

DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 7: ISO AUDITING PROCESS	Course Number:
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INSTRUCTOR NOTES	TRAINING MATERIALS AND SUGGESTIONS
ISO AUDITING PROCESS	Slide #7-1
AUDITING <p>Briefly discuss each of the items on this slide.</p> <p><i>Internal audits</i> are performed by personnel who are members of the organization being audited. They are conducted for the same purpose as second- and third-party audits with the additional responsibility of pointing out areas that must be improved to assure compliance with either second- or third-party audits.</p> <p><i>External Audits</i> may be performed by second or third parties outside the organization being audited. Second-party audits are usually performed by customers of the supplier. Third-party audits are performed on behalf of a customer or group of customers by a professional auditing firm not financially or otherwise connected to either the customer(s) or the supplier.</p> <p>The goal of both second- and third-party audits is to determine compliance with an agreed upon set of standards.</p> <p>For ISO 9000 audits, the auditing firm must be certified or registered by an ISO-recognized accreditation board.</p>	Slide #7-2
AUDIT: DEFINITION <p>"Quality audit" is defined as follows:</p> <p>"A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives." From ISO 8402, Quality – Vocabulary.</p>	Slide #7-3
PREPARATION FOR AUDIT <p>Emphasize the fact that the days leading up to the day of the audit and the day of the audit itself should be simply the performance of routine operations. The quality system should be the normal way of operation.</p> <p>Before the ISO 9001 audit (or any internal audit), training sessions should be held to prepare the employees for the audit by informing them of the audit process and answering any questions they have. Training should cover the following basic topics:</p>	Slide #7-4

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PREPARATION FOR AUDIT <ul style="list-style-type: none"> • The audit process • Information that the employees should know when questioned by an auditor • Suggested behaviors <p>An auditor examines standards, documented procedures, ongoing operations, and quality records.</p>	Slide #7-4 (concluded)
AUDIT ISSUES <p>Employees should have a clear grasp of the following fundamental issues:</p> <ul style="list-style-type: none"> • The system – not the staff – is under scrutiny. • Necessary documentation should be readily available to employees. • Employees should respond honestly and concisely about the question asked. • Employees should not volunteer information beyond what the auditor requested. • If a question is outside the employee's area of responsibility, he or she should say so. • If an employee does not understand the question, he or she should ask for clarification. • Auditors will take notes. This does not mean there is a problem. 	Slide #7-5
INTERNAL AUDITING <p>Stress the importance of internal auditing and the value it is to performing well on an external audit as well as the most important task of continual improvement.</p> <p>All these audits must have certain aspects:</p> <ul style="list-style-type: none"> • They must be objective. • The auditor(s) must know the requirements and intent of applicable standard in detail. • They must be well organized. • The auditor should be familiar with the auditees products, processes, and procedures. 	Slide #7-6

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<p>INTERNAL AUDITING (CONTINUED)</p> <ul style="list-style-type: none"> • A complete, objective report must be issued immediately following the audit. • Management must participate in an effective program to correct any shortcomings found during the audit. <p>Audits include both documentation and records examination and personnel interviews. Among other things, the auditor must be able to follow a "paper trail" and be a good interviewer.</p> <p>"Internal audit" implies the audit is performed by someone belonging to the organization. This person will probably be well known to the functions being audited, and all parties must overcome the temptation to "let things slide." The objective is not to make departments or individuals "appear" in compliance; rather, the objective is to uncover any shortcomings that may pose a problem at the formal second- or third-party audit. Everything possible must be done to keep the audit objective and honest. If there are those in the organization who resist the ISO concepts, the time to find out is not during the third-party audit.</p> <p>The internal audit is a vehicle to help the organization reach compliance with a standard. In this case, the standard is the ISO 9000 series of standards. The goal of the internal audit is to measure conformance/non-conformance to each of the quality system requirements set forth in the appropriate standard. The results of the internal audit are used to formulate plans to achieve compliance.</p> <p>The audit examines the organization's Quality Assurance System, which leads to the need to define a Quality Assurance System. The Quality Assurance System has the following characteristics:</p> <ol style="list-style-type: none"> 1. It is the organization's normal work planning and management control system aiming at time and cost effectiveness. 2. It should have the additional aim of progressively improving quality. 3. It must be defined and documented. 4. The organization must be able to produce objective evidence of a planned and controlled approach to the achievement of quality. 	<p>Slide #7-6 (continued)</p>

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INTERNAL AUDITING (CONTINUED) 5. The system must be subject to periodic senior review and internal audit . Records of such reviews and audits must be maintained. 6. The organization must be able to demonstrate that corrective action is effectively carried out. Taking the above characteristics into consideration, one should see that the organization should "live" the standard to which it will be audited. It should be the sum total of all the daily activities carried on throughout the organization. If this is true, there will be no need to "get up to speed" for any audit.	Slide #7-6
EXTERNAL AUDITING The system of third-party audits is intended to remove the possible non-objectivity of internal and second-party audits and to lend credibility to certification. Study the relationships depicted in the chart.	Slide #7-7
CONDUCT OF AUDIT BY EXTERNAL FIRM The conduct of audits is described in ISO 1001-1, -2 and -3. Preliminaries Once the organization seeking certification/registration has contracted with a certified auditing firm, it is customary to have a preliminary audit performed. This preliminary audit may consist of a documentation review followed by a preliminary on-site audit. The document review is usually performed at the auditing firm's offices. The organization seeking certification will send a set of requested documents to the auditing firm to be reviewed. If the auditing firm deems the documents to be satisfactory, an on-site preliminary audit will be scheduled. This preliminary on-site audit may be foregone if both parties feel it is not necessary.	Slide #7-8

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CONDUCT OF AUDIT BY EXTERNAL FIRM (CONTINUED) Execution of Audit <p>In the opening meeting, the auditing firm, as a minimum, accomplishes the following:</p> <ul style="list-style-type: none"> • Introduces the auditors and their roles • Explains the purpose and scope of the audit • Explains the manner of identifying and recording non-conformities • Communicates the audit schedule • Explains and coordinates the use of guides • Is briefed on any safety, security, and/or proprietary concerns Conduct of Audit <p>During the conduct of the audit, the auditor(s) should perform the following tasks:</p> <ul style="list-style-type: none"> • Explain what is seen as the audit progresses • Focus on understanding and executing the ISO standard • Investigate and verify observations as much as necessary • Resist assuming the role of a consultant • Prevent becoming confrontational with any auditee Non-conformities <p>Non-conformities are conclusions that one or more of the elements of the standard are not functional or at least not fully functional. A major non-conformity means that an entire element is not functional or is non-existent. A minor non-conformity means that some small portion of an element is non-functional. One major or two or three minor non-conformities are enough to preclude certification.</p>	Slide #7-8 (continued)

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CONDUCT OF AUDIT BY EXTERNAL FIRM (CONTINUED) <p>Non-conformities must be well documented and should be recorded at the time of finding. The non-conformity may not be reported until the end of each day. However, there should be no surprises at the exit meeting. When recording and reporting a non-conformity, explicit information should include the following:</p> <ul style="list-style-type: none"> • Where the non-conformity was found • The exact facts and corroboration of the facts • The reason the findings constitute a non-conformity • Information helpful to initiate corrective action <p>Daily Reports</p> <p>If the audit takes more than one day, a daily report should be given to the auditee. The auditors should first meet together, compare and corroborate facts, and coordinate their findings. The findings of the day should then be reported to the auditee.</p> <p>Exit Meeting</p> <p>The following events should occur at the exit meeting:</p> <ul style="list-style-type: none"> • A record should be made of the attendees. • The scope of the audit should be reconfirmed. • Any non-conformities should be revisited. • Any corrective action requests should be discussed. • Recommendations of certification or non-certification must be discussed. <p>Formal Report</p> <p>The audit is prepared under the direction of the lead auditor, who is responsible for the accuracy and completeness of the report.</p> <p>The report should contain no surprises. It should reflect both the tone and content of the exit meeting, which, in turn, should be a faithful summary of the audit itself. ISO 10011-1 states that the report should contain the following:</p>	Slide #7-8 (continued)

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<p>CONDUCT OF AUDIT BY EXTERNAL FIRM (CONCLUDED)</p> <ul style="list-style-type: none"> • The scope and objectives of the audit (audit to ISO 900X with objective to determine recommendation for certification/non-certification) • Details of the audit plan, names of audit team members and auditee's representatives, dates, and identification of the specific organization audited • Identification of reference document against which the audit was conducted • Observations of non-conformities • Audit team's judgment of the extent of the auditee's compliance with the applicable quality system standard • The system's ability to achieve defined quality objectives • The audit report distribution list <p>The report should be sent to the client by the lead auditor. It is the client's responsibility to provide the auditee's senior management with a copy of the report. Any additional distribution should be determined in consultation with the auditee.</p> <p>The audit is completed upon submission of the audit report to the client.</p> <p>Corrective Action</p> <p>Corrective action is a function of the auditee and its management. Auditors describe non-compliance, and the auditee determines corrective action activities.</p>	Slide #7-8 (concluded)