EARSC Guideline Document

EARSC EO Industry Certification Scheme

Management System Requirements for Earth Observation Data Based Products and Services

Self-Assessment Checklist

EARSC/CERT/REQ/2015/003

July 2016

Contents

This document contains a total of 26 Pages

Change Record Sheet

Date	Issue/ Rev.	Pages Affected	Description	DCR	Approval Authority
March 2015	1.0	All	First Issue		
July 2016	2.0	All	Revision for ISO9001:2015	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 (AD02), based on the relevant ISO standards and Guidelines pertaining to certification schemes.
- Management System Requirements (AD01) based on ISO9001:2008 (RD02) and focusses on the needs of the Earth Observation industry with respect to management system requirements
- Document Requirements Definition for Product Specifications (AD03).

During the course of a Pilot Study into the feasibility of an EO Certification Scheme, it became apparent that it would be desirable to produce a checklist to enable organisations and certification bodies to develop implement and assess any management system implemented to comply with the requirement s of the =scheme as stated in AD01.

EARSC has now decided to issue this document in support of AD01 to the industry, to be available for use by organisations supplying EO Products and Services

1.2 Purpose and Use

The purpose of this document is to provide a checklist for the application of the Earth Observation Industry Certification – Management System Requirements (AD01). It is intended to be used both by organisations implementing AD01 and by certification/auditing organisations auditing EO companies against its requirements.

2 SCOPE

The scope of this document covers only those elements of AD01 that contain a requirement, i.e. the word **shall** appear in the text. Notes, explanations and examples are not covered by this checklist.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Definitions

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

3.2 Abbreviations

The following abbreviations are used in this document:

EARSC	European Association of Remote Sensing Companies
KPI	Key Performance (or Process) Indicator
RACI	Responsibility Assignment Matrix
SLA	Service Level Agreement

4 RELATED DOCUMENTS

4.1 Applicable Documents

The following documents are applicable to this document:

AD01 EARSC/CERT/REQ/2015/002	Earth Observation Industry Certification Scheme – Management System Requirements for Earth Observation Data Based Products and Services
AD02 EARSC/CERT/REQ/2015/001	Earth Observation Industry Certification Scheme – Scheme Description
AD03 EARSC/CERT/DRD/2013/001	Earth Observation Industry Certification Scheme – Document Requirements Definition for Earth Observation Product Specifications

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
RD02 IS09001:2015	Quality management systems: Requirements

5 CHECKLIST

The following table constitutes the checklist for compliance with the requirements of AD01. In addition, and where applicable, the corresponding reference to ISO9001 (RD02) has been inserted in the table.

Note: where there is no RD02 reference, the requirements is stated within AD01, but may not be explicitly stated in RD02.

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
5.1	**7.5**	**Documented information**		
	7.5.2	Documented information numbering in place?		
	7.5.3	File structure in place?		
	7.5.3	Records identified and stored?		
	7.5.3	Can documents and records be found?		
5.2	**7.1**	**Resources**		
5.2.1	**7.1.3**	**Infrastructure**		
	7.1.3 b)	Is a record of equipment, including serial number and/or version type retained?		
	7.1.3 b)	Are equipment requirements defined in the product documentation?		
	7.1.3	Are there areas of single point failure?		
	8.3.4	Is replacement equipment retested and validated?		
	8.3.4	Does the product require re-validation when equipment changes? Has this been performed?		
5.2.2	**7.1.5**	**Monitoring and Measurement Resources**		
		See 7.8		
5.3	**7.2**	**Competence**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	7.2 a) d)	Are individual specific personnel (training and education) records held?		
	7.2 b)	Are there definitions of qualifications required for specific roles?		
		Are there any areas where there is only one person with the required knowledge?		
	7.2 c)	Are there (documented) standard training courses/regimes that are used?		
		Are training requirements defined in product documentation?		
6	**8.1**	**Planning of Product Realisation**		
	4.4	Is there a procedure covering product planning?		
	8.1	Does the procedure include the need for: 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		
	8.1	Have Product Plans been generated in accordance with these procedures?		
7	**8.3**	**Design and Development**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	4.4	Is there a, or are there procedures covering the following: • Determination of requirements related to the product? • Review of requirements related to the product? • Design and development planning? • Design and Development Review? • Design and development outputs? • Verification and Testing? • Validation (including as appropriate non-operational and operational validation)? • Tools Used for Verification and Validation?		
7.1	**8.3.2**	**Determination of requirements**		
	8.3.2	Do all products have a product requirements document covering: • 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		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.3.2	Do detailed technical requirements 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 • requirements with respect to the content, format and quality of data		
	8.3.2	Are requirements for verification and validation of the product documented? Do they contain the validation methodology (protocol) that is to be implemented?		
	8.3.2	Are operational requirements documented? Are they included in the requirement set used for development?		
		Is a product specification in the format required by the DRD generated for each product?		
7.2	**8.2.3**	**Review of Requirements Related to the Customer.**		
	8.2.3	Are requirements 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?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.2.3	Is the review documented and does it address that: • The requirements are complete and documented? • Any issues with the customer (if any) been clarified? • The organisation has the capability and resources required to design and develop the product? • Operational requirements are known and documented? • Trade-off are fully understood and documented?		
7.3	**8.3.2**	**Design and Development Planning**		
	8.3.2	Has a Design and Development plan been generated, does it follow the 'Plan-Do-Check-Act' cycle? Does it contain: 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 d) Specific expertise and experience that shall be required for the development e) Identification of geographical coverage and associated dataset requirements f) Identification of key human resources and qualification/ experience profile		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.3.2	Does the plan include identification of management tools such as responsibility assignment matrices and risk management standards that are to be utilised for the activity?		
	8.3.2	Does the Plan include a section on quality management? Does it identify the processes in place for the management of the Design and Development and how they are to be applied to the activity, including processes for design review and verification and the management of design changes?		
	8.3.2	Has the plan been updated during its lifetime?		
7.4	**8.3.4**	**Design and development review**		
	8.3.4	Have Design reviews been held? Do they: a) Evaluate the ability of the results of design and development to meet requirements? b) Identify any problems and propose necessary actions?		
	8.3.3	Have the following inputs been used? • 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		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.3.4	Did participants in the reviews include representatives of all functions concerned with the design and development stage(s) being reviewed? Was the customer invited to the review?		
	8.3.4	Was the review and resulting decisions and actions formally documented and key issues communicated to the design team?		
7.5	**8.3.5**	**Design and Development Outputs**		
	8.3.5	Are design and development outputs one or more 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.		
	8.3.5	Are the outputs from design and development activities directly traceable to the requirements for the design?		
	8.3.5	Have all outputs from the design and development process been approved prior to the release of the product or service?		
	8.3.5	Do design and development outputs provide enough information for the complete recreation of the product or service?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.3.5	Have any requirements for the review of design and development outputs by the customer been met?		
7.6	**8.3.4**	**Verification and Testing**		
	8.3.4	Is there planning in place for verification and testing?		
	8.3.4	Is verification testing performed on a version of the product or service that is under configuration control?		
	8.3.4	Are records of the results of the verification and any necessary actions maintained?		
	8.3.4	Is validation performed on each element of the product or service by the relevant team involved in the development?		
	8.3.4	Where validation is being performed as a Factory Acceptance Test, is the customer invited and required to sign each Test record?		
	8.3.4	Are problems or failures raised during testing formally recorded? Is testing repeated to ensure that the problem is repeatable? Is the record of the problem complete and include disposition, remedial or corrective work performed, record of re-test and sign off by the customer (if required)?		
	8.3.4	Are retests performed only on formally issued version of the product or service (not on software patches, for example)?		
7.7	**8.3.4**	**Validation**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Is a validation plan generated describing in detail the validation approach and protocol to be undertaken for the product/service? Is the validation plan maintained under configuration control (See AD01 section 10) and directly linked to the version of product or service being validated?		
		Does the validation protocol within the validation plan define the mix of Non-Operational Validation and Operational Validation?		
		Is the customer made aware where validation on a product or service prior to delivery is not possible?		
		Is revalidation 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? Also is revalidation 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, does the validation plan include the education, training and experience requirements relating to this person?		
		Are Records of all validation activities maintained?		
7.7.1	**8.3.4**	**Non-Operational Validation**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Where non-operational validation is being performed, does the validation plan clearly define the processes, methods and equipment to be used?		
		Where data sets are being used, does the validation plan define the requirements for the data, including, as appropriate: • Source of the data • Format of data • Validation level of the data		
		Has any equipment used or developed for the validation been, itself, formally validated, including any required acceptance by the customer?		
		Have any processes and methods to be used for non-operational validation been subject to review and approval?		
		Has validation been outsourced? If so: • Has the organisation satisfied itself that the validation service supplier has the required capability and knowledge? • Have all requirements relating to validation been passed to the supplier?		
7.7.2	**8.3.4**	**Operational Validation**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Where ground truthing is used, has the organisation established the chain between the physical measurement and the product, including the calibration status of any measurement instrument? Is this documented in the validation records?		
		Are records of qualification, experience and training of any personnel used for validation retained?		
		Where the customer is involved in the validation process, have they been invited to review and approve the validation plan? Does the validation plan clearly state the roles and responsibilities of the customer with respect to validation?		
		Where elements relating to validation have been outsourced, have the requirements relating to traceability and calibration of instrumentation been passed to the supplier?		
7.8	**7.1.5**	**Tools Used for Verification and Validation**		
	7.1.5.1	Have the tools to be used for verification and validation testing been defined during the development phase? Have tools used for validation been subject to a similar or equivalent development cycle as for the original system?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	7.1.5.2	Is measuring equipment: a) calibrated or verified, or both, at specified periods, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, is the basis used for calibration or verification recorded; b) adjusted or re-adjusted as necessary; c) identified in order to determine its calibration status; d) safeguarded from adjustments that would invalidate the measurement result; e) protected from damage and deterioration during handling, maintenance and storage.		
	7.1.5.2	Where problems or failures are found with tools, have the necessary measurements and tests carried out with the tools been reviewed to ensure validity of previous measurements. • Where this validity is called into questions, tests been repeated? • Where the testing relates to a product or service in operation with the customer; has the customer been informed of the issue and the appropriate measures to be taken to ensure product integrity?		
	7.1.5.2	Are records of calibration and verification maintained?		
		Are the tools used for verification and validation subject to the Configuration Management Process as applicable to their importance and use?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
8	**8.4**	**External Providers**		
	8.4.1	Are there standard forms and processes for procurement, ensuring that purchasing forms cover all the salient requirements for the purchased product?		
	8.4.1	Is procurement based on the ability of the supplier to provide the product or service needed as well as in value for money criteria?		
8.1	**8.4.2**	**Control of External Providers**		
		Is a list of external providers used for high value items and items that have an impact upon products and services established?		
		Does the list contain: ▪ 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		
		Is the list 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 on which the item was used?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Where a new provider is to be used, is the information required for the providers list and a judgement made based on this information? Are references requested?		
		Where a visit to the provider is made to assess and confirm capabilities and information provided by the provider, is this activity recorded and retained with the provider information?		
8.2	**8.4.3**	**Purchasing Information**		
		Does purchasing information include, as appropriate: a) Requirements for approval of product, procedures, processes and equipment? b) Requirements for qualification of personnel? c) Quality management system requirements?		
		Are required data standards, verification and quality defined?		
		Is this information reviewed prior to the issue of the order?		
8.3	**8.4.2**	**Verification of Externally Provided Product**		
	8.4.2 d	Has the organization established and implemented the inspection or other activities necessary for ensuring that externally provided product meets specified purchase requirements?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.4.2 d	Where the organization or its customer intends to perform verification at the provider's premises, have the intended verification arrangements and method of product release been defined in the purchasing information?		
9	**8.5**	**Production and Service Provision**		
9.1	**8.5.1**	**Control of Production and Service Provision**		
		Are processes relating to production and service provision documented?		
		Are processes implemented and documented for the release of products and services including definition of responsibilities and reviews prior to release?		
		Is any relevant information defined within the product specification?		
		Where service provision is the subject of a Service Level Agreement (SLA) with the customer, does the SLA document all services to be provided, responsibility for provision and key performance measures (KPIs) associated with the service?		
		Is the process for controlling changes in services documented?		
		Are changes reflected in a change to the relevant agreement and/or SLA?		
9.2	**8.5.1**	**Validation of Processes for Production and Service Provision**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Are processes for production and service provision documented and validated to ensure that the delivered product or service is as defined in the product specification and the agreement with the customer?		
		Are 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 defined?		
9.3	**8.5.4**	**Preservation of Product**		
		Are 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 in place? Does this include the identification and implementation of delivery techniques and processes that assist in this?		
9.4	**N/A**	**Service Failures and Restitution**		
		Are documented processes and procedures for service restitution should any event occur that compromises the service in place? Do these processes 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		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Do the processes 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		
		Are issues identified subject to the problem review and resolution process in place (See 10.1)?		
10	**8.3.6, 8.5.6, 8.7, 10.2**	**Problem and Configuration Management**		
10.1	**8.7**	**Problem Management**		
	8.7	Is a problem management system documented identifying the processes for: ▪ Anomalies (possible problems), ▪ Deficiencies (failure to meet requirements), ▪ Corrections (correcting failures) ▪ Corrective actions (preventing the recurrence of failures		
		Are processes identified for preventive actions based on inputs from project reviews and process monitoring tools?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
	8.7, 10.2	Do they include processes for identification, review, resolution, tracking of actions and verification that actions have had the intended effect?		
	8.7	Are records for problem management retained?		
10.2	**8.3.6, 8.5.2, 8.5.6**	**Configuration Management**		
		Are all changes formally documented and subject to a formal review? Are records of the review, including acceptance or rejection maintained? Is the review 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, is the customer requested to approve the change before implementation?		
		Is documentation within the configuration management system such as design requirements updated according to the approved changes, with the change highlighted or referenced within the document?		
		Have configuration baselines been established and defined?		
10.2.1	**8.3.6**	**Changes during Design and Development**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Are all changes formally reviewed and approved, including, where required, by the customer? Does the design review result in all requirements and design documentation being baselined?		
10.2.2	**8.3.6**	**Changes during test and Validation**		
		Are changes during teat and validation subject to the same review as for 10.2.1?		
		Are issues raised fully investigated and any changes formally implemented prior to any retesting being performed?		
10.2.3	**8.3.6**	**Changes during Operations**		
		Are all changes subject to formal review and the relevant established baseline identified?		
		Is all documentation relating to the changes and the changed product or services fully traceable to the requirement and the reason for change?		
10.3	**8.5.2**	**Identification and Traceability**		
		Does all documentation relating to a product carry an identification that allows clear traceability to the product?		
		Is version control 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, is the test status of all elements of the product identified?		
11	**8.2.1, 8.5.3**	**Customer Interfaces**		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
11.1	**8.2.1**	**Customer Communication**		
		Is documentation concerning communication with the customer available?		
		Are one or more of the following available? ▪ 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		
11.2	**8.5.3**	**Customer Property**		
		Is customer property provided for use or incorporation into the product identified, verified, protected and safeguarded? If any customer property is lost, damaged or otherwise found to be unsuitable for use, is this reported to the customer and records maintained?		

AD01 Para	ISO9001 (RD02)	Requirement	Procedure Ref	Evidence
		Where data is provided by the customer, does the requirement for the data form part of the agreement between the organisation and the customer? Does this include all data properties is agreed between the parties and also contains timeliness and method of supply and, if required, eventual return?		