# PRODUCT ASSESSMENT SCHEME RULES & REQUIREMENTS

PAS-Mark

Product

Conformance

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| AMENDMENT HISTORY | |
|---|---|
| **Date** | **Amendment Summary** |
| 12/01/2007 | Original issue, Issue 1, Revision 0. |
| 01/10/2008 | Issue 1, Revision 2, ISO 9001 reference updated to 2008. |
| 01/06/2011 | Issue 1, Revision 3, Review of document, updated references, formatted document. |
| 01/04/2016 | Issue 1, Revision 4, Review of document, updated references, formatted document. |
| 01/02/2017 | Issue 1, Revision 5, Review of document, updated references |

# 1.0 Introduction

The aim of the Certification Solutions International Pty Ltd, Type 5, Product Assessment Scheme is to address consumer concerns over product attributes, such as suitability for intended purposes and to generate confidence in the community that products manufactured, tested and marked with the PAS-Mark, comply with a particular National or International Standard, Specification or Industry Code.

The Product Assessment Scheme has been planned to give:

- Credibility with clients, consumers, manufacturers, retailers, warehouses, industry suppliers and regulators.
- Users of the conforming product the opportunity to make informed decisions
- High-value, cost competitive certification services to clients across the broad spectrum of small, medium and large organisations in an ever increasing global trading marketplace.
- National and International recognition of the Product Assessment Scheme, that fulfils the accreditation requirements for a product certification program.
- A business review processes focused on the compliance of the product to the relevant standard, specification or industry code and a clients' documented management system in compliance with this document to demonstrate the client's ongoing ability to consistently manufacture compliant products.

This document shall be taken to represent the minimum requirements acceptable to Certification Solutions International Pty Ltd. (**CSi**)

# 2.0 Scope

This document defines the minimum requirements of the Product Assessment Scheme to be placed into operation and maintained by the client and/or their sub-contracted manufacturer, hereafter commonly referred to as the client. This document requires the client to put into practice a documented quality management system to address the requirements of the Product Assessment Scheme and relevant requirements of ISO 9001:2016 - A global quality management system standard, recognised as an integral part of good management practice.

Where questions of interpretation arise in regards to the requirements of this document then ISO 9001:2016 may be used as the reference document to assist with interpretation.

# 3.0 Referenced Documents

The following documents have been referenced in relation to the Product Assessment Scheme.

### *3.1 External Standards;*

- ISO 9000:2015 Quality management systems – Fundamentals and vocabulary.
- ISO 9001:2016 Quality management systems – Requirements.
- ISO 9004:2011 Managing for the sustained success of an organization - A quality management approach.
- AS ISO/IEC 17000-2005 Conformity assessment – Vocabulary and general principles.
- AS/NZS ISO 10005-2005 Quality management systems – Guidelines for quality plans.
- ISO 10012-2003 Measurement management systems - Requirements for measurement processes and measuring equipment.
- ISO/IEC Guide 17065-2012 Conformity Assessment – Requirements for bodies certifying products, processes and services.
- ISO/IEC Guide 17067:2013 Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes.

### *3.2 CSi Reference Documents;*

- PAS-002 Terms, Conditions & Appeals Process.
- PAS-003 Use of Certificate & Trade Mark Logo.
- PASTS-000 Technical Specification, General Requirements.

# 4.0 Definitions

The terms used in this document have meanings defined by AS ISO/IEC 17000, ISO 9000, and ISO 9001 except where the following definitions apply:

Business Review

A systematic, independent, documented process for obtaining evidence and evaluating such evidence objectively to determine the extent to which the Business Review Criteria are being fulfilled. (AS ISO/IEC 17000 clause 4.4)

Batch

A batch or lot is a collection of products – all identical in size, type, conditions and time of production – from which a sample will be taken to decide whether or not it conforms to the acceptance inspection.

Client's Premises

The location where critical components are manufactured and/or critical processes are implemented and the final assembly, inspection and testing of the Certified Products takes place.

Client

A client may be a manufacturer, assembler, distributor, agent or retailer. The client shall be the legal entity issued with a certificate of conformance ad associated product compliance schedule and granted the right to use the PAS-Mark, a certification trademark of **CSi**. The client shall have, and be able to demonstrate, effective control over the manufacture, inspection & testing, marking and packaging and delivery of the certified product.

Certificate of Conformance

A document used in conjunction with a product compliance schedule by a supplier to declare the product they have supplied has been verified as being in conformity with a specified standard or other technical specification.

Conforming Product

Completed product which has been tested and approved as complying with a recognised National or International Standard, Specification or Industry Code and the requirements of the **CSi**, Product Assessment Scheme – Rules and Requirements.

Critical Component

Any component of the finished product (being in compliance with the standard) is dependent upon for safety and or performance.

Declaration of Conformity

The action by which a supplier declares under their sole responsibility that a product is in conformity with a specific standard or other technical specification, without being under the procedures of a third-party certification system.

Evidence

Records, statements of fact or other information, relevant to the Business Review criteria and which are verifiable.

Note: Business Review Evidence can be qualitative or quantitative.

Management Representative

A nominated Client representative having specific roles and responsibilities.

Management System

The system to:

- establish and document a quality management system. Implement, and maintain the quality management system;
- direct and control an organisation with regards to product quality and product conformance with the specified Standard.

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Product

The result of an act or process.

Recognised Test Report

- In Australia, a report produced by an establishment accredited for the relevant standards by the National Association of Testing Authorities (NATA). In New Zealand a report produced by an establishment accredited for the relevant standards by the International Accreditation New Zealand (IANZ);
- Test reports from overseas accreditation establishment are acceptable provided they have in place a Mutual Recognition Agreement, ILAC, MRA, IEC accredited laboratories. The report should be endorsed with the respective logo of the accreditation body;
- A CB test report and certificate issued under the IECEE CB Scheme;
- A report from a testing establishment which has been included as part of a test report from a NATA or IANZ laboratory that is accredited for the standards and test concerned;
- A report that has been produced under the supervision of **CSi**;
- A report which has been issued within the last five (5) years, prior to the date of application for product certification. Demonstrates conformance to the standard, relevant technical specification.

Subcontractor

A Subcontractor is any person or manufacturing organization undertaking work on, or production of, any sub-assembly or component parts of the certified product in accordance with specific requirements of the client.

Standard

The Product Assessment Scheme "shall only be offered in respect of a standard that:

1. is produced by a national standards body, ISO, IEC or another international standards making body that is recognised by the World Trade Organisation; where that body regards the standard[1] as being appropriate for accredited certification; or
2. is used by a national or State regulatory authority in a regulatory context and is regarded by them as being a standard that is appropriate for accredited certification[2]; or
3. is a standard that meets the following criteria:
    - has been developed with the participation of technically competent representatives of interested parties, or has been subjected to formal review by such parties and subsequently revised as appropriate;
    - is such that it is possible to assess whether an applicant is in compliance;
    - has credibility with industry, appropriate regulatory authorities and relevant professional groups;

- is periodically reviewed and updated with the involvement of representatives of interested parties;
- is publicly available for implementation without restriction by number or membership or other limitation[3].

Notes

1 In this context the term “standard” includes an interim-standard.

2 In such cases, the scope of accreditation of a certification body would normally make reference to the regulatory authority or authorities concerned.

3 The levying of a reasonable fee for the purchase of the standard would not be regarded as a restriction or limitation, but, for example, the imposition of a fee as a condition of the implementation of the standard would be likely to be regarded as such.”

Technical Documentation

Documentation that enables the conformity of the product to be assessed against the requirements of the standard(s). It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and would typically include:

- a general type-description;
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.,
- a list of Critical Components;
- detailed colour photographs;
- a list of standards referred to in the design of the product, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Standards;
- results of design calculations made, examinations carried out, etc.;
- labelling, packaging and instructions for use, care, installation and maintenance;
- recognised test report.

Technical Specification

A document issued by **CSi** that defines inspection and testing requirements for Certified Products manufactured to comply with the specified standard. (Refer to PASTS_General Requirements

# 5.0 Management System Responsibility

### *5.1 Documentation Requirements;*

Senior management are responsible for the quality planning and continual improvement of the company and shall develop, implement and maintain a documented and controlled management system containing relevant procedures, work instructions, forms and records to ensure that all products manufactured under the **CSi**, Product Assessment Scheme are;

- manufactured in accordance with a documented management system for the certified product;
- are inspected and tested in accordance with the specified standard. Where the specified standard does not clearly define inspection and testing, then the applicable **CSi** technical specification is to be used; and
- when sold are in compliance with the specified standard and Product Assessment Scheme documents, PAS-001, PAS-002 and PAS-003.

It is a requirement of the Product Assessment Scheme for the client to submit a summary of their management system for review, acceptance and registration. The management system summary shall contain as a minimum the following information;

- ✓ A position description for ae nominated management representative and deputy who shall be appointed and given authority to ensure compliance with the Rules and Requirements of the Product Assessment Scheme is adhered to.
- ✓ An organisational chart for the client's manufacturing site.
- ✓ A quality policy, which shall make a statement of compliance to the product standard.
- ✓ A process flowchart that;
    - clearly shows all major steps in the administrative and manufacturing processes related to the certified product.
    - clearly identifies all inspection and testing processes from incoming goods through to final inspection & testing.
    - clearly identifies any part of the processes that shall be sub-contracted off-site.
    - shows specific references to quality system documentation such as procedures, work instructions, inspection and test reports
    - includes a legend of symbols or terms used in the document.

Should a standard be amended or reissued, and the standard nominates an implementation timeframe, **CSi** shall require the client to adopt the same timeframe. Where a standard does not nominate an implementation timeframe, the client shall be notified by **CSi** and given six (6) months to upgrade their product compliance to the standard. This may require re-testing of some or all components of a compliant product.

### *5.2 Record Management;*

The company shall document a written procedure for controls to be put in place to identify, store, protect, retrieve and dispose of records. Records shall at all times remain legible and shall be available to **CSi** representatives for a period of 10 years after the date of filing, even if the contractual arrangement between **CSi** and the client has been terminated.

Records shall be established, maintained and retained to provide evidence the compliant product was manufactured, inspected, tested and sold in accordance with the specified standard, quality plan and/or technical specification, where applicable. Records of compliant product shall also be identifiable to, approved suppliers, material specifications and declarations of conformity, critical components, test and measuring equipment, personnel involved in the manufacture, inspection and testing of the product.

The following records shall as a minimum be maintained/retained by the company in relation to product conformity;

- Type test records
- Batch test records
- Work order records
- Product component records
- Supplier specifications
- Complaints records
- Process monitoring records, final inspection records
- Inspection, maintenance and calibration records
- Contractor and approved supplier records
- Internal and external audit records
- Competence, Training and awareness
- Planning of product realisation
- Review of requirements related to the product
- Design and development inputs
- Design and development review
- Design and development verification
- Design and development validation
- Control of design and development changes
- Purchasing process
- Validation of processes for production and service provision

### *5.3 Statutory and Regulatory Requirements;*

The client shall take into consideration the statutory and regulatory requirements that apply to its products for local and export markets it may enter.

### *5.4 Internal Audits;*

Management shall plan and conduct internal audits to ensure the administrative and production systems in place are suitable, adequate and effective in complying with planned arrangements and are properly implemented and maintained. It is a requirement of the Product Assessment Scheme for internal audits to be conducted at a frequency of not less than once per calendar

year. Records of internal audits shall be retained for review by the **CSi** representative during each Business Review.

### *5.5 Purchasing;*

Management shall maintain a list of approved suppliers, evaluated and selected on their ability to supply components, materials and services in accordance with the product design requirements. Reviews of approved suppliers shall be conducted on at least an annual basis; records of these reviews shall be maintained. Purchasing documentation shall include detailed information on purchased components, materials and services including any requirement for a certificate of conformity for any material or service consumed in the manufacture of a conforming product.

### *5.6 Management Review & Customer Focus;*

Management shall define the boundaries and applicability of their management system. Management shall review the organisations management and production systems at planned intervals. Management shall verify customer requirements are determined and met to ensure customer satisfaction, as well as monitoring customer feedback and customer complaints. Management reviews and customer focus reviews shall be conducted on at least an annual basis; records of these reviews shall be maintained.

## 6.0 Product Compliance

### *6.1 Infrastructure, Work Environment;*

Management shall define and maintain the infrastructure required for the realisation of compliant product. For example factory workspace, plant and equipment, storage, transport facilities, development of maintenance procedures etc.

Management shall ensure the work environment is maintained to consistently produce compliant product and is suitably, monitored and controlled.

### *6.2 Resource Management;*

Management shall determine the resources needed to implement, maintain and improve the quality management and production system.

Resource management shall ensure personnel are competent and suitably trained in processes or operations which have a significant influence on the compliance of the product to the standard, its safety or performance. Records shall be maintained for all personnel involved with the management or production of certified product. These records as a minimum shall detail, education, training, job skills and experience of the individual. Such training records shall be review on at least an annual basis.

The organisation shall determine and maintain the knowledge necessary for the operations of its processes to achieve product conformance.

### *6.3 Design & Development;*

The organisation shall plan and control the design and development of products to be certified. This shall include keeping records of design inputs and outputs, design reviews, verification, validation and developmental changes. On completion of a product Type Test evaluation, all components and materials used in the product during the manufacturing, assembly and testing processes shall have a design freeze applied.

Future design changes and modifications to the certified product shall be identified, documented and reviewed for possible effects on product conformity against the requirements of the specified standard. **CSi** shall be notified in writing, for acceptance and registration, prior to the implementation of any design changes to the certified product or to technical documentation that shall affect compliance with the specified standard.

Changes that do not affect compliance of the product with the standard are not required to be communicated to **CSi**.

### *6.4 Quality Control;*

The management systems shall address those activities which have a critical bearing on the compliance of the product to the standard, its safety or performance. Management shall arrange for the collection and analysis of appropriate data to demonstrate the suitability and effectiveness of the management and production systems.

### *6.5 Verification of Purchased Product;*

Management shall ensure purchased components; materials and services comply with specified purchase requirements and/or relevant standards. The extent of verification will vary in accordance with the nature of the item and the relationship of its quality to the specified design requirements of the certified product.

Where a client relies on and shall use a certificate of conformity as evidence of product compliance for the acceptance of incoming goods to the specified standard or purchasing requirements. The certificate of conformity shall clearly identify the products to which it refers, the specified standard or purchasing requirements against which the declaration has been made, batch testing undertaken to verify compliance and the quantity of items covered.

Records shall be maintained for verification of purchased product.

### *6.6 Customer Supplied Product;*

Where a customer supplies components for inclusion in the certified product, it is the manufacturer's responsibility to identify and verify compliance of the components with the specified standard or purchasing requirements. The manufacturer is responsible for the protection and safe storage of customer supplies components.

Records shall be maintained for customer supplied components.

### *6.7 Identification & Traceability;*

Management shall establish and maintain documentation to ensure that a certified product is traceable by unique identification of individual product or batches. This identification shall be recorded on inspection or test reports. The form and manner in which the PAS-Mark can be applied to conforming product is detailed in **CSi** document PAS-003 Use of certificate and trademark logo.

### *6.8 Production Inspection & Testing;*

The manufacturer shall ensure production is monitored and inspections are conducted at all stages of the manufacturing process to ensure that piece-parts, components and sub-assemblies, remain in accordance with the original product detailed in the design and development.

The manufacturer is required to conduct ongoing compliance inspections and tests, which shall include testing in accordance with the specified standard. Where the standard does not clearly specify ongoing testing a technical specification shall be issued by **CSi** which shall state minimum requirements for in-house inspection and testing of certified products.

The manufacturer shall document their system of inspections and tests. This documentation shall clearly state the inspections and tests are planned and implemented to ensure the finished product complies with the requirements of the standard.

### *6.9 Control of non-conforming product;*

It is a requirement for non-conforming product to be identified and segregated (where practicable), by a person with appropriate authority and responsibility to report non-conformities. Records of non-conforming products are to be maintained. These records shall detail as a minimum, the date, the nature of the non-conformity, product identification details, action taken to repair/rework the product, re-inspections undertaken and concessions granted.

Products which cannot be re-worked/repaired to compliance requirements shall have the PAS-Mark logo de-faced or removed prior to sale, should this not be possible then the product is to be destroyed.

The client shall maintain a documented procedure to manage a recall of certified product from the market place.

CSi as a minimum require the client to notify and report the following in regards to a product recall;

- The identification of the type of failure;
- Notifying **CSi** of the extent of the non-conformance
- Investigation of the non-conformance (including corrective & preventative action);
- Recall of the certified products already sold;
- Maintenance of an historical summary of events

### *6.10 Inspection Measuring & Test Equipment;*

Inspection measuring and test equipment, used in determining the compliance of the product to the standard shall be calibrated at specified intervals or subject to an operational check prior to use. Inspection measuring and test equipment shall be clearly identified to allow traceability of calibration status to records or certificates of calibration. The inspection measuring and test equipment shall be capable of being re-adjusted when necessary by a qualified person, and be safeguarded from adjustments.

All calibrations undertaken on inspection measuring and test equipment shall be traceable to national or international standards. Where this is not possible, records are to be maintained on the basis used for calibration and/or verification.

When in use and during storage, inspection measuring and test equipment shall be protected from deterioration or damage.

Records of calibrations undertaken for inspection measuring and test equipment shall be retained for a period of 10 years. The records shall include: equipment identification, recalibration interval, reference standards/equipment, method of calibration, uncertainty of measurement where necessary, the environmental conditions where relevant, the calibration results, a statement of compliance with the relevant specification, name and signature of the authorised person who performed the calibration, together with identification of the organisation they represent and date of calibration/adjustment.

Re-calibration intervals shall be determined given the results of previous calibration records and its usage.

### *6.11 Preservation of Product;*

Management shall define and implement processes for the handling, packaging, storage, perseveration and delivery of the product. These processes shall ensure systems are in place to prevent damage, deterioration or misuse of the product during internal processing and thought to final delivery of the product to the customer/end user.

# Appendix “A” Typical scope of a Business Review.

The Account Manager shall as a minimum review the following areas in administration, production and quality control at the manufacturing site against the Product Assessment Scheme- PAS-001, Rules & Requirements, and applicable product standard during each Business Review.

**Incoming Goods**

- ✓ Approved supplier’s names
- ✓ Product types/codes/descriptions
- ✓ Incoming goods verification/acceptance, certificates of conformity, documentation
- ✓ Verification of customer supplied products
- ✓ Quarantine of non-conforming product
- ✓ Safe storage of incoming goods to prevent damage
- ✓ Handling of incoming goods (cranes, forklift, racking)
- ✓ Work instructions/procedures for the area
- ✓ Names of persons interviewed to cross check training records
- ✓ Operators appropriately dressed in safety clothing/equipment for area
- ✓ Unsafe working conditions (electrical/air hoses on ground, pits uncovered, noise, rubbish on floor etc)
- ✓ Inspection and approval of incoming goods for release into production

**In process manufacturing**

- ✓ Suitability of the infrastructure, working environment to manufacture compliant product.
- ✓ Work order documentation, (as a minimum contains details on; customer name, contact name, date of order, purchase order number, quantity, sizes, delivery address, delivery date, batch or work order number)
- ✓ Traceability of customer orders (are component pieces identified individually/by batch)
- ✓ Each manufacturing process clearly identified and signed off when inspected, completed
- ✓ Non-conforming product identification, segregation, appraisal, re-work, release, disposal
- ✓ Operators competent and appropriately trained, have access to documentation such as work instructions, records, dressed in suitable safety clothing/equipment for area
- ✓ Work environment managed to achieve conformity of certified product in accordance with the nominated standard.
- ✓ Unsafe working conditions (electrical/air hoses on ground, pits uncovered, noise, rubbish on floor etc)
- ✓ Application of compliance marking in accordance with the standard
- ✓ Product quality control, inspection, batch testing, batch test reports
- ✓ Standards, technical specifications in use by company
- ✓ Maintenance of plant and equipment
- ✓ Functional check of calibration equipment
- ✓ Operators able to demonstrate skills, knowledge, experience in their duties
- ✓ Names of persons interviewed to cross check training records

**Despatch**

- ✓ Identification of customer order on completed components
- ✓ Packaging of finished product
- ✓ Delivery documentation
- ✓ Checklist, verification of finished goods prior to shipping
- ✓ Transportation of finished goods
- ✓ Names of persons interviewed to cross check training records

**Administration/Management**

- ✓ Operational plan available to demonstrate management of the processes
- ✓ Raw material specifications from suppliers
- ✓ Annual review of suppliers
- ✓ Design & development of products, including the certified product
- ✓ Purchasing process
- ✓ Documented Quality Management System (implementation, maintenance, improvement off) Procedures or work instructions in compliance with the Product Assessment Scheme
- ✓ Management Review Meeting Minutes
- ✓ Archiving of records in compliance with the Product Assessment Scheme
- ✓ Management System and document control
- ✓ Changes to management system or standards that may affect compliance with the Product Assessment Scheme
- ✓ Changes to company registered name, trading name, management representative
- ✓ Recall Procedure
- ✓ Computer data backup
- ✓ Review of records
- ✓ Internal Audits
- ✓ Customer complaints, market surveillance by company. Procedure for a product recall in place.
- ✓ Calibration records
- ✓ Changes to management structure, manufacturing location, use of sub-contractors, evaluation of sub-contractors, raw material suppliers, certified product.
- ✓ Training records of employees

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# Appendix "B" Cross reference PAS-001 against ISO 9001:2016

| 5.0 Management System Responsibility | |
|---|---|
| **PAS-001** | **ISO 9001:2016** |
| **5.1 Documentation Requirements** | 4.2 Documentation information<br>4.4 Quality management system and its processes<br>5.1.1 Leadership and commitment for quality management<br>5.2 Quality Policy<br>5.3 Organisational roles, responsibilities and authorities<br>6. Planning for quality management system<br>6.2 Quality objectives and planning to achieve them<br>7.5.1 General<br>7.5.2 Creating and updating<br>7.5.3 Control of document information |
| **5.2 Record Management** | 4.2 Documentation information |
| **5.3 Statutory and Regulatory Requirements** | 4.1 Understanding the organisation and its context<br>4.2 Understanding the needs and expectations of interested parties<br>4.3 Determining the scope of the quality management system |
| **5.4 Internal Audits and Management Reviews** | 9.2 Internal audit |
| **5.5 Purchasing** | 8.4.1 General<br>8.4 Control of externally provided products and services<br>8.4.2 Type and extent of control of external provision<br>8.4.3 Information for external providers |
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| | |
| **6.0 Product Compliance** | |
| **6.1 Infrastructure, Work Environment** | 7.1.3 Infrastructure<br>7.1.4 Environment for the operation of processes |
| **6.2 Resource Management** | 7 Support<br>7.1 Resources<br>7.1.1 General<br>7.1.2 People<br>7.2 Competence<br>7.3 Awareness<br>7.4 Communication |
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| **6.4 Quality Control** | 6.1 Actions to address risks and opportunities<br>9.1 Monitoring measurement, analysis and evaluation<br>9.1.1 General<br>9.1.2 Customer satisfaction<br>9.1.3 Analysis and evaluation |
| **6.5 Verification of Purchased Product** | 8.4.2 Type and extent of control of external provision |

| | |
|---|---|
| | 8.6 Release of product and services |
| **6.6 Customer Supplied Product** | 8.5.3 Property belonging to customers or external providers |
| **6.7 Identification & Traceability** | 8.5.2 Identification and traceability |
| **6.8 Production Inspection & Testing** | 8.5.1 Control of production and service provision<br>8.5.5 Post-delivery activities |
| **6.9 Control of Non-Conforming Product** | 8.7 Control of nonconforming process outputs, products and services<br>10 Improvement<br>10.1 General<br>10.2 Nonconformity and corrective action<br>10.3 Continual improvement |
| **6.10 Inspection Measuring & Test Equipment** | 7.1.5 Monitoring and measuring resources |
| **6.11 Preservation of Product** | 8.5.4 Preservation |

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