



Mongolia:
Enhancing Resource
Management through
Institutional Transformation



QUALITY MANAGEMENT SYSTEM

ISO 9001:2015

STEP BY STEP (CLAUSE 7 TO 10)

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7- SUPPORT

7.1 Resources

- People (competent), Infrastructure (Ex: IT, back up, maintenance program), environment (social, psychological, physical). Monitoring & measuring resources (Ex: traceability).
- Organizational knowledge (Acquire = Store = Access)
- ✓ Knowledge for process
- ✓ Additional knowledge: changing needs and trends
 - ❑ SOURCES:
 - ❖ Internal (experience, lessons learned, results of improvement).
 - ❖ External (standards, academia, conference, knowledge from customers & providers).

7.2 Competence

- Determine competence, acquire, evaluate, document
- ✓ Training plan, mentoring, re-assignment, hiring, contracting, skill test.

7.3 Awareness

- Quality policy, objectives, contribution to the effectiveness of QMS, implication of not conforming with QMS.
- ✓ Induction program, staff reviews.

7.4 Communication

- Determine internal & external communications (what, when, with whom, how, who)
- ✓ Meetings, noticeboards, in-house publications (newsletter), awareness raising seminar, toolbox talks, intranet, E-mail

❖ PLANNED  ACHIEVED

TEAM

Together

Everyone

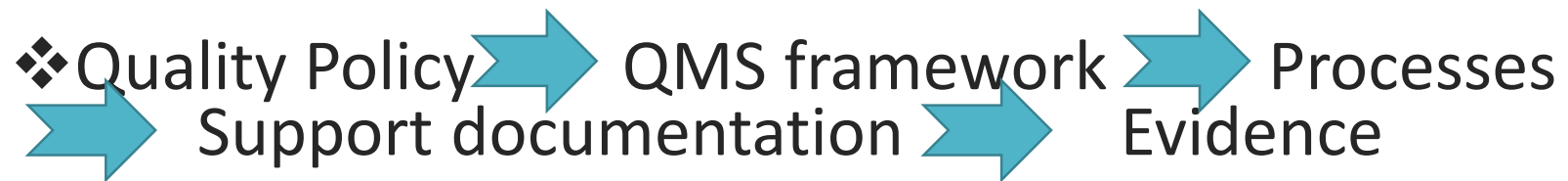
Achieve

More

7.5 Documented information

- Simplified, flexible
- Guidance from ISO: ISO/TC 176SC2/N1286
- **Documented Information:** Information (ISO 9000:2015 section 3.8.2) required to be Controlled and Maintained.
- **Record:** Document (3.8.5) Stating Results Achieved or Providing Evidence
- Objective Evidence:** Data (3.8.1) Supporting The Existence or Verity of Something

- Documented information:
 - ❖ Required by the Standard
 - ❖ Determined by the organization as being necessary for the effectiveness of the QMS
- Concepts of Good Documentation Practice (GDP):
Ex: ID, format, control
- DOCUMENTATION NEEDED



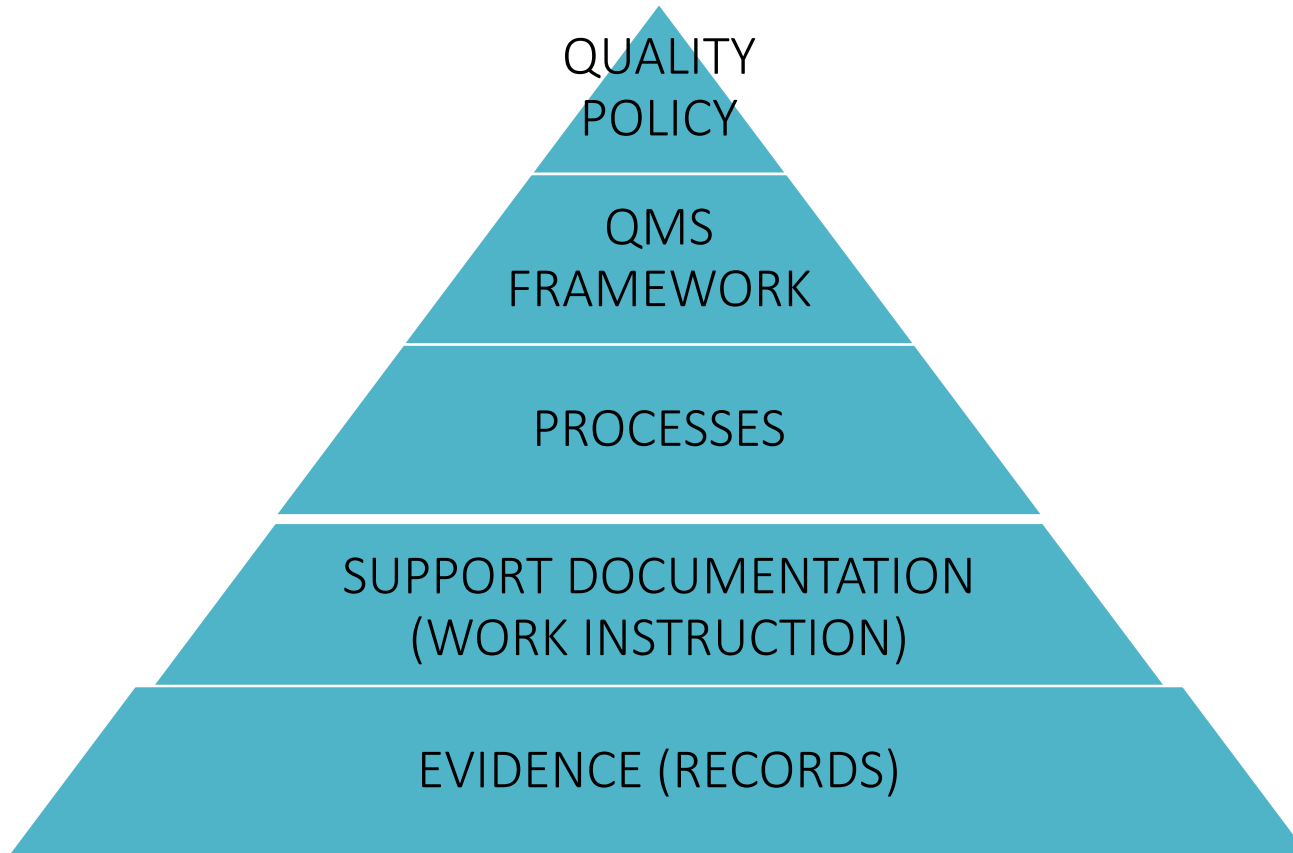


Table of ISO 9001 clauses and Documented Information Requirements.

CLAUSE	DOCUMENTED INFORMATION REQUIREMENTS	PRACTICAL DOCUMENTS
4.1 & 4.2	No specific request to maintain & retain documented information	NO REQUEST
4.3	Maintained scope	Statement
4.4	Maintained documented information to the extent necessary to support the operation process. 	Process approach
.....		

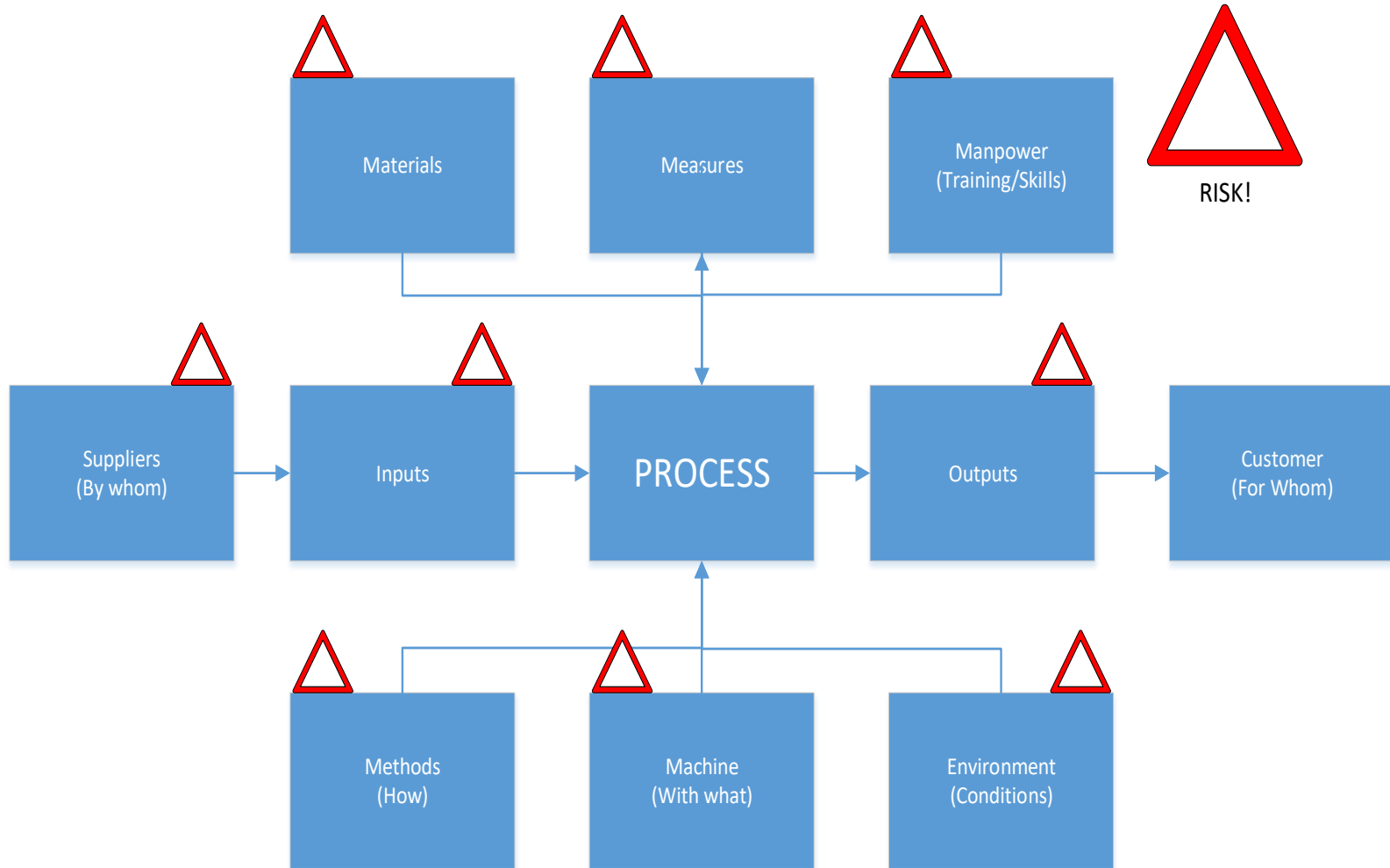
**SAY WHAT YOU DO
DO WHAT YOU SAY
RECORD WHAT YOU DO
GET IMPROVEMENT!**

8- OPERATION

8.1 Operational planning and control

- An example of your process?
- PDCA
- Refer to clauses 4.4 (Process) & 6 (planning)
- A process is a set of interrelated or interacting activities that use inputs to deliver an intended result.
- ISO 9001:2015: Three concepts are the based of the standard = Risk-based thinking, PDCA and the process approach

6M APPROACH



8.2 Requirements for products and services

- Communication with customers
- Determine and review customer requirements

8.3 Design and development of products and services

- Do you do Design and Development?
- Perform Design and Development = Determine requirements = Control of D & D = Ensure quality of output = Control changes

8.4 Control of externally provided processes, products and services.

- Identify your main supplier (impact on customer)?
- How do you evaluate, select, monitor and re-evaluate your externally provided products/services?
- Provide all necessary information to the supplier.

8.5 Production and service provision

- To provide service provision under controlled conditions
- Many documents already in place?
- ❖ Process, Procedures, Drawings, Specifications, Work instructions, Quality plans, operating criteria, process criteria.
- Traceability, preservation (Ex: Customer personal data: passport, records of receipt. Ex: preservation of data or reports on electronic media)
- Post-delivery activities: legal requirements, customer requirements, customer satisfaction
- Control of changes

8.6 Release of products and services

- Verify the service requirements have been met.
- Retained documented information: conformity with acceptance criteria + traceability of person authorizing the release.

8.7 Control of non-conforming outputs

- Correction, segregation, inform customer, use under concession, scrapping, alternative uses, rework.
- Retain documented information: non-conforming reports (description, action taken, concession obtained, ID of authority)

9- PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

- Data to measure effectiveness of the management system
- Identify opportunities for improvement.
- ❖ Method selected should only be as complex as needed
- ❖ Analysis of customer survey, meeting, interviews, service performance, processes and supplier performance

9.2 Internal audit

- Plan, establish, implement and maintain an audit program.
- ❖ Key element (input to management review), auditor, ISO guidance, action of management

9.3 Management review

- Top management to review QMS at planned interval
- ❖ Inputs: agenda well defined, ex: customer satisfaction, quality objectives, non-conformity, audits results, opportunities for improvement, adequacy of resources...12 points
- ❖ Outputs: Opportunities, need for changes, resource needs

10- IMPROVEMENT

10.1 General

- Review of process, services & QMS.
- Meets requirements & address future needs and expectations
- Correcting, preventing or reducing undesired effects.
- Improvements = correction, corrective action, continual improvement, breakthrough change, innovation, re-organization

10.2 Non-conformity and corrective action

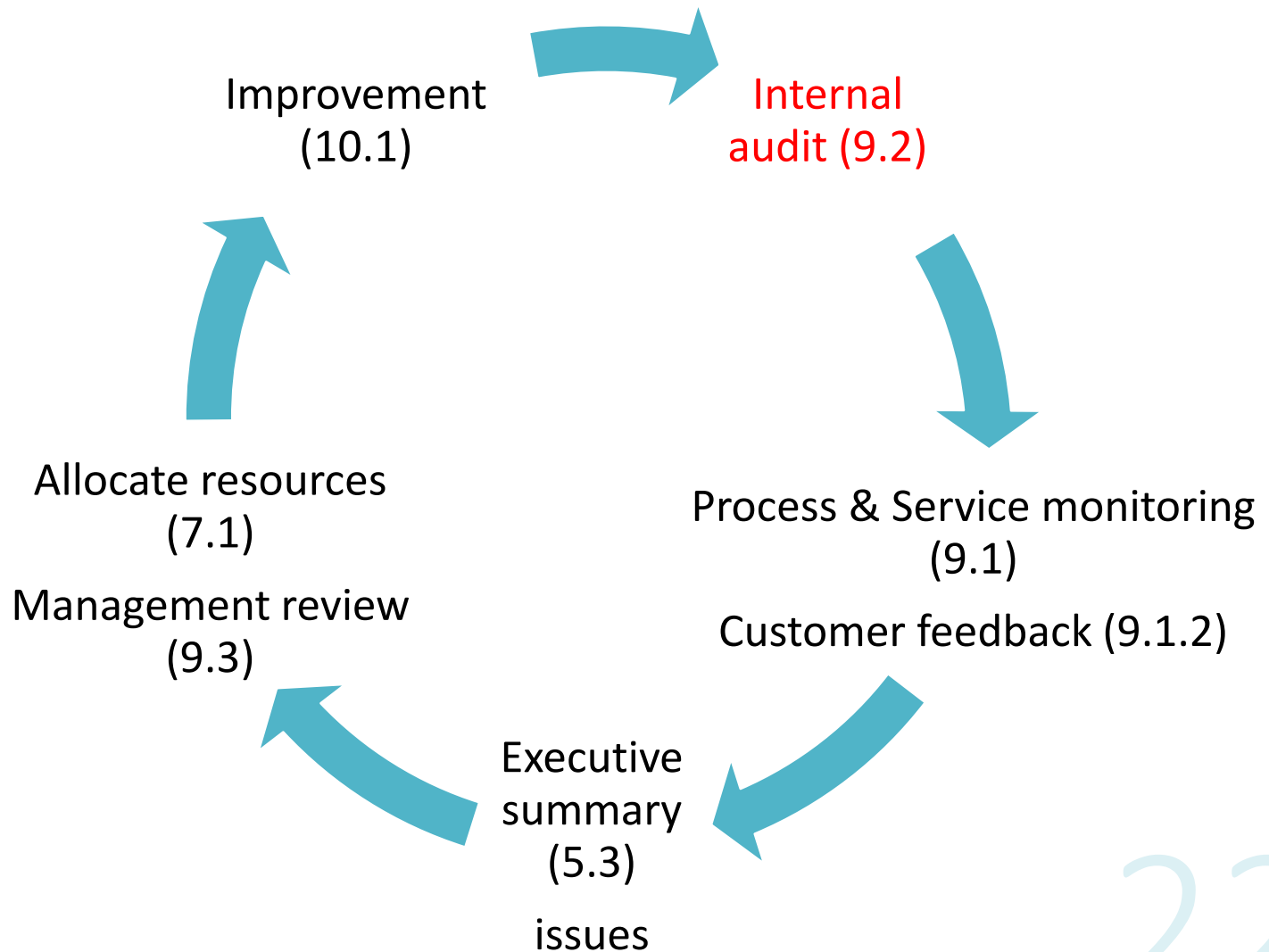
- React, evaluate, eliminate the cause (**5 WHY?**), take action, review effectiveness of corrective action, update risks and opportunities, make change to QMS.
- Retained documented information: nature of non-conformity & action taken. The result of any corrective action.

10.3 Continual improvement

- Analysis & evaluation + Management review
Needs or opportunities for improvement



IMPROVEMENT CYCLE



QUESTIONS ?

BAYARLALAA !