

Joseph Co.

Internal Quality Audit

Document #:
JSC-PR-003-00

Issue Date:
01-01-2014

Issue #:
01

Rev. Date:
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Rev. #:
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Prepared by: _____

Signature: _____

Approved by: _____

Signature: _____

DOCUMENT CHANGE RECORD

Revision No#	Date of Issue	Initiated By	Page No.	Section	Description of Changes	Done By

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Distribution List:

- a) Managing Director
- b) Quality Manager

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1. PURPOSE:

The purpose is to define the process for conducting periodic audits of the QMS. The procedure defines the process for scheduling, conducting, and reporting of QMS audits.

2. SCOPE:

This procedure applies to all internal QMS audits conducted at the Joseph Co. The scope of QMS audits may cover all activities and processes comprising the QMS or selected elements.

3. RESPONSIBILITIES:

- a) The Management Representative is responsible for maintaining QMS audit records, including lists of trained auditors, auditor training records, schedules and protocols, and reports.
- b) The Management Representative is responsible for notifying QMS auditors of any upcoming audits a reasonable time prior to the scheduled audit date. Company areas and functions subject to the QMS audit will also be notified a reasonable time prior to the audit.
- c) The Lead Auditor is responsible for ensuring that the audit, audit report and any feedback to the factory areas or functions covered by the audit is completed per the audit schedule.
- d) The Management Representative, in conjunction with the Lead Auditor, is responsible for ensuring that Corrective Action Notices are prepared for audit findings, as appropriate.

4. PROCEDURE:

4.1 Audit Team Selection:

- 4.1.1 One or more auditors comprise an "Internal Audit Team", (JSC-FM-003-02-R/00). When the team consists of more than one auditor, a Lead Auditor will be designated. The Lead Auditor is responsible for audit team orientation, coordinating the audit process, and the preparation of the report.
- 4.1.2 Personnel responsible to conduct Internal Audits are appointed by the Managing Director. The internal auditors are selected from different organizational functions based on their experience and professional skills.
- 4.1.3 Internal auditors should be Lead auditor or attend the internal audit trainings.
- 4.1.4 The internal auditor should not belong to the department being audited.

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4.1.5 The internal auditor should be an independent auditor.

4.1.6 QMS audits are scheduled to ensure that all QMS elements and functions are audited at least twice each year.

4.2 **Audit Team Orientation:**

The Lead Auditor will assure that the team is adequately prepared to initiate the audit. Pertinent policies, procedures, standards, regulatory requirements and prior audit reports are made available for review by the audit team. Each auditor will have appropriate audit training.

4.3 **Written Audit Plan:**

The Lead Auditor is responsible for ensuring the preparation of a written plan for the audit (JSC-FM-003-04-R/00). The Internal QMS "Internal Audit Checklist" (JSC-FM-003-05-R/00) may be used as a guide for this plan.

4.4 **Prior Notification:**

The company areas and / or functions to be audited are to be notified a reasonable time prior to the audit.

4.5 **Conducting the Audit:**

Before starting an audit, the auditors ensure the possession of:

- a) Internal Audit Plan (JSC-FM-003-04-R/00)
- b) Copy of ISO 9001:2008 standard
- c) Observation Sheet or Pad
- d) Copies of Quality Management System Manual and Procedures & if available Standard Operation Procedures and Work Instruction.
- e) Internal Audit Checklist (JSC-FM-003-05-R/00).

4.5.1 Lead Auditor shall prepare "Internal Audit Checklist" (JSC-FM-003-05-R/00) with the help of co-auditors & sends to auditee department well in advance. The audit begins with a briefing to the management on the methodology of the audit, its scope and any administrative arrangements required.

4.5.2 A pre-audit conference is held with appropriate personnel to review the scope, plan and schedule for the audit.

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4.5.3 Auditors are at liberty to modify the audit scope and plan if conditions warrant.

4.5.4 Objective evidence is examined to verify conformance to QMS requirements, including operating procedures. All audit findings must be documented.

4.5.5 Specific attention is given to corrective actions for audit findings from previous audits.

4.6 Closing Meeting:

4.6.1 A post-audit conference is held to present audit findings, clarify any misunderstandings, and summarize the audit results.

4.6.2 On completion of the audit, a closing meeting is arranged by the Management Representative with the auditors to review findings and to obtain clarifications if required. Appropriate corrective measures are also discussed.

4.7 Reporting Audit Results:

4.7.1 The Audit Team Leader prepares the "Internal Audit Report" (JSC-FM-003-06-R/00), which summarizes the audit scope, identifies the audit team, describes the sources of evidence used, and summarizes the audit results.

4.7.2 Findings requiring corrective action are entered into the "CPA Request Form" (JSC-FM-004-01-R/00).

4.8 Audit Report Distribution:

4.8.1 The Management Representative is responsible for communicating the audit results to responsible area and / or functional management. Copies of the "Internal Audit Report", (JSC-FM-003-06-R/00), are made available from the Management Representative.

4.8.2 The Management Representative is responsible for ensuring availability of audit reports for purposes of the Management review Meeting.

4.9 Audit Follow-up:

4.9.1 Management in the affected areas and / or functions is responsible for any follow-up actions needed as a result of the audit.

4.9.2 The Management Representative is responsible for tracking the completion and effectiveness of corrective actions.

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4.10 Corrective action & Follow up:

4.10.1 Management Representative initiates the "CPA Request Form" (JSC-FM-004-01-R/00), on the non-conformities observed during the audit and gives it to the concerned Departmental Heads. The concerned Departmental Head investigates the cause of the problem, proposes a corrective action to be taken and indicates the date by which the corrective action will be fully implemented.

4.10.2 Internal Auditors verify that the agreed action have been correctly taken, either in the next planned audit or on the follow-up date.

4.10.3 On, or immediately after, the due date for implementation of the corrective action, the auditors follow up with an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the audit non-compliance report is closed. If more work is needed to fully implement the corrective action, a new follow-up date is agreed upon.

4.11 Close of CPAR:

Management Representative closes any CPAR if the audit or follow-up audit verifying that the agreed corrective actions have been taken satisfactorily. If the agreed actions have not been taken, or are ineffective, Management Representative gives a new audit date for follow-up audits.

4.12 Inputs to Management Review Meetings:

The results of internal audit are submitted in management review by Management Representative as input.

4.13 Record Keeping:

Audit reports are retained for at least two years from the date of audit completion. The Management Representative is responsible for maintaining such records.

5. RELATED RECORDS:

- | | |
|-----------------------------|--------------------|
| 1) Audit Calendar | JSC-FM-003-01-R/00 |
| 2) Internal Audit Team | JSC-FM-003-02-R/00 |
| 3) IQA Circular | JSC-FM-003-03-R/00 |
| 4) Internal Audit Plan | JSC-FM-003-04-R/00 |
| 5) Internal Audit Checklist | JSC-FM-003-05-R/00 |
| 6) Internal Audit Report | JSC-FM-003-06-R/00 |
| 7) CPA Request Form | JSC-FM-004-01-R/00 |