SAI GLOBAL Product Services

Product Compliance Program – Type 5

Excellence. Assured.

Contents

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 consistently meet the requirements of the relevant Standard.

1. SCOPE AND GENERAL

1.1 Scope

This document sets out the requirements on implementation of SAI Global Certification Scheme - Type 5. It shall 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 shall 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 shall ensure that the Certification Trademark is applied only to conforming product only.

1.3 Relationship to ISO 9001

The Quality documentation requirements within this document are based upon the adoption of 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 17000 Conformity assessment-Vocabulary and general principles
- ISO/IEC 17025-General requirements for the competence of testing and calibration laboratories.
- *ISO/IEC 17065 – Conformity assessment – Requirements for bodies certifying products, processes and services*
- *ISO/IEC 17067 – Conformity assessment-Fundamentals of product certification and guidelines for product certification schemes*
- Guide to Applicants – A step-by-step guide through the Product Services process
- Guidelines for Product Services Testing
- The StandardsMark Rules of Use[1]
- The WaterMark Rules of Use and Licensing Agreement[2]
- SAI Global Terms & Conditions for Certification and Certification Mark.

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

Design Control

A process where the certified product design and materials cannot be changed without SAI Global approval. It applies to all components and materials used in the production of the certified product.

[1] StandardsMark is a registered Certification Trademark of SAI Global Limited
[2] WaterMark is a registered Certification Trademark of Standards Australia

Licensee

Organisation or individual that has been granted the right to use an SAI Global registered certification trademark. Licensee may also refer to licence applicants.

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 certification Trademark of SAI Global Limited.

StandardsMark Label

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

Technical Schedule

SAI Global document that defines certification requirements and provides guidance for testing and auditing against the Standard, where applicable.

Type Test

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

WaterMark

A registered certification Trademark of Standards Australia.

Non Conforming Product

Product which does not comply with the Product Standard, or is otherwise not fit for use.

2. LICENCE CONDITIONS

2.1 Product Testing

The certified product shall 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 initially 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 shall 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.
Note: For some external Scheme such as ANZEx the validity is for four years. (In case of doubt contact the SME)

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 Non-Conforming Product

If a non-conforming certified product marked with a Certification Trademark is identified, the licence may be suspended pending the results of investigation. The full cost of such investigation shall be borne by the Licensee.

3. TESTING

3.1 Test Laboratory

All testing shall 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 shall be conducted for the initial certification of the product. Type testing shall 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 the licence.

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

In the event that the type testing fails, then retesting of failed product will be conducted by the same test laboratory that performed the original test unless otherwise agreed by SAI Global. SAI Global shall 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.

3.3 Test Sample Selection

SAI Global staff or nominated person(s) shall select test samples.

The samples selected shall 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) shall be the model that can be expected to give the worst test results. SAI Global shall make the final decision on test groups and worst-case models.

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

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

3.4 Test Results

Test reports shall comply with the requirements of ISO/IEC 17025. Original test reports shall be sent by the laboratory 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 evaluate, accept or reject the test reports based on the information provided.

4. QUALITY MANAGEMENT REQUIREMENTS

4.1 General

The organisation shall 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 shall 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 shall 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 shall 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 shall 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

Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation (including Management Representatives)

A management representative shall be appointed who shall 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 top 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 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.
    - 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 organisation shall appoint a Deputy Management Representative who may act on behalf of the Management Representative in his/her absence.

4.5 Resource Management

4.5.1 Human Resources

The organisation shall;

1. Determine the necessary competence, such as education, training and experience for personnel performing work affecting product quality.
2. Provide appropriate resources to satisfy these needs.
3. Evaluate the competency of the staff on an ongoing basis.
4. Ensure that personnel are aware of how they contribute to the manufacture of compliant product.
5. Maintain appropriate records of education, training, skills and experience.

4.5.2 Infrastructure and Work environment

The organisation shall provide and maintain suitable infrastructure and work environment to manufacture a compliant product.

4.6 Product Realisation

4.6.1 Design Control

On successful completion of type testing, the design of all critical components, materials and processes, including labelling, packaging, installation and maintenance instructions, shall be documented and controlled; changes shall not be permitted without SAI Global approval.

Product samples, drawings or photographs representative of type test specimens shall 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 organisation shall ensure that purchased product or service conforms to specified requirements. Purchasing documentation shall include a comprehensive and accurate description of the product.

The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with requirements. Criteria shall be established and records of the results of evaluations maintained

4.6.3 Production

The organisation shall plan and carry out production under controlled conditions. Controlled conditions shall 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 organisation shall identify the product by suitable means throughout production.

The organisation shall ensure that finished certified product is traceable to relevant inspection or test report/s. Where, due to the size of product, full marking is not possible, certified product shall maintain traceability on primary packaging or through relevant records.

The organisation shall identify any product test, inspection or measurement status during production.

4.6.5 Product Marking

The Certification Trademark is the means of identifying certified product. The licensee shall ensure that application of Trademark is not misleading. Prior to use the licensee shall 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.

Licensees shall ensure that distributors of their certified products are aware of and observe these requirements.

The Certification Trademark shall only be applied to certified products. It shall 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 shall 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 shall be responsible for the control and security of all labels that bear the certification trade mark. The serial numbers of the labels shall be recorded in the batch release register. Damaged and unused labels shall be recorded and disposed of under controlled environment.

4.6.6 Release of Certified 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. Records shall indicate the person(s) authorising release of product

4.6.7 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.

4.7 Measurement, Analysis and Improvement

4.7.1 Methods of monitoring and measurement

The organisation shall apply methods for monitoring and measurement of the quality processes. Methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved corrective action shall be taken.

The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. Evidence of conformity with the acceptance criteria shall be maintained.
Where the output is not verified by monitoring and measurement the organisation shall validate the processes concerned. Validation shall 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 shall determine the monitoring and measurement to be undertaken and the equipment needed.

Monitoring and measurement devices shall

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.

The organization shall 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 shall be maintained.

4.7.3 Control of nonconforming product

The organisation shall 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 shall be defined in a documented procedure.

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

Where non-conforming certified product has been detected, the organisation shall:

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. Obliterate the Certification Trademark completely from the product.

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

4.7.4 Recall of Product

Where the Licensee or its distributor or its agent becomes aware of Certified product/s which does not comply with the Standard and that have been released or sold, the following actions shall be taken in accordance with a documented procedure;

1. The Licensee shall promptly notify SAI Global and provide in writing the action(s) being taken.
2. The Licensee shall immediately investigate the problem to determine its nature and severity.
3. If indications of non-compliance remain, the Licensee shall immediately withdraw and quarantine the certified products concerned or remove the certification trademark from the released product and action as requested by SAI Global.
4. Records of all steps taken in the recall shall be maintained and made available to SAI Global.

The organisation shall be responsible for all costs involved for the above actions.

4.7.5 Corrective and Preventative Action

The organisation shall take action to eliminate the cause of nonconformities in order to prevent re-occurrence. Actions shall be appropriate to the effects of the nonconformities.
A documented process shall be established to define requirements for;

1. Reviewing nonconformities (including customer complaints),
2. Determining the causes of nonconformities,
3. Evaluating the need for action to ensure that nonconformities do not recur,
4. Determining and implementing actions,

5. Recording the results of action taken, and
6. Reviewing the effectiveness of actions taken.