



Product Compliance Program

StandardsMark



SAI Global
Product Certification

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AMENDMENT HISTORY

Date	Issue	Brief Summary of Amendments
1/11/91	01	Original Issue as Quality Assurance Program (QAP01/02)
14/12/93	02	Minor Editorial Amendments
12/8/96	03	Major revision to incorporate ISO 9002:1994
1/12/96	04	Change of title to Product Compliance Program
1/11/98	05	Editorial Amendments
5/2/04	06	Review including alignment with ISO 9001:2000
19/8/05	06.02	Addition of Customer Related Processes, Minor Editorial Amendments

Authorising Manager: General Manager, SAI Global Certification Services Pty Ltd

PREFACE

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 bearing the StandardsMark consistently meet the requirements of the relevant Standard or Specification.

This Product Compliance Program has been designed to include where relevant the following criteria:

- Certification for SAI Global's clients at competitive prices.
- International recognition – based on the criteria in ISO Guide 67 for product certification system 5 and quality system elements of ISO 9001.
- Credibility amongst its stakeholders.
- Accreditation requirements for ISO Type 5 product certification programs – ISO Guide 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.
- Specific requirements relating to relevant product or service standards (the Technical Schedule has been designed for this purpose, and in some cases it may vary the general PCP requirements).

The changes to this document version have been made in line with the above objectives.

I. SCOPE AND GENERAL

I.1 Scope

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

- compliance of the product with Australian, National or International Standards, or other published specifications;
- quality plan elements;
- use of SAI Global's certification trade mark, known as the Australian StandardsMark.

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

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

I.2 Application

I.2.1 Licence Requirements

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.

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.

I.2.2 Relationship to ISO 9001:2000

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.

I.3 Related Documents

ISO 9001:2000 Quality Management Systems – Requirements.

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

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

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

SMG 03 – Guidelines for Product Certification Testing

Q100A – The Australian StandardsMark Rules Governing the Product Certification Scheme

QGD17 – Terms & Conditions for Certification and Certification Mark.

I.4 Definitions

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

I.4.1 Batch

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

I.4.2 Certified Product

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.

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

I.4.3 Critical Defect

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.

I.4.4 Design Freeze

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.

I.4.5 Licensee

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.

In terms of the StandardsMark program the licensee is the manufacturer of the product. This may be multiple legal entities where those entities perform a task that is critical to the manufacturing process in relation to the product .

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

I.4.6 Major Defect

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.

1.4.7 Product

Result of activities or processes.

Notes:

1. A product may include a service, hardware, processed materials, software or a combination thereof.
2. A product can be tangible (eg. assemblies or processed materials) or intangible (eg. knowledge or concepts) or a combination thereof.

1.4.8 Quality Plan

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.

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.

1.4.9 Standard

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

1.4.10 StandardsMark

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.

1.4.11 StandardsMark Labels

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

Note: StandardsMark labels are not available for all products.

1.4.12 Subcontractor

Organisation that supplies a product to the Licensee.

1.4.13 Technical Schedule

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

1.4.14 Type Test

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.

2. LICENCE CONDITIONS

2.1 Product Compliance

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.

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.

The Licensee remains responsible at all times for ensuring that the StandardsMark is applied and remains on conforming product only.

2.2 Confidentiality

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

- i) the Licensee authorises (expressly or by implication) the release of such information to a third party, such as an agent, a test facility or a government authority;
- ii) SAI Global has been served with a subpoena, summons, notice or other legally enforceable order to disclose the information;
- iii) a relevant accreditation body seeks access to the information as part of an accreditation audit or process; or
- iv) the information is in the public domain.

2.3 Surveillance Audits

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.

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.

2.4 TERMS & CONDITIONS

Refer to Terms & Conditions for Licence for details.

2.5 Licence Review and Renewal

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

3. TESTING

3.1 Type Testing

A type test shall be conducted when:

- a) a manufacturer completes an application form in respect of a StandardsMark licence; and
- b) at the discretion of SAI Global when –
 - i) certified product has undergone or may have a design change; or
 - ii) testing of certified product indicates a failure to comply with the Standard; or
 - iii) the Licensee wishes to add another product to the licence.

3.2 Submission of Products for Type Testing

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

- a) full identification of the product;
- b) detailed supportive test data;
- c) an indication of when samples for type tests may be selected;
- d) samples of packaging and labelling; and
- 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. Retesting of failed product will normally be conducted by the same test laboratory that performed the original test unless otherwise agreed by SAI Global.

3.3 Test Sample Selection

3.3.1 General

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.

3.3.2 Samples from stabilised production

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.

3.3.3 Prototypes

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.

3.3.4 Condition of Samples

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.

3.3.5 Test groups and worst case samples

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.

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.

3.3.6 Delivery of samples

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.

3.4 Test Laboratory

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

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.

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.

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

3.5 Test Results

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.

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.

3.6 Re-Test

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.

3.7 Existing Type Test Reports

Where the manufacture submits type test reports conducted prior to the application, these will be considered 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 REQUIREMENTS

4.1 General

The organisation shall establish, document, implement and maintain a quality plan for the certified product, as a means of 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.

Note: Some of the requirements have been taken from ISO 9001:2000 and where these have been directly taken it is shown in italics. 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.

4.2 Documentation requirements

4.2.1 General requirements

The quality documentation shall include

- a) Quality Plan Summary
- b) documented procedures as required by this PCP
- c) *documents needed by the organisation to ensure the effective planning, operation and control of processes.*
- d) records required by this PCP

4.2.2 Quality Plan Summary (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:

- a) For suppliers with a certified quality system, as a process flowchart including references to the manufacturing processes, test methods 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
- b) For suppliers who do not have a certified quality system, a document incorporating the following items:
 - i) Organisation Chart;
 - ii) Quality Policy;
 - iii) Responsibilities and authorities of management representative and deputy/s;
 - iv) Flow chart referenced with the applicable procedures, methods, work instructions and inspection and test points (including sub-contracted processes) in accordance with document PCD 30.

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

4.2.3 Control of documents

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.

A documented procedure shall be established to define the controls needed

- a) *to approve documents for adequacy prior to issue,*
- b) *to review and update as necessary and re-approve documents,*
- c) *to ensure that changes and the current revision status of documents are identified,*
- d) *to ensure that relevant versions of applicable documents are available at points of use,*
- e) *to ensure that documents remain legible and readily identifiable,*
- f) *to ensure that documents of external origin eg. Standards or documents critical to the certification are identified and their distribution controlled, and*
- g) *to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.*

4.2.4 Control of records

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.

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

- a) final release eg. batch release (in English), including serial numbers (where appropriate), date, batch identity and signature of the authorised person for release of the batch;

Notes:

- i) An example of a batch release record is given in Appendix B.
- ii) The organisation's licence signatory is ultimately responsible for the correctness, completeness and validity of the data shown in the record.

- b) if serially numbered labels are used, a StandardsMark label register is required to be maintained;

Note: The StandardsMark label register may be combined with batch release records.

- c) type test reports;
- d) inspection and test reports;
- e) acceptable sub contractors;
- f) design changes;
- g) traceability;
- h) calibration;
- l) training;
- j) customer complaints.

The organisation 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:

- a) final release test reports;
- b) final release records; and
- c) StandardsMark label records (where relevant).

In deciding the retention period of other records, the organisation 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.

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

4.3 Management responsibility

4.3.1 Quality policy

Top management shall ensure that the quality policy

- a) *is appropriate to the purpose of the organisation,*
- b) *is communicated and understood within the organisation, and is reviewed for continuing suitability.*
- c) Makes a statement of commitment to supporting ongoing compliance of the certified product with the appropriate Standard.

4.3.2 Responsibility and authority

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

4.3.3 Management representative

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

- a) *ensuring that processes needed for the quality system or quality plan are established, implemented and maintained,*
- 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},*
- c) *ensuring that adequate control is exercised at all stages of the processes to ensure that the delivered product, together with related marking and information, meets all the relevant requirements of the product Standard the PCP and relevant Technical Schedule,*
- d) *informing SAI Global of changes to:*
 - i) *product specifications or production processes that could affect compliance of the product with the Standard; and*
 - ii) *licence conditions such as company ownership, company name, address, key personnel, etc;*
 - iii) *subcontracting/outsourcing of parts of the manufacturing process.*
- e) *notifying SAI Global of any information or evidence that may indicate that non-conforming StandardsMarked product has been released from the place of manufacture, and*

- 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.*

The organisation 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.

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.

4.3.4 Internal communication

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

4.4 Resource Management

4.4.1 Human Resources

4.4.1.1 General

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

4.4.1.2 Competence, awareness and training.

The organisation shall

- a) *Determine the necessary competence for personnel performing work affecting product quality.*
- b) *Provide training or take other actions to satisfy these needs.*
- c) *Evaluate the effectiveness of the actions taken.*
- 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.*
- e) *Maintain appropriate records of education, training, skills and experience (see 4.2.4).*

4.4.2 Infrastructure

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

- a) *buildings, workspace and associated utilities,*
- b) *process equipment (both hardware and software) and*
- c) *supporting services (such as transport or communication).*

4.4.3 Work environment

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

4.5 Product realisation

4.5.1 Planning of product realisation

The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality plan.

In planning product realisation, the organisation shall determine the following, as appropriate

- a) requirements to ensure finished product conformity with the relevant product standard.
- b) the need to establish processes documents and provide resources specific to the product.
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
- d) records needed to provide evidence that the realisation processes and the resulting product meet requirements (see 4.2.4).

4.5.2 Customer related processes

4.5.2.1 Review of requirements related to the product

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 contract or orders, acceptance of changes to contract or orders) and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organisation has the ability to meet the defined requirements.

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

4.5.2.2 Customer Communication

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

- a) product information,
- b) enquiries, contracts or other handling, including amendments, and
- c) customer feedback, including customer complaints.

4.5.3 Design Freeze

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.

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.

4.5.3.1 Reference Specimens

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).

4.5.3.2 Changes to the Product Standard.

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.

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

4.5.4 Control of design and development changes

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.

Records of the results of the review of changes and any necessary actions shall be maintained (see 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 authorisation from SAI Global.

4.5.5 Purchasing

4.5.5.1 Purchasing process

The organisation 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 realisation or the final product or service.

The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisation'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).

4.5.5.2 Purchasing information

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

- a) the type, class, grade or other precise identification
- b) the title or other positive identification; and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- c) requirements for approval of product or service, procedures, processes and equipment, and
- d) requirements for qualification of personnel

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

4.5.6 Production provision

4.5.6.1 Control of production provision

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

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

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

4.5.6.2 Validation of processes for production and service provision

The organisation 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 become apparent only after the product is in use or the service has been delivered.

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

The organisation shall establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

4.5.7 Identification

The organisation shall identify the product by suitable means throughout product realisation.

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

4.5.7.1 StandardsMark

The StandardsMark 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.

4.5.7.2 Approval of the form and manner in which the StandardsMark is used

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:

- a) the form and manner in which the StandardsMark is used on the product;
- b) the form and manner in which the StandardsMark is used on promotional material, packaging, swing tags, informative labelling or instructions for use; and
- c) proposed references in any form to the StandardsMark Licence number or to certification by SAI Global.

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

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

4.5.7.3 Extent of marking

The Licensee shall apply the StandardsMark only to products which:

- a) are of the type and size specifically listed on the current Schedule to the Licence; and
- b) the Licensee warrants comply in all respects with the relevant Standard and are manufactured in accordance with this PCR.

4.5.7.4 Application at Licensee's premises

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

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-contractors premises to determine that the StandardsMark is applied under the conditions of the licence.

4.5.7.5 Manner of application

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

- a) serially numbered labels available from SAI Global;
- b) incorporation into the Licensee's label with wherever possible a date code or batch number; or
- c) directly onto the product by casting, moulding, stamping, etching, etc, together wherever possible with a date code or batch number.

4.5.7.6 Quality of Marking

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

4.5.7.7 Use of StandardsMark Labels

Security

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.

Records

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)

Damaged Labels

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)

4.5.8 Traceability

The organisation 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 at least maintain traceability on primary packaging.

4.5.9 Preservation of product

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

4.5.10 Control of monitoring and measuring devices

The organisation 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.

The organisation 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.

Where necessary to ensure valid results, measuring equipment shall:

- 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;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation 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).

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.

Note: See ISO 10012 for guidance.

4.6 Measurement, analysis and improvement

4.6.1 General

The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a) to demonstrate conformity of the product to the Standard, and;
- b) to ensure conformity with the quality plan.

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

4.6.2 Monitoring and measurement

4.6.2.1 Monitoring and measurement of processes

The organisation 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.

4.6.2.2 Monitoring and measurement of product

The organisation 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 realisation process in accordance with the planned arrangements (see 4.5.1).

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

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

4.6.3 Release of StandardsMark Product

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.

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

4.6.4 Control of nonconforming product

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

The organisation shall deal with nonconforming product by taking action to eliminate the detected 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 relevant product standard/s.

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

4.6.4.1 Review and disposition of nonconforming StandardsMark product

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

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

- i) rectify all defects before the product is released; or
- ii) destroy the product and dispose of securely; or
- iii) obliterate the StandardsMark completely from the product before releasing it.

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

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.

4.6.4.2 Recall of StandardsMark Product

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

- i) the existence of StandardsMarked items manufactured by the Licensee which do not to comply with the Standard;
- ii) the existence of a test report of a certified product manufactured by the Licensee that indicates a FAIL test result ; or
- iii) StandardsMarked items with critical or major defects, which –
 - have been released for sale;
 - are being offered for sale; or
 - have already been sold,

the following action shall be taken:

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

- 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.

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.

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

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

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

4.6.5 Corrective action

The organisation 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.

A documented procedure shall be established to define requirements for

- a)** reviewing nonconformities (including customer complaints),
- b)** determining the causes of nonconformities,
- c)** evaluating the need for action to ensure that nonconformities do not recur,
- d)** determining and implementing action needed,
- e)** records of the results of action taken (see 4.2.4), and
- f)** reviewing corrective action taken.

4.6.6 Preventative action

The organisation 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.

A documented procedure shall be established to define requirements for

- a)** determining potential non conformities and their causes,
- b)** evaluating the need for action to prevent the occurrence of nonconformities,
- c)** determining and implementing action needed,
- d)** records of the results of action taken (see 4.2.4), and
- e)** reviewing preventative action taken.

APPENDIX A

COMPARISON BETWEEN PCP06, PCP05 AND ISO 9001:2000

PCP06.02	PCP05	ISO 9001:2000
1 Scope and general 1.1 Scope 1.2 Application 1.3 Related Documents 1.4 Definitions	1 Scope and general 1.1 Scope 1.2 Application 1.3 Related Documents 1.4 Definitions	
2 Licence conditions 2.1 Product compliance 2.2 Confidentiality 2.3 Surveillance audits 2.4 Terms and conditions 2.5 Licence review and renewal	2 Licence conditions 2.1 Product compliance 2.2 Confidentiality 2.3 Surveillance audits 2.4 Terms and conditions	
3 Testing 3.1 Type testing 3.2 Submission of products for type testing 3.3 Test Sample selection 3.4 Test laboratory 3.5 Test results 3.6 Re-test 3.7 Existing type test reports	3 Testing 3.1 Type testing 3.2 Submission of products for type testing 3.3 Sample selection 3.4 Test laboratory 3.5 Test results 3.6 Re-test	
4 Quality requirements 4.1 General 4.2 Documentation requirements 4.2.1 General requirements 4.2.2 Quality Plan Summary 4.2.3 Control of documents 4.2.4 Control of records	4 Quality plan requirements 4.2.2 Quality procedure 4.2.3 Quality plan summary 4.5 Document and data control 4.16 Records	4 Quality requirements (title only) 4.2 Documentation requirements 4.2.1 General requirements 4.2.2 Quality Manual 4.2.3 Control of documents 4.2.4 Control of records
4.3 Management Responsibility 4.3.1 Quality policy 4.3.2 Responsibility and authority 4.3.3 Management representative 4.3.4 Internal communication	4.1.1 Quality policy 4.1.2.1 Responsibility and authority 4.1.2.3 Management representative	5 Management Responsibility (title only) 5.3 Quality policy 5.5.1 Responsibility and authority 5.5.2 Management representative 5.5.3 Internal communication
4.4 Resource Management 4.4.1 Human resources 4.4.2 Infrastructure 4.4.3 Work environment	4.1.2.2 Resources 4.1.8 Training 4.9 Process control 4.9 Process control	6 Resource management (title only) 6.2 Human resources 6.3 Infrastructure 6.4 Work environment
4.5 Product realisation 4.5.1 Planning of product realisation 4.5.2 Customer Related Processes 4.5.3 Design freeze 4.5.4 Control of design and development changes 4.5.5 Purchasing 4.5.6 Production provision 4.5.7 Identification 4.5.8 Traceability 4.5.9 Preservation of product 4.5.10 Control of monitoring and measuring devices	4.2.3 Quality plan summary 4.10.1 Inspection and testing, General 4.4.9.1 Design freeze 4.4.9 Design changes 4.6 Purchasing 4.9 Process control 4.15.6 Delivery 4.8 Product identification and traceability 4.10.5 Inspection and testing records 4.12 Inspection and test status 4.8 Product identification and traceability 4.15 Handling, storage, packaging, preservation and delivery 4.11 Control of inspection, measuring and test equipment	7 Product realisation (title only) 7.1 Planning of product realisation 7.2 Customer Related Processes 7.3.7 Control of design and development changes 7.4 Purchasing 7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision 7.5.3 Identification and traceability 7.5.3 Identification and traceability 7.5.5 Preservation of product 7.6 Control of monitoring and measuring devices
4.6 Measurement, analysis and improvement 4.6.1 General 4.6.2 Monitoring and measurement 4.6.3 Release of StandardsMark product 4.6.4 Control of non-conforming product 4.6.5 Corrective action 4.6.6 Preventive action	4.20 Statistical techniques 4.10 Inspection and testing 4.10.4.2 Release of StandardsMark product 4.13 Control of non-conforming product 4.14 Corrective and preventive action 4.14 Corrective and preventive action	8 Measurement, analysis and improvement (title only) 8.1 General 8.2.4 Monitoring and measurement of product 8.3 Control of non conforming product 8.5.2 Corrective action 8.5.3 Preventative action

APPENDIX B

EXAMPLE OF A BATCH RELEASE RECORD

Batch or Sub Batch	I001				
Date Made	23 March 2011	23 March 2011	23 March 2011	23 March 2011	23 March 2011
Model	XYZ	XYZ	XYZ	XYZ	XYZ
Size	XL	L	M	S	XS
Quantity	34	40	30	70	30
StandardsMark Labels	R000100 R000133	R000134 R000173	R000174 R000203	R00020 R000273	R000274 R000303
Sampling Plan	4/404				
Test Result & Report No.	Pass 122653				
Signature Authorising Release	A. Sample				
Release Date	25 April 2011				

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