MERIT

Mongolia:
Enhancing Resource
Management through
Institutional Transformation

QUALITY MANAGEMENT SYSTEM

ISO 9001:2015

INTERNAL AUDIT TRAINING

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June 2018

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INTERNAL AUDIT

- AUDIT PROCESS
  - IDENTIFY – PLANS
  - MAKE OBSERVATIONS
  - EVALUATE
  - REPORT RESULTS
  - FOLLOW UP

- INTERNAL – EXTERNAL (supplier of service)

INTERNAL AUDIT

- PRODUCT AUDIT (SERVICE AUDIT)
  - CHECK VERSUS ATTRIBUTES

- PROCESS AUDIT
  - VERIFY ACTIVITIES VERSUS AN ESTABLISSHED PROCEDURE, PLAN, METHOD

- SYSTEM AUDIT
  - EVALUATE IF SYSTEM REQUIREMENTS (POLICY, STANDARDS, REGULATIONS) ARE MET.

INTERNAL AUDIT

- FIRST, AGREE ON:
  - WHO, WHAT, WHEN, WHERE AND WHY.
- ACCEPT IF:
  - AVAILABLE (time, $, priority)
  - NO CONFLICT OF INTEREST.
  - COMPETENT

INTERNAL AUDIT
AUDIT PROCESS INPUTS

- When & where?

- What area (scope)?

- What standards?

- Why? Purpose? Objective?

- Need for other audit services?

  Ex: Training new auditors.

INTERNAL AUDIT
PREPARING FOR THE AUDIT

- Audit team – Lead auditor
- Contact the Auditee and issue an audit plan.
  - To Auditee: arrange date and place, identify units, areas, schedule meetings and events, set report time and distribution, confirm scope and purpose.
  - From Auditee: obtain documents, identify special requirements (confidential, safety, clearance)

INTERNAL AUDIT
IDENTIFYING REQUIREMENTS AND PLANNING

- Auditing objectives – ISO 9001
  - Determine the extent of conformity or compliance of the system or process to the defined audit criteria (Ex: ISO 9001…)
  - Determine whether the management system controls are effectively implemented and maintained.

INTERNAL AUDIT
IDENTIFYING REQUIREMENTS AND PLANNING

- Requirements – customer, mandatory regulatory, contract, self-imposed.
  - Mandatory – auxiliary verbs: shall, must and will
  - Optional –auxiliary verbs: may, should, can and might.
- Checklist
  - Provide structure and order
  - Assures required coverage
  - Provide opportunities for discussion
  - Is a place to record data / evidence
  - Is a time management aid.

INTERNAL AUDIT
IDENTIFYING REQUIREMENTS AND PLANNING (cont'd)

- Collection plan
  - List of things you want to see

- Sampling plan
  - How many and what samples (data) you need to look at. Random / Directed (important or potential problems)

INTERNAL AUDIT
Desk Audit - Flowcharting

- Desk Audit
  - Sit at a desk and compare the auditee's documented management system to the requirements of the standard.

- Flowcharting
  - Drawing a picture of the process – symbols – checkpoints – who does what – documents
  - Information on process steps and sequence.
  - ID of problems / improvements
  - Training tools / ID checkpoints / Responsibilities.

INTERNAL AUDIT
BEGINNING THE AUDIT

- Opening meeting - Purpose
  - Audit plan, communication channels, summary of audit activities, answer auditee questions.
- Opening meeting agenda
  - Introductions – everyone knows each other.
  - Thank you host.
  - Review the audit plan
  - Logistics / limited access (safety, confidentiality)

INTERNAL AUDIT BEGINNING THE AUDIT

- Opening meeting agenda (cont'd)
  - Audit methods and techniques
  - Reporting process
  - Established the interview schedule.
  - Confirm the exit meeting

INTERNAL AUDIT
DATA COLLECTION

- Collect evidence
  - Documents and procedures: review procedures and examine retain documented information.
  - Physical examination: count. Tangible.
  - Observing activities: watch what is going on.
  - Interviewing: talk to people connected with the process.

PERFORM AN AUDIT

- If sufficient time, perform an audit. (Workshop)

AUDIT TECHNIQUES

- VAGUES REQUIREMENTS
  - Words such as: timely, periodic, readily, promptly, without undue delay and Based on importance…
  - The organisation shall carry out service under controlled conditions.
  - The Management must ensure that the QMS is suitable!
  - The organization shall preserve conformity of the product.
  - ====➔ Ask to define timely….Ask HOW?

AUDIT TECHNIQUES
PDCA

- PLAN:

  Establish what needs to be done =>

  Is there a plan for conforming to the requirements? What is it? Has it been established? Ask: How do you know what to do (Verifies the existence of a predetermined method / plan)?

AUDIT TECHNIQUES
PDCA

- DO:

    Do what was planned =>

    Has it been implemented?

    Ask: Tell / show me how you do it (Verifies   training and competency / knowledge)?

- CHECK:

    Plan measured against criteria =>

    Are there planned results (criteria)? Achieved?

    Ask: How do you know it is done right?

AUDIT TECHNIQUES PDCA

- ACT:

  Analyse and adjust the process =>

  Does the organization / person act on the results (make adjustments).

  When it is not right, what do you do?,

AUDIT TECHNIQUES PROCESS AUDITING

– Evaluation of the sequential steps and interactions of a process within a system.

– EXAMPLE:

During a tour of the department, the auditor could:

Note the PO # of a software being used.

Ask purchasing to see requisition request

Supplier approval, Purchase order records

Potential verification / validation of the software at the site of use.

Verify on-time delivery

Verify that supplier performance is being monitored

ANALYSING THE DATA

- Conformance and non-conformance must be verifiable and traceable.
- Classification of observations: minor, major (occurrence, risk), observations, best practice.
- Writing: Follow ENRC4
  - Evidence
  - Nature of the nonconformity
  - Requirement
  - Nonconformity statement: clear, concise, complete and correct.

ANALYSING THE DATA EXAMPLE of ENRC4

- Evidence: Retain documented information available on Management review covers only resources needs.

- Nature of the nonconformity: Absence of retain documented information on opportunities for improvement and need for changes to the QMS as evidence of the results of the Management Review.

- Requirement: ISO 9001:2015 clause 9.3.3 Management review output.

ANALYSING THE DATA EXAMPLE of ENRC4

- Nonconformity statement: QMS does not have evidence of retain documented information on management reviews results regarding opportunities for improvement and need for changes to the quality management system. ISO 9001:2015, clause 9.3.3 a & b.

REPORTING
EXIT MEETING

- Exit meeting:
  - Keep the auditee informed during the audit (no surprise).
  - Management involved.
  - Lead auditor / minutes / define classification / Report findings and conclusion.
  - Explain follow-up (Corrective action).
  - Keep records.

REPORTING
REPORT FORMAT

- Audit report ID.
- Ensure confidentiality.
- Background (audit purpose, scope, standards used, area audited...)
- Summary / Conclusion.
- Audit results: best practice, observations, major/minor nonconformities.
- Follow-up.
- Signature, date

REPORTING
REPORT FORMAT

- AVOID:
  - Emotional words…There is *absolutely* no management commitment.
  - Reporting minor imperfections.
  - Reporting names of individuals.
  - Do not take ownership of problems found.

AUDIT FOLLOW-UP CORRECTIVE ACTION and CLOSURE

- CA
  - Root cause
  - Complete solution
- Follow-up meeting, if necessary.
- CLOSURE
  - Record of closure
  - Communication of the closure information to the auditee.
  - The time the CA was closed vs original estimate.

ISO REQUIREMENTS

- Section 9.2
- Key Management Process: Audit program
- Conduct at planned intervals.
- Planned taking into account the status and importance of the process and results of previous audits.
- Requirements for planning audits is defined in a documented procedure. Criteria, scope, frequency and method of auditing are defined. Retain documented information.

ISO REQUIREMENTS

- Shall plan, establish, implement and maintain an audit program 9.2.2

- Scope of audit must cover:
  - QMS – conformity to ISO 9001
  - QMS – conformity to Organizational requirements
  - QMS processes effectively implement and maintained

ISO REQUIREMENTS

- Define audit frequency, program, criteria, method.

- Must define the minimum requirements for internal auditor (properly trained and impartial)

- Appropriate resources available.

ISO REQUIREMENTS

- No conflict of interest

- Ensure audit process is respected (audit the audit!)

- Follow-up and Corrective action (10.2). Process owners must take timely corrective action on nonconformities.

- Audit results reported to Management review.

ISO REQUIREMENTS

- Audit records kept.
- Performance indicators to measure the effectiveness of the internal audit. Ex: reducing the # of audit postponed.

- DISTRIBUTE AN EXAMPLE OF AUDIT REPORT
- CUSTOMER SATISFACTION
- CUSTOMERS' PERCEPTION MONITORING

- THANK YOU

- ENJOY AUDITING

- ➢3 TEAMS (5 persons per team)

- ➢IDENTIFY A LEADER (FACILITATOR), PRESENTER & SCRIBE (NOTE TO BE KEPT AND REPORTED TO M & E)

- ➢FOLLOW INTERNAL AUDIT TRAINING SESSION.

- ➢AUDIT THE DEPARTEMENT MONITOR CUSTOMERS PERCEPTION (Group # 1: Adm., M&E, # 2 Investment…, Social dev., Env. # 3 Fin., Law & Justice)

- ➢PERFORM THE AUDIT AND COMPLETE AN AUDIT REORT FOR THIS SUB-CLAUSE 9.1.2

- ➢PP PRESENTATION

- ➢30 MINUTES FOR THE PREPARATION

- ➢45 MINUTES TO PERFORM THE AUDIT AND REPORT

- ➢15 MINUTES PER TEAM FOR PRESENTATION.