



# INTERNAL AUDIT PROCEDURE

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## 1. PURPOSE

The purpose of this procedure is to define the steps that Thomas Keating Limited follow for planning, performing, reporting, recording, and following up on internal audits.

Thomas Keating Limited conducts internal audits to determine whether the quality management system:

- Conforms to planned arrangements, to the requirements of ISO 9001 and to the management system requirements established by Thomas Keating Limited (QMS policies, procedures, work instructions, and forms)
- Is effectively implemented and maintained.

## 2. SCOPE

This procedure applies to all company personnel who are responsible for the development, use, and maintenance of the quality management system (QMS) at Thomas Keating Limited.

## 3. DEFINITIONS

None

## 4. REFERENCES

4.1 Quality Manual. TK-QM

## 5. ASSOCIATED DOCUMENTS

- 5.1 Audit Check List and Report. TK-QF-031
- 5.2 Corrective Action Request. TK-QF-032
- 5.3 Audit Status Log. TK-QF-033
- 5.4 Audit Schedule. TK-QF-034.
- 5.5 Quality System Review TK-QF-010

## 6. PROCEDURE

**NOTE 1:** This procedure is typically initiated about four weeks prior to the execution of an internal audit as called for by Thomas Keating Limited's audit schedule. The audit schedule is established and maintained by The Quality Assurance Manager.

**NOTE 2:** Every element in the quality system is audited on a regular basis on a minimum of once per year. Activities are audited more frequently if there are significant changes taking place (i.e., many new hires/high turnover of personnel, modified procedures and work instructions, etc.) or if there is a history of problems in that area.

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**NOTE 3:** Only qualified personnel may perform internal auditing activities. These qualified personnel are classified as internal auditors and have received the following training as a minimum: 1 day training on internal auditing techniques, training on the ISO 9001 Standard, this training may be performed by pre-trained internal auditors.

## 6.1 AUDIT PLANNING, COORDINATION, AND PREPARATION

6.1.1 The Quality Assurance Manager defines the specific criteria, scope, methods and objectives for the upcoming internal audit based on the status, maturity, and importance of specific elements in Thomas Keating Limited's quality system.

Audits shall be carried out to a defined scope and shall be as follows,

- a) Planned: as per the internal audit plan (TK-QF-034)
- b) Unplanned: arising as a result of,
  - Customer complaints
  - Following the implementation of actions defined in a corrective action report
  - Following the identification of additional or amended procedures for products

**NOTE 4:** In planning the particular audit, these activities include determining the extent and boundaries of the audit (locations, activities, processes); set of procedures and/or requirements to be audited against; auditing methods and audit objectives.

6.1.2 The Quality Assurance Manager selects the appropriate auditor to ensure objectivity and impartiality of the audit process.

6.1.3 The Quality Assurance Manager and the auditor review the proposed audit program to ensure that it is consistent with and effective for the defined audit criteria, scope, methods, and objectives.

6.1.4 Prior to the audit date, auditor reviews the appropriate quality system documents, records of completed corrective and preventive actions, and past audit findings to identify activities to be audited, and then develops a checklist (TK-QF-031) covering the system elements and activities to be audited.

## 6.2 INTERNAL QUALITY AUDIT INVESTIGATION

6.2.1 The auditor will contact the personnel in the area being audited at the time indicated in the audit program, and briefly review the audit criteria, scope, methods and objectives with them.

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**NOTE 5:** The checklists only serve as a guide to the auditors, and other areas not investigated as deemed necessary by the auditors or as requested by the auditee.

6.2.2 When a nonconformance is identified, the auditor presents the nature of the nonconformity and the evidence to the personnel involved for verification, clarification, and addresses any questions or concerns that the personnel may have, as well as give advice, when requested, regarding any problems which are uncovered.

6.2.3 If the nonconformance is confirmed, then go to step 6.2.5.

6.2.4 If the possible nonconformance requires further clarification the auditor will discuss the situation with the Quality Assurance Manager.

6.2.5 After the facts of the nonconformity are verified (or modified), the auditor either documents the nonconformance statement or documents the necessary information for writing one.

**NOTE 6:** The nonconformance statement includes the nature of the nonconformity, the factual evidence obtained, and the nature of the requirement that is not complied with (i.e., the appropriate ISO 9001 clause number, the appropriate quality system document section/page/paragraph, what the personnel says about normal practice, contract requirements, statutory regulations, current standards, and any other relevant requirements).

### 6.3 REPORTING AND FOLLOW-UP

6.3.1 Within 1 week of completing the internal audit program, the auditor prepares the internal audit report and submits it to The Quality Assurance Manager for review and approval.

**NOTE 7:** The audit report includes the audit's criteria, scope, methods and objective names and titles of the audit team members, a summary of general observations (i.e., general degree of compliance and any significant problems encountered), statements of nonconformities, weaknesses, and/or opportunities for improvement, and verification results for follow-up activities performed during the audit.

6.3.2 The Quality Assurance Manager reviews and approves the internal audit report, and distributes copies of the report to senior management and the personnel of the areas that were directly involved in the audit.

**NOTE 8:** Any additional comments or observations that The Quality Assurance Manager may have can be attached to the report, but the auditor's observations cannot be deleted or modified by The Quality Assurance Manager.

6.3.3 The Quality Assurance Manager raises a Corrective Action Form (TK-QF-032) for any nonconformity listed in the Internal Audit Report and for any weaknesses or "opportunities for improvement" identified and documented.

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- 6.3.4 The Quality Assurance Manager updates and maintains the long-range audit schedule based upon the documented results of the audit and the planned corrective preventive actions.
- 6.3.5 The Quality Manager shall maintain an audit status log (TK-QF-033) detailing all internal and external audits carried out.
- Long-range audit schedule
  - Internal audit program
  - Completed checklists- signed and dated by each auditor
  - Audit report

## 7. REVIEW PROCEDURE

Any suggested improvements or modifications to this procedure are to be passed on to the Quality Assurance Manager for discussion at the next Quality Review Committee meeting.

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