TRANSNET

Academy

Faculty of Leadership and Functional Development

Basics of Auditing

Learner Guide

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This manual is an integral part of Quality Management. It is intended as a reference guide for learners having attended the training to continue self-learning. It is not in any way intended to be used as a sales tool or sales presenter of any kind during customer interactions.

PURPOSE OF THE COURSE

This course has been custom designed for Transnet Academy to assist the integrated oversight audit team to understand the basics of Auditing as a building block towards the Integrated Management Systems Auditing Course.

LEARNING ASSUMED TO BE IN PLACE AND RECOGNITION OF PRIOR LEARNING

It is assumed that a learner will be competent in:

1. Communication at ABET Level 3 or equivalent.
2. Mathematical Literacy at ABET Level 3 or equivalent.

UNIT STANDARD RANGE

N/A

FACILITATOR'S ROLES AND RESPONSIBILITIES

The Facilitator is expected to (but not limited to):

1. Encourage collaboration and self-learning
2. Building a safe, structured environment that promotes communication, collaboration and creativity amongst the group
3. Stimulate discussions, ask questions to get the group thinking, and encourage peer-to-peer communication
4. Where necessary, assist with practical demonstrations

LEARNER'S ROLES AND RESPONSIBILITIES

The learner is expected to:

1. Submit their ID Documents
2. Sign the Attendance Register
3. Complete the Programme Evaluation Form
4. Complete and submit all assessments
5. Participating professionally where interaction is required
6. Being punctual when breaks are allowed
7. Avoiding all outside distractions – working on laptops or phones during training is not allowed leaving the classroom silently if there is a need to attend to an external situation, which they are welcome to do
8. Asking questions when in doubt

LEARNING OUTCOMES

This course will enable you to:

1. Learn universal auditing terminology
2. Differentiate audit techniques
3. Compare internal and external audits
4. Determine if you are qualified to accept an audit assignment
5. Determine the meaning of the audit purpose
6. Determine the meaning of the audit scope
7. Learn the responsibilities of the audit team
8. Match audit team members with the audit purpose/scope
9. Make final arrangements with the auditee using the given audit information
10. Complete a desk audit
11. Construct a flowchart
12. Compare element and department methods

NOTES TO THE LEARNER

1. You are responsible for your own learning – make sure you manage your study, practical, workplace and portfolio time responsibly.
2. Learning activities are learner driven – make sure you use the Learner Guide and Portfolio Guide in the manner intended and are familiar with the Portfolio requirements.
3. The Facilitator is there to reasonably assist you during contact, practical and workplace time of this programme – make sure that you have his/her contact details.

COURSE PREREQUISITES

N/A

ASSESSMENT METHODS

Learners will be assessed in any of the following ways of assessment:	**1. Formative Assessment** In this e-learning course, several activities are spaced within the content to assist you in understanding the material through application. Please make sure that you complete ALL activities. **2. Summative Assessment** You will be required to complete a Portfolio of Evidence for summative assessment purposes. A portfolio is a collection of different types of evidence relating to the work being assessed. It can include a variety of work samples.

TARGET AUDIENCE

People who are involved in Systems Auditing

TABLE OF CONTENTS

1 Welcome to Auditing

Learning outcomes:
- Learn universal auditing terminology
- Differentiate audit techniques
- Compare internal and external audits

1.1 Auditing Terminology

Audits

An **audit** is some type of **formal independent examination** of a product, service, work process, department, or organization. Conducting an audit is a process, work practice or service. Some organizations prefer the word evaluation, survey, review, or assessment instead of the word audit.
Throughout the class there will be guiding audit principles. They will be in a box and labeled as an audit principle as the one below.

> **Audit Principle : Support the advancement of the public well being for safe products and services.**

Since auditors are entrusted with information, they must be ethical in their dealings with the organizations they audit as well as with the general public.
The audit process steps are to:
- **identify plans** (what people are supposed to do)
- **make observations** (what people are actually doing)
- **evaluate** the facts collected (sort the evidence)
- **report** the results (conformance or noncompliance)
- **follow-up** (ensure action taken and problems are corrected)

Terminology

It is time to think about the ABC's of auditing to help you communicate effectively. Your organization may have its own terms that are different from standard audit terminology or even different from the dictionary. If during the class, the terminology is starting to get confusing, consider starting your own cross-reference table showing the word you are familiar with compared to the more generic terminology used in class.
For Example:

Your Terminology Cross - Reference Table			
No.	Universal Terminology		Your Organization's Term
1.	Audit		Assessment, evaluation
2.	Survey		Review
3.	Audit Program Department		Regulatory Compliance Dept.
4.	Employee		Associate
5.	Customer		Client, patient, member, passenger, student
6.	Client, patient, member, passenger, student		Program Manager, Quality Mgr.
7.	Audit Program Manager		Compliance Director

Controls to Examine

An **audit** is a process of investigating and examining evidence to **determine whether agreed-upon requirements (criteria) are being met**. An effective audit depends on how information is gathered, analyzed and reported. The results may verify conformance or specify noncompliance to rules, standards, or regulations. A quality audit is linked to quality requirements, environment to environmental requirements, financial audits to financial statements, and safety audits to safety rules and regulations. One of the things that makes an **audit different** from an inspection is that the individual performing an audit **must be able to do so impartially and objectively**. It means the **person performing the audit must be independent of** or have no vested interest in the area being audited. The level of independence necessary to ensure impartiality and objectivity will vary from industry to industry, type of organization, risk involved and organization culture.

1.2 Types of Audits

Internal and external audits

All audits are either internal audits or external audits. The diagram on this page shows how audits are classified as first (internal), second (external), and third (external) party

Think of your organization as the circle. Internal or first-party audits are conducted inside the circle. You must go outside the circle to conduct external or second-party audits (audit your suppliers).

On the right hand side of the diagram is an area marked for third-party audits. Third-party audits are independent of the customer-supplier relationship. Third-party audits may result in certification, license or approval of a product, process, or system by an independent organization. Your organization may have their quality system or environmental system registered by a third-party registrar or licensed by a government oversight agency.

One of the reasons internal audits are conducted is to help prepare organizations for audits conducted by external audit organizations (customers, certification bodies, registrars, government agencies).

Audit Types

Audits are also classified by scope or object of the audit. You may be assigned to conduct a system, process, or product audit. Different audits may require different methods, personnel, or equipment.

The product audit (or service audit), in the green area, determines if tangible characteristics and attributes of a product or service are being met. Typically, an auditor checks the object or service to ensure it has the proper markings, weight, size, viscosity, smoothness, amount, hardness, color, texture, placement, arrangement, count, etc.

The auditor checks the object or service output against a predetermined set of characteristics or attributes. A product or service audit is just like an inspection except there must be some level of independence and the results of the audit are not used to approve the release of a product or the delivery of a service.

A process audit determines if process requirements are being met. During a process audit, the auditor will examine an activity or sequence of activities to verify that inputs, actions, and outputs are in accordance with an established procedure, plan, or method. A process audit may examine a particular task such as stamping, welding, serving, sterilizing, filing, cleaning, transacting, or mixing or sets of processes within processes, such as manufacturing, delivering, purchasing, or designing.

The activity audited during a process audit is normally described as a verb where action is taking place. A process audit normally follows a process from beginning to end or end to beginning.

A system audit determines if system requirements (manual, policy, standards, regulations) are being met. When processes are interrelated and interacting, you get a system. A system is made up of processes organized to achieve an objective such as quality, safety, or income. During a system audit, you may examine the operation of a department, company, division, or program. Auditors may conduct a product or process audit as part of a system audit. Typically, an auditor will audit an organization against clauses of a quality, safety, or environmental management system standard.

Audit Classification

It may help you to think of this type of audit classification as zooming in or out of a picture.:

- A product audit is checking the helmet or helmets for such attributes as size, color, hardness, markings, identification, webbing, chin strap adjustment, and so on against requirements (specifications). You may decide to check the team helmets, all the helmets at the skating rink, or visit the manufacturer and sample a number of helmets. A service audit would be checking the arrangements for clean and smooth ice, inspecting the integrity of rental skates, noting the proper storage of gear before usage, etc.

- A process audit may be evaluating the methods used for skating during a race or methods for skating in a sharp turn. You may ask about training, techniques to be employed, types of required equipment, measures for determining a successful turn, adjustments for ice conditions, and equipment prep and maintenance.

- A system audit may be evaluating the management of the skating team or management of the skating arena. You may be interested in how events are scheduled, communication with team members, how changes are implemented, preventive maintenance programs, operating the box office, maintaining and operating the Zamboni, how customer needs are determined, and so on.

Most internal audits are either process or system audits. Many organizations divide up their system into little pieces and assign their internal auditors to each one. Other organizations may divide up the system into big chunks and assign teams of auditors to evaluate them.

Keen Observations
Regardless of the type of audit, an auditor must be good at observing and reporting factual information.

Auditors and auditees

The person conducting the audit is the **auditor. Other equivalent descriptive words are evaluator, assessor, examiner, reviewer, etc.**

The organization being audited is called the **auditee. Any type of organization can be an auditee such as your department, a corporation, government agency, non-profit organization, retail sales store, manufacturer, and so on.**

The person or organization who requested the audit is the **client.**

When we are referring to an individual within the organization who is audited, we can refer to that person as an "**interviewee**".

Audits are only conducted when someone or some group requests one. You might think of the client as the person who had authority to assign you to do an audit. This person is **one of your customers** of the audit service for which you are accountable. This person (the client) is normally your superior, the audit program manager, or the quality/environmental manager.

2 Getting the Assignment

Learning outcomes:
- Determine if you are qualified to accept an audit assignment

2.1 Internal Audit Job Steps

The first phase of the audit is getting agreement and specifying the job assignment. As an auditor, you will be waiting for your next assignment.

Questions?

The first step is finding out the who, what, when, where, and why. Normally, the person responsible for the audit program or the lead auditor will contact you about conducting the audit. This person could

be the audit program manager, quality manager, compliance director, management representative, and so on. The **person that had authority to require the audit is called the** client. The client could be one of the people mentioned or someone entirely different such as the VP of Operations.

It is very important to fully understand the assignment because you will have some decisions to make. You have been contacted because the audit program manager decided you are qualified to conduct the audit. **If you do not think you are qualified or there is a possible conflict of interest, you need to immediately tell the audit program manager or lead auditor.**

Accepting the Assignment

You should be told
a - the area to be audited
b - the standard to audit against, and
c - the date and time or time frame.

Ask yourself three questions.

Question 1: Are you available for the audit? **YES/NO**

Availability may include the means, budget, and permission. Do you have a schedule conflict? Are there any financial constraints such as budget or spending limitations? Are you working on another project that has a higher priority? If you are not available on the dates requested, you may provide alternate dates for consideration.

Question 2: Are you free of any conflict of interest? **YES/NO**

For internal company audits, it is impossible to be totally independent. Based on the situation, you will need to declare any potential conflict of interest. For internal audits, acceptance of gifts as a cause for a conflict of interest is unlikely. Employee relationships and auditing your own work are the two major areas that could result in a conflict of interest.

Audit Principle: Be honest and impartial by avoiding conflicts of interest.

Examples of conflict of interest are:

1. You are being asked to audit something you developed.
2. A close friend or relative works in the area.
3. You are currently doing other work for the department or area being audited.
4. There is bad blood or personality conflict with personnel in the area to be audited
5. There has been acceptance of, or promise of, a gift having value.
6. You are a previous employee of the department or area to be audited.
7. You have a previous close working relationship with the people in the area to be audited. (Note: Some audit programs require a waiting period before auditors can audit prior work areas).

Be objective and impartial

Internal audits by their very nature may make it impossible to avoid all conflicts of interest. For internal audits, you should **be on your guard for any biases** that could cloud your judgment. However, properly collected facts speak for themselves regardless of any potential bias.

Also, some **audit program situations are more formal than others depending on the organizational needs**. For example, you may be a full- time compliance auditor that works for the Regulatory Compliance Director who reports directly to the President. Independence from the area to be audited is not only desirable; it may be a regulatory requirement.

In other situations, auditors may only be part-time and normally have other full-time duties. For example, you may work in the logistics, quality, or purchasing department and only conduct one audit each quarter of the year. A potential conflict of interest may be more likely to occur when part-time auditors are used. What is important to remember here is: **The goal is to ensure audits are conducted in an objective and impartial manner**.

Organizational culture plays a major role in determining the amount of independence needed to assure objective and impartial audits. In some organizations, relationship issues are not a concern because everyone is expected to be open, honest, and willing to change as part of their team contribution.
Conflicts of interest may shed doubt on the objectivity and impartiality of audit results. **This will adversely affect the integrity of the entire audit program.**

Question 3: Do you feel you can do a competent job? **YES/NO**

Do you feel comfortable auditing your assigned area against the standard selected? If you have been trained and qualified by your organization, you should be able to do the job. However, perhaps you were assigned the Computer Information Systems Technology Solutions Group (CISTSG) and you are still trying to figure out SD chips, USB ports, URL addresses and RWs. Or, you may be missing a certification or clearance rating. If so, let the lead auditor or audit program manager know. For a system audit, you need to understand the requirements in the system standard being audited against and a general understanding of how the area you will be auditing operates.

For example, you would need to interpret the requirements in ISO 13485 and their application. For a process audit, you will need to understand the procedures and the process being audited. For example: You were going to audit the coatings process, you should be familiar with good coating practices

Audit Principle: Assigned auditors must be competent/ qualified.

If you can say yes to all three questions, accept the assignment with enthusiasm.

2.2 Conflict of Interest

Code of Conduct

Last, but perhaps the most important, is that auditors must adhere to a code of conduct. Auditors should be willing to sign and attest their willingness to abide by a code of conduct. An Auditor Code of Conduct has been provided for you to sign as a handout link below. If your organization does not already have a code of conduct, print it, sign it and turn it into the audit program manager or person over the audit function.

Please review, print, and sign the Auditor Code of Conduct, if appropriate.

Internal Auditor Code of Conduct

1. I will be honest and impartial
2. I will hold paramount the safety, health, & welfare of the public in the performance of my duties
3. I will perform my duties in a professional manner by following procedures and doing what is reasonable and normally expected
4. I will perform services in areas that I am competent
5. I will not represent conflicting or competing interests and will disclose to any client or employer any relationships that may influence my judgment
6. I will not accept any inducement, commission, gift or any other benefit from the auditee or competing organization
7. I will not intentionally communicate false or misleading information.

Name:..... Date:.....

Signature:.....

3 Audit purpose, scope, and other inputs

Learning outcomes:
- o Determine the meaning of the audit purpose
- o Determine the meaning of the audit scope

3.1 Information Needed

You will need certain basic inputs before you can plan for the upcoming audit. Note: A desk audit is an evaluation of specified documents.

The schedule
You will need to know the time and place of the audit so that you can make needed arrangements. Being at the audit site can range from walking down the hall to flying from the east coast to west coast operations.

What area(s) are to be audited? - What and Where

Will you be auditing administrative processes such as records control, or technical areas such as research, or operation areas such as production, loading, or treating? The **scope may reference location, product line, market, customer, function, department, realization process**, and so on. How much of the organization will be looked at and how many departments will be involved? If it is a multiple shift operation, all shifts may need to be audited (may involve evenings, nights and weekends). All auditors need to know the parameters of the audit investigation.

Once the audit starts, the scope should not be changed. Only the audit boss (client) can change the scope of an audit once it is agreed upon. **If the scope is changed, auditors should be given sufficient time to prepare for the new requirements.**

3.2 What and Where

What standards are you auditing against? – What

You need to know which standard(s) or which elements of the standard you are being asked to audit against. Auditors do not make up the rules, auditors audit against existing rules, requirements, procedures, instructions, etc.

The requirements can be found in documents. A popular approach is to think of documents as coming from different levels (see diagram).

You will be told which standards to audit against. However, your assignment could be very general and only state, "Audit against standard XYZ and the company's quality system documents." This leaves you

with the responsibility of specifying the applicable quality system documents and clauses of the standard that apply.

A convenient way of thinking of documents is where higher level requirements flow down to lower level requirements.

As an auditor, you are also responsible for understanding the requirements in the standards and documents being audited against. If you are not familiar with the standard(s) or quality system documents, it will be necessary to take a training class or to initiate a self-study program.

When possible at least two document levels (see document level triangle) should be audited. An example is auditing against requirements in both the ISO 9001 standard and procedures.

Some audits use an entire standard and some audits use only one element (clause) of a standard. If you have been assigned as lead auditor of an audit team, you may be given the standards to audit against such as ISO 9001 and quality management system documents (procedures). Then, it will be up to you to make individual audit team member assignments (Paul gets clause 8 and Rachel gets clause 6).

Also, note that the 'process approach' could have the scope of the audit expressed as a number of key business processes of the organization. In this case, each auditor would audit the requirements that pertain to each process (Paul gets the Purchasing Process and Rachel gets the Calibration Process).

What is the purpose (objective) of the audit? – Why

This is **the why** of the audit. By definition, the purpose of **an audit is to determine the extent to which agreed-upon criteria have been met**. In regulated industries and organizations that have registered quality systems, audits are used to **establish conformance or non-conformance** to standards. For example, 1) conformity may result in registration of the quality system, supplier approval, or product license and 2) nonconformity may result in suspension of registration, supplier disapproval, or license suspension.

When you get the assignment, you should also be told the purpose (objective) of the audit.

Example purpose statements for internal audits:

- To determine the finishing area's adherence to ISO 9001 and QMS procedures.
- To verify that X product is being processed in accordance with contract XYZ and cGMPs.
- To determine conformance to ISO 9001 for purposes of preparing the area for an external compliance audit (registrar, government agency, certification body).
- In general, the purpose of a system or process audit is to determine, confirm, and verify compliance to the audit criteria.

Need for other Audit Services

Other internal audit services may be requested and may be included in the purpose statement. Other purposes can include:

- Verifying that corrective actions from prior audits are implemented
- Assessing progress toward implementation of a quality/environmental system
- Assessing progress of project implementation at one or all locations

- Identifying areas for improvement
- Evaluating capacity to ensure compliance
- Evaluating effectiveness of meeting management objectives
- Assessing process validation status
- Preparing for a customer audit
- Assessing on-site supplier services (e.g., observe calibration checks or equipment maintenance)
- Training new auditors

Be sure to plan your time according to the work required.

Key questions and concerns should be resolved by the lead auditor or audit boss before the audit.

4 Preparing for the Audit

Learning outcomes:

- Learn the responsibilities of the audit team
- Match audit team members with the audit purpose/scope
- Make final arrangements with the auditee using the given audit information

4.1 Audit Team Members

The audit team may be one person or a team of two or more. The lead auditor or audit team leader and audit program manager are responsible for ensuring there are sufficient resources (i.e. auditors) to accomplish the purpose for the defined scope. If the purpose, scope, and resources don't match up, one of them must be changed (e.g., add more auditors, reduce the scope, change the purpose, etc.).

Team member responsibilities

The number of auditors selected must be sufficient to carry out the audit for the time allocated. Some organizations publish guidelines for determining the audit time needed for a certain purpose and scope. If the guidelines required two audit days, two auditors should be able to complete the audit in one day. If no guidelines exist, **audit days may be estimated by the lead auditor or audit program manager**. The availability of the auditors, schedule conflicts at the auditee area, and many other considerations must be factored in to come up with the number of audit days on site.

Audit Principle: Ensure sufficient resources are available to accomplish the purpose of the audit.

Audit team members are responsible for **gathering** audit evidence of conformance or nonconformance of the area audited. Audit team members **analyze data** and report nonconformities to the lead auditor. Audit team members report to the lead auditor.

Every audit has a lead auditor, even if there is only one person conducting the audit. The lead auditor is **responsible for preparing the audit plan, conducting opening and closing meetings, analyzing all findings to be reported, and preparing**

and submitting the final report. The lead auditor is responsible for performance of the audit team and for initiating and maintaining communication with the audit program manager and auditee organization (unit). The lead auditor normally reports to the audit program manager for matters concerning the audit.

4.2 Planning

Contact the Auditee and Issue an Audit Plan

As the audit date approaches you will need to contact the auditee. Making contact to **confirm the upcoming audit is important**.

This will avoid any miscommunications about the time of the audit and what is going to be audited. You should always follow your organization's guidelines for when and how you contact the auditee. Some organizations may require contact a month in advance and others may require only two weeks.

The **lead auditor has the responsibility to make the final arrangements**. If you are on a one-person team, you are automatically the lead auditor.

When you make contact, go over the following audit information:

- Scope
- Purpose
- Standards and procedures that will be audited against
- Audit team members
- Overall audit schedule for the area (start and end times)
- When to expect the final report

Some organizations conduct surprise or unannounced internal audits. This may be a management preference or company policy to practice for unannounced regulatory agency audits.

Surprise audits are normally compliance audits that emulate the same methods used by regulatory agency auditors. The surprise compliance audit helps ensure the organization is in a state of readiness for external oversight and is normally limited to that objective.

However, whether it is two weeks or two minutes, the lead auditor is responsible for contacting the auditee to confirm the audit schedule

4.3 Communication

The **schedule should be mutually-agreed** upon so that there will be no surprises. **Never just show up and start an audit** unless conducting a surprise audit is a mutually agreed upon audit strategy.

There are some situations in which management may request a surprise audit (e.g., to uncover wrongdoing). Because of their nature (we don't trust you), surprise audits can create a "we (the auditee) versus them (the auditors)" mentality if not properly managed. The **auditee should be notified in advance** of the planned audit.

Before the audit (at initial contact or later) you should **obtain any needed documents and records or determine their location**. Be aware that some **documents and records may need to be safeguarded**. Some information is sensitive and may have restrictions for legal, competitive or security reasons.

Audit Principle: Protect auditee property entrusted to you.

Audit plans

For internal audits, it is also perfectly okay to ask the auditee representative if there is something in particular they want the auditors to examine within the scope. This could be a new process, a change since the last audit, historical problem area, or source of recent complaints.

Even though the scope of the audit is not being changed, the auditee's needs may be a factor in your interview and sample plans. If additional audit time is needed, contact the audit program manager.

Follow-up your contact with the auditee by issuing the information as an Audit Plan, sending a copy of the work order (if there is one), or including the information in a message to the auditee (memo, notification letter, e-mail). The amount of formality depends on your organization's situation and culture.

Audit Principle: Communicate agreed upon information to auditee such as audit times, purpose, areas to be audited, and standards to be audited against.

If you want to be formal, send out a notification letter along with the audit plan. According to our formal audit rules, the **notification letter should be signed by the client**.

There should be an audit plan for every audit. It may be thought of as your contract with the auditee. It spells out the parameters for the auditing service.

Before you start auditing make a list of the information, documents, records, standards, etc. that you will need.

5 Identifying Requirements and Planning

5.1 Audit Criteria

No one is born with the knowledge and skill to conduct a proper audit. Auditing is the application of various techniques to collect factual evidence relative to the standard being audited against. Auditing can be hard work, but if you are successful in confirming conformity or identifying opportunities for improvement, you will feel a great sense of accomplishment.

Auditing Objectives
Looking at the definition of an audit and ISO 9001, Internal Auditing 9.2 clause, we can identify two primary audit objectives for determining compliance/conformance:

- Determine if extent of conformity or compliance of the system or process to the defined audit criteria is adequate. The audit criteria may be internal documents such as procedures, work instructions, or external documents such as ISO 9001, TS 16949, ISO 13485, AS9100, GMPs, OSHA, FAA, Corporate Policy, etc.
- Determine whether the management system controls are effectively implemented and maintained.

Adequate?
Adequate means the designed controls (procedures, methods, manual) of the organization are sufficient for specified requirements (e.g., ISO 9001, IATF 16949, TL- 9000, GMPs, FAA, etc.).

Requirements Technique
Implemented and maintained means the controls are deployed and people are following the rules (procedures, methods, manuals). Is there ongoing adherence to the rules?
When there are higher level requirements (such as in ISO 9001, GMPs, EPA Regulations), you should check to see if the auditee has addressed the requirements in some manner.

Every place where there are required actions or promises in organizational procedures, work instructions, or other methods, you can check to determine if they have been implemented and maintained. This technique is called the Requirements Technique. This is also called the Element Technique because elements (i.e., clauses) of a standard are selected and used as the audit criteria. For example, if a department is required to calibrate their inspection devices, you could audit them against the ISO 9001 clause 7.1.5 on Monitoring and measuring resources.

Every place where there is a requirement for a tangible deliverable such as a schedule, record, procedure, flowchart, and/or log, you can check to ensure it exists. When procedures are required, you can verify they exist and that they have been implemented and maintained. This technique is very efficient and traceable to each requirement.
Process Approach Technique

However, when requirements are vague (do your best to keep the kitchen clean versus run the dishwasher and sweep the floor everyday), the effectiveness of the Requirements Technique starts to breakdown because auditors and auditees may be unsure of what the requirements mean. Other techniques must be used such as the Process Approach Technique or PDCA Technique to ensure auditees are in conformance with the standard requirements.

The process technique could be described as:

1) Is there a plan or method to keep the kitchen clean?

2) Is it being followed?

3) Is the process monitored against acceptance criteria?

4) Is action taken when outputs do not agree with the acceptance criteria?

When requirements are vague, auditors should employ the process technique. However, most standards have prescriptive requirements that organizations can be audited against. **Auditors should be prepared to employ several techniques during the investigation**.

The Requirements

Requirements come from many different sources. Your organization adheres to **mandatory regulatory requirements, customer imposed requirements, contractual requirements, and self-imposed requirements**. For most internal audit programs, someone has already decided which requirements you should audit against and may provide a ready-made checklist for you to use. However, you need to be able to recognize a requirement (know it when you see it) because **all auditing requirements must be traceable** to a source.

Many formal standards such as ISO 9001, CFR 820 Quality System Regulation use auxiliary verbs (see image below) to identify a requirement as well as degree of compliance. Some auxiliary verbs may denote mandatory compliance while others are used to denote suggestions or guidance. These auxiliary verbs are used as indicators of the importance of certain requirements.

Authoring conventions

However, there is no guarantee that the standards you are going to audit against follow the above conventions and there is no requirement to do so. When you read a standard or procedure, you should be aware of the authoring conventions being used.

Internal organization procedures may not follow any set convention. When there is no established convention, auditors should look for the action verbs (i.e., the 'to do' statements) to identify what was promised or required actions. For example, there may be several requirements in the following procedural step:

> 6.4 The person assigned the CAR investigates by collecting data to determine the cause(s) of the problem (nonconformance, complaint). The person assigned (or team) determines the cause(s) and the results of the investigation must be recorded on the CAR form. Reference: Excerpt from a Corrective Action Procedure.

Document triangle

Requirements are found in different documents issued from different levels within and external to the organization. A popular practice is to depict the documents in a triangle with external requirements being at the top and internal detailed instructions at the bottom.

Variations of the document level diagram are to number the levels zero through 3 instead of 1 through 4. Some also include records as a document in level 4. Dictionary definitions would support that a record is a type of document, but many professionals in the quality field find it less confusing if documents and records are considered to be in two separate categories. Many consider a document as something that happens before an activity (plan) and a record as something that happens after an activity (results).

An auditor can audit against requirements in external standards such as ISO 9001 or internal self-imposed controls (see document triangle image). What an auditor should never do is to make up the rules they think the auditee should comply with.

Audit Principle: Verify conformance to agreed upon requirements (the rules). Auditors don't determine auditee requirements.

5.2 Checklists

A **checklist is an important auditor tool** that is used to match what the auditee is supposed to be doing with what is actually being done. A checklist is like a grocery list. You write down the items you are going to check for and you prepare the list before you go to the store. It also provides a place to put your notes, keep track of your interviews, and record observations (evidence). The checklist should be designed to help you, the auditor, during the performance phase of the audit. A checklist **may contain questions or statements**, but all should be **linked to a requirement**. An auditee has every right to ask for the source of any requirement they are being audited against. You should be able to respond chapter and verse with the standard, procedure, clause, paragraph, and so on.

You may be provided a canned or pre-made checklist, but you must still know how checklists are constructed and how to add questions that need to be answered by the auditee.

Checklist purpose

The **purpose of a checklist is to gather information**. It helps guide the investigation and provides a place to record information. A checklist can be questions, a series of statements, or even key words organized in an outline, spreadsheet, flowchart, or tree diagram.
A technical approach to writing checklist questions is that they be yes-no and single issue.

Review the requirement below and be prepared to identify one or more single issue yes-no checklist questions based on the requirement from clause 8.5.3.

Requirement 8.5.3:

When property of the customer or external provider is incorrectly used, lost, damaged, or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider.

Checklist structure

Keep in mind the suggestion in the image below when creating checklists.

The checklist should be properly identified (page, version, title) to include your referenced question or statement and allow space for collection plans and recording observations. A good practice is to include checklist questions from at least two document levels (e.g., ISO 9001 and departmental procedures).

Read over the following paragraph found in the operating department's procedure for marking and tagging. While reading the paragraph, note places where the operating group made promises (established requirements) of things they were going to do.

Think of at least three yes-no single-issue checklist questions (more are possible). Then compare your answer questions to the image below.

Questions for each requirement

Discovering how many checklist questions can be generated by a simple paragraph is surprising. See if you can guess the answer to the following questions and then click the question to see the answer.

Who do you want to talk to (interview)?

What do you want to touch or see (audit evidence)?

Now, when you go to the area where they keep defective items, you will know exactly what to look for and listen to. As you are observing and listening to the people in the area explaining how they mark and tag, you are getting your checklist questions answered. This technique is thorough, traceable, and probably the key to successful and effective audits.

If the auditee asks to see the checklist, it is normally okay to share blank checklists. However, you should not share any data collection or sample plans that might provide advance information concerning the audit evidence you plan to collect. Your checklist does not normally go in the final report, but there may be a requirement that it be filed with other audit working papers.

A checklist is a tool

Canned checklists (like pre-made checklists or off-the-shelf checklists) may not provide the flexibility that you may need for a specific audit. **Canned checklists are good to use for comparison purposes** such as different suppliers or comparing operating organizations. When internal auditors are given these pre-made/canned checklists to use, they should **study and understand the pre-made checklists prior to the audit**. Internal auditors should also be ready to augment the pre-made checklist questions based on the controls being examined during the audit.

5.3 Sampling Plans

You should determine what it is that you need to see during the audit (data collection) in order to verify controls are being followed. You can put that information in the checklist or keep it separate. A **collection plan is the list of what you want to see** such as purchase orders, defective items, and inspection records. A **sampling plan specifies how many and what samples** you need to look at such as the kind and number of purchase orders, defective item reports, and inspection records.

Audit Principle: Ensure sufficient samples (records, product, processes, interviews, etc.) are taken to match the purpose and scope of the audit.

Auditors must choose the samples they require unless it is a 100% examination. For example, if you need to verify that customer complaints are recorded and there were only three complaints this quarter, you can examine all three of them.

Audit Principle: Samples must be random and representative unless specified objectives require otherwise.

Working papers - working documents

Working papers include checklists (discussed earlier), guidelines, log sheets, forms, sampling plans, flowcharts, and **anything that will aid you in conducting the audit**. Some examples are:
Working papers may not be papers at all. You can use electronic media as well as paper media. You may create your own working papers or they may be given to you by the audit program manager.
There are two basic rules for working papers:

1. **Working papers must be flexible** and not detract from the effectiveness of the audit. If the use of a form restricts an auditor from doing the best job possible, the form should be redesigned or deleted.
2. **Working papers must be safeguarded**. In some cases such as sampling plans, working papers must be safeguarded from the auditee. In other cases where working papers contain sensitive information about an auditee organization, they must be safeguarded from outsiders.

6 Desk Audit and Audit Strategies

Learning outcomes:

- Complete a desk audit
- Construct a flowchart
- Compare element and department methods

Before the onsite portion of the audit, you must become familiar with the controls used in the area to be audited. The familiarization could be 1) a formal document evaluation (desk audit) and report, or 2) reviewing documents to add questions to your checklist, and/or 3) flowcharting processes to help in your understanding of them.

Auditors should use various techniques to understand the system and processes they will be auditing.

6.1 Complete Desk Audit

Desk Audit/ Document Evaluation

Auditors evaluate documents to ensure the auditee's management system (controls) are adequate to meet higher-level standards or guidelines. You can sit at a desk or table and **compare the auditee's documented management system to the requirements of the standard(s)**. Desk audits (document evaluations) are normally **conducted when there are either new requirement standards or changes to your organization's management system controls**.

Document assessment
When it is not clear that high-level requirements are addressed by lower level documents (procedures, work instructions, etc.), you must **determine if the intent of the requirement is addressed**. Then later during the performance phase, that intent can be tested and confirmed. Not all requirements can be verified as a result of a desk audit because not all requirements require traceability to a controlled document (any medium). The desk audit helps prepare you for the on-site investigation.

To conduct a desk audit, you must first create a checklist or acquire one from the audit manager of the higher-level standard(s) (performance standards, contracts). Then, for each higher-level standard requirement such as ISO 9001 or ISO 14001 you check off where you found the requirement addressed in the auditee's quality management system.

Some requirements are very clear such as a requirement for a procedure. If the desk audit reveals that no procedure has been issued, there is a basis for a nonconformity. Similarly, if there is a requirement for record or review and there is no provision in the management system for a record or review, there is a basis for a nonconformity.

Nonconformity

There is a potential nonconformity if the requirement (intent) is not addressed in the organization's documents. If you find several major nonconformities, there may be reason to cancel or delay the audit. As an auditor, you cannot audit a system that does not yet exist. There must be a system or process,

it must be implemented, and there must be records that the system has been maintained for a period of time.

Audit Principle: Verify there is an established system/process to audit before the audit.

People have characterized a new procedure by saying the ink is not dry yet. An auditor cannot determine if a procedure has been effectively implemented and is working unless it has been used for a period of time.

Your organization must determine what that period of time should be. For me, 30 days is not enough. Perhaps three months is sufficient. The bottom line is that if determination that a specified control has been effectively implemented and it was just published, you can only conclude the procedure exists.

If a procedure cannot be determined to have been implemented and that it is working, such a situation could result in rescheduling the audit to not waste resources.

1. **Read the standard requirement:**

Requirement Clause: The organization shall react to the nonconformity, and as applicable, take action to control and correct it, and deal with the consequences. The organization shall evaluate the need for action to eliminate the cause(s) of the nonconformity... by reviewing the nonconformity, determining the causes of the nonconformity, and determining if similar nonconformities exist, or could potentially occur. Corrective action shall be appropriate to the impact of the problems encountered.

2. **Next, read the corrective action below:**

ISO 9001:2015, International Organization for Standardization, Clause 10.2

8501 Corrective Action Procedure

1. Purpose To establish controls for taking corrective action on identified problems or negative trends identified through analysis of quality records.
2. Scope This procedure applies to internal or external concerns relating to quality, reliability, safety, or performance of any product or service offered by the company. Specifically, the procedure covers action to be taken when there are nonconforming product (including purchased product), customer complaints, audit findings, and negative trends identified from analysis of quality records (to include complaints, findings, nonconforming product reports, work processes, concessions, and service reports).
3. Responsibilities All employees have the responsibility to initiate corrective action requests for known problems. The quality assurance manager is responsible for establishing, implementing, and maintaining the ongoing effectiveness of the corrective action program.
4. Reference Documents Purchasing Procedure 7.401 Control of Nonconforming Product Procedure 8.301 Internal Quality Audit Procedure 8.201 CAR form F8.508
5. Definitions Remedial action: an action taken to alleviate the symptoms of existing nonconformities or any other undesirable situation. Corrective action: an action taken to eliminate the cause(s) of existing nonconformities (problems) or any other undesirable situation in order to prevent recurrence. Corrective action will include actions taken to prevent recurrence.
6. Procedure

- 6.1 The person who detected the problem (originator) should initiate a corrective action request (CAR) form. Problem sources include supplier nonconformance, internal nonconforming product, customer complaints, audit findings, and the results of analysis of quality records. The CAR form should be forwarded to the quality assurance manager.
- 6.2 The quality assurance manager logs and reviews the CAR to assess the magnitude (importance) of the problem. If the problem is assessed as significant, the quality assurance manager then assigns an employee to resolve the problem and requests a corrective action plan within a certain time frame (depending on the complexity and importance of the problem). The CAR is forwarded to the employee assigned the corrective action. For audit findings, the CARs are automatically assigned to the area that was audited.

- 6.3. Example ends here.

Determine:

- if the corrective action procedure adequately addresses the requirements of the standard (above) and,
- where in the procedure were the requirements addressed.

Desk Audit

The desk audit report can be a list of nonconformities referencing the requirement or the checklist itself can be used to indicate (YES/ NO) requirements not addressed in the quality management system documentation.

Other documents that can be used to better understand the organization to be audited are prior audit reports, history of performance, and records.
Resolve any concerns about the adequacy of the quality system or quality process before you proceed.

Note: Creating a document evaluation master cross-reference map is an opportunity for improvement for your organization.

6.2 Construct Flowchart

Flowcharting is a wonderful technique to help you **understand the system or processes you will be auditing**. You can use flowcharts to bring confusing procedures to light or to understand the key elements of the process you are about to audit. A flowchart is the primary tool used to perform a **process approach** audit.

The purpose of a **flowchart is to describe a process or system** (e.g., how work is performed). Flowcharting is like drawing a picture.

There are many different flowchart styles and techniques. Flowcharts can be constructed using pictures and/or symbols and put in horizontal and vertical arrangements. Flowchart symbols can be found at ANSI/Y15.3.

To construct a flowchart:

- Define the process steps by brainstorming (new process) or from a reference document (existing process).
- Sort the steps as they occur in the process.

- Place a box or the appropriate flowchart symbol around each process step.
- Evaluate the steps for completeness, conflicting or useless steps, duplication of effort, and other inefficiencies.

Tips

- You may observe some manufacturing flowcharts starting with the incoming raw materials. This approach is technically correct, but starting with the need or customer requirements is more powerful. After all, a product or service is only provided to meet a need upon demand. This helps to ensure the organization remembers why they are doing it and maintains a customer focus.
- Limit the number of blocks so that your chart is not too complicated. If there are many blocks, move to higher-level controls. For example, instead of showing the 12 detailed steps for the product transformation or service delivery, simply block it as stamping, forming, reacting, finishing, cleaning, account transaction, and so on.
- For auditing, you will be most interested in checkpoints where a decision is made or should be made. Outputs of processes should meet a predetermined criteria to know the output is acceptable. If the output does not meet the criteria, something has to be done about it.
- Your flowchart should also contain who does what. This will help you know who to talk to about an activity or step.
- Add any documents that relate to an activity and records required to be done about it.

Understand the process/system

Starting with the customer (need) is exactly how standards using the 'process approach' (such as ISO 9001) are organized.

Auditors should use various techniques to understand the system and processes they will be auditing. Besides the desk work (reviewing procedures and flow-charting), auditors can tour an area beforehand to better understand how the work flows.

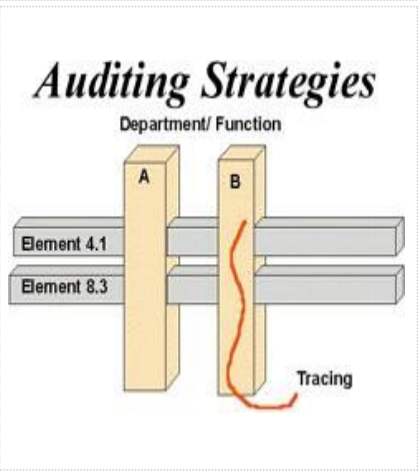
- **Auditing Strategies**

As an internal auditor, you may be assigned a process, area, function, or department to audit. Or, you may be assigned a common element such as document control or corrective action to audit in one area or across several departments.

These are called element, departmental, and process approach strategies.

- **Element** approach is horizontal and is auditing according to the standard element. Good for linkage to standards. The element approach has been abused in the past and resulted in very narrowly defined audit scopes (audit final testing or review of customer orders). New auditing approaches suggest the element approach should be limited to common system elements such as the corrective action process.
- **Departmental** method is vertical and is auditing according to each department or function. Good for accountability.
- **Process approach** method is horizontal and cuts across departments as it follows the natural flow of the process through the organization. This audit takes an example(s) and follows it from start to finish through the process and audits all requirements (e.g., all applicable clauses of ISO 9001) that impact upon that process.

Normally, the person scheduling the audit will decide what strategy to use and where.



When you audit the **element, department, or process, you can use tracing** techniques to examine the controls. **Tracing** is used to follow the path of a process (procedure or method) to test out controls. You can trace the process forward or backward. As you trace, you can ask questions about the procedure or process and get your checklist questions answered.

For example: Tracing will work for how a document gets changed, how a part is finished, or how a service is conducted. If you are uncertain of conformance or nonconformance, tracing can be used to verify that the requirements are either addressed or not addressed by the auditee.

At times, tracing may take you to other departments to verify an input or output of the area you are auditing. However, you must ensure the auditee understands that this is part of the audit scope and not an attempt to move outside the agreed purpose and scope.
For example: If the scope is production controls, a switch to checking calibration in the lab could be perceived as moving outside the original scope.

6.3 Scope issues

Audit Principle: Stay within the agreed scope unless risk necessitates other actions.

Once the scope is set, you should stay within the scope and use your judgment when problems are found outside the scope. An auditor has an obligation not to ignore problems found outside the original scope.
Method to handle **problems outside the scope**:

1. Determine if the problem is **major or minor**.
2. If minor, report to the auditee and continue auditing within the scope.
3. If major, report to the lead auditor (audit program manager if you are the lead auditor) and auditee management. Determine if the situation warrants further investigation, if the audit should be stopped, or if the audit should continue within the original scope.
4. Report major problems found, but it is not necessary to put them in the audit report as a nonconformity.

Scope guidelines

Finding problems outside the scope that require your immediate attention is unusual, but you must be prepared for it. Certainly, events that could result in personal injury, hazardous spills, fire, or shipping

defective product require immediate attention. How you handle yourself in such situations may be scrutinized by auditee management.

When auditors stray outside the agreed scope, it may appear to the auditee that the auditor is on some type of witch-hunt or is trying to trick the auditee. It can also be upsetting to the auditee when they expect one type of audit and get another. Some auditees may become frustrated and even hostile.

7 Beginning the Audit

Learning outcomes:

- Conduct an Opening Meeting
- Conduct other audit meetings

In the last lesson, you made your final preparations for the audit. You are now ready to start the performance phase. You are ready to collect evidence to verify that people are complying with external standards and internal procedures. The opening meeting represents the start of the performance phase and **establishes the official communication links** between the audit team and the auditee.

7.1 Opening Meeting

The **lead auditor is responsible for the opening meeting**. As lead auditor, you will need to assess the need to determine how formal the opening meeting should be.
Generally, opening meetings for internal audits are less formal than opening meetings for external audits. The lead auditor is in charge of the opening meeting. The purpose of the opening meeting is to confirm the audit plan, verify communication channels, provide a summary of audit activities, and answer auditee questions (ISO 19011:2011, clause 6.4.2).

You should always **schedule an opening meeting**. Even if this is a routine system audit, it is common courtesy to let everyone know that the audit team is in the area and what your plans are for the audit. If the audit is routine and everyone knows what to expect, you can keep the meeting short. A short meeting may be held in the supervisors office and take less than five minutes. A more formal meeting should be held for larger audit scopes, when the audits are not routine, and when risks are higher. A formal meeting may be held in a conference room and take 30 to 60 minutes.

The meeting **ensures that everyone is aware of the audit and allows any last-minute issues to surface**. If it is an audit of a new area or there are new people involved (new to the audit process), then expect the meeting to take longer.

You should keep a **record** **of who attended** the opening meeting. Some auditors pass out a sign-up sheet. You should also **record any audit plan changes** or concerns by the auditee. The agenda items in the next section should be key discussion points.

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7.2 Audit Methods

Audit Principle: Comply with auditee rules (safety, environmental, health, restricted area, etc.).

Audit methods and techniques: Explain how **data will be collected such as review of records, observations, and individual interviews**. For mature audit programs, it may not be necessary to cover this agenda item for every audit. You may simply ask if there are **any questions about how the audit will be performed**. Be prepared to explain your approach to sampling (i.e., random or directed). If you are likely to audit more than one area using tracing techniques, explain that, too.

Informing.
Reporting process: Explain how the data collected during the investigation will be reported and followed up. The results of an audit may be reported
as nonconformances or noncompliances. **Explain how the relative importance of results are categorized such as major and minor nonconformances**. For routine audits, everyone should already be familiar with the reporting process.

Establish the Interview schedule: For routine audits where everyone is expected to be available for the auditor, the schedule may simply be a time period (interviews 9 to 12). However, most organizational cultures require formal interview schedules. Be sure to follow your organizational guidelines. Confirm the availability of personnel (interviewees) and **resolve and record schedule changes or limitations**.

An Example Audit Schedule:

Detailed Audit Schedule for Home Office Audit - Issue 3

Assignment	Area/ Function	Contact	Auditor	Date/ Time
DAY ONE				***Oct. 27th***
Auditor Team Meeting	2nd Floor Conference Room		ALL	8:00-9:30 am
Opening Meeting	2nd Floor Conference Room	Selected by Management Representative	ALL	9:30-10:00 am
8.4.1Purchasing & QMS 7401		Dennis Power, Manager	JR	10:00-10:30 am
8.4.1, 8.4.2, 8.4.3 and QMS 7401		Daniele Cable, Buyer	JR	10:00-11:00 am
7.5.1, 7.5.2, 7.5.3, and QMS 4232		Department Coordinator	JR	1:00-2:00 pm
8.4.3 and QMS 7405	Issuing POs	Bob Port, Clerk Dave Beam,	MH	10am-12 Noon
8.4.2 QA 7439	Receiving Inspection	John Transom	MH	1:00-2:00pm
Prepare Report	Conference Room		ALL	2:00-3:00 pm
Exit Meeting	Conference Room	Auditee Personnel	ALL	3:00 pm

Review logistics: Verify meeting room locations and homebase for the auditors with necessary equipment and services (i.e., electrical power outlets, rest rooms, telephones, etc.).

Confirm exit meeting: The exit meeting is very important so it deserves special mention. **Confirm the date and time of the exit meeting** and who will be attending. You should also verify the times of any interim meetings.

Professionalism

How you handle yourself and your presentation techniques in the opening and subsequent meetings will have a significant effect in setting the **tone** for the audit (attitude). An audit, whether internal or external, is **always serious**. Internal audits may be less formal, but the process of interviewing, probing, and examining to judge conformance or nonconformance should be done in a **cordial business-like** manner.

The audit team should meet with the department manager, supervisor, or the area coordinator who arranged for the audit. Exactly who attends the opening meeting may depend on the organizational culture and upcoming events. If the organization is due for a visit from a regulator or registrar, managers may use the audit experience to prepare their personnel.

If the auditee provides escorts for the auditors, the escorts should be at the opening meeting, too. Many internal audit programs don't require internal auditors to be escorted, but there are exceptions. Company proprietary issues and organizational culture could result in the need for escorts.

Escort
If an escort is provided, he/she may perform the duties listed in the image below.

Share information and end meeting
Sometimes, senior management attends the opening meeting to show support for the audit program or because they are deeply concerned with the performance of the area to be reviewed. Your organization may have guidelines for opening meetings that need to be followed.

In addition, the lead auditor can also:
- **Share the checklist with auditee** (if not sent earlier)
- **Identify needed documents or records to be supplied by the auditee**
- Explain how improvement areas will be reported, if at all
- Identify any union - management issues

At the end of the meeting, the lead auditor should ask **for any questions or items that need to be clarified**. For routine internal audits, you may only need to let the auditee know you are ready to start, confirm the interviews, and establish a report time.

Tip: Meeting time is not audit time. You are not collecting data to verify compliance while you are in the opening meeting. Keep meetings short, don't let the auditee take over meetings, stay focused, and get busy auditing.

Other meetings during the audit
If the audit lasts more than one day, you should schedule **daily meetings** to keep the auditee informed of your progress. You will also need to schedule **audit team meetings** to coordinate the audit. The timing of the meeting is at the discretion of the lead auditor. Meetings should be as brief as possible.

Working Papers
Auditors may use several different forms and documents called working papers to help them perform the audit. Working papers may be provided by audit program management or created by the auditor. Examples of working papers:

The working papers represent a place to record data and to provide guidance during the audit.

8 Data, Collecting Evidence

Learning outcomes:

- Compose a data collection plan
- Examine documentation
- Conduct interviews
- Conduct a physical examination of the area being audited
- Verify
- Validate

The purpose of the performance phase of the audit is to collect audit evidence. Conformance or nonconformance is determined by the audit evidence collected.

Match requirements with evidence

Your job is to collect factual evidence of conformance to requirements. Requirements are found in standards, procedures and other documents listed in the audit plan. The requirements you audit against are called the audit criteria. Audit criteria can include: ISO 9001, ISO 14001, FAA or FDA regulations.

The vast majority of audits are conducted to determine the degree of conformance to national/ international standards and organizational documents (policy, procedures, instructions).
You should collect data (evidence) according to your collection plan.

8.1 Data Collection Plan

The data collection is your compass for gathering evidence. You will need evidence from:

- documents and records - review procedures and examine records
- physical examination - you count it, it is tangible
- observing activities - watch what is going on
- interviewing - talk to people connected with the process

As part of the preparation for the audit, you reviewed documents (procedures, flow charts) that described the system or process to be audited. You should have made a **note of things that can be checked to verify an activity in your checklist or data collection plan**. During the audit, you may discover additional items that can be checked and should be noted, too.

Example checklist or data collection plan entry:
Procedure 7206, paragraph 3.11: When in the speed lab, check to see if customer complaints are filed by customer name and if they are on form 8201. Has the QA manager signed off as required by procedure? Check 10% of this quarter's complaints for product/ service related issues.

When reviewing documents, look for where promises were made. In particular, note promises that link with higher level standard requirements.

Examination of Documents and Records

Documents
Prior to the audit, **documents were evaluated to determine the adequacy of the system** and used to develop checklist questions. During the performance phase, documents may again be referenced to **verify process steps** or the proper sequence of activities.
Documents can be procedures, manuals, policies, or work instructions. Documents specify what should be done.

Documents should be checked:
1) to see if rules exist
2) to compare them with actual practice
3) to better understand the auditee's operation or business

Records
Records can be thought of as **specifying what has been done**. Checking records is one way to **verify performance standards are being followed**. Verification of requirements through records provides a very **high level of confidence** of compliance. People don't normally falsify records and if they do, they are subject to severe penalties.

Audit Principle: When unethical activities are observed, verify it, record it, and report it.

Records are created when someone observes data and places it on a form (records it).

Documents

The **Process Approach** is an effective way to verify controls where we can **flow-chart a procedure, then to trace the actual steps** of the procedure. All the while, be looking at records, interviewing people, observing work, and collecting physical evidence.

Document mediums and controls
Documents and records can be in **any medium such as electronic or paper**. If performance standards call for document and records control, there may be additional requirements for approval, removing obsolete documents, or establishing retention times, etc.
Since documents and records are such a big part of auditing, we have provided an article on Evaluating Document Control and a Document Control Checklist as supplemental job aids. The article is the handout that you can use the next time you audit document and record controls.

Interviewing People
Interviewing people may be the most challenging and rewarding part of audit performance phase. Some auditors view interviewing as a contest between the auditor and auditee with the auditor trying to find nonconformances and the auditee trying to hide them. That is the wrong approach and will promote conflict. You should remind yourself that you are on a **fact-finding mission** and the interview is just another opportunity to get the facts.

Many consider the interview as the most difficult part of the audit to do effectively. Dealing with people is always more of a challenge than dealing with inanimate objects. **Interviews provide very valuable information** that you may not be able to learn from other means. However, **interviewee**

statements are not as reliable as a written record. Interview information to be used in the audit report should be corroborated For third and second party audits, information should always be corroborated. For internal audits, you can normally **accept an admission of guilt** without seeking corroboration. If you have a question about your policy, check with the audit learder.

Be assertive, polite and professional
Being an effective interviewer requires assertiveness skills. If you feel this is an area that can be improved upon, you should consider taking a Learning to be Assertive course. Both aggressive and non-assertive (passive) auditor behaviors will result in ineffective interviews.
Why do you suppose both aggressive and passive behaviors don't work
While interviewing, note when the interviewee uses the words normally, most of the time or usually. These are red flags for you to ask about what happens when it is 'not normal.' The best processes function well even **when things are not normal or during a crisis.**

The interview
One-on-one, face-to-face interviews are preferred and usually the most effective. See image below for interview scenario outcomes.
When interviewing **more than one person at a time,** one interviewee may start answering for the other or the interviewees may team up against the auditor. If the auditor does not take back control of the interview, the interview information may be worthless. If the auditor takes back control of the interview in an abrasive or aggressive manner, the interviewees will become defensive or hostile. However, there may be times when **group interviews** are appropriate. For example you may want to interview an entire team to encourage team building and reduce individual stress.

Guarded

When **several auditors are interviewing one auditee,** the auditee can become defensive or overwhelmed. If you have a another person with you on the audit interview you should explain why they are there. It may be that the second person is there to take notes, be an observer, is a subject matter expert (technical specialist), auditor in training, or another auditor that will be asking questions (against a different criteria). When multiple auditors are interviewing one person, be very courteous and aware of over pressuring the interviewee. Some auditors can sense changes in interviewee moods and attitudes and can adjust for it.

Interview steps

The **Six Step Method** for interviewing, popularized by Dennis Arter, is a commonly accepted practice. Before starting the interview, you should remind yourself that you are a guest in someone else's area. At first, try to put the interviewee at ease. You may need to discuss the weather or a national news item to lower the interviewee's anxiety. Be polite, shake hands, introduce yourself and explain why you are there.

Listen and take notes
It is during step 3 (question and answer) that you are getting your checklist questions answered. Be sure to take good notes and keep a record of the responses.

Interview Guidelines:

1. Interview questions should be open-ended (e.g. ask, "What is the role of your area/department?" "What do you do?" etc.).
2. Ask to see the records or documents or other means to verify controls.

Listen, don't talk except to ask questions or paraphrase their answer.

Phrasing questions
It is not considered good practice for an auditor to ask yes-no questions in an interview unless you are specifically using that type of question as a technique to calm a person or to refocus on the topic. There are times during an audit when the auditor needs a yes/no verification, such as "Are you maintaining the records or not, yes or no." However, getting yes-no answers will not give you any additional data about how the requirement is implemented, the person's knowledge about the requirement or where to go to gather additional evidence.

Communication problems (between the auditor and interviewee) are probably the principle difficulty that must be overcome during an audit1. If you think you might benefit from some communication pointers, consider taking a course on improving communication skills.

Physical examination

Physical examination is tangible. You can count it or measure it in some way. It is the most reliable source of objective evidence. Numbers are generated. If you use measuring devices, the devices should be accurate and be under calibration control.

Recording physical evidence may include:

- There were 12 items in the nonconforming bin.
- The three trucks in the yard passed the weight test.
- The check scan confirmed the original scan.
- All packages on the dock complied with regulations

Observation of activities

Observing is using your senses. You may look around, be aware of smells that may be improper (chemical release), listen to people and the work area sounds, and in some cases even touch and feel something (e.g. Is the spot wet or greasy? Is it rough or smooth?)

You can observe processes to confirm implementation and on-going maintenance of the system. It is best to **observe an actual task being**performed rather than a practice run, or one that was created for you (the auditor). At the same time, avoid interfering with the performance of the activities. If you do interrupt or redirect the process, be aware of the artificial influence being created. If you sense or observe an operator is nervous, take time to put him/her at ease and return to a normal work environment before you proceed.

8.2 Verification and Validation

Auditors collect evidence to ensure requirements are being met. Auditors may verify and/or validate requirements (audit criteria) are being met. In general, **verification is checking or testing and validation is actual performance of its intended use.** The dictionary does not support the distinction normally associated between verification and validation in the management systems and system-process audit fields. Hence we need to draw on the verification and validation definitions

provided In ISO 9000:2005 (3.8.4 and 3.8.5) and the design and development model outlined in ISO 9001:2015, Clause 8.3.4.

Verification

Verification should be performed to ensure that the system-process outputs have met the system-process requirements (audit criteria). **Verification is the authentication of truth or accuracy**by such means as facts, statements, citations, and measurements, all of which are confirmation by evidence.

An ingredient or element of verification is that it is independent or separated from the normal operation of a process. The fact an auditor is checking that the process/service

or product conforms to requirement, is itself verification (as opposed to inspection checks).
For example, the ISO 9001, Design and Development Controls clause requires verification by ensuring that the design outputs meet the design and development inputs.
The most common method of verification used by auditors is **examination of documents and records.** Records verify a process or activity is being preformed and results recorded. Interviewing is another method to verify that processes meet requirements via affirmation by the interviewee.

Validation

Validation should be performed to ensure that the system-process outputs are capable of meeting the requirements for the specified application or intended use. Validation is the **demonstration of the ability of the system-processes under investigation to achieve planned results. Sometimes an activity cannot be verified by record or interviews and the actual process must be observed as intended to be operated or performed.** The observation can be the real process or a simulated one (depending on cost and practicality).

Some activities can only be verified because it would be too costly or impractical to validate a process such as a plant shutdown, start-up or use of emergency procedures. Sometimes products or activities are only verified because the product would be destroyed or process ruined by validating it (such as checking the seal on a container).

Another is example may be that the auditee explains that a computer program automatically determines the product markings and notices. The auditor may ask the auditee to submit a couple of products to view the selected markings and notices and compare to requirements.
Many processes are required to be validated such as sterilization. Auditors must ensure the validations and re-validations are being carried out properly.

Conclusion

As you go through your checklist, match up audit evidence with every requirement. The existence of audit evidence is proof that the area under review:

- has **adequate controls** to meet requirements and
- has **implemented** and maintained the controls.

Stay alert during the entire audit. By the end of the audit, you will be mentally drained from trying to assimilate all the data and how it relates to the audit criteria (requirements).

9 Applying Process Techniques

Learning outcomes:

- Contrast open-end and closed-end requirements
- Use PDCA techniques
- Conduct an audit using process auditing techniques

Auditors need to be able to employ several auditing techniques and strategies to accomplish the audit objectives as well as improvement effectiveness of the audit. It is difficult to verify conformity when requirements are vague or open-ended. Auditing by element or clause has good traceability to requirements but can leave the linkages between processes untested. Auditors may **encounter situations where there is no documented procedure** yet must determine if the process is controlled and conforms to requirements.

In the absence of prescriptive requirements, auditees must still **demonstrate to the auditor that they conform to requirements.** This lesson is about approaches for verification of conformance to open-ended requirements and using process techniques to test the management system linkages. For the auditor, **it is important that all requirements are verifiable and traceable.**

9.1 Contrast Open-End and Closed-End Requirements

Closed-ended requirements

Most standards contain very specific requirements. We can think of prescriptive requirements as being closed-ended because they are very explicit.

For auditors, closed-ended requirements can be listed and checked off with a yes or no answer (on the checklist). The user creates the record, procedure or plan and the auditor checks off his/her corresponding observations. This is the requirements approach that we have been using in class.

Closed-ended requirements are easy to check and are traceable.
However, standard writers don't write or style a standard for ease of auditing. Standards and procedures are likely to contain vague and non-prescriptive requirements that may be difficult to confirm. Auditors must not avoid or gloss over verification of any requirement but must employ techniques to verify conformance to all requirements. If you ever encounter a requirement that you could not verify and is not auditable, report it to audit program manager and client.

Open-ended requirements

Some standards and internal organization procedures may have open-ended type requirements that are not very specific and can leave the auditor with a lot of questions. You may notice various open-ended requirements during the document evaluation and during the performance of the audit. Open-ended requirements are very popular for internal procedures and instructions in order to give the users of the documents as much flexibility as possible (but can be abused). If instructions are too vague even the users of the instructions are not sure what they are supposed to do.

Open-ended vague requirements are not clearly defined, prescribed or in many cases not understood. If a requirement is so fuzzy or unclear that a nonconformity could not be written citing the requirement, then the requirement is meaningless.
I have identified four types of open-ended requirements you may encounter during your audit.

Types of Open-Ended Requirements

Type I and III discussion

Type I requirements may be **clarified by a registrar, regulator or the organization being audited**. For example, periodic management reviews may be annually, or timely corrective action may be within 30 days. The planning of audits based on the importance of the process may be taken to mean auditing all ISO 9001 clauses annually. When interpretations are agreed upon (between the auditing and auditee organizations), auditors are bound to audit against the interpretations.
Type III open-ended requirements cause problems from time to time due to lack of word definitions and consistent usage.

Seek guidance

To audit the type of open-ended requirements found in types I and III, auditors should seek additional guidance. The guidance could come from researching other standards (e.g. ISO 9000 vocabulary standard) and guidelines or from the auditing organization documents. Also, the application of some words may vary from industry to industry or area to area. A requirement to be prompt in the medical field or nuclear industry may be applied differently for a soap manufacturer or boat company. If word definitions are a **problem, auditors should seek guidance from their audit organization management**.

In the absence of other guidance or regulatory requirements, an auditor should **ask the auditee for their interpretation and audit the organization against it**. For example: What is timely? What is without undue delay? What is an acceptable planned interval? Organizations may set time periods or agree to a time on a case-by-case basis. You can audit them to see if they are doing what they said they would do.

Type II and IV discussion

Type II requirements **are very general** and may require the auditee to **manage and control processes.** These types of requirement statements make perfect sense. It is only when an auditor must prove the negative (issue a nonconformity) that guidance issues surface. When is there lack of control?

When is a process not being adequately managed? What evidence will withstand the scrutiny of the exit meeting and a subsequent review, if a nonconformity is contested? Auditors want to be right the first time and not withdraw a nonconformity or noncompliance once they have determined one is justified. It is in everyone's best interest that the basis for a nonconformity is clear and not appear to be the auditor's subjective opinion.

Type IV open-ended requirements have **no specific auditable requirements**. Verification of conformance to type IV requirements is challenging for auditors and audit organizations. This is particularly true for traditional compliance assessments where supplemental industry guidance may be appropriate.

When type IV requirements appear, auditors must challenge the auditee to explain how they comply.

9.2 Process Approach Techniques

Process Approach Technique

To audit type II and IV open-ended clauses, you can verify that the organization conforms to the intent of the requirements of the standard by using process approach techniques. The auditor must seek to determine the existence of a process, how it was planned and implemented, and its outcomes. You can use the process approach to examine how the auditees address open-ended requirements. Also, the process approach helps the auditor to understand the nature of the process, and its objectives and outcomes, and draw more effective audit conclusions.

Questions needing answers
You should seek answers to the following questions for the less prescriptive Type II and IV clauses in assessing conformance to requirements:

- Is there a plan or method for conforming to the requirements? What is it? Has it been established? Evidence may include an outline, flowchart, markings in a work area, a procedure, work instructions, specifications or criteria. Clause 6,
- Planning for the Quality Management System, and Clause 8.1, Operational Planning and Control, contains requirements to be considered in planning.
- **Has it been implemented?** Evidence may be the existence of records, corroboration by interviews, observations, etc.
- **Are there planned results (criteria)?** Have they been achieved? Evidence may consist of trend diagrams, record results, bar charts, matrices, comparisons, etc
- **Does the organization/person act on the results (make adjustments)?** When the output does not match the acceptable criteria, action should be taken to remedy the situation.

Open-ended questions
The process technique is a very powerful method to test all processes. You can use this technique in every interview where someone is assigned a job or task.

9.3 Process Auditing Techniques

Process Approach Auditing
In this section, we will discuss process auditing that may be used in a process or system audit. The definition for a process is "a series of steps that lead to a desired result or transforming inputs into outputs." **Process auditing techniques are simply auditing the steps or activities and testing the linkages or hand-offs between processes.**

A Process Approach audit is an evaluation of the sequential steps and interactions of a process within a system. For example, an auditor may use process audit techniques during a management system audit of the purchasing or quality control department.

By its very nature, process auditing implies an action such as transforming inputs into outputs. **The Process Approach is evaluating the steps and activities that create the action or transform the inputs into outputs.** This is a very useful technique because **it focuses on the work cycle and deliverables instead of isolated requirements/controls.**

Process model
The process model shows inputs, outputs, sequential steps and feedback loop for control purposes. Auditing a process or system using process techniques **verifies conformance to the required sequential steps from input to output.**

For system and complex process audits, the process cannot be followed in real time but requirements still need to be verified. A technique to use to link processes within a system is for the auditor to record identification numbers or names that are traceable, such as current customer names, customer order numbers, purchase order numbers, routing numbers and project numbers during the first part of the audit (perhaps during a tour of the area to be audited), so you can link and verify process steps during the audit. For example, it would be impossible for any auditor to follow the requisition request, to supplier selection and approval, to issuing the purchase order, accepting delivery, receiving inspection, use in operations. However, during a tour of operations you could get a purchase order number of material being used, then in purchasing you could ask to see the requisition request, supplier approval, purchase order records, check inspection records in QC, verify on-time delivery, verify supplier performance is being monitored, and so on. The use of process auditing techniques is more powerful and effective than auditing purchasing this month, QC next and shipping next quarter. By using process auditing techniques you can test the linkages and communication issues between function and groups.

Process model
The use of process techniques is a natural steppingstone from conformance to performance auditing. When collecting evidence, **auditors also observe performance issues** that would be of value to management.
Auditors should report process performance indicators that support improvement efforts. These indicators include:

All process performance issues should support your organization's improvement programs.
Most organizations are still auditing a process or a group of processes by element or clause and missing out on the value of process auditing techniques. Use of **process auditing techniques provides added value.**

10 Analyze the Results

Learning outcomes:

- Evaluate observations
- Write an audit report draft

10.1 Evaluate Observations

Gather up your evidence
Now that you have completed the investigation and collected evidence, it is time to analyze the information. You may analyze the audit evidence on your own, with your team, or both. Remember the **four types of evidence** that we discussed earlier.

There should be **evidence to verify conformity or nonconformity to the requirements**. There should be sufficient **audit evidence to fulfill the purpose and scope of the audit**. If there is not sufficient evidence, you should continue to audit or report any limitations or contingencies at the exit meeting or to the lead auditor.
Any contradictory evidence or **unresolved issues must be resolved** prior to reporting the results of the audit. If not resolved, either the report should be delayed or the unresolved issues should be made clear to all parties (client, auditee, auditors, etc.).

Classification of observations

The evidence that you collected before and during the audit must be examined (analyzed). The data may be recorded on a checklist, in a log (record of auditor's observations) or seen in a photograph, on notes on blank forms, or in references to auditee documents and records.

Datum is considered objective **evidence if it can be proven true** and is free of bias. It can be **proven true if it is traceable** (to verify) or reproducible (another auditor could collect the same datum).

Audit Principle: Conformance and nonconformance must be verifiable and traceable.

How you sort the data should be consistent with your organization guidelines for types of classifications used by your organization to report the results. Most of the time the results are in the form of a nonconformity statement, as a violation of a specified requirement. Reporting audit results as nonconformity statements (as opposed to other techniques) is a very **effective tool for implementing and maintaining a quality system and monitoring conformance** to a particular standard or contract.

The next step is to **sort the data based on importance (significance) and relevance**. Is it relevant to the organization being audited? Does it violate a requirement?

Importance can be judged based on:

1) **repeat occurrences**(quantitative data), and
2) one time occurrences that have **high risk** (qualitative data).

However, observing repeat occurrences does not necessarily make the evidence important. **Consequences must be considered too** (rework, loss of certification or license, nonconforming product, lost customer, etc.).

Qualitative

Qualitative data (single occurrence) comes into play regarding such issues as safety, environmental, and wrongdoing (e.g. not wearing protective equipment, dumping hazardous waste, stealing, fabrication of records, etc.).

There is little concern when the table lamp bulb burns out, but there are significant consequences and concerns when a light house signal light goes out.

Classify evidence

Audit evidence may be captured in any of the following classifications:

- **nonconformity:** violation of a requirement that can be major or minor
- **finding:** systemic problem, supported by audit evidence **improvement**
- **point:** an opportunity for improvement, not a violation
- **defect:** minor violation of little consequence
- **concern or issue:** possible future problem for the organization
- **positive practice or noteworthy achievement:** some aspect of their system/process that is done very well (very effective)

Though I recommend against it, many organizations report concerns, observations, remarks or issues. My view is that the observation type of category becomes a dumping ground for unresolved issues, an auditor's subjective opinion or a place for auditors to park requirements not fully investigated. My second point is that though the auditee states they are interested in knowing any concerns or observations, almost nothing is ever done about them. I recommend that you continue investigating to determine if the evidence goes in a different category such as a nonconformity or improvement point. If you must, use the observation category sparingly. In this book, an **observation is something the auditor does to collect audit evidence;** he or she makes observations.
Most all auditor energy now is going into matching audit evidence with requirements. Reporting other data (e.g., improvement points) is at the discretion of the auditor with approval from the client or audit program manager. An auditor must know the report terminology and reporting procedures prior to the audit.

Write it up
You must be able to **communicate the results of the investigation**. One of the most common techniques is to write nonconformity (noncompliance) statements. It is very important to write clear nonconformity statements so the auditee fixes the right problem and fellow auditors will be able verify corrective actions.

When writing nonconformance statements, you may want to follow the **ENRC4** formula: what is the Evidence that you looked at? What was the Nature of the nonconformity?
What was the Requirement? and Is the statement Clear, Concise, Complete, and Correct (C4)? The nonconformity statements will be the most read parts of the audit report.

Audit Principle: Ensure results are traceable to requirements.

Example Nonconformity Statement:

Worksheet
You should recall that one of the areas of concern was that the procedure did not mention that marketing handles customer complaints.

Evidence:
Procedure 8501 does not address how marketing is supposed to handle customer complaints.

Nature of the nonconformity:
Documented information needed to ensure control of processes has not been updated as necessary.

Requirement:
ISO 9001 4.4.x.y

Nonconformity Statement (Combining ENR):
Quality Management System documents have not been updated to reflect current practice. The corrective action procedure 8501 did not reference that marketing handles customer complaints or their responsibilities. ISO 9001 Clause 4.4.x.y).

This would normally be a minor nonconformity since it is a one-time occurrence and would not result in a nonconforming product or service.

Now it is your turn to write a nonconformity statement. Write a nonconformity about assessing the importance of problems found in the prior exercise. Use the worksheet

Solution
Now compare to the solution provided. You will find that no two nonconformity statements are the same, but the nature of the nonconformity and reference to the requirement should be on the same track.

Example statements
Your ability to write good nonconformity statements will improve with practice. What is important, is that you **communicate the problems you observed to the auditee so that they can be addressed**. Many internal audit programs use some type of form to report nonconformances. It may be a nonconformance form or a corrective action request form.
The relative importance of the nonconformities can be reported as major or minor (or other means such as a whopper or minuscule).

10.2 Write Draft Audit Report

Report opportunities for improvement:

You may also report opportunities for improvement and best practices observed. An opportunity for improvement is an observation that is not a violation of a requirement but might improve the effectiveness of the process or organization under review. A best practice is an observation of an activity that is so outstanding it should be shared with other parts of the organization. The subsequent implementation of a best practice by others in the organization will improve the organization's effectiveness and efficiency.

Overall audit conclusion

As **lead auditor you may be asked to report** an overall conclusion based on audit results.

Your audit conclusion may reference a state of readiness for a pending customer audit or report the degree of compliance to internal standards (procedures and specifications) or external standards (such as ISO 9001, FAA or 21 CFR 820). You may report any **conclusion based on the evidence** and your judgment or understanding of the auditee situation.
At the very minimum, an audit conclusion should be:

- **relevant** (linked to the purpose and scope) and
- **consistent with the audit evidence** (based on fact).

For Example: If the audit was conducted to determine the degree of compliance to ISO 9001, the conclusion should not be about readiness of starting up the next product line.

The conclusion should be consistent with audit evidence collected during the audit. If there were several significant nonconformities or major findings, it would not be appropriate to state that everything looked

fine. If there were no nonconformities, it would not be appropriate to state that the area needs a lot of work.

Conclusions relate to purpose
An example of matching the audit conclusion with the purpose is:

- **Conclusions are based on objective evidence**. The auditor should **point out areas of strength and weakness,** because it will help auditee management decide where to concentrate their resources.

- **Conclusions based on results Report** Reporting a grade or percentile score can be considered as part of an audit conclusion, such as an 'A' being an excellent rating or 77% matching required for on-going approval levels. A score or grade is normally the result of some type of mathematical calculation based on the response to certain questions. Scoring provides an immediate reference to gauge an organization. However, scoring has certain shortcomings and can result in organizations implementing unneeded costly controls to achieve higher scores or organizations may resist making changes to avoid risking a lower audit score.

Normally, the overall audit conclusions are reported in a summary, brief, synopsis section, or as pre-matter attached to the detailed audit results. The **conclusion should provide the big picture (key issues of importance) for management**.

Some internal audits require conclusions and others do not. Good practice requires some type of conclusion because **the number of nonconformities does not always correspond to the situation**.

An organization can have 10 nonconformities but the auditor observed a very good and solid management system. An organization can have 3 nonconformities but the auditor observed deep-rooted systemic problems that could be a risk to the organization's future.
First you will report the results at the exit meeting and then in a written report.

11 Reporting the Results

Learning outcomes:
- Conduct an Exit Meeting
- Compare auditor/auditee responsibilities in the Exit Meeting
- Write the final audit report

11.1 Conduct an Exit Meeting

There **must be an exit meeting** to conclude the performance phase of the audit. Internal or first party audit exit meetings are less formal than second or third party ones. However informal or brief the meeting, reporting results is always serious business. Exit meetings should be well organized and professional

It is good practice to keep the auditee informed throughout the audit of any significant problem areas so that the audit conclusion will be of no surprise to the auditee. Some organizations require the auditee to **acknowledge the audit findings** before or during the exiting.

The lead **auditor is responsible for the exit meeting and preparing an agenda**. Your organization may have a set agenda based on your circumstances.

Attendance should be taken and someone should be assigned to take minutes. The lead auditor may assign someone to take minutes or take his/her own minutes.
Present purpose, scope and method of prioritization of the results Inform the auditee about the classification of the observations and what it means. This agenda item may be skipped for routine internal audits.
Pass out copies of the nonconformities (findings) Just before you pass out the nonconformities and while you have everyone's attention, you may want to state that: **"**It is very important to identify the nonconformities that are systemic problems to ensure corrective action is taken and problems do not recur. Repeat problems waste the organization's resources and could result in additional oversight from the auditing program"

Next, pass out the findings and read aloud the finding/nonconformity statement(s). This is a serious time. Maintain good eye contact throughout the exit meeting. **Hold questions** until you are finished (ask if any of the results need to be clarified; **avoid discussing solutions,**corrective action or arguing). The nonconformities/findings are normally written on a nonconformance or corrective action request form and copies are handed over to the auditee.
If an auditee objects to a nonconformance, **the objection should be noted** in the meeting minutes. Do not attempt to resolve the issue at the meeting. As lead auditor, you can offer to review any new evidence after the meeting and promise to respond based on the new evidence. However, auditees have been known to **withhold**
data until the exit meeting to **discredit auditor findings.** If you think the auditee is intentionally withholding data, bring it to the attention of the auditor program manager, client or both.
Lead auditor presents overall conclusions Based on your analysis, you can present the overall conclusions. The lead auditor must present the audit findings to management in such a manner that they **clearly understand the results** of the audit
Explain follow-up actions. If there are nonconformities, there will be some type of follow-up to **correct what was found**. Follow-up action normally includes the expected times **for corrective action plans**. The lead auditor should also indicate any required follow-up audits as a result of the nonconformities identified. Normally, follow-up and close out of nonconformities is handled at the next audit.
If one of the nonconformities represents a high risk to the organization, a special follow-up audit can be scheduled by the auditor program manager (person in charge of the audit program).

Keep records of exit meeting The attendance roster, results and minutes taken during the meeting are the exit meeting records. The audit records must be safeguarded (protected).

11.2 Compare Auditor/Auditee Responsibilities

Responsibilities

For the **Auditee**

- Notify personnel of time and place of the exit meeting
- Ensure appropriate management/supervision is invited

- Listen to the report

Present any additional relevant facts For the **Auditor(s)**

- Attend the closing meeting
- Support the lead auditor
- Provide clarification details if asked to do so by the lead
- Safeguard information

Audit Principle: Do not disclose auditee proprietary information to others

11.3 Write the Final Audit Report

Prepare for the report

The report is the official product of the audit. It is the record that will be referenced when there are questions. The report must be clear and it must be **written in terms the user can understand** if it is to be effective. If you use a term that many may not understand, **define it in the audit report.** Put the nonconformities and/or findings in **order of importance** (such as major and minor). Remember your **findings are only as good as the weakest one**.

Audit Principle: Communicate the importance of findings/nonconformities.

Report format

In most all cases, the audit program manager will specify a report format and provide you with report writing guidelines. Consider the following report format points when completing the final report.

Audit Report Identification (Title, number, other)
Confidential Classification: Company Confidential, Proprietary Information, Need-to-Know Only Basis, Secret, and so on. **Safeguard** the audit report to protect its confidential nature.
Introduction or background: This section contains much of the material previously developed for the audit plan. The introduction may include: audit purpose, scope, dates of the on-site audit, standards audited against, auditee organization and areas audited, client, the auditing organization, and the audit team members.
Qualification/Limitations: Report any sampling limitations or scope changes. Reflect on issues that may qualify the results such as: the auditing results are based on production of the X bracket. No other products were being manufactured at the time of the audit.
Conclusion/Summary: Overall Assessment as to compliance to the standard or achievement of the quality objectives.
Best Practice/Noteworthy Achievement: Report the good things found during the audit.
Detailed Audit Results: Details of the major/ minor nonconformities/ findings.
Improvement Points: Include improvement points in your report if agreed upon prior to the audit.
By and Date

Reporting

Audit Principle: Report the results of the investigation truthfully and in a clear, correct, concise, and complete manner.

Turn in your report as required. Many internal audit programs require the auditor to submit the audit report to the audit program manager for approval and distribution. In other cases, the report automatically goes to the area audited with copies going to the audit program manager.

What to avoid

- Using **emotional words and phrases** such as: grossly mismanaged, totally out of compliance, there is absolutely no management commitment, and so on. Such statements will get management attention but are unlikely to lead to improvement.

- Using words that may create the **appearance of bias** or a slanted view point. e.g."The way that you do things is totally different than how we did it in the engineering department or I focused on the X bracket project since that seems to be where most of the problems have been."
- Reporting **minor imperfections** found during the audit that do not add value. One of the Four Audit Management Realities[1] is that 'nothing is perfect.' As an auditor, you can always find something wrong. Looking for imperfection is more akin to inspecting, not auditing.
- Reporting **names of individuals** unless it is germane to understanding or correcting the problem found.
- Making recommendations or telling auditee how to go about addressing the nonconformity.

Recommending solutions

Good audit practice is that auditors **should not take ownership of the problems identified** during the audit. Making recommendations implies that the auditor has the ready-made solution for the problem or nonconformity.

Making recommendations can result in the following outcomes.

- Auditee implements the recommendation even though they may know it is wrong, just to get the report closed out. This is called **malicious compliance by the auditee**.
- Recommendations are ridiculed as being unrealistic and even silly due to the **auditor's lack of process knowledge** of the area audited.
- The **auditee becomes defensive** and will not recognize or affirm even a good recommendation. The auditee may actually implement a sub optimal solution, just to avoid lending any credence to the auditor's recommendation.
- When the auditee expects the auditor to come up with the solutions to the problems, there will be an auditor bias to **find fewer problems**. If asked to audit the same area later, the auditor's **objectivity would be compromised**.

Don't tell them what to do

Audit Principle: Do not take ownership of problems found.

When audit program management requires auditors to make recommendations for corrective action of the audit nonconformities, the auditor must comply. A technique for **helping but not telling auditees how to fix the problem is to provide examples** of how others have addressed similar problems. Also, the **auditor making recommendations should not audit the area again to verify corrective action.**

In order to take full advantage of the knowledge and skills of the internal auditor team, some organizations **assign auditors as advisors** for areas they will never audit. The area personnel can ask their advisor for input when addressing corrective action of findings.

12 Follow Up, Corrective Action and Closure

Learning outcomes:

- Contrast elements of remedial, corrective, and preventive actions
- Bring about an effective closure

12.1 Contrast Elements of Remedial, Corrective, and Preventive Actions

Elements of the corrective action process

Let us assume that an audit report has been issued and there are nonconformities that require corrective action. The auditee has agreed to submit a corrective action plan to the audit organization by an agreed-upon date. The auditee must submit the corrective action plan to be reviewed by the appropriate authority in your organization (lead auditor, audit program manager, QM or client). **It is the auditee's responsibility to take corrective action and issue the corrective action plan.** The corrective action plan should be issued within a specified time (agreed upon between the audit organization and the auditee). **If the corrective action is not on time, it is overdue.**

Corrective action plan contents

The corrective action plan contains the following:
I. Definition of the problem or restatement of the finding.
II. Remedial Action (containment, correction). This is considered temporary.
III. Measurement and data gathering. Identify the root cause based on the data/measures.
IV. Solution(s) Solves the problem permanently to prevent recurrence of the problem.
V. Action plan steps (the Do, Check, Analyze steps.
VI. Responsibilities and completion date.

The auditee proposes the solution and determines the importance of fixing the problem. Too often auditees want the auditor to tell them what to do to close out the finding so they can check it off and continue with other duties. It is important for the auditee to assess the importance of the finding and respond (act) accordingly (work on the important stuff). It is perfectly okay to take remedial action (containment action) as a first step toward corrective action or to address minor nonconformities that do not represent a systemic problem.

Quick fixes

Remedial actions (containment, correction, counter measures, quick fix) only address the immediate nonconformity or defect. They include: reworking, rejecting, repairing, re- grading, replacing, releasing as-is, retraining. Remedial actions do not eliminate the cause of the nonconformity. If the nonconformity is systemic, it will recur. If the nonconformity is an isolated incident, the probability of recurrence is very unlikely.
Please note that ISO 9000 uses the term correction to describe repair and rework activities. However, the nuance between making corrections and taking corrective action is confusing. It would be best to use the terms "remedial action" and "corrective action" where applicable.

Submit plan

The corrective action plan is submitted for review and approval (See Follow-up Cycle, Step 1 to Step 2). You may not be the one reviewing the corrective action plan, but later on, you may verify actions taken and their effectiveness. The reviewer should determine if the root cause has been identified and the stated corrective action plan is consistent with the stated finding. The review output may be a simple matter of acknowledgment of the action to be taken.

The reviewer verifies that the actions address issues relevant to the finding (Step 2) and that they are adequate to provide a complete solution (Step 3).

A corrective action plan may be **rejected because:**
1) the finding is not addressed,
2) the root cause is not identified,
3) priority or timing is not appropriate, and 4) relevant information is missing.

The auditee may claim that no corrective action is necessary and provide additional information to support their claim. In other cases, the auditee may request more time to address the finding. Normally, **a request for an extension should be granted unless it is a safety or environmental (high-risk) issue or the courtesy of granting extensions has been abused.**

Verification methods
Corrective actions should be verified according to established procedures and methods (Step 4 of the audit follow-up cycle). Methods for corrective action verification include:

- Verification during a subsequent audit of the same area (same or different auditor)
- Scheduling a follow-up audit specifically to verify the corrective action(s) (same or different auditor)
- Examination of implementation and performance records provided by the auditee

The **verification should be recorded in some manner**, such as on the corrective action form or in a report (or both).
Corrective actions can be verified one at a time regardless of the source or number of corrective action requests from a single audit. **Corrective actions can be tracked and closed individually**.

The follow-up audit

The **client will determine if a follow-up audit is required** (Step 5 of the audit follow- up cycle). If a follow-up audit is required to verify that the corrective action has taken place, it should be **scheduled at a time sufficient for implementation**. The auditee should be notified of the follow-

up audit and standard audit conventions should be practiced. **The follow-up audit can be conducted by the same or different auditor(s)**.
Second-party and third-party audits are normally done under a contract. Thus, correcting the problems found in second-party and third-party audits is not optional. **For second-party audits (your customer audits you), failure to correct problems**

could result in loss of business, and for third-party audits it could result in loss of certification (management system registration/certification, product certification) or endorsement of the organization or product. Because of the commitment of the organization (the contract), **follow-up and effective corrective action become a very serious matter.** The completion of the corrective action plan and its implementation should be verified. The investigation can include verification of document changes, employee awareness of the change, observing work practices, and review of records.
There should be a record confirming that the corrective action completion was verified. An example would be signing or initialing and dating a section of a corrective action form or in a report (or both).

Assess the effectiveness of the corrective action
Besides verification that the corrective actions were implemented, auditors or other assigned persons, should verify the corrective actions were effective. The auditee should be required to list the measures for determining if the corrective action was effective in the corrective action plan.

There are **two elements** involved in determining if the corrective action was effective:

1. Did it achieve the **desired result**. This is proof that the process improved and the actions implemented are consistent with business goals.
2. Is the **process capable**, efficient, and meets stated objectives. There is evidence that the process will consistently achieve the desired result in a cost-effective manner.

12.2 Bring About an Effective Closure

Closure criteria

Action has been taken on the audit finding and has been implemented and reviewed. All that remains is closing out the finding (corrective action request). You have many options. The most important things are that:

1. there is a **record of the closure** (letter, memo, report)
2. the closure **information is communicated** to the client (and in turn to the auditee) the corrective action is completed within the **agreed time**

Closure notification
In most cases the **closure notification is sent to those on the original report distribution list.** Depending upon your organization's procedures, there might be others who are approved to receive a copy of the closure notification.
Upon issuing the closure notification, it is a good time to discard all working papers associated with the audit except for the formal documents and records.

Timeliness

Timeliness with regard to corrective action implementation is not considered to be a fixed time period but a specified time period. The specified time should be based on the importance (effect on the organization) of the corrective action and the availability of resources. Corrective actions **completed on schedule should be considered timely**. Schedule delays could be due to a lack of resources. The auditee should keep the auditing organization informed of any delays and the reason for the rescheduled implementation. The auditing organization (or other designated function) should monitor auditee progress.

NOTES