PURPOSE

The purpose of this procedure is to define the processes and to assign responsibilities for conducting internal audits of the quality management system. This document defines the Internal Audit Program for Acme Equipment Co.

SCOPE

This procedure applies to all processes and activities of the quality management system, and to all areas where the quality system is implemented.

DEFINITIONS AND ACRONYMS

QMS	Quality Management System
NC	Nonconformance or Nonconformity

REFERENCES

QOP-200	Competence & Awareness
QOP-420	Control of External Providers
QOP-500	Performance Evaluation & Improvement
QOP-530	Management Review
QOP-540	Nonconformity & Corrective Action
FM-520-01	Internal Audit Plan
FM-520-02	Audit Checklist (ISO 9001:2015)
FM-520-03	Audit Notification
FM-520-04	Audit Report

ROLES AND RESPONSIBILITIES

Chief Executive

- Creating, communicating, and supporting a culture of improvement throughout the organization, within the internal audit process, and during management review activities.
- Providing the resources necessary to effectively execute the internal audit process and associated corrective actions and improvements.

Quality

- Planning, scheduling, communicating, and execution of all QMS audit activities. This includes 1st Party (internal), 2nd Party (customer), and 3rd Party (Certification) audits.
- Establishing competence and training requirements for internal auditors, providing training and development programs, and documenting audit competencies and qualifications.
- Facilitating an environment of objectivity and partiality during all audit activities.
- Ensuring effective corrective actions are implemented for all identified audit nonconformances.
- Properly documenting all relevant internal audit activities and associated actions.
- Reporting audit results and corrective action responsibilities to functional area management following the conclusion of each audit.
- Facilitating follow-up to verify that corrective actions taken against audit nonconformances are effective.
- Evaluating audit results and adjusting the audit schedule based on audit results.
- Reporting internal audit measures, metrics, and data to Management Review Team (see QOP-530, Management Review).

All Acme Employees

- Managing their respective areas with regard to ISO QMS compliance and audit readiness.
- Providing auditor with QMS information and documentation when requested.
- Timely completion of assigned corrective action responsibilities for audit nonconformances.
- For internal auditors, completion of required training and maintaining auditor qualifications and competence.

BACKGROUND

Guidance

Internal audit is positioned under section 9, Performance Evaluation, of the ISO 9001:2015 standard. The objective of this activity is to:

- Assess the organization's level of compliance against the ISO standard and the established QMS processes.
- Determine the effectiveness of the organization's processes and the QMS.
- Identify and drive improvement to the organization's processes and the QMS.

Auditors should approach and execute audit activities with these end goals and objectives in mind. While small and isolated nonconformances should be identified and noted to allow for correction, the focus should always remain on the bigger picture and whether the QMS is effective and appropriate for the organization and stakeholders (Interested Parties), especially the end customer.

The organization and its staff, particularly top management, should also be focused on the audit objectives while creating and supporting a culture of improvement. They should welcome, if not celebrate, findings, especially those that drive improvement into the organization.

Introduction

Acme Equipment periodically assesses the conformance and effectiveness of the management system through planned systematic audits. These assessments are executed against the ISO 9001:2015 QMS standard and internal requirements, processes, and procedures.

This procedure in conjunction with form FM-520-01, Audit Schedule, constitutes the Internal Audit Plan.

In addition to internal audits (1st party), customer (2nd party) and certification (3rd party) audit findings and nonconformances should be addressed following the applicable parts of this procedure.

While Acme Equipment currently maintains and utilizes internal personnel (auditors) for all internal audit activities, Acme may augment audit resources or fully outsource the execution of internal audit to qualified and competent contracted auditors if circumstances necessitate. All internal audit contractors are evaluated and controlled per QOP-420 (Control of External Providers).

Application of Risk Management

Internal Audit contributes to risk management activities through a "risk-based" approach when defining the audit program and schedule to ensure that those processes which pose the greatest risk to the organization receive commensurate resources for audit activities. Additionally, Quality may assess risk associated with audit findings and nonconformances when assigning resources and due dates for investigation and corrective actions.

PROCEDURE

1. Audit Schedule / Frequency

Internal audits cover all quality management system and operational processes, products and/or services, and are conducted in all relevant departments, functions and areas.

Quality is responsible for planning and scheduling internal audits. Additional audits beyond those in the initial audit schedule may be completed where quality system performance data indicates a need for increased audit activity. While the general approach is to audit each quality system process and/or functional area approximately once a year, consideration of the following may alter the audit frequency:

- The status and importance of the processes, function, products, and/or services
- Results of previous audits,
- Nonconformities and corrective actions,
- Customer complaints and feedback, or

- Changes to the QMS or operations resulting from the change management process and management review activities.

Quality is responsible for monitoring quality system performance and audit results, determining the need for additional audits, and revising the audit schedule accordingly.

2. Auditor Qualification and Training

Acme utilizes internal employees as auditors and strives to keep a minimum of 3 employees trained at all times. Any employee, no matter their position, title, or status, may be considered for internal auditor training.

Training includes:

- Completion of online or classroom internal auditor training program approved by Quality. Certificate received at completion of training must be retained in the employees training files.
- Completion of one internal audit as an assistant auditor supporting a qualified internal auditor.
- Completion of one internal audit as lead auditor under the supervision of a qualified internal auditor.

Quality may request that the auditor in training complete additional training as deemed necessary to ensure competence. All training activities should be documented and retained in the employees training file.

3. Preparing for Audit

Quality notifies internal auditor(s) and their immediate supervisor or manager of pending audit responsibilities at least four weeks prior to the audit. If conflicts exist the auditor with support from their supervisor should immediately notify Quality of the issue along with possible solutions. Quality can either adjust the audit date to accommodate the conflict or assign the work to a difference auditor.