EARSC Guideline Document

EARSC EO Industry Certification Scheme

Management System Requirements for Earth
Observation Data Based Products and Services

EARSC/CERT/REQ/2015/002

Contents

This document contains a total of 23 Pages

Change Record Sheet

Date	Issue/ Rev.	Pages Affected	Description	DCR	Approval Authority
March 2015	1.0	All	First Issue		
July 2016	2.0	4, 5, 6, 14, 15, 16	Revision for ISO9001:2016	N/A	EARSC

1 INTRODUCTION

1.1 *Background*

The European Association of Remote Sensing Companies (EARSC) is the European organization which – on a non-profit basis – coordinates and promotes activities of their members in the area of services based on the delivery of geo-information products on customer demand. Formed in 1989 EARSC has been acting for over 24 years on behalf of the geospatial services industries in Europe and especially those dealing in EO services. The members of EARSC are active on the growing market for the exploitation of EO data by converting these data in geo-information suitable and accessible for their clients. This conversion process, the customization of the products and the development and provision of services is characterized by addition of value for users/customers in the chain between data collection and exploitation of information.

During the period 2010 to 2013, the European Space Agency has financed a project to look into the feasibility of a quality certification scheme for the Earth Observation Industry. This project, with Hollidge Consulting Limited, has led to a close working relationship with EARSC and the founding of the EARSC Industry Best Practices Working Group.

As a result, the following documentation has been developed:

- A Scheme Description (AD01), based on the relevant ISO standards and Guidelines pertaining to certification schemes.
- Management System Requirements (this document) based on ISO9001:2008 (AD03) and focusses on the needs of the Earth Observation industry with respect to management system requirements
- Document Requirements Definition for Product Specifications (AD02).

EARSC has now decided to issue this document as a guideline for the industry to be available for use by organisation supplying EO Products and Services.

1.2 *Purpose and Use*

The purpose of this document is to provide management system requirements for an organisation providing Products or Services based on EO data. This document supports the Earth Observation Industry Certification Scheme defined in AD01 and is based on the requirements of ISO9001:2015 (AD03).

As such this document may be used by:

- Earth Observation Organisations needing to meet the management system requirements of the product certification scheme defined in AD01

- Earth Observation Organisations implementing AD03 for processes specific to EO Products and Services
- Certification bodies carrying out certification assessments of Earth Observation Organisations to AD03 with respect to processes specific to Earth Observation (EO) Products and Services
- Any organisation wanting to develop EO Products and Services that want to put in place industry standard practices for assuring quality.

This document is **not** intended to replace AD03 and so does not address those of its requirements that are not specific to EO Products and Services (such as management system review, internal audits, etc.) Therefore this document should be used in conjunction with AD03 by companies wishing to have fully AD03 compliant management systems.

1.3   Changes to this Document

This document is intended as a living document that shall evolve as the requirements of the industry and its customers change. As a result, suggestions for changes to this document to improve its utility are welcomed. Suggestions for change shall be forwarded to the EARSC Secretariat for consideration.

2   SCOPE

The scope of this document covers those elements of ISO9001:2008 (AD03) that are considered necessary for the effective management of the development and production of EO Products and Services

This document is not intended to be a replacement for (AD03), it is merely to highlight specific processes to be considered by an organisation providing EO Products and Services.

In addition, many EO Products either are, or are strongly based on, software tools or applications. This document is not intended to define a method, model or requirement for software development. There are already many of these in the software industry. The only requirement is that one of these standards be adopted or that the organisation develops and documents its own methods.

It should be noted that requirements within this document are expressed in a form that includes the word **'shall'**. In some cases, the word may is used to indicate options that exist in implementing a requirement. Where a statement includes the phrase where(ever) possible, the organisation implementing these requirements may be required to provide a statement of the reasons why it decided not to meet the stated requirement.

For the purposes of the development, implementation and assessment of a management system meeting the requirements stated herein, this document is supported by a self-assessment checklist (AD04).

3   DEFINITIONS AND ABBREVIATIONS

3.1   Definitions

For definitions and vocabulary relating to Quality and Quality Management Systems please refer to RD01.

In particular, the following should be noted:

Validation: Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a *validated status* is achieved. The process of *validation* can be carried out under realistic use conditions or within a simulated use environment.
In the context of AD03, the term *validation* is used in at least two different situations: design and development and production and service provision.

Design and development validations use objective evidence to confirm that products meet the requirements which define their intended use or application.

Production and service provision processes must be *validated* whenever process outputs cannot be measured, monitored, or verified until after the product is in use or the service has been delivered (by then it's too late to do anything about output deficiencies and defects). In this case, *validations* use objective evidence to confirm that production and service provision processes are capable of producing planned results.

Verification: Verification is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a *verified status* is achieved.

In the context of AD03, the term *verification* is used in at least two different situations: design and development and purchasing. *Design and development verifications* use objective evidence to confirm that design and development outputs meet specified input requirements. Similarly, objective evidence must be used to *verify* or confirm that *purchased products* meet specified purchasing requirements.

There are many ways to *verify* that requirements have been met. For example, you could do tests, perform demonstrations, carry out alternative calculations, compare a new design specification with a proven design specification, or you could inspect documents before you issue them.

3.2   Abbreviations

The following abbreviations are used in this document:

CRM   Customer relationship Management
EARSC   European Association of Remote Sensing Companies
EO   Earth Observation

ISO   International Organisation for Standardisation
KPI   Key Performance (or Process) Indicator
RACI   Responsibility Assignment Matrix
SAP   Systemanalyse und Programmentwicklung (Company)
SLA   Service Level Agreement

4   RELATED DOCUMENTS

4.1   Applicable Documents

The following documents are applicable to this document:

AD01 EARSC/CERT/REQ/2015/001   Earth Observation Industry Certification
                                 Scheme – Scheme Description
AD02 EARSC/CERT/DRD/2013/001   Earth Observation Industry Certification
                                 Scheme – Document Requirements Definition
                                 for Earth Observation Product Specifications
AD03 IS09001:2015   Quality management systems: Requirements
AD04 EARSC/CERT/REQ/2015/003   Earth Observation Industry Certification
                                 Scheme – Management System Requirements
                                 for Earth Observation Data Based Products and
                                 Services – Self-Assessment Checklist

4.2   Reference Documents

The following documents allow a better understanding of some of the issues raised by this document:

RD01 ISO9000:2015   Quality management systems – Fundamentals and
                                 vocabulary

5   GENERAL REQUIREMENTS

5.1   Documented Information

In general there are two types of documented information to be controlled:

- Documented Information relating to the business and business processes
- Documented Information relating to the product

These are to be maintained separately.

All documented information is to be identifiable and retrievable. A document numbering system shall be formally defined (documented) and applied across the organisation. Documents can be in any format, including electronic.

Records are defined as any documented information that provides evidence of an activity or process having been performed. Examples of these are test records relating to products. Records should be subject to the same numbering system as other documented information.
.
Notes:

- Documented information relating to the product must be sufficient to re-create the product or any version of it.
- The documented information relating to process must be sufficient to understand the processes applied to each instance of the product.
- For the purposes of the Product Specification required by 7.1 of this document and for further guidance on the numbering to be implemented, refer to Chapter 2 of AD02.

5.2   Resources

5.2.1   Infrastructure

The organisation shall identify and record any specialist equipment or facilities required for the development, production and delivery of the product or service. These shall be documented as part of the product documentation. This shall include any specific requirements to be placed in the customers' infrastructure to enable the product to be utilised effectively.

Where possible, single points of failure shall be avoided and backups procured.

Where a key infrastructure item is replaced by another with different properties (including improved performance, updated operating system, etc.), the organisation shall identify any product re-verification or re-validation that shall be required. This shall then be performed and recorded in the same manner as the original product.

In all cases where key infrastructure items are replaced, full testing shall be performed to ensure that the items are operating in accordance with requirements.

5.2.2   Monitoring and Measuring Resources

Monitoring and measuring resources shall be managed in accordance with section 7.8

5.3   Competence

The organisation shall identify and record any personnel with specific skill sets that are required for the delivery of the product or service. The skill sets involved shall be documented as part of the product documentation.

Where possible, there shall be more than one person with the required skills/knowledge available to the organisation.

Where this is not the case, and wherever possible, the organisation shall make arrangements for the training and/or appointment of a back-up person to the key resource.

6   PLANNING OF PRODUCT REALISATION

The organisation shall identify and develop those procedures required to allow a new product to be introduced.

These procedures shall include the need to identify:

a) quality objectives and requirements for the product;
b) the processes and documents specific to the product
c) resources specific to the product;
d) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
e) records needed to provide evidence that the realization processes and resulting product meet requirements

Where a new product is being introduced, the organisation shall develop a Product Plan that shall include the elements listed above.

Quality objectives of a product should ultimately link to the overall quality objectives of the company or specific group/team. They "must" answer what requirements and conformities one is trying to meet with the product, which should depend on customer requirements and may differ with each project.

Each product may need to follow processes differently. Processes should be determined by the given input and the output one desires and should ideally be at such level that it applies to multiple products (establishing, following, and maintaining numerous processes different for each product becomes unrealistic).

Documents on the other hand should be specific to each product (standard or non-standard) and should be part of the project life-cycle document requirements. From a strategic perspective, resources should not be solely dedicated to a specific product as one loses structural flexibility (unless a company can really effort it based on the revenue stream derived from a certain product).

Introduce control gates throughout the product/service delivery life-cycle to address verification and validation. Tools such as RACI matrix may be used to define accountability.

Product acceptance criteria will differ from case to case but ensure that tests cover technical and functional requirements based on user/customer needs. In many cases the customer is given a certain period to ensure the product has met specifications.

Records should be stored so that a relationship can be traced back between the different records.

All this should be part of a project plan as it entails the different stages of the life-cycle, each producing its own set of configuration items and resources different in each stage

7 DESIGN AND DEVELOPMENT

The organisation shall develop procedures describing how each of the following design and development steps are undertaken, managed and recorded within the company.

7.1 Determination of Requirements Related to the Product

All requirements related to the products shall be documented. This shall include

- The methodology to be used for development (noting agile development will not determine all requirements ahead of time)
- All requirements for which a standard product has been developed
- Any customer specific requirements relating to a standard product
- All requirements relating to a bespoke product

Detailed technical requirements shall include

- functional and performance requirements,
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs, and
- other requirements essential for design and development

Technical requirements shall also include requirements with respect to the content, format and quality of data. These shall refer to existing ISO Standards plus any that relate to specific industry sectors such as oil and gas, marine and land survey.

The requirements for verification and validation of the product shall be documented; this shall contain the validation methodology (protocol) that is to be implemented.

In addition operational requirements shall be documented. These may be documented later in the form of an SLA but shall be included, where possible, in the requirement set used for development.

Requirements relating to the product shall be described in a Product Specification in accordance with AD02.

The organisation shall identify other documents required to meet the requirement to fully document product requirements to allow development to take place.

7.2 Review of Requirements Related to the Product

Requirements shall be reviewed before a commitment is made to the customer to supply a product or service, or before development begins where the product is intended to be a general offering to the market.

The requirements review shall answer the following questions:

- Are the requirements complete and documented?
- Have any issues with the customer (if any) been clarified?
- Does the organisation have the capability and resources required to design and develop the product?
- Are operational requirements known and documented?
- Are trade-off fully understood and documented?

The review shall be documented and any changes required to the requirements document shall be implemented before development begins.

The set of requirements at this stage shall for the 'Requirements Baseline' for the product/service and shall be subject to formal change control over the life of the product/service (See Section 10).

Notes

1. For products with multiple customers, versions of the requirements baseline may be established. These versions shall be traced via the Configuration Management system and be traceable to the specific customer.
2. Requirements can include elements such as: Identification of geographical coverage and associated dataset requirements

7.3 Design and Development Planning

A Design and Development Plan shall be generated. The plan shall follow the 'Plan-Do-Check-Act' convention and shall include:

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development and associated interfaces

In addition, the plan shall define:

a) Specific expertise and experience that shall be required for the development
b) Identification of geographical coverage and associated dataset requirements
c) Identification of key human resources and qualification/ experience profile

The plan (or key elements such as budget and schedule) shall be updated as required during the execution of the design and development phase. The plan shall include identification of management tools such as responsibility assignment matrices and risk management standards that are to be utilised for the activity.

The Plan shall include a section of quality management that shall identify the processes in place for the management of the Design and Development activities within the organisation and define how they are to be applied to the activity. This shall include processes for design review and verification and the management of design changes.

Note: Often the design and verification/validation includes people with different background as it would also include scientists/geologists, business managers, and IT specialists. This can often lead to difficulties in communication/interpretation of what customer requirements actually are. Business ownership with the right skill set becomes imperative here as it will determine internal collaboration, prioritization, and customer communication.

7.4   Design and Development Review

Dependent upon the complexity and length of the activity one or more Design and development reviews shall be held.

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

The review shall also consider the design approach taken and any operational safety issue that may arise. Inputs to the review shall include

- Design/development documentation and records
- Latest requirements relating to the product or service
- Delta requirements where the development is an evolution of an existing product or service
- Test and Verification plans relating to the intermediate and final testing of the product as applicable

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Where required, the customer shall be invited to the review.

Records of the results of the reviews and any necessary actions shall be maintained and any changes decided at the review shall be communicated to all members of the team.

Notes:

- Small developments may be catered for in one review (for example a post mortem meeting (i.e.: Lessons Learnt) review)

▪ Larger developments should be subject to a number of reviews as stated in a development plan where the review is used as a control gate as part of each development stage.

7.5   *Design and Development Outputs*

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall consist of:

▪ Documentation, describing the product or service to be offered, its limitation, performance characteristics and technical specification
▪ Plans for the verification and validation of the product or service and its transfer into operations
▪ Prototypes or pre-operational products or services that are to be used for verification and/or validation.
▪ User documentation, including education, experience and training requirements for human operators.

The outputs from the Design and Development Phase shall be sufficient for the complete creation of the product or service and to allow someone not versed in the product to be able to follow the development process.

For bespoke products, the design and development output may be subject to review by the customer and/or the customer may have specific requirements relating to the form and format of the output. These requirements shall be met.

7.6   *Verification and Testing*

Verification (testing to ensure that technical requirements are met) shall be performed in accordance with the relevant plan. Verification test shall be performed on a version of the product or service that is under configuration control.

 Records of the results of the verification and any necessary actions shall be maintained.

Validation shall be performed on each element of the product or service by the relevant team involved in the development.

Where validation is being performed as a Factory Acceptance Test, the customer shall be invited and required to sign each teat record.

Any problems or failures raised during testing shall be formally recorded. The testing shall be repeated to ensure that the problem is repeatable. The record of the problem shall be complete and include disposition, remedial or corrective work performed, record of re-test and sign off by the customer (if required).

Retest shall be performed only on a formally issued version of the product or service (not on software patches, for example)

7.7   Validation

A validation plan shall be generated describing in detail the validation approach and protocol to be undertaken for the product/service. The validation plan shall be maintained under configuration control (See section 10) and be directly linked to the version of product or service being validated.

There are two types of validation considered here

- Non-Operational Validation
- Operational Validation

Either of these or a mix of the two may be used. This shall be described as part of the validation protocol within the validation plan. It is intended that all elements of the product or service will be validated. However, where validation is not possible, the customer shall be made fully aware of the fact and any associated risk associated with the use of the product or service.

Revalidation shall be performed whenever there is a change to requirements, design, personnel or facilities which have a material effect upon the performance of the product or service. In addition, revalidation shall be performed wherever changes have been made as a result of serious non-conformities discovered during testing or operations.

Where the validation process includes human intervention or interpretation, the education, training and experience requirements relating to this person are to be defined within the validation plan.

Records of all validation activities shall be maintained.

7.7.1   Non-Operational Validation

Non-operational validation shall be performed where there is no possibility of validation in the operational state. Where non-operational validation is being performed, the organisation shall clearly define the processes, methods and equipment to be used within the validation plan.

Where data sets are being used, the validation plan shall define the requirements for the data, including, as appropriate:

- Source of the data
- Format of data
- Validation level of the data

Any equipment used (for example simulators) shall, themselves, be subject to a development activity in the same manner as the system for which they are being developed. This includes verification and validation of the equipment, and, where applicable, acceptance by the customer.

The processes and methods to be used shall, themselves, be subject to review and approval by the organisation.

Non-Operational validation may be outsourced. Where this is the case, the organisation shall satisfy itself that the validation service provider has the required capability and knowledge to perform the activity.

In addition, requirements stated here relating to validation shall be passed to the validation service supplier.

7.7.2 Operational Validation

Operational validation is the preferred method of validation and occurs with the product or service in its operational environment.

Where ground Truthing is used, the organisation shall establish the chain between the physical measurement and the product, including the calibration status of any measurement instrument. This shall be documented in the validation records.

The result of the validation process should be a 'level of confidence' in the product. This should consist of a stated accuracy plus confidence limits.

Where the product or service includes human intervention, it is recommended that the person involved is not part of the development team. (They shall be trained in the use of the tool or system involved – requirements for training, etc, shall be included in the validation plan). Records of qualification, experience and training of personnel used shall be retained.

Where the customer is involved in the validation process, they shall be invited to review and approve the validation plan. The validation plan shall clearly state the roles and responsibilities of the customer with respect to validation.

Elements of operational validation may be outsourced to a supplier to the organisation, including the collection and collation of ground truth data. Where this is the case, the requirements relating to traceability and calibration of instrumentation shall be passed to the supplier.

7.8 Tools Used for Verification and Validation

During the development phase, the organisation shall define the tools to be used for verification and validation testing. In general, tools used for validation shall be subject to a similar or equivalent development cycle as for the original system.

In general, to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, periodically, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

Note: Where measuring equipment is calibrated and/or verified periodically, this is normally expected to be defined as at least annually.

Where problems or failures are found with tools, the organisation shall review all necessary measurements and tests carried out with the tools to ensure validity of previous measurements.

- Where this validity is called into questions, the organisation shall repeat the tests.
- Where the testing relates to a product or service in operation with the customer, the customer shall be informed of the issue and the appropriate measures to be taken to ensure product integrity.

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

The organisation may use virtual environments to emulate production systems for testing purposes, especially when changes in configuration occur as part of release process.

This is to include the calibration and validation of any instruments or techniques used for 'Ground Truthing' the products and services.

The tools used for verification and validation shall be subject to the Configuration Management Process as applicable to their importance and use.

8   EXTERNAL PROVIDERS

The organisation shall set up standard forms and processes for procurement from external providers, ensuring that any standard forms cover all the salient requirements for the purchased product.

The level of control applied to procurement is dependent upon the impact of the purchased item on the final product/service and/or the value of the purchase. Where items (such as stationary supplies) have no effect on the product/service being offered, and are below a defined threshold, less formal process can be applied.

Procurement shall always be based on the ability of the supplier to provide the product or service needed as well as on value for money criteria.

8.1 Control of External Providers

The organisation shall generate and maintain a list of suppliers used for high value items and items that have a direct impact upon products and services. The list shall include:

- Name address, telephone numbers, e-mails etc. for the provider
- Name and contact details of contact point in the provider
- Products and services supplied
- Any applicable certification including certification to Quality Standards or information relating to approved supplier status for other organisations
- Assessment of performance on previous contracts

Each time a provider is used, the list shall be updated to include an assessment of satisfactory performance on the procurement, including item of supply, date of supply and any issues found (Lateness, quality, etc.) and the project the item was used on.

Where a new provider is to be used, the organisation shall request the information required for the provider list and make a judgement based on this information. Where possible, the provider shall be asked for references.

In addition, the organisation may arrange a visit to the provider to assess and confirm capabilities and information provided by the provider. This activity shall be recorded and retained with the provider information.

8.2 Purchasing Information

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

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

In particular required data standards, verification and quality shall be defined.

This information shall be reviewed by the organisation prior to the issue of the order.

8.3 Verification of Externally Provided Product

The organization shall establish and implement the inspection or other activities necessary for ensuring that externally provided product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the provider's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Often purchase requirements can only be confirmed after a certain period of usage or after implementation/integration of purchased product. Information on implementation and maintenance procedures should support the requirements as the performance / effectiveness of a purchased product also depends on how it is implemented and managed.

9 PRODUCTION AND SERVICE PROVISION

9.1 Control of Production and Service Provision

The organisation shall develop documentation relating to the processes for production and service provision.

Internally these include procedures for production and service provision that detail any tools used, their configuration and the experience, qualification and training of any people involved in the process.

In addition processes shall be implemented and documented for the release of products and services including definition of responsibilities and reviews prior to release.

The organisation shall define any relevant information within the product specification (AD02).

Service provision may the subject of a Service Level Agreement (SLA) with the customer. Where this is the case, the SLA shall document all services to be provided, responsibility for provision and key performance measures (KPIs) associated with the service.

When determining KPIs for measuring, answer and document the following:

1. Why are we measuring what we measure?
2. When do we stop measuring?
3. Is anyone using the data?

Notes:
- Automate system monitoring where possible. Regular reviews should indicate trends which can be pro-actively managed.
- Use technical and commercial release notes depending on level of detail communicated to the client / user. Also keep the "version" methods consistent with all products / services. SLAs should capture this point (Service Delivery Manager role would help to monitor and measure performance on product / services delivered).

Changes in the services to be provided shall be managed via a process defined in the documentation generated above. Where required, changes shall be negotiated with the customer and reflected in a re-issue of any relevant agreement, including any applicable SLA.

9.2 Validation of Processes for Production and Service Provision

This applies to the processes for Production and Service Provision and not the validation of the Product itself and when deficiencies become apparent only after the product is in use or the service has been delivered. Processes for production and service provision shall be documented and validated to ensure that the delivered product or service is as defined in the product specification and the agreement with the customer.

In addition, the organisation shall define mechanisms for the capture, processing and resolution of deficiencies that includes a review of the processes for Production and Service provision and the identification of corrective actions.

9.3 Preservation of Product

The organisation shall put in place mechanisms to protect data and software from corruption, unauthorised access and other things that may affect the integrity of the data and hence the product.

This includes the identification and implementation of delivery techniques and processes that assist in this.

9.4 Service Failures and Restitution

The organisation shall put in place documented processes and procedures for service restitution should any event occur that compromises the service.

These processes shall give the restitution of the service the first priority unless it is deemed that to do so would, in itself, represent a risk to the organisation's ability to operate.

The processes shall include:

- Identification of Service Issue
- Preliminary review
- Restoration of Service
- Detailed review of issues
- Communication with the customer/users with respect to the service interruption, its cause and resolution

Such issues identified shall be subject to the problem review and resolution process in place (See 10.1).

10   PROBLEM AND CONFIGURATION MANAGEMENT

10.1   Problem Management

The organisation shall document a problem management system identifying the processes for:

- Anomalies (possible problems),
- Deficiencies (failure to meet requirements),
- Corrections (correcting failures)
- Corrective actions (preventing the recurrence of failures

In addition processes shall be identified for preventive actions based on inputs from project reviews and process monitoring tools.

These shall include processes for identification, review, resolution, tracking of actions and verification that actions have had the intended effect.

Records of problem management shall be retained.

10.2   Configuration Management

The acid test for configuration management is the ability to recreate exactly a product or service based on documentation retained by the organisations and to manage changes to these products and services in a controlled and verifiable manner.

All changes shall be formally documented (the use of electronic forms within a database is commonplace) and subject to a formal review. Records of the review, including acceptance or rejection are maintained. The review shall be conducted via a Configuration of Change Control Board or Panel under the chairmanship of the person with overall responsibility for the product or service.

Where the change has an impact upon a specific customer requirement, the customer shall be requested to approve the change before implementation. Documentation within the configuration management system such as design requirements shall be updated according to the approved changes, with the change highlighted or referenced within the document.

Configuration management is based around the concept of baselines where all elements of the product/service and the documentation relating to them are frozen and then placed under a formal control and change system.

It is recommended that the following baselines are adopted:

- Requirements Baseline – the set of ALL requirements relating to the product, established after the requirements review.

- Design Baseline – the set of ALL design documents relating to the product, established after the design review
- Production Baseline – all elements of the product plus all documentation relating to the implemented product, established after validation.

10.2.1   Changes During Design and Development

The Design and Development phase results in a design baseline, so for mal change control is applied to the Requirements Baseline only.

During Design and Development the objective of the configuration management process is to ensure that the requirements are under control and are communicated to all involved in the design process and that design and development is occurring in accordance with these requirements. During this phase, changes can occur due to:

- Change in customer requirements communicated by the customer
- Change in design approach, leading to a change in requirements being necessary.

All changes shall be formally reviewed and approved, including, where required, by the customer. The design review shall result in all requirements and design documentation being baselined.

10.2.2   Changes During Test and Validation

Failures during test and validation processes may result in changes to the design and hence requirement baselines. These shall be subject to the same review as above.

It should be noted that issues raised shall be fully investigated and any changes formally implemented prior to any retesting being performed. The use of un- or semi-controlled patches to achieve test results is expressly discouraged.

10.2.3   Changes During Operations

Configuration changes during operations can come from a number of differing sources:

- Failures or performance issues revealed during operational service
- New requirements from the customer or new features decided by the organisation
- Changes in technology

All such changes shall be subject to formal review and may affect any or all of the established baselines.

All documentation relating to the changes and the changed product or services shall be fully traceable.

10.3   Identification and Traceability

All documentation relating to a product shall carry an identification that allows clear traceability to the product.

In addition, version control shall be established to enable traceability between documentation and differing implementations of the product or service that may be in operation.

During the development and validation and verification processes, the organisation shall ensure that the test status of all elements of the product is identified.

Note:
A CRM systems and the accounting approach used within the company will influence this. Traceability can end with Client ID or Project ID and an ABC or TAC cost structure may support this even further in terms of measuring effectiveness and efficiency of particular production and delivery projects / products.

11   CUSTOMER INTERFACES

11.1   Customer Communication

The organisation shall develop and retain documentation concerning communication with the customer. The following types of communication shall be pursued.

- Product information
- Orders and order handling, definition of requirements
- Progress and design reviews, requirement changes
- Validation and verification activities progress and feedback
- Product release notes (as generated by the applicable configuration management system processes
- Customer feedback, including complaints

Notes:
1. Implementation of a "Customer Feedback Program" would help, covering various ways to collect feedback for corrective & preventive actions.
2. Perform Post Mortem meeting after each product delivery, even if no problems occurred.
3. Use escalation process (Incident, Problem, and Change Management) to continue with customer feedback for a particular project as part of post-production support.

11.2   Customer Property

The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or

otherwise found to be unsuitable for use, the organisation shall report this to the customer and maintain records.

Customer data can be managed through actual systems used for client relationship management and financial record systems (e.g. SAP). Other ways are to include this section into the "documentation & record control policy", defining customer property, the maintenance and security aspects of this property, and most importantly its return or disposal.

Where data is provided by the customer, the requirement for the data shall form part of the agreement between the organisation and the customer. This shall include all data properties and agreed between the parties and also the timeliness and method of supply and, if required, eventual return.

Requirements for the use of data can include and therefore is not limited to:

- Use solely on a specific project
- The anonymizing of data
- Deletion of data
- Ownership of data (e.g. retention of data by the customer)
- Return of data
- Limitations or bans placed on the redistribution of data
- Technical requirements for storage media