

Product Compliance Program (PCP) Type 5 Product Services



PREFACE

The aim of the SAI Global Product Services Product Compliance Program (PCP) is to provide confidence to all stakeholders, including customers and regulators, that the products bearing the SAI Global Certification Trademarks meet the requirements of the relevant Standard.

1. SCOPE AND GENERAL

1.1 Scope

This document sets out the requirements of SAI Global Type 5 Certification Programs. It must be read in conjunction with the relevant standard, SAI Global Technical Schedules, the Rules of Use for the relevant Certification Trademark and SAI Global Terms and Conditions.

1.2 Licensing Requirements

The Licensee must comply with this document and SAI Global Terms & Conditions for all certified products. The Licensee, by applying the Certification Trademark to a product, warrants that the product meets all the requirements of the specified Standard. The Licensee must ensure that the Certification Trademark is applied to conforming product only.

1.3 Relationship to ISO 9001

The Quality documentation requirements within this document are based on the relevant requirements of the International Standard ISO 9001 Quality Management Systems – Requirements. Additional requirements have been incorporated where necessary.

1.4 Related Documents

- ISO 9001 Quality Management Systems – Requirements.
- ISO 9000 Quality Management Systems – Fundamentals and Vocabulary.
- ISO 10012 Measurement management systems – Requirements for measurement processes and measuring equipment
- ISO/IEC Guide 65 - General Requirements for Bodies operating Product Certification Systems
- ISO/IEC Guide 67 – Conformity Assessment – Fundamentals of product certification
- Guide to Applicants – A step-by-step guide through the Product Services process
- Guidelines for Product Services Testing
- The StandardsMark Rules of Use
- The WaterMark Rules of Use and Licensing Agreement
- SAI Global Terms & Conditions for Certification and Certification Trademark
- SAI Global Technical Schedules, where applicable.

1.5 Definitions

The definitions in ISO 9000 and the following apply:

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

Certified Product Finished product for which a Licensee may apply the Certification Trademark to demonstrate that the product conforms to the specified Standard and complies with SAI Global Product Compliance Program. Certified products are listed on the SAI Global website.

Client A Licensee or applicant.

Defect Anything that makes the product non-compliant to the Standard.

Licensee Entity that has been granted the right to use a Certification Trademark owned or licensed by SAI Global in accordance with SAI Global Terms and Conditions and scope of Certificate issued. Licensee may also refer to licence applicants. The Licensee is responsible for ensuring the ongoing compliance of the Certified Product.

Non Conforming Product A product which does not comply with the Product Standard.

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Product Result of activities or processes. A product may include a service, hardware, processed materials, software or a combination thereof. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts) or a combination thereof.

Quality Documentation A documented system including specific quality practices, procedures and processes implemented and maintained by the Licensee.

Standard Standard, Specification or other publicly available criteria.

StandardsMark A registered or unregistered Certification Trademark belonging to SAI Global Limited incorporating a device with 5 ticks in a box.

StandardsMark Label SAI Global issued labels, serially numbered, incorporating the StandardsMark.

Technical Schedule SAI Global document, referable to a specific standard, the subject of certification that defines certification requirements and provides guidance for testing and auditing against the Standard, where applicable.

Type 5 A Type 5 Product Certification Scheme is defined in ISO/IEC Guide 67 as involving sampling of products, determination of characteristics, evaluation, decision and licensing, and surveillance by quality system audits and sample testing.

Type Test Test(s) defined by the relevant Standard to determine product compliance

WaterMark A registered Certification Trademark of Standards Australia.

2. LICENCE CONDITIONS

2.1 Product Testing

The certified product must undergo initial type testing and ongoing batch testing according to the requirements of the relevant standard and technical schedule.

2.2 Initial Certification and Surveillance Audits

The manufacturing and design locations will be assessed through an Initial Certification audit and on an ongoing basis through Surveillance audits. The frequency of such ongoing audits is determined by SAI Global.

The Licensee must ensure that SAI Global has access to all organisations that conduct manufacturing processes or hold records for the certified product.

2.3 Licence Renewal

The License will expire 5 years from the initial certification date. The license will be renewed subject to confirmation of ongoing compliance to the current Standard. In some cases SAI Global may issue a licence with an alternative validity.

When a standard is reissued, there will be a 12 month transition period from the date of implementation for the Licensee to upgrade any certified product to the new requirements, unless an alternative timeframe is nominated by the Regulator, Standard, JAS-ANZ or SAI Global.

2.4 Suspected Non-Conforming Product

If a certified product is suspected or alleged to be non-conforming, it must be dealt with in accordance with clauses 4.7.3 and 4.7.4, as applicable.

The full cost of any investigation must be borne by the Licensee.

Product which does not comply must not be marked with a Certification Trademark.

2.5 Subcontracting or Outsourcing of Manufacturing Process

Where a Licensee subcontracts or outsources its manufacturing processes relevant to a Certified Product, it must ensure that the terms and conditions of this Product compliance Program are complied with at the manufacturing site.

3. TESTING

3.1 Test Laboratory

All testing must be carried out at a recognised SAI Global laboratory. SAI Global recognises ILAC MRA signatories and IEC member accredited laboratories that have the relevant test methods/standards in their scope of accreditation. Laboratories not covered by these accreditations can be recognised through a separate SAI Global process.

3.2 Type Testing

A type test must be conducted for the initial certification of the product. Type testing may also be required (at the discretion of SAI Global) if:

1. the certified product has undergone a design change; or
2. testing of certified product indicates a failure to comply with the Standard; or
3. another product is to be added to the licence.

Type testing must demonstrate conformance to all applicable requirements of the Standard.

Testing must be conducted within the Product Services Testing Guidelines and relevant Technical Schedule. All costs of testing must be borne by the licensee.

In the event that the type testing fails, then retesting of the product will be conducted by the same test laboratory that performed the original test unless otherwise agreed between SAI Global and the client. SAI Global must be advised of the details of the failure and the corrective action(s) taken.

3.2.1 Pre existing test reports

Where the client submits type test reports conducted prior to the certification, these may be considered, provided the reports:

1. come from an SAI Global recognised laboratory; and
2. are less than 5 years old (Note: for some standards different time frames may apply); and
3. are traceable to a production batch; and
4. meet the requirement of this document, the relevant technical schedule and Guidelines for Product Services Testing.
5. demonstrate conformance to the Standard

3.3 Test Sample Selection

The samples selected must be fully representative of the certified products that the Licensee intends to sell. A range of models may be grouped together for type testing if the models are expected to perform similarly during testing. The selected sample(s) must be the model that can be expected to give the worst test results. SAI Global will make the final decision on test groups and worst-case models.

SAI Global reserves the right to select samples for testing and/or determine a sampling regime.

Labelling, marking, instructions for use, care, installation and maintenance may be assessed separately.

The Licensee must deliver samples to the agreed laboratory and be responsible for preservation and packaging.

3.4 Test Results

Test reports must comply with the requirements of ISO 17025. Original test reports must be sent to SAI Global and include the following information:

1. full identification of the product, including photographs (where appropriate);
2. detailed supportive test data;
3. packaging and labelling details (if applicable)
4. indicate compliance or otherwise with the relevant standard

SAI Global reserves the right to accept or reject any test reports.

3.5 Re-Test

SAI Global reserves the right to require a Licensee 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 must be borne by the licensee.

4. QUALITY MANAGEMENT REQUIREMENTS

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4.1 General

The Licensee must establish, document, implement and maintain a quality management system for the certified product as a means of ensuring that the product consistently conforms to the relevant standard.

The quality documentation must comprise;

1. Documents, including;
 - Quality policy
 - Organisation chart(s)
 - Responsibilities and authorities of management representatives
 - Process flow chart(s) referencing the applicable procedures, methods, work instructions, inspection and test points (including sub-contracted processes), and
2. Records, including:
 - Type test reports
 - Inspection and test reports
 - Design changes
 - Suppliers
 - Calibration
 - Training
 - Final batch release
 - Customer feedback and complaints
 - A label register (if applicable)

4.2 Control of documents

Documents required by or referenced within the quality documentation must be controlled.

The controls required include:

1. initial review and approval by authorised personnel
2. review, approval and identification of changes
3. identification of current revision status
4. the availability of relevant versions at points of use
5. identification and withdrawal of obsolete documents.

4.3 Control of records

Records required by or referenced within the quality documentation must be controlled.

The controls required include:

1. identification,
2. legibility,
3. storage,
4. protection,
5. retention time
6. disposal

Records that demonstrate conformance of product to Standard must be retained for a minimum of 10 years from the date of the certified product release unless a longer period is specified.

4.4 Management Responsibility

The Licensee must ensure that the relevant responsibilities and authorities are defined and communicated within the organisation that is responsible for manufacturing the Certified Product.

A management representative must be appointed who will have responsibility and authority on all matters relevant to the licence, including:

1. Ensuring that the management system is established, implemented, controlled and maintained in accordance with the requirements of this document.
2. Reporting to management on the performance of the quality management system.
3. Ensuring that the product, together with related marking and information, meets the requirements of the product Standard, the PCP and any relevant Technical Schedule.
4. Informing SAI Global of : -
 - Changes to product specifications or production processes that could affect compliance of the product with the Standard; and
 - Changes to licence conditions such as company ownership, company name, address, key personnel, etc;
 - Changes to subcontracting/outsourcing of parts of the manufacturing process.

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- Any information or evidence that may indicate that non-conforming certified product has been released to the market,
- Corrective and preventative actions taken in relation to SAI Global audit findings, or non-conforming products.
- Any changes to the management representative(s)

The Licensee must ensure that a Deputy Management Representative is appointed and who may act on behalf of the Management Representative in his/her absence.

4.5 Resource Management

4.5.1 Human Resources

The Licensee must ensure that:

1. The necessary competence, such as education, training and experience, for personnel performing work affecting product quality, is identified.
2. The appropriate resources to satisfy the identified requirements in Clause 4.5.1(1) above are provided.
3. The competency of staff is evaluated on an ongoing basis and action is taken where appropriate.
4. The appropriate records of education, training, skills and experience are maintained.

4.5.2 Infrastructure and Work environment

The Licensee must ensure that suitable infrastructure and work environment to manufacture a compliant product is provided and maintained.

4.6 Product Realisation

4.6.1 Design Control

On successful completion of type testing and granting of certification by SAI Global, the design of all critical components, materials and processes, including labelling, packaging, installation and maintenance instructions, must be recorded and maintained.

If the product changes in any respect from that certified, the Licensee must advise SAI Global in writing of the changes prior to applying a Certification Trademark to the product. SAI Global may require testing and/or assessment at the Licensee's cost to maintain certification.

Product samples, drawings or photographs representative of type test specimens must be identified and retained for no less than 10 years after last manufacture of the licensed product. SAI Global reserves the right to retain any product samples submitted in the certification process, or to retain other samples.

4.6.2 Purchasing

The Licensee must ensure that purchased product or service conforms to specified requirements. Purchasing documentation must include a comprehensive and accurate description of the product and any certificate and/or proof of required certification for the product, if applicable

The Licensee must ensure that suppliers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria must be established and records of the results of evaluations maintained

4.6.3 Production

The Licensee must ensure that production is planned and carried out under controlled conditions. Controlled conditions include, as applicable

1. information that describes the characteristics of the product,
2. procedures and work instructions,
3. use of suitable equipment,
4. use of monitoring and measuring devices,
5. final inspection and testing

4.6.4 Identification and Traceability

The Licensee must ensure that the appropriate identification marking system is applied throughout production.

The Licensee must ensure that finished certified product is traceable to relevant inspection or test report/s. Where full marking is not possible, certified product must maintain traceability on primary packaging or through relevant records.

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The Licensee must ensure that the product test, inspection or measurement status can be ascertained and recorded at all stages of the production process.

4.6.5 Product Marking

The Certification Trademark is the means of identifying certified product. The licensee must ensure that the application of the Certification Trademark is not misleading. Prior to use the licensee must gain approval from SAI Global for:

1. The form and manner in which the Certification Trademark is used on the product;
2. The form, manner and context in which the Certification Trademark is used on promotional material, packaging, swing tags, informative labelling or instructions for use; and
3. Proposed references in any form to the certification licence number or to certification by SAI Global.

Licensee must ensure that distributors of their certified products are aware of and observe these requirements.

The Certification Trademark must only be applied to certified products. It must be applied prior to dispatch from the manufacturing/assembly/testing premises approved by SAI Global as the point of control for the marking.

The Certification Trademark must be applied directly onto the product in a manner that is permanent and tamper-evident. Where it is not practical to apply the Certification Trademark to the product, an alternative may be approved by SAI Global.

For some products SAI Global offers serially numbered labels. The Licensee must be responsible for the control and security of all labels that bear the Certification Trademark. The serial numbers of the labels must be recorded in the batch release register. Damaged and unused labels must be recorded and disposed of under controlled environment.

4.6.6 Release of Certified Product

The Licensee must 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. Records must indicate the person(s) authorising release of product

4.7 Measurement, Analysis and Improvement

4.7.1 Methods of monitoring and measurement

The Licensee must ensure that effective methods for monitoring and measurement of the quality processes are applied. Methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved corrective action must be taken.

The Licensee must ensure that the characteristics of the product are monitored and measured to verify that product requirements have been met. Evidence of conformity with the acceptance criteria must be maintained. Where the output is not verified by monitoring and measurement the Licensee must ensure that the processes concerned are validated. Validation must demonstrate the ability of these processes to achieve planned results including, as applicable:

1. Defined criteria for review and approval of the processes,
2. Approval of equipment and qualification of personnel,
3. Use of specific methods and procedures,
4. Requirements for records
5. Revalidation.

4.7.2 Control of monitoring and measuring devices

The organization must determine the monitoring and measurement to be undertaken and the equipment needed.

Monitoring and measurement devices must

1. be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards or known physical constants;
2. have identification in order to determine its calibration status;
3. be protected from adjustments, damage and deterioration during handling, maintenance and storage;
4. be maintained as necessary.

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The organization must take appropriate action on monitoring and measurement equipment and any product affected if the equipment is found not to conform to requirements.

Records of the results of calibration and verification must be maintained.

4.7.3 Control of nonconforming product at place of manufacture

The Licensee must ensure that product which does not conform to product requirements is identified at any point of production and controlled to prevent its unintended use or delivery. The controls and related responsibilities must be defined in a documented procedure.

Records of the nature of nonconformities and actions taken must be maintained.

Where non-conforming certified product has been detected, the Licensee must:

1. Rectify all defects and re-test to verify compliance before the product is released; or
2. Destroy the product and dispose of securely; or
3. Remove the Certification Trademark from the product.

The licensee takes full responsibility for ensuring that noncompliant product is not marked with the Certification Trademark.

4.7.4 Control of Nonconforming product released or sold

Where the Licensee or its distributor or its agent becomes aware of or are notified of certified product/s which may not comply with the Standard that have been released or sold, the following actions must be taken in accordance with a documented procedure;

1. The Licensee must promptly notify SAI Global and provide in writing the action(s) being taken;
2. The Licensee must immediately investigate the allegation of non-conformity to determine its validity, nature and scope;
3. If allegation of non-conformity cannot be rebutted by the Licenses, the Licensee must take whatever steps are necessary to remove the Certification Trademark from all non-compliant product; and
4. Complete and accurate records of all steps taken under paragraph 4.7.4.3 must be retained and made available to SAI Global upon request.
5. If the Licensee does not comply with their obligation, the licence may be suspended.

The Licensee must be responsible for all costs involved for the above actions.

4.7.5 Corrective and Preventative Action

The Licensee must ensure that effective action is taken to eliminate the cause of nonconformities in order to prevent re-occurrence.

A documented process must be established to define requirements for;

1. Reviewing customer complaints;
2. Reviewing nonconformities;
3. Determining the causes of nonconformities;
4. Evaluating the need for action to ensure that nonconformities do not recur;
5. Determining and implementing actions;
6. Recording the results of action taken; and
7. Reviewing the effectiveness of actions taken.