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CMI Guidance Document

for

Product Quality Plan

Requirements

This document has been produced by the Administration Department of CertMark International (CMI).

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Published by:

CertMark International Pty Ltd
14/76 Wises Road
Buderim QLD 4556

PO Box 7144
Sippy Downs QLD 4556

Phone: 1800 CertMark (237 862)
Phone: (07) 5445 2199
Email: office@CertMark.org
Website: www.CertMark.org

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REQUIREMENTS FOR A PRODUCT QUALITY PLAN

A Product Quality Plan (PQP) is a requirement, under both the Type Test and CodeMark schemes, which has been written in line with ISO10005. To assist in breaking down the requirements of a PQP, the following tables identify what is looked at when your PQP is audited and the requirements under ISO10005.

An evaluation of a Product Quality Plan should include the following (but is not limited to):

SCHEME RULES

#	Questions to Consider
1	Does the Product have a quality plan for its manufacturing?
2	What are the quality plan inputs? For example, what are the requirements on resources, and what are the Product specifications?
3	What are the quality objectives as set out in the quality plan? As a minimum, the quality objectives must ensure that Certified Products released in the marketplace are the same as those that are submitted for certification, meet the Certificate of Conformity requirements and are expressed in measurable terms.
4	What are the individual management responsibilities for the quality plan?
5	How are documents and data for the quality plan controlled, for example, identified, reviewed, approved, distributed and accessed?
6	How are records related to the quality plan controlled? For example, what records are established and maintained? How long must records be stored for? What records will be made available to product users?
7	How are resources provided to meet each requirement in the quality plan? In particular: a) material resources; b) human resources; and c) facility resources.
8	What does the quality plan state are the requirements to be met for the Product? All requirements must be stated in measurable terms.
9	Are the production provisions, related monitoring and measurement processes for the Product set out in the quality plan?
10	Does the quality plan specify how non-conforming Products will be controlled?
11	Does the quality plan have recall procedures complying with, or similar to, the 'ACCC Consumer Product Safety Recall Guidelines 2015' that would effectively deal with non-conforming certified Products?*
12	What are the internal audit processes set out in the quality plan and are they suitable for the Product?
*Please note CMI now requires that the certificate holder has a Product Safety Recall procedure. All certificate holders must have a procedure for recalling any product in the market place that is found to be non-compliant to the specifications as given on the certificate. This will include products that are found to have been installed in the market place. The certified holder will be responsible for making sure the non-conforming product is removed and replaced with conforming product.	

Source: CodeMark scheme rules Version 2016.1

ISO10005 REQUIREMENTS

ISO Section Reference	Requirements/Considerations
5.2 Scope	The scope should be clearly stated in the quality plan. This should include: a) a simple statement of the purpose and expected outcome of the specific case; b) the aspects of the specific case to which it will be applied, including particular limitations to its applicability; c) the conditions of its validity (e.g. dimensions, temperature range, market conditions, resource availability or quality management systems certification status).
5.3 Quality plan inputs	It may be necessary to list or describe the inputs to the quality plan (see 4.2), to facilitate, for example, — reference to input documents by users of the quality plan, — checking consistency with input documents during maintenance of the quality plan, and — identification of changes to input documents that may necessitate a review of the quality plan.
5.4 Quality objectives	The quality plan should state the quality objectives for the specific case and how they will be achieved. Quality objectives may be established, for example, in relation to — quality characteristics for the specific case, — important issues for satisfaction of the customer or other interested parties, and — opportunities for improvement of work practices. These quality objectives should be expressed in measurable terms.
5.5 Management responsibilities	The quality plan should identify individuals within the organization who are responsible, in the specific case, for the following: a) ensuring that the activities required for the quality management system or contract are planned, implemented and controlled, and their progress monitored; b) determining the sequence and interaction of the processes applicable to the specific case; c) communicating requirements to all affected departments and functions, subcontractors and customers, and resolving problems that arise at the interfaces between such groups; d) reviewing the results of any audits conducted; e) authorizing requests for exemption from the organization's quality management system requirements; f) controlling corrective and preventive actions; g) reviewing and authorizing changes to, or deviations from, the quality plan. Reporting lines of those involved in implementing the quality plan may be presented in the form of a flow chart.
5.6 Control of documents and data	For documents and data applicable to the specific case, the quality plan should state: a) how the documents and data will be identified; b) by whom the documents and data will be reviewed and approved; c) to whom the documents will be distributed, or their availability notified; d) how access to the documents and data can be obtained.
5.7 Control of records	The quality plan should state what records should be established and how they will be maintained. Such records might include design review records, inspection and test records, process measurements, work orders, drawings, minutes of meetings. Matters to be considered include the following:

	a) how, where and for how long records will be kept; b) what the contractual, statutory and regulatory requirements are, and how they will be satisfied; c) on what media the records will be kept (such as hard copy or electronic media); d) how legibility, storage, retrievability, disposition and confidentiality requirements will be defined and satisfied; e) what methods will be used to ensure that records are available when required; f) what records will be supplied to the customer, when and by what means; g) where applicable, in what language textual records will be provided; h) the disposal of records.
5.8 Resources **5.8.1 Provision of resources**	The quality plan should define the type and amount of resources needed for the successful execution of the plan. These resources may include materials, human resources, infrastructure and work environment. Where a particular resource has limited availability, the quality plan may need to identify how demand from a number of concurrent products, projects, processes or contracts will be satisfied.
5.8.2 Materials	Where there are specific characteristics for required materials (raw materials and/or components), the specifications or standards to which the materials have to conform should be stated or referred to in the quality plan.
5.8.3 Human resources	The quality plan should specify, where needed, the particular competences required for defined roles or activities within the specific case. The quality plan should define any specific training or other actions required for personnel. This should include: a) the need for, and training of, new personnel; b) the training of existing personnel in new or revised operating methods. The need or applicability of team development and motivational strategies should also be considered. NOTE The qualification of personnel is addressed in 5.13, and training in the use of quality plans is addressed in 6.2.
5.8.4 Infrastructure and work environment	The quality plan should state the particular requirements of the specific case with regard to the manufacturing or service facility, workspace, tools and equipment, information and communication technology, support services and transport facilities necessary for its successful completion. Where the work environment has a direct effect on product or process quality, the quality plan may need to specify the particular environmental characteristics, for example: a) the air-borne particle content for a clean room; b) electrostatic sensitive device protection; c) biological hazard protection; d) the temperature profile of an oven; e) ambient light and ventilation.
5.9 Requirements	The quality plan should include or make reference to the requirements to be met for the specific case. A simple overview of the requirements may be included to help users to understand the context of their work, for example an outline of a project. In other cases, there may be a need for a comprehensive list of requirements, developed from input documents. The quality plan should state when, how and by whom the requirements specified for the specific case will be reviewed. The quality plan should also state how the results of this review will be recorded and how conflicts or ambiguities in the requirements will be resolved.
5.10 Customer communication	The quality plan should state the following: a) who is responsible for customer communication in particular cases; b) the means to be used for customer communication; c) where applicable, communication pathways and contact points for specific customers or functions;

	d) the records to be kept of customer communication; e) the process to be followed when a customer compliment or complaint is received. 5.11 Design and development
5.11.1 Design and development process	The quality plan should include or make reference to the plan(s) for design and development. The quality plan should take account of applicable codes, standards, specifications, quality characteristics and regulatory requirements, as appropriate. It should identify the criteria by which the design and development inputs and outputs should be accepted, and how, at what stage(s), and by whom, the outputs should be reviewed, verified and validated. Design and development is a complex process and guidance should be sought from appropriate sources, including the organization's design and development procedures. NOTE ISO 9004 provides general guidance on the design and development process. ISO/IEC 90003 provides specific guidance for the software sector.
5.11.2 Control of design and development changes	The quality plan should state the following: a) how requests for changes to the design will be controlled; b) who is authorized to initiate a change request; c) how changes will be reviewed in terms of their impact; d) who is authorized to approve or reject changes; e) how the implementation of changes will be verified. In some cases there may be no requirement for design and development. However, there may still be a need to manage changes to existing designs.
5.12 Purchasing	The quality plan should define the following: a) the critical characteristics of purchased products that affect the quality of the organization's product; b) how those characteristics will be communicated to suppliers, to enable adequate control throughout the product or service life cycle; c) the methods to be used to evaluate, select and control suppliers; d) requirements for, and reference to, supplier quality plans or other plans, where appropriate; e) the methods to be used to satisfy the relevant quality assurance requirements, including statutory and regulatory requirements that apply to purchased products; f) how the organization intends to verify purchased product conformity to specified requirements; g) the facilities and services that will be outsourced. NOTE See website www.iso.org/tc176/sc2 for guidance on “outsourced”.
5.13 Production and service provision	Production and service provision, together with the relevant monitoring and measurement processes, commonly form the main part of the quality plan. The processes involved will vary, depending on the nature of the work. For example, a contract may involve manufacturing, installation and other post-delivery processes. The interrelationship between the various processes involved may be effectively expressed through the preparation of process maps or flow charts. Production and service processes may need to be checked, to ensure they are capable of delivering the required output; such a check should always be undertaken if the output of a process cannot be verified by subsequent monitoring or measurement. The quality plan should identify the inputs, realization activities and outputs required for carrying out production and/or service delivery. Where appropriate, the quality plan should include or refer to the following: a) the process steps; b) relevant documented procedures and work instructions;

	c) the tools, techniques, equipment and methods to be used to achieve the specified requirements, including details of any necessary material, product or process certification; d) required controlled conditions to meet planned arrangements; e) mechanisms for determining compliance with such conditions, including any specified statistical or other process controls; f) details of any necessary qualification and/or certification of personnel; g) criteria for workmanship or service delivery; h) applicable statutory and regulatory requirements; i) industry codes and practices. Where installation or commissioning is a requirement, the quality plan should state how the product will be installed and which characteristics have to be verified and validated at that time. Where the specific case includes post-delivery activities (e.g. maintenance, support or training services), the quality plan should state how the organization intends to assure conformance to applicable requirements, such as: a) statutes and regulations; b) industry codes and practices; c) the competence of personnel, including trainees; d) the availability of initial and on-going technical support during the agreed time period. NOTE Guidance on project processes to be managed under this clause is provided in ISO 10006.
5.14 Identification and traceability	Where product identification is appropriate, the quality plan should define the methods to be used. Where traceability is a requirement, the quality plan should define its scope and extent, including how the affected products will be identified. The quality plan should state: a) how contractual, statutory and regulatory traceability requirements are identified and incorporated into working documents; b) what records relating to such traceability requirements will be generated and how they will be controlled and distributed; c) specific requirements and methods for the identification of the inspection and test status of products. NOTE Identification and traceability is part of configuration management. For further guidance on configuration management, see ISO 10007.
5.15 Customer property The quality plan should state	a) how products provided by the customer (such as material, tooling, test equipment, software, data, information, intellectual property or services) are identified and controlled, b) the methods to be used to verify that customer-supplied products meet specified requirements, c) how nonconforming customer-supplied products will be controlled, and d) how damaged, lost or unsuitable product will be controlled. NOTE Guidance on information security is given in ISO/IEC 17799.
5.16 Preservation of product	The quality plan should state: a) requirements for handling, storage, packaging and delivery, and how these requirements will be met; b) (if the organization is to be responsible for delivery) how the product will be delivered to the specified site, in a manner that will ensure that its required characteristics are not degraded.
5.17 Control of nonconforming product	The quality plan should define how nonconforming product will be identified and controlled to prevent misuse, until proper disposal or acceptance by concession is completed. The quality plan may need to define specific limitations, such as the degree or type of rework or repair allowed, and how such rework or repair will be authorized.

5.18 Monitoring and measurement	Monitoring and measurement processes provide the means by which objective evidence of conformity will be obtained. In some instances, customers request submission of monitoring and measurement plans (commonly referred to as "inspection and test plans") alone, without other quality plan information, as a basis for monitoring conformity with specified requirements. The quality plan should define the following: a) process and product monitoring and measurements to be applied; b) the stages at which they should be applied; c) the quality characteristics to be monitored and measured at each stage; d) the procedures and acceptance criteria to be used; e) any statistical process control procedures to be applied; f) where inspections or tests are required to be witnessed or performed by regulatory authorities and/or customers, for example, — a test, or series of tests (sometimes referred to as "type tests"), directed towards the approval of a design and conducted to determine if the design is capable of meeting the requirements of the product specification, — site testing including acceptance, — product verification, and — product validation; g) where, when and how the organization intends, or is required by the customer, statutory or regulatory authorities, to use third parties to perform inspections or tests; h) the criteria for product release. The quality plan should identify the controls to be used for monitoring and measuring equipment intended for use for the specific case, including its calibration confirmation status. NOTE 1 Guidance on the management of measurement systems can be found in ISO 10012. NOTE 2 Guidance on the selection of statistical methods can be found in ISO/TR 10017.
5.19 Audits	Audits may be used for several purposes, such as: a) to monitor the implementation and effectiveness of quality plans; b) to monitor and verify conformity with specified requirements; c) for surveillance of suppliers to the organization; d) to provide independent objective assessment, when required, to meet the needs of customers or other interested parties. The quality plan should identify the audits to be performed for the specific case, the nature and extent of such audits and how the results of the audits should be used. NOTE Further guidance for auditing is given in ISO 19011.
6 Review, acceptance, implementation and revision of the quality plan **6.1 Review and acceptance of the quality plan**	The quality plan should be reviewed for adequacy and effectiveness, and should be formally approved by an authorized person or a group that includes representatives from relevant functions within the organization. In contractual situations, a quality plan may need to be submitted to the customer by the organization for review and acceptance, either as part of a pre-contract consultation process or after a contract has been awarded. Once a contract is awarded, the quality plan should be reviewed and, where appropriate, revised to reflect any changes in requirements that may have occurred as a result of the pre-contract consultation.
6.2 Implementation of the quality plan	In the implementation of the quality plan, the organization should give consideration to the following issues. a) Distribution of the quality plan The quality plan should be distributed to all relevant people. Care should be taken to distinguish between copies that are distributed under document control provisions (to be updated as appropriate), and those that are supplied for information only.

	b) Training in the use of quality plans In some organizations, for example those engaged in project management, quality plans may be used as a routine part of the quality management system. However in others, quality plans may be used only occasionally. In this case, special training may be needed to assist users in applying the quality plan correctly. c) Monitoring conformity with quality plans The organization is responsible for monitoring conformity with each quality plan that it operates. This may include — operational supervision of the planned arrangements, — milestone reviews, and — audits. Where many short-term quality plans are used, audits are generally undertaken on a sampling basis. Where quality plans are submitted to customers or other external parties, these parties may establish provisions for monitoring conformity with the quality plans. Whether carried out by internal or external parties, such monitoring can assist in 1) assessing the commitment of the organization to the effective implementation of the quality plan, 2) evaluating the practical implementation of the quality plan, 3) determining where risks may arise in relation to the requirements of the specific case, 4) taking corrective or preventive action where appropriate, and 5) identifying opportunities for improvement in the quality plan and associated activities.
6.3 Revision of the quality plan	The organization should revise the quality plan: a) to reflect any changes to quality plan inputs, including — the specific case for which the quality plan is established, — the processes for the realization of the product, — the organization's quality management system, and — statutory or regulatory requirements; b) to incorporate agreed improvements to the quality plan. An authorized person or persons should review changes to the quality plan for impact, adequacy and effectiveness. Revisions to the quality plan should be made known to all those involved in its use. Any documents that are affected by changes in the quality plan should be revised as necessary. The organization should consider how and under what circumstances the organization would authorize a deviation from the quality plan, including — who will have the authority to request such deviations, — how such a request will be made, — what information will be provided and in what form, and — who will be identified as having the responsibility and authority to accept or reject such deviations. A quality plan should be treated as a configuration item and should be subject to configuration management.
6.4 Feedback and improvement	Where appropriate, experience gained from the application of a quality plan should be reviewed and the information used to improve future plans or the quality management system itself.

Source: ISO10005:2005

PRODUCT QUALITY PLAN EXAMPLE

A.2.4 Example 4: A "text" type of quality plan (for the development of software, for a pedestal mounted display unit)

1 Scope

The purpose of this quality plan is to identify the quality management methods being applied to the contract between the company and its client for a garment distribution system.

a) Inclusions

This quality plan applies to the development and supply of the distribution, concession management and marketing subsystems. The financial management systems are the subject of a subcontract with the subcontractor and so the quality plan is concerned solely with the subcontract management aspects of that part of the project.

b) Exclusions

The development work being undertaken by the subcontractor is covered by the purchase order and is not included in detail in this plan.

2 Quality objectives

The client has made no specific demands in terms of quantified quality objectives. Accordingly, the company standard of releasing software with no known category A defects, no known category B defects, and category C defects only with client agreement shall apply. A defect is defined as system behaviour showing evidence of nonconformity against the agreed requirements.

In addition, the company objective of commissioning systems within a 5% margin of the contractual date based on the contractual elapsed time for the project shall also apply.

3 Responsibilities

The Project Manager has overall responsibility for the successful execution of the project, including conformity with the company's QMS and meeting the above objectives.

The Quality Manager is responsible for project audits and for following through any corrective actions from them. Any required deviation from the QMS is to be approved by the Quality Manager before the deviation takes place.

4 Documentation

Some documents used in this project have references that do not conform to the latest QMS requirements. The existing references shall be retained. In all other respects, the QMS applies.

5 Records

The project file and associated records are to be retained for a period of not less than three years after the warranty period has expired. Disposition at that time shall be by agreement with the client. In accordance with the company policy, the client may view any contract-related records at any reasonable time. All contract-specific computer files shall be backed up at least weekly.

6 Resources

The client is to supply a sample of OCR forms (at least 2 000) for use in testing the document reader being supplied as part of the system. The subcontractor shall obtain and commission the document reader as part of their supply of the financial management system.

All of the development team shall be employees of the company. Appropriately qualified individuals will be made available by the Human Resources Manager to meet the needs of the project. The Project Manager shall be J. Smith.

7 Project inputs

The primary input is the Requirements Specification KLOB-D-001 prepared by the client's advisors. Sample marketing documents and Annual Reports are to be provided by the company for familiarization purposes.

8 Customer communications

Any queries with the specification are to be raised with the client through the Project Manager at project meetings. Their decision is final. The client does not have a software technical capability so technical queries should be addressed through the Project Manager or his delegate. Minutes of project meetings will be prepared by the Project Manager. Similarly, communications from the customer (queries, complaints, compliments) should be routed through the Project Manager.

9 Design and development

The project schedule will be presented using an approved scheduling tool. The critical dates are customer acceptance tests (by end October) and system roll-out (before April next year).

All of the company standards in the Software Development Manual shall apply. Review and approvals shall be as in the company's Quality Manual.

Change requests that affect the functionality as seen by the users must be approved by the company. Detailed design changes at the subcontractor and the company must be approved by the Project Manager before work in them commences.

The approach to testing shall be as the company's Quality Manual. The document data capture testing will require the document reader. The final tests of the marketing subsystem will need the pedestal mounted display unit, to test customer reaction. The distribution system as a whole is to be tested at the company before shipment and customer acceptance at their premises.

10 Purchasing

All equipment is being purchased by the client (computers through the subcontractor, other items directly). Any other purchases must be handled to the company's procedures.

11 Installation and commissioning

The document reader will be delivered to the client's HQ. The pedestals will be rolled out by the client to their programme after field trials. Support may be needed for the first installations while customer staff are gaining familiarity with the systems.

12 Special processes

There are no special processes in this project.

13 Configuration management

Document identifiers shall conform to the version of the Quality Manual in place at the start of the project, except for those documents already identified beforehand.

Current company approved configuration management tools shall be used.

14 Customer property

Any equipment belonging to the client must be so identified while in the company or its subcontractors' possession. Customer property of any kind must be recorded in the project log.

15 Product handling

Software will be delivered on CD-ROM. All CDs will be virus checked.

16 Nonconformities

No software shall be delivered with known nonconformities other than cosmetic ones without a written concession from the client. The process will be as given in the company QM and SDM.

17 Monitoring and measurement

The project progress will be recorded on time sheets and registered on the Project Schedule on a weekly basis. A report shall be prepared for and presented to the progress meetings with the client. The subcontractor will be invited to selected meetings. Records shall be kept by the programming team leader of any problems identified with the software at second and third level testing. Categorization of problems into problem origin: Requirements Spec. (missing or incorrect), Design (missing or incorrect), coding (missing, incorrect logic, interface error, data handling error) shall be performed.

18 Internal audit

An audit of the implementation and effectiveness of the quality plan shall take place at the end of the design stage.

This quality plan has been prepared by the project manager of the client's Distribution Project and applies to all work carried out under the contract.

Author:	Date:
Quality Manager:	Date:
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Source: ISO10005:2005