I PURPOSE

The purpose of this procedure is to provide instructions and responsibilities for conducting internal audits of the quality management system.

II APPLICATION

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

III PROCEDURE

1 Audit plan

Planning of internal audits is based on the QMS Map diagram (QM Section 4.1) and the Process Applications Matrix used to derive the Internal Audit Checklist.

The ISO 9001 Management Representative (General Manager) is responsible for overseeing the planning and scheduling internal audits of the quality system. Audit frequency is based on the status and importance of the processes, products, and areas to be audited, as well as results of previous audits, internal/external nonconformities and customer complaints, if any. Each quality system process is audited at least once per year.

Quality system audit planning and schedule comes together in the table called the Internal Audit Plan. The table lists processes of the quality system to be audited along with the audit dates and assigned auditors. More detailed scope and reference for the audit areas/functions and reference clauses of ISO 9001 standard are provided in the Process Applications Matrix diagram and each Internal Audit Checklist.

Internal audit plans and cycles are synchronized with management reviews of the quality system so that complete results from the full auditing cycle are available in time for the management review meeting.

2 Audit team

The ISO 9001 Management Representative (General Manager) is responsible for qualifying, training and assigning internal auditors. Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity.

Internal auditors are qualified on the basis of their experience and training. Minimum requirements are:
Experience: Two years in this industry

Training: External or in-house internal audit training

The training can be by an external course or seminar provided by a qualified institution (such as a registrar, training organization, etc.), or in-house training provided by a qualified consultant/trainer. If training is provided in-house, the trainer must have at least 3 years experience in ISO9000 consulting and auditing.

If the audits are outsourced, the outside auditor must have at least three years consulting experience in the field of ISO 9001 and an RABQSA certificate or equivalent. The outsourced auditor may also be a key member of another company (at least 2 years’ experience) certified to ISO 9001.

3 Preparing for audit

Auditors prepare for an audit by:

- Reviewing the Quality Manual Section 4.1 Process Map diagram and the Process Applications Matrix.
- Refreshing their knowledge of the quality manual and relevant process flowcharts and procedures;
- Reviewing the last audit report of this area, nonconformity reports (NCR’s), customer complaints, and any applicable corrective or preventive action files.
- Preparing an audit checklist. Even though there is no set format for an internal audit checklist, the checklist should clearly indicate the main questions to be asked and the origin of the question (such as an ISO 9001 clause or a company document).

4 Conducting and reporting the audit

In conducting the audit, auditors generally follow the Internal Audit Checklist derived for the audit. The checklist defines the minimum scope criteria (requirements) for the audit and provides relevant questions. The checklist is also used for referencing reviewed evidence and keeping audit notes.

When a nonconformance is noted, it is brought to the attention of, and discussed with, the responsible manager. At the end of the audit, the auditor(s) will compile an internal audit report. This report will be given to the ISO 9001 Management Representative who will share it with the managers/supervisor/lead responsible for the area audited.

5 Corrective action and follow up

The Management Representative will issue a corrective action (using the CAR form) for each nonconformance documented during the audit. This will be sent to the responsible supervisor or lead. The responsible supervisor or lead will investigate the cause of the problem noted as a nonconformity and determine the required correction.
The ISO 9001 Management Representative (General Manager) must review and approve the proposed action. Once approved, the action will be implemented.

When there is objective evidence that the corrective action is effective, the Corrective Action Report is closed out. It is perfectly normal for management to decide to hold a CAR open for a while to ensure that the action is effective, after the corrective action is implemented.

6 Documentation and records

At the end of an auditing cycle, all audit reports established during the cycle are compiled and analyzed, and are presented at the next management review meeting.

IV ASSOCIATED DOCUMENTS

- Process Applications Matrix
- Internal Audit Plan form
- Corrective Action Report Form

V ASSOCIATED RECORDS

- Internal Audit Plans
- Internal Audit Checklists
- Audit Reports