



Mongolia:
Enhancing Resource
Management through
Institutional Transformation



DOCUMENTED INFORMATION (CLAUSE 7.5)

Michel Greaves
TA MERIT
June 2018



7.5 Documented information

- Simplified, flexible
- Guidance from ISO: ISO/TC 176SC2/N1286
- **Documented Information:** Information (ISO 9000:2015 clause 3.8.2) required to be Controlled and Maintained.

- Documented information
 - ❖ Required by the Standard
 - ❖ Determined by the organization as being necessary for the effectiveness of the QMS
- Concepts of GDP: Ex: ID, format, control
- DOCUMENTATION NEEDED
 - ❖ Quality Policy → QMS framework → Processes
 - Support documentation → Evidence

MAINTAINED DOCUMENTED INFORMATION

- Typically information that requires review and is updated on a regular basis (ex: quality policy, scope of the QMS)

RETAINED DOCUMENTED INFORMATION

- Documentation that is retained is used to provide objective evidence that a requirement has been fulfilled. Typically called records

Table of ISO 9001 clauses requiring Documented Information to be **maintained**.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
4.3	Maintained scope	Statement
4.4.2	QMS and its processes. Information to the extent necessary to support the operation process.	Process approach Procedure Included in the law
5.2.2	Communicating the quality policy	Statement
6.2.1	Quality objectives and planning to achieve them	Statement + Quality plan
8.1	Operational control	Process approach Process description Flowcharts

Table of ISO 9001 clauses requiring Documented Information to be **retained**.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
4.4.2	Evidence (records) that the processes are carried out as planned	Internal audits output Criteria (KPI)
7.1.5.1	Evidence that monitoring & measuring resources are fit for purpose	Software check (virus free, proper version)
7.2	Retained appropriate evidence of competence	Training records
7.5	7.5.1a Required by standard 7.5.1b Necessary for effectiveness of QMS 7.5.3.2 Documented information from external origin	General clause on documented information. Ex: Citizen providing an official document

Table of ISO 9001 clauses requiring Documented Information to be retained.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
8.1	Operational planning and control	Performance level for a service. Ex: timely, efficient communication
8.2.3.2	Review of the requirements for services.	Ex: check request from citizen. Review by, initial date.
8.2.4	Changes to requirements services	If change, initial by both citizen & employee

Table of ISO 9001 clauses requiring Documented Information to be retained.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
8.3.3 8.3.4 8.3.5 8.3.6	Design and development inputs Design and development controls Design and development outputs Design and development changes	Not part of the scope at Dornod Aimag. Justification needed: Design and development performed at the national level (To be confirmed)
8.4.1	External providers evaluation & revaluation	Ex: Audit, questionnaire
8.5.2	Traceability of outputs	Ex: permits number list
8.5.3	Property belonging to a customers or providers	Ex: Evidence that no official document are lost, damaged.

Table of ISO 9001 clauses requiring Documented Information to be retained.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
8.5.6	Control of changes	Person authorizing the changes. Signature, date
8.6	Release of services, including acceptance criteria and traceability to the authorizing person	Ex: A judgment is provided. Under what criteria and by who.
8,7	Records on non-conformities, action taken, authorization	Non-conformity form to be completed.
9.1.1	Results of the evaluation of the performance of the QMS system	Key performance indicator Dashboard
9.2.2	Evidence of the implementation of the audit program and audits results	Audit performed. Reports and actions
9.3.3	Evidence of the results of management review	Management review minutes, Actions and correctives actions.

Table of ISO 9001 clauses requiring Documented Information to be retained.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
10.2.2	Evidence of the nature of the non-conformities and action Results of corrective action	Completed non-conforming form. Completed corrective action forms

**SAY WHAT YOU DO
DO WHAT YOU SAY
RECORD WHAT YOU DO
GET IMPROVEMENT!**