****Internal Auditor Training Materials****

**Part 1: Fundamental Requirements for Internal Audit**

**1.Develop an audit procedure**.

**2.Focus of internal audit**: To verify the **conformity** of quality activities and related results, ensure the **effectiveness** of the quality management system, the **reliability** of processes, and the **validity** of products. It also involves evaluating the extent to which intended objectives are achieved and identifying opportunities and methods for quality improvement.

**3.Formulate an audit plan**.

**4.Auditors shall maintain relative independence and impartiality**, be specially authorized by organizational management, and possess sufficient qualifications. The number and competence of auditors shall meet the needs of internal auditing.

**5.Audit resources**: Organizational management shall provide all necessary resources required for internal auditing to achieve audit objectives.

6. Audit results shall be systematically consolidated and analyzed to form a formal report, which shall be distributed and utilized promptly and effectively in accordance with established procedures.

7. Audit documentation, including procedures, criteria, records, reports, and forms, shall be complete, valid, and maintained in a standardized format. All documents shall be archived systematically.

8. Corrective actions shall be implemented in response to issues identified during the audit, with follow-up and monitoring to ensure the corrective system is responsive and effective.

An internal audit program that fulfills the above eight requirements essentially meets the core expectations of the ISO 9001 standard.

**Part 2: Basic Concepts of Auditing**

I. Definition and Understanding of Auditing

Definition of Auditing  
A systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Objectives of Auditing  
(1) Auditing serves as an effective management tool for examining activities and processes. The results of audits provide information for management to take action.  
(2) The primary objective of an audit is to ensure that audit criteria are met. Examples include:  
 ① Verifying the conformity of the auditee’s management system with specified requirements.  
 ② Evaluating compliance with legal requirements.  
 ③ Confirming the effectiveness of the implemented management system in achieving defined objectives.

When confirming audit objectives, the following aspects should be considered:  
① The priorities of management.  
② Business intentions.  
③ Requirements of the management system.  
④ Needs of regulatory and contractual obligations.  
⑤ Necessity of supplier evaluation.  
⑥ Customer requirements.  
⑦ Requirements of other relevant stakeholders.  
⑧ Potential risks existing within the organization.

1. Audit criteria serve as the basis for auditing.  
   Audit criteria are “a set of policies, procedures, or requirements used as a reference.”  
   ① ISO 9001:2000 Quality Management System Requirements.  
   ② Quality manuals, documented procedures, and other related quality management system documents.  
   ③ Applicable laws, regulations, and other requirements.
2. To ensure the effectiveness of audits, three core principles shall be maintained: objectivity, independence, and a systematic approach.

The objectivity of an audit is demonstrated by:  
① Audit evidence obtained must be “records, statements of fact, or other information relevant to the audit criteria and verifiable.”  
② The audit shall involve objective evaluation of collected evidence against audit criteria to form audit findings.  
③ Auditing is a documented process, including but not limited to: audit plans, checklists, on-site audit records, nonconformity reports, audit reports, and records of opening and closing meetings.

The independence of an audit is demonstrated by:  
① Auditing is an authorized activity, with authorization deriving from management decisions, company policies, contractual requirements, commissioning parties, and legal or regulatory provisions.  
② Auditors shall maintain impartiality throughout the audit process and avoid any conflicts of interest.  
③ Audit team members shall perform audits professionally and adhere to a professional code of conduct.  
④ Auditors must possess competence to carry out the assigned audits and shall have no direct responsibility for the activities/areas being audited.  
⑤ Evaluations of the auditee shall be objective, based solely on audit criteria and audit evidence.

The systematic approach of an audit is demonstrated by:

1. Auditing includes both document review and on-site audit. On-site audit can only be conducted after the document review shows conformity.  
   ② Auditing covers two levels: conformity and effectiveness.  
   ③ Planning shall be performed prior to the audit to ensure its effectiveness, consistency, and the reliability of the audit conclusions.  
   ④ Auditing applies established methods and skills to ensure the relevance, reliability, and sufficiency of audit evidence and findings. Therefore, independent audit teams auditing the same object should reach substantially similar conclusions.  
   ⑤ Audits shall be carried out according to the plan and checklist. The audit plan is generally structured by department or activity, with emphasis on auditing top management. The checklist shall specify the key processes and activities to be audited in each department, as well as the review methods.  
   ⑥ The systematic nature of an audit is achieved within a defined audit scope. The scope shall be confirmed before the audit begins.  
   ⑦ ISO 9001:2000 applies the same systematic approach to quality management both in planning the overall system and in managing individual processes.
2. Concepts Related to Auditing

①Quality Management System (QMS)  
A quality management system is a management system used to direct and control an organization with regard to quality.

②Audit Scope  
The audit scope refers to the extent and boundaries of an audit.

③Nonconformity  
A nonconformity is the "non-fulfillment of a requirement." Requirements may be specified by different interested parties and generally include the following three aspects:  
Explicit requirements: Stated or specified requirements.  
Generally implied requirements: Expectations or practices that are customary or commonly accepted.  
 Obligatory requirements: Needs or expectations that are mandatory or essential.

④Defect  
A defect is the non-fulfillment of a requirement related to an intended or specified use.

⑤Audit Criteria  
A set of policies, procedures, or requirements used as a reference for comparison.

⑥ Audit Evidence  
Records, statements of fact, or other verifiable information relevant to the audit criteria.

⑦ Audit Finding  
The result of evaluating collected audit evidence against audit criteria.

⑧ Audit Conclusion  
The ultimate outcome of an audit, formulated by the audit team after considering the audit objectives and all audit findings.

⑨ Audit Client  
The organization or person requesting an audit.

⑩ Auditee  
The organization being audited.

⑪ Auditor  
A person with the competence to conduct an audit.

⑫. Audit Team  
One or more auditors conducting an audit, supported by technical experts if needed.

⑬Technical Expert  
A person who provides specific knowledge or expertise to the audit team.

⑭Audit Program  
A set of one or more audits planned for a specific time frame and directed toward a particular purpose.

⑮ Audit Plan  
A description of the activities and arrangements for an audit.

⑯ Competence  
Proven ability to apply knowledge and skills.

****I**nternal Audit Process**

**I. Audit Planning**In accordance with the internal audit procedure, an annual audit plan is developed. Management authorizes the formation of an audit team, after which the lead auditor prepares a specific audit activity plan, organizes the audit working documents, and issues audit notifications.

**II. Audit Execution**The on-site audit begins with an opening meeting. Auditors employ various review methods and techniques to gather audit evidence, derive audit findings, conduct analysis and verification, issue nonconformity reports, and conclude the on-site audit with a closing meeting. The lead auditor is responsible for controlling the entire audit process.

**III. Audit Reporting**Upon completion of the on-site audit, an audit report shall be submitted. Key tasks include:

Preparation, approval, distribution, and archiving of the audit report;

Evaluation of performance and implementation of rewards or penalties;

Proposal of corrective, preventive, and improvement measures;

Confirmation and requirement for layered and step-by-step implementation of actions.

**IV. Follow-up Audit**  
Tracking and verification shall be strengthened for the implemented actions and corrections in audited areas and processes. During the subsequent audit, the effectiveness and implementation status of these measures shall be reviewed and evaluated. The results shall be documented in the audit report to achieve closed-loop audit management and drive continuous quality improvement.

**Internal Audit Planning**

I. Developing Audit Plans  
Audit planning includes annual audit plans and individual audit activity plans. The annual audit plan serves as the starting point and overarching framework for audit planning, while individual audit activity plans are implemented according to the arrangements outlined in the annual audit plan. Audit plans include: audit objectives, scope, audit criteria, audit team members and their responsibilities, key audit activity schedules, times for opening and closing meetings, etc.

Annual Audit Plan  
(1) Objectives  
① To ensure internal audits are conducted in a planned manner.  
② To facilitate the management, supervision, and control of internal audits.

(2) Considerations  
① Implementation of the audit organization.  
② Audit scope.  
③ Requirements from customers, certification bodies, and relevant regulations.  
④ Requirements for internal audits as specified in the quality management system documentation.

⑤ Audit frequency.

(3) Types  
① Centralized annual audit work plan.  
② Rolling annual audit work plan.

2. Audit Activity Plan

II. Establishing the Audit Team  
Based on the objectives, scope, departments, processes, and schedule of the audit activity, select the lead auditor and team members to establish the audit team.

Auditors shall perform the following tasks according to their assignments:  
① Familiarize themselves with the necessary documents and procedures.  
② Prepare checklists as required.  
③ Consider follow-up items from previous audit results.

III. Preparing Checklists

1. Similar to developing an audit plan, when department-specific audits are prioritized, the checklist should list the key processes and activities for which the department is responsible, along with the audit content and review methods.

2. Attention should be paid to the rationality of sampling.

3. When auditing by process, fully apply the PDCA process approach.

4. The basis for the checklist includes the ISO 9001:2000 standard, the auditee's quality management system documentation, and other audit criteria.

5. Note that only verifiable information can serve as audit evidence.

6. The format and level of detail of the audit checklist can be flexible; sometimes only an outline or key points may be listed, but requirements of ISO 9001:2000 must not be omitted.

**Internal Audit Implementation**

I. Fundamental Content of Audit Implementation  
The implementation begins with the opening meeting. Following the standards, documents, checklists, and planned arrangements, auditors proceed to the on-site audit and verification, initiating the key activity of the audit—the on-site audit. During the on-site audit, auditors employ various audit strategies and techniques to collect objective evidence, which is promptly recorded in the "On-site Audit Record Sheet." Through the consolidation, analysis, and confirmation of audit evidence and findings, and after confirmation by the auditee, nonconformity reports are issued. The on-site audit concludes with the closing meeting.

II. Opening Meeting  
The opening meeting marks the commencement of the audit implementation. It is a meeting attended by all members of the audit team and the top management and relevant personnel of the auditee.

1. Purpose of the Opening Meeting  
(1) Introduce participants, including an overview of their responsibilities.  
(2) Confirm the audit objectives, scope, and criteria.

(3) Confirm the audit schedule and other relevant plans of the auditee.  
(4) Explain the methods and procedures to be used for the audit, including notifying the auditee that audit evidence is only a sample of available information, thus introducing an element of uncertainty.  
(5) Confirm formal communication channels between the audit team and the auditee.  
(6) Confirm the language to be used during the audit.  
(7) Confirm that the auditee will be informed of the audit progress during the audit.  
(8) Confirm the availability of resources and facilities required by the audit team.  
(9) Confirm confidentiality matters.  
(10) Confirm safety, emergency, and security procedures relevant to the audit team's work.  
(11) Confirm the role and responsibilities of the guide(s).  
(12) Explain the reporting method, including the classification of nonconformities.  
(13) Provide information on conditions for terminating the audit.  
(14) Provide information on the procedure for handling complaints related to the audit.

2. Requirements for the Opening Meeting  
a) Establish the tone and style for the audit activities.  
b) Be punctual, concise, and clear; the meeting should not exceed 30 minutes.  
c) Secure the understanding and support of the auditee.  
d) The meeting shall be chaired by the lead auditor.  
e) Attendees of the opening meeting should include: all members of the audit team, top management, representatives of the audited departments, and key personnel.

3. Content of the Opening Meeting  
a) Commencement of the meeting.  
b) Introduction of attendees.  
c) Statement of audit objectives and scope.  
d) Communication of the audit plan.  
e) Emphasize audit principles, highlighting impartiality and objectivity. Explain that the audit is a sampling process with inherent limitations but will strive to select representative samples to ensure fair conclusions. Clarify that mutual cooperation is essential for the smooth progress of the audit and obtaining objective outcomes. Specify the format for reporting nonconformities.  
f) Address and clarify any relevant questions.  
g) Finalize logistical arrangements.  
h) Adjournment of the meeting.

4. Notes for the Opening Meeting  
a) The opening meeting should start and end on time.  
b) The meeting should remain focused on the agenda and be concise.  
c) For audits with a smaller scope, shorter duration, or routine internal audits, the opening meeting may be omitted. Relevant matters can be communicated through alternative means such as notifications. Even if the meeting is held, the content and procedures mentioned above may be adjusted based on specific circumstances.  
d) The opening meeting should aim to establish a positive audit tone and atmosphere.  
e) Attendees should sign in. If the lead auditor notices the absence of key personnel from the audited department, the reason should be inquired.  
f) The audit objectives, scope, and plan generally should not be altered during the opening meeting. Minor adjustments to the plan are acceptable.  
g) Role of escorts: Provide support to the audit team, act as witnesses on behalf of the auditee during audit activities, and fulfill other responsibilities.  
h) Emphasize that the heads of the audited departments should be present during the scheduled audit periods.

IV. On-site Audit  
On-site audit is the process of collecting objective evidence through sampling methods.

1. Principles of On-site Audit  
A. Adhere to the principle of relying on objective evidence.  
B. Adhere to the principle of comparing standards with actual practices.  
C. Adhere to the principles of independence and impartiality.  
D. Adhere to the "Three Do's and Three Don'ts" principle:

Do base conclusions on objective evidence; do not rely on emotions, feelings, or impressions.

Do trace back to actual practices; do not merely focus on documents or verbal statements.

Do follow the audit schedule as planned; avoid the mindset that not finding issues equates to failure.

Collection of Audit Evidence  
2. Methods for collecting audit evidence may include:  
a) Interviews with personnel of the auditee  
b) Review of documents and records  
c) On-site observation and verification  
d) Verification of actual activities and results  
e) Aggregation, analysis, charts, and performance indicators of data  
f) Reports from other sources, such as customer feedback, external reports, and evaluations from intermediaries  
g) The extent of relevant sampling plans and the quality control measures and procedures implemented for the sampling and measurement processes

Forms of collected audit evidence include:  
a) Existing objective facts  
b) Statements made by interviewed personnel regarding their areas of responsibility  
c) Existing documents and records

The following points should be noted regarding the collection of audit evidence:  
a) More evidence is not necessarily better; focus should be placed on identifying genuinely required key information.  
b) Audit evidence must be valid.  
c) Attention should be paid to verifying the correlation and consistency among audit evidence, as issues or clues may be identified by cross-referencing two or more related pieces of evidence.  
d) The authenticity of evidence should be verified, as evidence provided by the auditee may contain inaccurate information.  
e) Audit evidence that can confirm whether the audit objectives can be achieved should be collected.

1. On-site Audit Records  
   (1) Purpose of Records  
   a) Serve as the basis for preparing nonconformity reports  
   b) Act as a reference for memoranda and verification  
   c) Provide a reference for review and traceability
2. Requirements for Records  
   a) Records should be clear, comprehensive, and easily understandable to facilitate review  
   b) Records should be accurate and detailed  
   c) Records should be made promptly and on-site, avoiding reliance on post-audit recollection or delayed entries as much as possible
3. Fundamental Skills for On-site Auditing  
   (1) Communication Skills  
   Interviewing Skills: Ask appropriate questions; speak less and listen more; maintain a harmonious relationship.  
   a) Select appropriate interviewees.  
   b) Questioning Skills: Use open-ended questions; reflective questions; closed-ended questions.  
   c) Listening Skills: Speak less and listen more; do not fear silence; eliminate distractions; ask more open-ended questions; encourage the speaker; maintain a constructive attitude.

(2) Verification Skills  
Focus on the following aspects:

Whether procedures exist (if they are established)

Whether activities are performed (if they are implemented)

How well they are performed (the effectiveness of implementation)

Relevant records (documentation supporting the activities)

1. Principles for Determining Nonconformities  
   (1) Principle of Appropriateness
2. Principle of Closest Association

(3) Principle of Maximum Effectiveness

(4) Principle of Criticality

(5) Principle of Strongest Correlation

(6) Principle of Consolidating Similar Items

1. Coping Skills for Some Typical Situations  
   (1) The "No Problem" Type  
   (2) The "Confrontational" Type  
   (3) The "Cover-Up" Type  
   (4) The "Know-Nothing" Type  
   (5) The "Rambling" Type  
   (6) The "Can't Be Done" Type  
   (7) The "Defensive" Type  
   (8) The "Voluntary Disclosure" Type  
   (9) The "Pleading" Type  
   (10) The "Intentional Delaying" Type  
   (11) The "Overly Enthusiastic" Type
2. **On-site Audit Control**  
   (1) Adherence to audit objectives  
   (2) Maintaining audit rhythm  
   (3) Conducting audit team meetings  
   (4) Control of the audit plan  
   (5) Management of audit progress  
   (6) Control of the audit atmosphere  
   (7) Management of audit scope  
   (8) Control of nonconformities  
   (9) Communication with the auditee  
   (10) Other controls
3. IV. Reporting of Nonconformities
4. Meaning of Nonconformities  
   a) Requirements of standards  
   b) Stipulations in documents  
   c) Contractual agreements  
   d) Statutory and regulatory requirements  
   e) Other stipulated requirements  
   f) Customer complaints
5. Types of Nonconformities  
   a) Document-related nonconformities  
   b) Equipment-related nonconformities  
   c) Product-related nonconformities  
   d) Personnel-related nonconformities  
   e) Work environment-related nonconformities  
   f) Other types of nonconformities
6. Principles for Determining Nonconformities  
   (1) Principle of comparing requirements with actual practices  
   (2) Principle of relying on objective evidence
7. Classification of Nonconformities  
   (1) Major Nonconformity  
   a) Serious noncompliance with the agreed quality management system standard or documented requirements  
   b) Nonconformity leading to systemic failure  
   c) Nonconformity leading to localized failure  
   d) Nonconformity that may cause serious consequences  
   e) Nonconformity violating laws or regulations

(2) Minor Nonconformity  
(3) Observation Item

5. Content of the Nonconformity Report  
Includes: Name of the auditee, auditor, accompanying personnel, date, description of the nonconformity, conclusion on the nonconformity, nature of the nonconformity, confirmation by the auditee, corrective actions and completion timeline, verification records after implementation of corrective actions, etc.

6. Format of the Nonconformity Report

V. Closing Meeting

1. Objectives of the Closing Meeting  
a) To present the audit findings to the auditee, ensuring they clearly understand the results and can confirm them.  
b) To outline follow-up actions required.  
c) To conclude the on-site audit.

2. Content of the Closing Meeting  
a) Reiterate the audit objectives and scope.  
b) Emphasize the limitations of the audit.  
c) Read out the nonconformity reports.  
d) Specify requirements for corrective actions.  
e) Present the audit conclusions.  
f) Read the auditee's management response and commitment to corrective actions.  
g) Conclude the meeting, with the audit team expressing gratitude to the auditee.

3. Notes for the Closing Meeting  
a) The focus of the closing meeting should revolve around proposing corrective actions and requirements for nonconformities.  
b) Key departments and personnel involved in the audit results and conclusions should attend the meeting to facilitate the implementation of corrections.  
c) The timing of the closing meeting should be predetermined in the plan, maintaining the audit style and a positive atmosphere.  
d) The closing meeting should be documented and records retained, including attendance sheets of participants.  
e) If the auditee has already taken corrective actions for some nonconformities before the closing meeting and the auditor has verified them satisfactorily, these may not need to be raised during the meeting or may be acknowledged with satisfaction.  
f) The closing meeting should appropriately acknowledge the successful experiences and good practices of the auditee, rather than solely focusing on problems.  
g) When reading out nonconformity reports or conclusions unfavorable to the auditee, thorough preparation and careful wording should be employed to avoid deadlock.  
h) All audits inherently involve certain uncertainties.  
i) Prior to the closing meeting, the audit team should conduct internal discussions to review all audit findings, reach consensus on conclusions, and discuss follow-up methods for the audit.

**Part V: Internal Audit Report**I. Content of the Internal Audit Report  
II. Audit Conclusions in the Internal Audit Report

1. Whether the management system conforms to the audit criteria within the audit scope.
2. Whether the management system has been effectively implemented within the audit scope.
3. The capability of the management review process to ensure the continual suitability and effectiveness of the management system.

When evaluating the QMS, the following should be considered:

1. The effectiveness of the quality policy and quality objectives implementation.
2. The adaptability, effectiveness, and adequacy of the QMS.
3. The ability of products to meet customer requirements and legal/regulatory requirements, as well as the degree of customer satisfaction.
4. Whether a continuous improvement mechanism has been established.

**Audit Follow-up**  
I. Meaning of Audit Follow-up  
II. Objectives of Audit Follow-up

1. To prompt the auditee to take and implement effective corrective and preventive actions, preventing the recurrence of nonconformities.
2. To verify the effectiveness of corrective and preventive actions.
3. To ensure the elimination of nonconformities identified during the audit.

III. Key Points for Implementing Follow-up Audits  
a) Management of follow-up audits.  
b) The timing and scope of follow-up audits should generally be agreed upon with the auditee in advance and communicated prior to the audit.  
c) For purely documentation-related nonconformities, verification can be done through document review. For corrective and preventive actions involving on-site work, on-site re-inspection and verification are required.  
d) Follow-up audits may be conducted by members of the original audit team.  
e) Follow-up audit report.