

組織需決定、提供和維持周邊設施達成對產品的需求。周邊設施包括，如適合時

a) buildings, workspace and associated utilities.
建築物、工作空間和相關的公共設施。

b) process equipment (both hardware and software) and
處理設備（硬體和軟體）和

c) supporting services (such as transport or communication).
附帶服務（如運送或通訊）。

4.4.3 Work Environment

工作環境

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

組織需決定而且管理所需的工作環境達成對產品需求。

4.5 Product Realization

產品實現

4.5.1 Planning of Product Realization

產品實現的策劃

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent

with the requirements of the other processes of the quality plan.

組織需計畫與開發對產品實現所需的。計畫產品實現需和其他品質計畫的流程需求一致。

In planning product realization, the organization shall determine the following as appropriate:
在計畫產品實現方面，適當時組織需決定下列：

a) requirements to ensure finished product conformity with the relevant product standard.

確定成品符合相關產品標準的需求。

b) the need to establish processes documents and provide resources specific to the product.

建立產品特性程式文件和提供資源的需要。

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.

對產品特定和產品允收特性準則所需的查證、確認、監控、檢驗及測試活動。

d) records needed to provide evidence that the realisation processes and the resulting product meet requirements (see 4.2.4).

記錄提供實現程式和完成成品需求的證據 (參見4.2.4)。

4.5.2 Customer Related Processes

與顧客的相關流程

4.5.2.1 Review of Requirements Related to the Product

審查與產品有關的要求

The organisation shall review the requirements related to the product. The review shall be conducted prior to the organisations commitment to supply a product to the customer (eg submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

組織必須審核與產品有關的要求。在組織承諾提供產品給顧客之前必須評審 (例如：參加投標、接受合同或訂單、接受合同或訂單的變更) 和必須確定以下各項：

a) *product requirements are defined,*
產品要求的確定性，

b) *contract or order requirements differing from those previously expressed are resolved, and*

合同或訂單的要求與先前不同的表達的確定性，和

c) *the organisation has the ability to meet the defined requirements.*

組織具備能力符合規定的要求。

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

評審的結果記錄和從評審產生的行動須維持 (參閱4.2.4)。

4.5.2.2 Customer Communication

與顧客的溝通

The organisation shall determine and implement effective arrangements for communicating with customers in relation to

與顧客溝通前組織必須對以下相關專案作出決定和執行有效的安排：

a) *product information,*
產品要求，

b) *enquiries, contracts or other handling, including amendments, and*

詢價、合同或其他處理、包括修訂，和

c) *customer feedback, including customer complaints.*

顧客回應，包括顧客抱怨。

4.5.3 Design Freeze

設計凍結

On successful completion of type testing the design of all major and critical components and materials in the product and manufacturing, assembly and testing processes shall be documented and frozen. The design freeze shall include labelling, packaging and instructions for use, care, installation and maintenance as applicable.

在樣式測試通過後，產品所有重要的和關鍵性的構件與材料、製造、組裝和測試過程都必須建檔記錄同時凍結紀錄。凍結設

計須包括標籤、包裝、使用說明、保養、安裝和維修。

Note: The design freeze does not include minor changes that do not affect compliance of the product with the Standard. If in doubt, the Licensee should submit details of the proposed changes to SAI Global for consideration.

備註：設計凍結不包括不影響產品符合標準的小變更。如有疑問，持認證許可者必須將計畫的詳細變更提交給SAI全球公司考慮。

4.5.3.1 Reference Specimens 參照樣品

Reference specimens, drawings or photographs representative of type test specimens shall be made available as requested by SAI Global. Such specimens shall be identified and retained by the Licensee for no less than 10 years after last manufacture of the licensed product. (SAI Global may keep samples for an equal period of time at its discretion).

式樣測試樣品的參照樣品、圖紙或照片必須可隨時提供給SAI全球公司。這類樣品須由持認證許可者在生產最後一批時驗明並保存十年以上（SAI全球公司可選擇保存樣品達同樣年份）。

4.5.3.2 Changes to the Product Standard 產品標準的修訂

If the Standard is amended or re-issued, SAI Global will nominate a transition period, usually in consultation with relevant stakeholders. After the transition period the Licensee shall not apply the StandardsMark to any product covered by the Licence until compliance of the product with the revised Standard has been verified by SAI Global.

如果標準被修改或者重新發行，SAI全球公司將會提出一個審核期，通常在和有關的人員先聯繫。在審核期間持許可證者不可使用標準標誌（StandardsMark）在任何已認證通過的產品上，直到產品經SAI全球公司驗證符合修訂後的標準。

Note: A nominal transition period of 6 months is applied unless otherwise informed.

備註：所建議的審核期一般為期6個月，除非另被通知。

4.5.4 Control of Design and Development Changes

設計和開發變更的控制

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

設計和開發變更必須被鑑定與維持紀錄。變更需被覆查、驗證和確認有效，如適當時，而且在實施之前須核准。設計和開發變更的審查必須包括變更後對構成的零件部分和已交貨的產品的影響評估。

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

變更和任何必要的行動審查結果紀錄必須被維持（參閱4.2.4）。

SAI Global shall be notified of any proposed changes, which could affect product compliance with the Standard, and such changes shall not be implemented without written authorization from SAI Global.

任何被變更可能影響產品符合標準的作法的提議必須通知SAI全球公司，而且這些變更在未接到SAI全球公司的書面授權不得執行。

4.5.5 Purchasing 採購

4.5.5.1 Purchasing Process 採購過程

The organization shall ensure that purchased product or service conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product or service shall be dependant upon the effect of the purchased product or service on subsequent product realization or the final product or service. 組織需確定被購買的產品，或服務符合所敘述的採購需求。對供應商和被購買的產品或服務要求的控制類型和範圍需依據被購買的產品或服務對產品實現或成品或服務的效果。

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

組織需評估並選擇供應者應依所供應的產品是否符合組織需求的能力。需建立對選擇、評估和重評估的準則。評估結果和評估所產生的任何必要行動都須維持記錄(參閱4.2.4)。

4.5.5.2 Purchasing Information 採購資訊

Purchasing information shall describe the product or service to be purchased including where appropriate.

採購資訊需詳述購買的產品或服務包括。

a) the type, class, grade or other precise identification
類型、級別、等級或其他的精確識別；

b) the title or other positive identification; and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.

名稱或其他明確的識別，和適用的規格、圖紙、程式需求、檢驗指令和其它有關工藝計畫表的資料。

c) requirements for approval of product or service, procedures, processes and equipment, and
對產品或服務、程序、過程和設備需求的核准，和

d) requirements for qualification of personnel.
人員資格的需求。

The organization shall ensure the accuracy of specified purchase requirements prior to their communication to the supplier.

組織在對供應商溝通之前需先確定採購需求的準確性。

4.5.6 Production Provision 製造準備

4.5.6.1 Control of Production Provision 製造準備的控制

The organization shall plan and carry out production provision under controlled conditions. Controlled conditions shall include, as applicable:

組織在計畫與執行製造準備需在受控制的情況。受控制的情況須包括：

a) the availability of information that describes the characteristics of the product,
描述產品特性資訊的取得，

b) the availability of work instructions,
作業指導書的取得，

c) the use of suitable equipment,
使用適當的儀器，

d) the availability and use of monitoring and measuring devices,
監控和測定裝置的取得和使用，

e) the implementation of monitoring and measurement, and
監控和測量的實施，

the implementation of release, delivery and past-delivery activities.
放行、運送和過去運送動作的落實。

Note: An example of a batch release record is shown in Appendix B.

備註：附錄B顯示批量放行記錄的例子。

4.5.6.2 Validation of Processes for Production and Service Provision 製造和服務準備的驗證

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement. This includes any processes where deficiencies became apparent only after the product is in use or the service has been delivered.

組織需驗證任何製造和服務過程當結果無法在監控和測量輸出查證。這包括當產品在使用中或已經被交運後才顯現欠缺的程式。

Validation shall demonstrate the ability of these processes to achieve planned results.

驗證需展現這些流程達成計畫結果的能力。

The organization shall establish arrangements for these processes including as applicable.

組織需建立這些流程的安排包括適當時

- a) defined criteria for review and approval of the processes,
界定準則對流程的檢討和批准。
- b) approval of equipment and qualification of personnel.
設備和人事資格的批准。
- c) use of specific methods and procedures,
特定方法和程序的使用。
- d) requirements for records (4.2.4) and
記錄的需求 (參見4.2.4) 和
- e) revalidation.
重新使生效。

4.5.7 Identification 識別

The organization shall identify the product by suitable means throughout product realization.

組織需以適當的方法遍及產品實現識別產品

The organization shall identify the product status with respect to monitoring and measurement requirements.

組織需識別有關於監控和測量需求的產品狀態。

4.5.7.1 WaterMark 水標誌

The WaterMark is a common method of identifying certified released product. Where it is not practical to apply the StandardsMark to the product, an alternative may be approved by SAI Global provided that the organisation submits a written request.

水標誌 (WaterMark) 是對已認證通過的產品放行的一般識別方式。如果產品不適合標示標準標誌(StandardsMark)時, SAI全球公司可以同意替代方式只要組織提出書面要求

4.5.7.2 Approval of the Form and Manner in which the StandardsMark is Used

批准使用標準標誌 (StandardsMark) 的形式和樣式

The StandardsMark shall only be used in a manner, which has been approved in writing by SAI Global. The licensee shall gain approval from SAI Global for:

標準標誌 (StandardsMark) 只能依SAI全球公司書面核准的方式使用。持認證許可者需獲得SAI全球公司核准對 :

- a) the form and manner in which the StandardsMark is used on the product;
標準標誌(StandardsMark)在產品上使用的形式和樣式 ;
- b) the form and manner in which the StandardsMark is used on promotional material, packaging, swing tags, informative labelling or instructions for use; and
標準標誌 (StandardsMark) 使用在促銷材料上、包裝、吊牌、資訊標籤或使用說明等的形式和樣式 ; 和
- c) proposed references in any form to the StandardsMark licence number or to certification by SAI Global.
對標準標誌 (StandardsMark) 許可證編號或SAI全球公司認證以任何形式作為參考。

Submission for approval shall be made before the StandardsMark is used and shall be accompanied by all qualifying words and illustrations.

使用標準標誌 (StandardsMark) 標示之前必須事先呈送所有的形容文字和實例申請審核批准。

Licensees shall ensure that distributors of their certified products are aware of and observe the requirements of this clause.

持認證許可者需確定其認證產品的經銷商是否知道並遵守規定的要求。

4.5.7.3 Extent of Marking 標誌的使用範圍

The Licensee shall apply the StandardsMark only to products which:

持認證許可者僅可使用標準標誌 (StandardsMark) 在下列產品範圍：

- a) are of the type and size specifically listed on the current Schedule to the Licence; and
列明在執照的類型和大小；和
- b) the Licensee warrants comply in all respects with the relevant Standard and are manufactured in accordance with this PCP.
持認證許可者保證遵守所有與有關標準的要求並依據本產品符合計畫 (PCP) 製造。

4.5.7.4 Application at Licensee's Premises 在持認證許可者的場所提出申請

The StandardsMark shall be applied to certified products prior to dispatch from the manufacturing premises of the Licensee.

標準標誌 (StandardsMark) 需在持認證許可者製造場地出貨之前應用到認證產品上。

Where the Licensee wishes to incorporate a StandardsMark on components manufactured by a sub-contractor prior to further processing or assembly; details shall be submitted to SAI Global for approval. The Licensee shall ensure that SAI Global is guaranteed access to the sub-contractor's premises to determine that the StandardsMark is applied under the conditions of the license.

當持認證許可者希望在加工或裝配之前在協力廠所製造的零件上標示標準標誌 (StandardsMark) 必需將細節呈遞SAI全球公司審核批准。持認證許可者需向SAI全球公司保證可到協力廠場地評估以斷定所應用標準標誌 (StandardsMark) 是依照持認證許可者的條件。

Manner of Application 使用的方式

The StandardsMark shall be applied in a manner that is permanent or tamper-evident using one or more of the following methods:

標準標誌 (StandardsMark) 必須是固定的或使用下列一項或多項方法：

- a) serially numbered labels available from SAI Global.

從SAI全球公司可得的連續編號的標籤。

- b) incorporation into the licensee's label with wherever possible a date code or batch number; or

持認證許可者的標籤在允許之處標示日期或批號；或

- c) directly onto the product by casting moulding, stamping, etching, etc., together wherever possible with a date code or batch number.

直接以鑄造、衝壓、蝕刻等方法烙在產品之上，在允許之處標示日期或批號。

4.5.7.6 Quality of Marking 標誌的品質

Where required marking including the StandardsMark is applied by stamping, etching, printing, casting, moulding or other means directly onto the products, the resulting impression shall be examined at regular intervals and corrective action instigated when the visual marking quality shows signs of deterioration.

當需要以衝壓，蝕刻，印刷，鑄造，成型或其他的方法印記包括標準標誌 (StandardsMark) 直接在產品上，產生的印記結果需在固定間隔期檢查，而當印記品質在視覺上顯現腐化現象必須採取糾正動作。

4.5.7.7 Use of StandardsMark Labels

標準標誌 (StandardsMark) 標籤的使用

Security 安全

The Licensee shall be responsible for the control and security of labels issued by SAI Global. The labels shall be controlled and issued by a responsible person and when not in immediate use shall be stored in a secure place. They shall only be applied at the nominated manufacturing address of the Licensee to certified product.

持認證許可者需負責SAI全球公司發行的標籤的控制和安全。標籤需由一名人員責任控制和發放而且不立即使用的需保存在一個安全的地方。他們只可在持認證許可者指定的工廠位址使用到認證產品上。

Records 記錄

Where production permits, the Licensee shall apply the labels consecutively during manufacturing. The serial numbers of the labels shall be recorded in the batch release register; (see Clause 4.2.4 and clause 4.6.3)

在製造的地方，持認證許可者需按標籤序號連續應用。標籤的序號需在批量放行登記冊中記錄；（第4.2.4條款和第4.6.3條款）。

Damaged Labels 損壞的標籤

Damaged labels shall be mounted on a sheet of paper and retained for inspection by SAI Global. The serial numbers shall be recorded in the StandardsMark label register. (See Clause 4.2.4).

損壞的標籤需貼在一張紙上並保留給SAI全球公司檢查。序號需記錄在標準標誌 (StandardsMark) 標籤登記冊中 (第4.2.4條款)。

4.5.8 Traceability 可追溯性

The organization shall ensure that finished StandardsMark product is traceable to the relevant batch inspection or test reports on at least those items and materials which affect compliance of the product with safety aspects of the standard. As a minimum StandardsMark product shall be least maintained traceability on primary packaging.

組織需確實保證具標準標誌 (StandardsMark) 的成品可追溯到相關批量的檢驗或測試報告，至少對那些項目和材料可能影響符合產品標準的安全性。至少，標準標誌 (StandardsMark) 產品須能追蹤到主要的包裝。

4.5.9 Preservation of Product 產品的防護

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. The preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

組織需對產品在生產中到運送至目的地期間的保持符合。保存需包括識別、處理、包裝、儲藏和保護。保存也將需適用於產品的部份品。

4.5.10 Control of Monitoring and Measuring Devices 監控和測定裝置的控制

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product or service to the requirements of the relevant product standard.

組織需決定採取監控和測量和所需的裝置以提供產品的符合證據或對相關產品或服務的標準需求。

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measuring requirements.

組織需建立一套程式以確定可行的監控和測量並符合持續監控和測量需求的方式。

Where necessary to ensure valid results, measuring equipment shall:

為確定有效的結果，測量儀器需：

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, where no such standards exist, the basis used for calibration or verification shall be recorded.

所作間隔性校正或查核，或使用之前，在沒有此類的標準時，可使用一些可追溯至國際的或國家的測量標準，作為校正基礎或識別但仍需被記錄。

b) be adjusted or re-adjusted as necessary, necessary adjustments or re-adjustments,

c) be identified to enable the calibration status to be determined, 需識別以決定校正狀態，

d) be safeguarded from adjustments that would invalidate the measurement result. 需防止調整會使測量結果失效，

e) be protected from damage and deterioration during handling maintenance and storage.

需防護在操作維修和儲藏期間遭損害和劣化。

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

除此之外，當儀器被發現不符合要求時，組織需評估並記錄早先的測定結果的有效性。組織需對儀器採取適當動作，和任何被影響的產品。校正和確認測定的結果記錄仍需維持（參見4.2.4）。

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. 當用於監控和測量特定需求時，電腦軟體的能力是否對預定目的適用需證實。如必要在啟用之前，須重新確認才可使用。

Note: See ISO 10012 for guidance.

備註：參見ISO 10012指導。

4.6 Measurement, Analysis and Improvement

測量、分析和改進

4.6.1 General

概述

The organization shall plan and implement the monitoring measurement, analysis and improvement processes needed.

組織需計畫而且執行需要的監控測量、分析和改進程式。

- a) to demonstrate conformity of the product to the Standard, and;
展示產品符合標準，
- b) to ensure conformity with the quality plan.
確保符合品質計畫。

This shall include determination of applicable materials, including statistical techniques, and the extent of their use.

這需包括可適用材料的決定，包括統計技巧和其使用範圍。

4.6.2 Monitoring and Measurement

監控和測量

4.6.2.1 Monitoring and Measurement of Processes

監控和測量的流程

The organization shall apply suitable methods for monitoring and where applicable, measurement of the quality 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.

組織需應用適當監控方法與於可適用之處，如品質程式的測量。這些方法需顯示達成計畫能力的程式結果。當計畫結果不能達成時，需採取適當的更正和矯正動作以確定產品的符合。

4.6.2.2 Monitoring and Measurement of Product

產品的監控和測量

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 4.5.1).

組織須監控並測量產品的特性，以查證產品已經達到需求。依安排計畫需在適當階段實行產品實現程式（參見4.5.1）。

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the persons(s) authorizing release of product (see 4.2.4).

對於接受標準的符合證據需維持。記錄需指出授權產品放行的人員（參見4.2.4）。

Product release shall not proceed until the planned arrangements (see 4.5.1) have been satisfactorily completed.

產品的放行在計畫中的安排（參閱4.5.1）

未滿意完成之前不可著手進行。

4.6.3 Release of StandardsMark Product

標準標誌 (StandardsMark) 產品的放行

The supplier shall ensure that certified products are released by personnel who have defined responsibility and authority and that a register or batch release record showing the formal release of certified product is maintained.

供應商須確定認證產品的放行必須由獲得授權和負責的人並需有一本記錄或批量放行記錄顯示認證產品正式的放行被維持。

Note: An example of a batch release record is shown in Appendix B.

備註：附錄B中顯示一份放行記錄的例子。

4.6.4 Control of Nonconforming Product

不符合的產品的控制

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

組織需確定不符合產品需求的產品被識別並控制以避免在無意中被使用或交貨。處理不符合產品的控制和相關的職責和授權需在書面程序書中明確制定。

The organisation shall deal with nonconforming product by taking action to eliminate the detected nonconformity.

組織須去除已發現不符合的產品

。

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

不符合產品的性質和任何隨後採取的行動，包括取得的特採記錄，需被維持 (參見4.2.4) 。

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the relevant product standard/s.

當不符合產品被修正後，仍需再查證以顯示符合有關的產品標準。

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

當運送之後發現不符合產品的時候或已經開始使用，組織需採取適當的行動對不符合產品的影響或潛在的後果。

4.6.4.1 Review and Disposition of Nonconforming StandardsMark Product

標準標誌 (StandardsMark) 的不符合產品檢討和處置

The responsibility for review and the authority for the disposition of nonconforming certified product by competent personnel shall be defined.

需明確訂立檢討和職權對不符合的認證產品必須由能幹的人員負責。

Where non-conforming StandardsMark product has been detected prior to release, the organization shall:

當標準標誌 (StandardsMark) 的不符合產品在放行之前被發現，組織需：

- i)rectify all defects before the product is released; or
在產品被放行之前，修正所有的缺點；
或
- ii)destroy the product and dispose off securely; or
將產品銷毀或安全地處理掉；或
- iii)obliterate the StandardsMark completely from the product before releasing it.
在放行之前將產品上的標準標誌 (StandardsMark) 完全除去。

No such defective product shall be offered for sale as a certified product.

不准此類有缺陷的產品以認證產品提供售賣。

Note: Allowing the StandardsMark to be applied to or to remain on non-conforming products offered for sale exposes the Licensee to legal action. The licensee takes full responsibility for ensuring that noncompliant product (whether or not certified) is not marked with the StandardsMark.

備註：允許標準標誌 (StandardsMark) 被用於或留在不符合的產品上售賣會使持認

證許可者受法律制裁。持認證許可者須負起完全責任保證不符合的產品（不論是否經過認證）不可有標準標誌（StandardsMark）標示。

4.6.4.2 Recall of StandardsMark Product

標準標誌（StandardsMark）產品的回收

Should the Licensee or its distributor or its agent become aware of:

如持認證許可者或其經銷商或代理商發現：

i) the existence of StandardsMarked items manufactured by the Licensee which do not comply with the Standard;

由持認證許可者製造不符合標準的標準標誌（StandardsMark）專案的存在；

ii) the existence of a test report of a certified product manufactured by the Licensee that indicates a FAIL test result; or
由持認證許可者製造的一項已認證的產品經測試結果顯示不合格的存在，或

iii) StandardsMarked items with critical or major defects, which –

標準標誌（StandardsMark）專案含嚴重性或主要缺點，如：

- Have been released for sale;
已被放行售賣的；
- Are being offered for sale; or
正在售賣過程的，或
- Have already been sold,
已經被售賣的。

The following action shall be taken:
須採取下列各項動作：

a) The Licensee shall (directly or via its agent or distributor) promptly notify SAI Global that a problem with the product's conformity may exist.

持認證許可者需（直接地或經由其代理人或經銷商）即刻通知SAI全球公司產品的符合問題可能存在。

b) The Licensee shall immediately investigate the problem to determine its nature and severity.

持認證許可者需立刻調查問題以決定其性質和嚴重性。

c) If indications of non-compliance remain the Licensee shall immediately withdraw the StandardsMarked items described above which have been released or offered for sale.

如果顯示有不合產品存在，持認證許可者需立刻撤回上述已經被放行或提供售賣的標準標誌（StandardsMark）產品。

d) The Licensee shall arrange the recall of all of the StandardsMarked items as described above that have already been sold or take such other action as may be determined by SAI Global.

持認證許可者須排回收所有如上描述已經出售的標準標誌（StandardsMark）產品或由SAI全球公司決定採取其他類似動作。

During this investigation, withdrawal or recall, the Licensee shall keep SAI Global informed, in writing, of the action being taken and shall provide SAI Global with copies of correspondence related to the investigation, withdrawal or recall.

當在調查、撤回或回收中，持認證許可者須以書面方式告知SAI全球公司有關採取的行動並提供有關調查，並將撤回或回收的通信函副本給SAI全球公司。

StandardsMarked items that are withdrawn from sale or recalled from purchasers shall be quarantined pending further investigation and instruction from SAI Global.

標準標誌（StandardsMark）產品從售賣撤回或從買方收回需被隔離等候SAI全球公司進一步的調查和指示。

An historical summary of all the steps taken to resolve the problem shall be forwarded by the organization to SAI Global upon resolution.

當組織做出決議時需送一份所採取解決問題的步驟的摘要給SAI全球公司。

The organisation shall be responsible for all costs involve as a consequence of taking the above actions.

組織需負擔所有的費用包括採取上述的行動結果。

4.6.5 Corrective Action

矯正行動

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

組織需採取消除不符合的因素行動為了避免再發生。矯正行動對遇到的不符合的效果須適當。

A documented procedure shall be established to define requirements for:

一份書面程序書需被建立以明定需求供：

- a) reviewing nonconformities (including customer complaints).
檢討不符合事先 (包括客戶申訴) ,
- b) determining the causes of nonconformities,
決定不符合的起因 ,
- c) evaluating the need for action to ensure that nonconformities do not recur,
評估對行動的需要以確定不再發生不符合事件 ,
- d) determining and implementing action needed,
決定並執行必要的行動 , 決定並執行必要的行動 ,
- e) records of the results of action taken (see 4.2.4), and
記錄行動結果 (參見4.2.4) ,
- f) reviewing corrective action taken.
檢討採取的糾正行動。

4.6.6 Preventative Action

預防行動

The organization shall determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventative actions shall be appropriate to the effects of the potential problems.

組織需決定消除潛在的不符合因素動作為了要防止再發生。預防動作對潛在性問題的效果須適當。

A documented procedure shall be established to define requirements for:

一份書面程序書需被建立以明定需求供：

- a) determining potential non conformities and their causes,
決定潛在性不符合因素 ,
- b) evaluating the need for action to prevent the occurrence of nonconformities,
評估對需要防止發生不符合的動作 ,
- c) determining and implementing action needed,
決定並執行需要的動作 ,
- d) records of the results of action taken (see 4.2.4), and
記錄行動結果 (參見4.2.4) ,
- e) reviewing preventative action taken.
檢討採取的預防行動。

APPENDIX A

附錄 A

COMPARISON BETWEEN PCP14 AND ISO 9001:2000

PCP14與 ISO 9001:2000的比較表

PCP06.02	PCP05	ISO 9001:2000
1 Scope and general 範圍和概述 1.1 Scope 範圍 1.2 Application 應用 1.3 Related Documents 相關文件 1.4 Definitions 定義	1 Scope and general 範圍和概述 1.1 Scope 範圍 1.2 Application 應用 1.3 Related Documents 相關文件 1.4 Definitions 定義	
2 Licence conditions 認證許可證的條件 2.1 Product compliance 產品符合 2.2 Confidentiality 保密性 2.3 Surveillance audits 監督審核 2.4 Terms and conditions 條款與條件 2.5 Licence review and renewal 執照審查與更新	2 Licence conditions 認證許可證的條件 2.1 Product compliance 產品符合 2.2 Confidentiality 保密性 2.3 Surveillance audits 監督審核 2.4 Terms and conditions 條款與條件	
3 Testing 測試 3.1 Type testing 型式測試 3.2 Submission of products for type testing 提交產品作式樣測試 3.3 Test Sample selection 測試樣品的選取 3.4 Test laboratory 測試實驗室 3.5 Test results 測試結果 3.6 Re-test 重新測試 3.7 Existing type test reports 現有的樣品測試報告	3 Testing 測試 3.1 Type testing 型式測試 3.2 Submission of products for type testing 提交產品作式樣測試 3.3 Test Sample selection 測試樣品的選取 3.4 Test laboratory 測試實驗室 3.5 Test results 測試結果 3.6 Re-test 重新測試	
4 Quality requirements 品質計畫的要求 4.1 General 概述 4.2 Documentation requirements 檔作業的要求 4.2.1 General requirements 一般檔的要求 4.2.2 Quality Plan Summary 品質計畫的摘要 4.2.3 Control of documents 文件控制 4.2.4 Control of records 記錄的控制	4 Quality requirements 品質計畫的要求 4.2.2 Quality Plan Summary 品質計畫的摘要 4.2.3 Control of documents 文件控制 4.5 Product realization 產品實現 4.16 Records 紀錄	4 Quality requirements (title only) 品質管制體系 4.2 Documentation requirements 檔要求 4.2.1 General requirements 總則 4.2.2 Quality Manual 品質手冊 4.2.3 Control of documents 文件控制 4.2.4 Control of records 記錄控制
4.3 Management Responsibility 管理職責 4.3.1 Quality policy 品質方針 4.3.2 Responsibility and authority 職責與職權 4.3.3 Management representative 管理代表 4.3.4 Internal communication 內部溝通	4.1.1 Quality policy 品質方針 4.1.2.1 Responsibility and authority 職責與職權 4.1.2.3 Management representative 管理代表	5 Management Responsibility (title only) 管理職責 5.3 Quality policy 管理承諾 5.5.1 Responsibility and authority 職責與許可權 5.5.2 Management representative 管理者代表 5.5.3 Internal communication 內部溝通
4.4 Resource Management 資源管理 4.4.1 Human resources 人力資源 4.4.2 Infrastructure 基礎設施 4.4.3 Work environment 作業環境	4.1.2.2 Resources 資源 4.18 Training 培訓 4.9 Process control 製程管制	6 Resource management (title only) 資源管理 6.2 Human resources 人力資源 6.3 Infrastructure 環境資源 6.4 Work environment 工作環境
4.5 Product realization 產品實現 4.5.1 Planning of product realization 產品實現的計畫 4.5.2 Customer related processes 與顧客有關的過程 4.5.3 Design freeze 設計凍結 4.5.4 Control of design and development changes 設計與開發變更的控制 4.5.5 Purchasing 採購 4.5.6 Production provision 製造準備 4.5.7 Identification 識別 4.5.8 Traceability 可追溯性 4.5.9 Preservation of product 產品的保存 4.5.10 Control of monitoring and measuring devices 監控和測量裝置控制	4.2.3 Quality plan summary 品質計畫摘要 4.10.1 Inspection and testing, General 檢驗與測試, 概述 4.4.9.1 Design freeze 設計凍結 4.4.9 Design changes 設計變更 4.6 Purchasing 採購 4.9 Process control 控制程式 4.15.6 Delivery 交貨 4.8 Product identification and traceability 產品識別與追溯 4.10.5 Inspection and testing records 檢驗與測試紀錄 4.12 Inspection and test status 檢驗與測試狀況 4.8 Product identification and traceability 產品識別與追溯 4.15 Handling, storage, packaging, preservation and delivery 處理、儲存、包裝、保存和交貨 4.11 Control of inspection, measuring and test equipment 檢驗、測量和測試控制	7 Product realisation (title only) 產品實現 7.1 Planning of product realization 產品實現的策劃 7.2 Customer related processes 與顧客有關的過程 7.3.7 Control of design and development changes 設計和開發更改的控制 7.4 Purchasing 採購 7.5.1 Control of production and service provision 生產和服務提供的控制 7.5.2 Validation of processes for production and service provision 生產和服務提供的確認 7.5.3 Identification and traceability 標識和可追溯性 7.5.5 Preservation of product 產品防護 7.6 Control of monitoring and measuring devices 監視和測量裝置的控制
4.6 Measurement, analysis and improvement 測量、分析和改進 4.6.1 General 概述 4.6.2 Monitoring and measurement 監控測量 4.6.3 Release of WaterMark product 水標誌的放行 4.6.4 Control of non-conforming product 不合格品的控制 4.6.5 Corrective action 矯正行動 4.6.6 Preventive action 預防行動	4.20 Statistical techniques 統計技術 4.10 Inspection and testing 檢驗與測試 4.10.4.2 Release of StandardsMark product 標準標誌產品的放行 4.13 Control of non-conforming product 不合格品的處理 4.14 Corrective and preventive Action 矯正與預防行動 4.14 Corrective and preventive action 矯正與預防行動	8 Measurement, analysis and improvement (title only) 測量、分析和改進 8.1 General 總則 8.2.4 Monitoring and measurement of product 產品的監視和測量 8.3 Control of non conforming product 不合格品控制 8.5.2 Corrective action 矯正措施 8.5.3 Preventative action 預防措施

APPENDIX B

附錄 B

EXAMPLE OF A BATCH RELEASE RECORD

批量放行紀錄樣本

Batch or Sub-batch 批號	1001				
Date Made 製造日期	23 March 2011	23 March 2011	23 March 2011	23 March 2011	23 March 2011
Model 型號	XYZ	XYZ	XYZ	XYZ	XYZ
Size 呎碼	XL	L	M	S	XS
Quantity 數量	34	40	30	70	30
StandardsMark Labels 標準標誌貼紙編號	R000100 R000133	R000134 R000173	R000174 R000203	R00020 R000273	R000274 R000303
Sampling Plan 取樣計畫	4/404				
Test Result & Report No. 測試結果和報告編號	Pass 122653 通過122653				
Signature Authorising Release 簽名授權放行	<i>A. Sample</i> 如A先生				
Release Date 放行日期	25 April 2011				

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