

BURNHAM

Internal Auditing ISO9000 Quality Assurance

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B U R N H A M

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ISO 9004-2	Guidelines for Services

1. Review of ISO Elements

ELEMENT

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ISO 9000 Requirements

The word "shall" in the Standard indicates a mandatory requirement. The word "should" indicates a preferred approach. Suppliers choosing other approaches must be able to show that their approach meets the intent of ISO 9000. Notes in the Standard are for guidance only.

Element 4.1 MANAGEMENT RESPONSIBILITY

4.1.1 Quality Policy

Senior company management must define and document its policy and objectives for quality. The policy statement should avoid the trap of using meaningless cliches and must be relevant to how the company ensures that it meets its customers' needs and expectations, and achieves its own business objectives. The actual content of the policy statement will differ from company to company, but must be specific to the particular circumstances under which a company operates. As well as the company's commitment to quality and its customer focus, the policy statement may reflect the nature of the company's markets, products, services, structure, and size.

The quality objectives are the (hopefully) quantified goals and targets to be achieved by implementing the company's quality policy and system. Quantification is important if the company is to be able to monitor its achievement of goals and measure the effectiveness of the system and procedures. At the very least, the defined objectives should ensure that the current levels of nonconforming product and customer complaints do not get any worse. Preferably, however, the objectives should be set to ensure continual reduction in such negative factors and a continual improvement in the positive aspects of the company's performance, e.g., increased reliability, better delivery, faster response. Objectives must be reasonable, measurable, and attainable. Setting unrealistic objectives will de-motivate people.

It is management's responsibility to ensure that this policy is communicated in the most suitable form to people at all levels within the organization. All staff must understand the intent of the policy and, more important, understand their function and responsibilities in the system to implement and maintain that policy. Everyone should be able to explain the quality policy in the context of their role, rather than just be able to regurgitate the statement verbatim.

As a controlled document, the policy statement is commonly authorized (i.e. signed), preferably by the chief executive officer, as indication of the commitment of senior management to actively support the policy and the system necessary to implement it.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

Senior management alone has the authority necessary to decide on the organizational structure necessary to meet the company's quality objectives. The Standard recognizes that authority and responsibility are not the same thing, and requires both to be defined and documented for people whose work directly affects quality. A company must decide how far to implement this clause, but in practice it is usually limited to certain key positions involved in: (1) the detection and prevention of nonconformities related to products, processes and the quality system; (2) corrective action

activities; and, (3) the prevention of further processing, dispatch, or installation of nonconforming material until effective corrective action of the unsatisfactory situation is verified.

(One common way to address the clause is the preparation of schematic organization charts and job descriptions. The charts outline the interrelation of positions, identify the interfaces between different groups or functions, and clearly show the lines of authority. Job descriptions for the positions shown on the chart establish the limits of this authority and define the job holders' responsibilities and key task areas in terms of measurable objectives.)

4.1.2.2 Resources

This clause requires the company to ensure that the resources necessary for all activities covered by the quality system, including management, performance of work, and verification activities, are identified and provided. These resources include the assignment of staff trained in the required skills and procedures.

Verification activities cover all of the tasks performed to establish compliance with specified requirements at all stages of the company's operations, from contract review to after-sales service. These tasks may include reviews, inspections, measurements, tests, monitoring, and auditing of systems, products, services, processes, environmental conditions, equipment performance, and worker competence. Most of these activities can be done by the people involved in the functions being verified. The only requirement in the standard for independent verification is for internal quality audits, which must be done by people independent of those having direct responsibility for the work.

4.1.2.3 Management Representative

The senior management of a company must appoint one of its own as a Management Representative. Regardless of whether this position is a person's sole function or only part of that person's job, he/she will have the defined authority necessary to ensure that a quality system meeting the requirements of the Standard is established, implemented, and kept up-to-date. The Management Representative also has the responsibility for reporting to senior management on the performance of the quality system for review and as a basis for quality improvement. (How the performance of the system is to be evaluated is not mentioned, but the results of internal audits must be a significant factor.)

The actual functions performed by the Management Representative, (who may carry a different title), might include, but not be limited to, the following possibilities:

- Management of the internal audit system
- Participation in quality planning and management reviews
- Vendor evaluation and surveillance
- Measurement assurance and calibration
- Control and disposition of nonconforming product
- Management of the corrective action program
- Quality costs analysis
- Customer quality liaison and complaints analysis
- Participation in verification planning.

4.1.3 Management Review

To be successful, a company's quality system must deal with that company's present needs and also, where possible, deal with predicted future needs. This clause establishes the mechanism for ongoing development of the quality system and the management of change.

Management review is a senior management function that ensures that the continuing effectiveness and appropriateness of the quality system is re-evaluated in terms of satisfying both the requirements of the Standard and the company's stated quality policy and objectives. The review may be carried out by one person or a committee, but it will happen at some defined interval appropriate to the company's circumstances (probably not less than twice a year). Some form of record of the review will be kept to demonstrate active management of the system.

Inputs to the Management Review could include: monitors of past performance such as quality costs, scrap and rework levels, customer complaints, nonconforming product records, the results of both internal and external audits, and the preventive and corrective action programs. Future business developments also need to be considered such as changes in customers or customer requirements, the introduction of new technology, changes in resources, growth or contraction of business, and economic changes.

Element 4.2 QUALITY SYSTEM

4.2.1 General

The ISO 9001 Standard requires that a company's quality system be documented to ensure product conforms to specified requirements. Part of the documented quality system is a quality manual that addresses how all of the requirements of the Standard are applied in the company. Contents of the Quality Manual need not be limited only to the requirements of the Standard, but can include other information related to the company and how it operates.

The clause neither defines what constitutes a document within the system nor the type, size, or complexity of the documentation in the system. The structure of the system will be decided by the company and will depend on the size and organization of the business. In some companies, it may be possible to combine the quality manual and the quality system procedures into a single document, but in others the quality manual will refer to procedures that are documented elsewhere in a hierarchy of documents.

4.2.2 Quality System Procedures

A company is required to prepare documented procedures to be followed to implement the quality policy and be consistent with the requirements of the Standard, i.e., for almost every clause. In addition, the company must effectively implement the quality system and the documented procedures. The Standard makes no demands about the size or detail of the quality system procedures, but leaves it to the company to decide what is necessary based on its specific circumstances.

4.2.3 Quality Planning

Quality Planning requires a company to define and document how the requirements for quality will be met. This activity must be consistent with all of the other requirements of the company's quality system and must be documented in a format appropriate to the company's method of operation.

Quality planning in its simplest form may identify already-existing procedures, processes, techniques, equipment, measurement capacities, resources, and skills adequate to achieve the required quality for specific products, projects or contracts. It may involve, however, the preparation of quality plans or the identification and updating or acquisition of any new or additional resources that are necessary to meet quality requirements.

Element 4.3 CONTRACT REVIEW

4.3.1 General

ISO 9001 is intended to be a contractual agreement between a customer and a supplier. For this reason, the term "contract" is used when referring to the business relationship between the two organizations. The company must have documented procedures to ensure that the terms of each contract between it and a customer are reviewed. The company must also make certain that the review activities are coordinated to ensure that all relevant inputs are obtained and the necessary expertise is available.

4.3.2 Review

The contract review must be done before the acceptance of an order or contract. To achieve customer satisfaction, it is essential that the customer's requirements are clearly defined and documented and that any areas of conflict, confusion, or ambiguity are resolved. The company must then review these requirements internally to ensure that the necessary expertise, resources, facilities and capacity are available to meet commercial and technical specifications before agreeing to meet the order. (Being unable to meet any of the customer's requirements guarantees a dissatisfied customer and, by definition, a quality failure.)

The principle of contract review is exactly the same whether the customer is internal or external and whether he/she is buying a simple catalog item or seeking a supplier for a large project, although obviously there will be some differences in the details.

4.3.3 Amendment to a Contract

The documented procedures for contract review must make provisions for amendments to contracts or orders after they are accepted. These provisions must cover how an amendment is made and how affected functions within the company are involved and correctly notified of the change.

4.3.4 Records

Records of contract review must be kept to show that the company has actively sought an understanding of the customer's needs and has not knowingly taken on work involving requirements that it cannot meet. The form that these records will take will vary with the nature of the sale, as will the people who take part in the review.

Element 4.4 DESIGN CONTROL

4.4.1 General

Because manufacturing can only provide a product as good as the design it was made from, it follows that design control is fundamental to a successful system of quality management. The Standard requires documented procedures for the control and verification of the design of a product to ensure that the specified requirements are met.

4.4.2 Design and Development Planning

This clause requires a plan for each design and development activity that establishes the responsibility for its implementation and which provides either a detailed description of the activity or a reference to further information. Design activities must be assigned only to people who have been identified as having that combination of qualifications, training, and experience that management has decided is necessary for particular tasks. These individuals must receive whatever resources are necessary to ensure that the output of their activities is not adversely affected. As the design develops, the plan will need to be reviewed and, where necessary, revised to keep it up to date.

4.4.3 Organizational and Technical Interfaces

The intention of the Standard is to control the communication of information between the various groups which make inputs to the design process. It is important, therefore, that the points of interaction between these different groups, functions, or activities are identified and controlled to ensure that current information is available to everyone who needs it. This shared information should be documented, transmitted in the most effective way, and reviewed periodically for currency and completeness.

4.4.4 Design Input

Inputs to a design can come from many different sources-the results of contract review activities with a customer, legal or regulatory requirements, current production capability and sources of supply, or experience with previous designs. The relevant inputs to each design must be identified and documented to anticipate, as much as possible, all of the requirements that will have an impact on both the design and the product that results from it.

Before commencing the design, the identified inputs must be reviewed for adequacy by the people authorized by the company to do so. Any ambiguous or conflicting inputs must be clarified or resolved with those responsible for imposing the requirement.

4.4.5 Design Output

Outputs of the design function can be translated into a product or service that complies with the customer's request. They might be in the form of plans, drawings, specifications, formulations, calculations or analyses, or any combination of these requirements that can be verified. Design outputs must be documented and must be reviewed to ensure that: (1) input requirements are met (including any legal or regulatory ones that are applicable), (2) information is provided on the

criteria for acceptable product, and (3) factors of the design that are critical to the safe and effective functioning of the product are identified. All design output documents must be reviewed before release.

4.4.6 Design Reviews

Formal reviews of design results are a mandatory requirement to be planned and carried out at appropriate stages of the design process, regardless of any other design verification activities conducted. Design reviews must include representatives of all functions concerned with the design stage being reviewed, as well as other specialized personnel as required. (There is no requirement for independent people to be involved in design reviews.) Records should be maintained of the results of design review activities.

4.4.7 Design Verification

This is the inspection and test of the final design and any intermediate stages in its development to determine whether the design output meets the design input. As with the other verification activities in a company, it must be planned and carried out at defined stages of the design process, in accordance with documented procedures, and by trained and experienced people. Records of design verification measures must be maintained.

The note to this section of the Standard recognizes that there are several ways that designs can be verified (such as by prototype evaluations, alternative calculations, comparisons with existing designs, or design reviews), but it does not require any specific technique.

4.4.8 Design Validation

Where other elements of design control refer to the design, validation requires an evaluation of the product resulting from that design. The purpose of performing a design validation is to ensure that the final product, which is made following a successfully completed design process, meets the defined user needs and/or requirements.

The notes to this section comment that design validation is normally performed on the finished product, under defined operating conditions and after successful design verification at the final design stage. It is possible, however, that validation of earlier stages of the design may be necessary or that multiple validations may be necessary if a product has different intended uses.

4.4.9 Design Changes

Any changes or modifications to the design, from initiation to release for production and beyond, must be made in a controlled manner. The nature of the change must be identified and documented, and the effects of the change need to be evaluated by authorized personnel and approved before it is implemented.

The review should consider whether the product still conforms to customer or market requirements, whether it can still be made and tested; and whether it is safe, operable, and fit for use.

Element 4.5 DOCUMENT AND DATA CONTROL

4.5.1 General

Essentially, a document is anything that can be read by people or machines, including paperwork, computer files, and photographs. All procedures within the quality system must be documented and the company must have documented procedures to control all documents and data related to the requirements. This clause also applies to documents (and data) of external origin such as customer drawings, specifications, reference manuals and standards.

4.5.2 Document and Data Approval and Issue

Documents and data must be reviewed and approved by authorized personnel before they are issued. A master list or some equivalent system must be established and made readily available to prevent the use of invalid or obsolete documents.

Control must ensure that the correct issues of all relevant documents are available where they are needed and that obsolete documents are removed from all areas where they may be issued or used by mistake. The Standard does not require the destruction of out-of-date documents, and many companies find it useful to retain them as a record of product or process development. The retention of obsolete documents for reference or record purposes is allowed under ISO 9000, provided that such documents are clearly (and suitably) identified as such.

4.5.3 Document and Data Changes

Control of changes to documents requires that these can only be made, following review and approval, by the same function, department, or organization that produced the original document. This review and approval process can be delegated to a different group provided that group is given all of the relevant background information necessary to allow an effective review before approval.

As with the original documents, modifications and changes must be distributed to these locations or individuals that need them. To be truly helpful, the document control system must, if possible, clearly identify any changes either in the document or on attachments to the document such as a cover sheet.

Element 4.6 PURCHASING

4.6.1 General

A company must have documented procedures for, and maintain active control over, the system it uses for the procurement of products to ensure that they meet specified requirements. "Product" is now a generic term defined as the results of activities or processes, and may include hardware, software, processed materials, services, or a combination of these.

4.6.2 Evaluation of Subcontractors

The company must evaluate and select subcontractors on their ability to meet all of the requirements in the company's contracts or purchase orders. A company must define (and by implication, document) the type and extent of control it imposes on its subcontractors. The choice of subcontractors and the way that the conformity of the product provided is verified will depend on the nature of the purchase (e.g., price, technical specification, impact on product quality), and records of the subcontractors previously demonstrated ability (where available). The company must also maintain records of acceptable subcontractors.

Obviously, the ongoing performance of subcontractors must be monitored, recorded, and reviewed at defined intervals, again depending on the nature of the product and the subcontractor's performance. It benefits the company to therefore, establish an effective working relationship and feedback system with each subcontractor.

4.6.3 Purchasing Data

The information sent to a subcontractor in a company's order or contract documents must define exactly the products or services required. The information must include, where appropriate, precise identification (e.g., type, grade, catalog number) references to other applicable technical information (e.g., test methods, national, or international standards) and any other essential details necessary to ensure the quality of the procured products or services. Purchasing documents must be controlled. This means they must be reviewed and approved by authorized personnel before they are issued and must be periodically reviewed for continued accuracy and relevance.

4.6.4 Verification of Purchased Product

4.6.4.1 Supplier Verification at Subcontractor's Premises

Where a supplier chooses to verify at a subcontractor's premises that purchased product conforms to specified requirements, both the arrangements for such verification and the method for the release of product must be clearly communicated to the subcontractor in the purchasing documents.

4.6.4.2 Customer Verification of Subcontracted Product

An optional requirement, sometimes called for in a contract between a customer and a supplier, may affect a subcontractor. This requirement gives the customer the right to verify at the subcontractor's premises and at the supplier's premises that the purchased products comply with specification. Where such contract provisions exists, a company must ensure that this requirement is reflected in any subcontract or order documents that it places with a subcontractor.

Even if the customer expresses satisfaction with the subcontractor, the supplier must not relax its own verification activities. The supplier retains full responsibility for the quality of product or services that it provides to its customer. In addition, under clause 4.6.2, the supplier cannot use verification of the subcontractor's product by the customer as justification for the selection of that subcontractor.

Element 4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

Customer-supplied product is material owned by the customer and supplied to a company for use in meeting the requirements of the contract between them. While such product is never owned by the supplier, they are responsible for controlling the identification, maintenance, storage, handling, and use of the material as long as it is in their possession. Customer-supplied product must also undergo verification upon receipt in the company to check the quantity received, its identity, its compliance with specification, and to detect any damage in transit.

Any customer-supplied product that is unsuitable for use on receipt or is lost, damaged, or otherwise becomes unusable while in the supplier's possession, must be recorded and reported to the customer. The fact that the supplier will check this material does not remove the obligation from the customer to supply, as part of the contract, conforming material. There is no reason why a company cannot include the checking, handling, storage, of customer-supplied product into its existing system for bought-in material.

Element 4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

The Standard requires a company, where appropriate, to establish and maintain documented procedures for identifying the product from receipt through all stages of production.

The note to this section explains that "where appropriate" refers to those situations where the product identity is not inherently obvious.

The company must establish documented procedures to ensure that product is traceable when this is a specified requirement. Traceability involves the ability to track the history, application, or location of an item or activity (to the extent required) by means of some suitable, unique, recorded identification.

Traceability can entail high cost, and when called up in a contract, the extent of this requirement must be carefully defined. Traceability may arise from a customer requirement, a legal or regulatory requirement, or an internal quality management requirement, such as positive recall procedures.

Element 4.9 PROCESS CONTROL

This clause is called process control rather than production control because it covers production processes, installation processes, and servicing processes, where applicable. The Standard requires a company to plan these processes and to ensure the plan covers the conditions that must be controlled to produce conforming product. The features or characteristics most critical to the product or service quality must be identified and placed under the tightest process control. The company will obtain more benefit if this control can be focused on the prevention of nonconformities rather than relying on their detection during inspection phases.

The Standard requires that controlled conditions include- (1) the documentation of procedures (where necessary), (2) the use and maintenance of suitable equipment, (3) an acceptable working environment, (4) compliance with documented procedures, quality plans or other relevant codes, (5) the approval of processes and equipment as appropriate, (6) product and process monitoring and control, and (7) the definition of acceptance criteria for conforming product. Note that documented procedures are only required where their absence would cause problems, e.g., in circumstances

where there are differences in the interpretation of a procedure or where relatively untrained or inexperienced staff are involved. Process control often includes statistical process control methods as well as the training of staff both in the process and in the necessary statistical techniques.

In some cases, the company may use processes, often called "special processes," where the effects of the process cannot easily be measured in the product for a number of reasons. This may be because any nonconformities will not become obvious until some time after the process is completed or because the method of detection is too expensive, destructive to the product, beyond the present capabilities of the company, or does not presently exist. Examples of such processes include welding, soldering, casting, heat treatment, software coding, plastic molding, and training. Some alternative control procedures must be followed, therefore, to ensure compliance with specified requirements.

Once the company has determined how each special process will be controlled, it must qualify the processes, equipment, or people involved as appropriate. The intention is to determine, by tests in advance, that effective monitoring and control of each process can be maintained and that specified requirements are met. Records of such qualification tests must be maintained.

Element 4.10 INSPECTION AND TESTING

4.10.1 General

All inspection and testing activities must be carried out in accordance with documented procedures. The aim of inspection and testing activities is to demonstrate compliance of the product with specified requirements. The activities to be carried out and the records to be maintained are detailed in the quality plan (called a control plan in some companies) or documented procedures.

4.10.2 Receiving Inspection and Testing

Receiving inspection activities must ensure that shipments received are not used or processed until they have been demonstrated to comply with specifications, and are complete, correctly identified, and undamaged. Although not specifically required by this clause, material which is nonconforming upon receipt should be identified as such and the documented procedures should detail the actions to be taken in the event of such nonconformity being detected.

When considering the amount and nature of receiving inspection, the supplier must consider the amount of control exercised by the subcontractor and the documentary evidence of conformity provided.

Release of unverified incoming product subject to recall should be discouraged as a matter of good quality practice. If, however, it is necessary to do so for urgent production purposes, the released material needs to be clearly identified and this positive identification recorded. Should subsequent inspection find this released material to be nonconforming, its use can be traced and the product recalled and replaced.

4.10.3 In-Process Inspection and Testing

In-process inspection and testing applies to all forms of product. It allows early recognition of nonconforming material and timely review and disposition. Statistical process control techniques commonly are used to identify trends before problems actually occur. Early identification of nonconforming product, before the final inspection stage, increases the efficiency of the entire operation by avoiding the wasted time and costs of further processing.

As with receiving inspection, positive recall procedures are acceptable provided they are controlled. The company's procedures must ensure the objectivity of the inspection and test results, including situations where in-process verification is carried out by production personnel.

4.10.4 Final Inspection and Testing

Final inspection involves the activities upon which is based the Final release of product or service as conforming to specified requirements. It may be a formal inspection, measurement, or test, or an examination of all previous verification results to ensure not only that the necessary checks were done, but also that data met the specified requirements.

This clause does not allow positive recall. The procedures established within the company must ensure that each unit or batch of product or service is not dispatched until all of the required verification activities have been performed successfully for all designated release characteristics. The data establishing this conformance must be available, complete, reviewed, and authorized before the release of the product or service.

4.10.5 Inspection and Test Records

The company must maintain records which provide complete evidence of the fulfillment of inspection and test requirements on products. The evidence comprises all verification activities from receiving inspection, through all in-process inspections to the final inspection. It must show whether the product passed or failed the inspections and/or tests according to defined acceptance criteria. When the product fails any of the verification activities, the procedures for the control of nonconforming product must be applied.

The records must be legible and must also be traceable to the specific product or batch of product to which they refer. In considering the form and completeness of these records, regulatory requirements and the possibility of product liability claims should be considered. The person(s) responsible for the release of product must be clearly identified.

Element 4.11 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

4.11.1 General

Regardless of the ownership, any equipment used to measure the conformance of product to specified requirements must be controlled, calibrated, and maintained in accordance with documented procedures. This requirement extends to inspection, measuring and test equipment, test software and test hardware, such as comparative references. The capability of such devices to measure the acceptability of product must be established before they are released for use and at

prescribed intervals thereafter. Records of these activities must be maintained as evidence of control.

Technical data pertaining to inspection measuring and test equipment must be made available to customers for verification of functional adequacy when this is a specified requirement. The intent of the requirements of this clause is that when a company makes a measurement to verify process control or product conformity, it can have confidence in that measurement. This confidence derives from planning what measurements are to be made and determining the accuracies required, then selecting equipment that can measure to those tolerances.

4.11.2 Control Procedure

The equipment must be positively and uniquely identified, must be calibrated using documented procedures, and must provide measurements traceable to a recognized reference standard. Recalibration will be necessary either at set intervals or prior to use, and all calibration data must be recorded to demonstrate equipment capability. Any equipment found to be out of calibration must initiate a re-evaluation of past measurements, especially where there is a risk of product having been wrongly accepted as conforming because of them.

To assist company staff, the calibration status of equipment must be clearly indicated as uncalibrated, limited calibration, or full calibration. There are several methods of identifying status, and the company must choose which to use based on the type of equipment and perhaps the conditions under which it is used. Any circumstances that may invalidate calibrations or measurements (e.g., environment, handling, storage, or unauthorized adjustment) must be identified and controlled.

For both product and service measurement systems, statistical methods are valuable tools for achieving and demonstrating adequate conformance to requirements. In particular, statistical methods are preferred tools in fulfilling the overall requirement that, "Equipment should be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability. "

This clause of the Standard is very detailed, but additional information can be found in ISO 10012, *Quality Assurance Requirements For Measuring Equipment*.

Element 4.12 INSPECTION AND TEST STATUS

This clause has a clear requirement for some way of differentiating between conforming and nonconforming product. (Some companies, however, may identify more than two states requiring differentiation.) The clause does not provide a definitive list of possible mechanisms that can be used to identify status, but only requires a company to use some suitable means. The identification of inspection and test status must be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing. The intention is to ensure that only product that has passed the required tests (or been released under an authorized concession), is dispatched, used, or installed.

If a company opts to use a physical device such as a tag or label, the procedures should provide for what happens if this tag or label is lost or destroyed. Perhaps anything not positively identified as to its status automatically goes on hold until it is re-verified and re-identified.

Element 4.13 CONTROL OF NONCONFORMING PRODUCT

4.13.1 General

Product may become nonconforming for a variety of reasons including loss of identification, loss of inspection and test status, failure to meet specified requirements, and cosmetic damage. This clause requires documented procedures to control such nonconforming product and to prevent it from being used by mistake.

The status of the product as nonconforming must be identified, the nature of the nonconformity recorded, and its significance evaluated. The company must identify which product units are involved in the nonconformity to gauge the extent of the problem. Where possible, nonconforming product should be physically segregated from conforming material to prevent mistakes and to facilitate the movement, storage, and subsequent processing of the nonconforming product following a decision on its disposition.

Other functions that may be concerned with or affected by the nonconformity or involved in its disposition need to be notified, both within the company and, where appropriate, the customer.

4.13.2 Nonconforming Product Review and Disposition

Part of the control of nonconforming product is evaluation of the nature of the nonconformity and consideration of alternatives available for the disposition of this material. The responsibility for this review must be defined and may involve a formal committee or be delegated to an individual. In any event, the authority for the decision on disposition, which must also be defined, will only reside with certain authorized people.

Several things can be done with nonconforming product, and while this clause of the Standard gives several examples, it is neither an exhaustive nor an exclusive list. Different industries may have additional options available to them. The company must recognize that each of these options carries some degree of risk of failure to meet the customer's requirements. In the long term, the decision to reject or scrap nonconforming product may carry the lowest risk.

Reworked or repaired product must be re-verified in accordance with documented procedures or the quality plan.

Element 4.14 CORRECTIVE AND PREVENTIVE ACTION

4.14.1 General

The supplier is required to have documented procedures for the implementation of both corrective and preventive action. Any actions implemented to eliminate the causes of actual or potential problems must be appropriate to the risk and magnitude of the problems. This section also makes it

clear that any changes to the documented , procedures as a result of corrective and preventive action shall be implemented and recorded.

4.14.2 Corrective Action

Nonconformities can be indicated by numerous ways including the results of inspection and testing, process monitoring, internal or external audits, field or service feedback, or customer complaints. Procedures for corrective action must ensure the effective handling of customer complaints and reports of product nonconformities.

Investigation of the causes of nonconformities relating to product, process, and quality system should focus on the root cause, not the symptoms by which the problem was recognized. Cause-and-effect diagrams and Pareto analysis are useful tools in the investigation of nonconformity and identification of the most likely cause. Results of the investigation must be recorded.

The corrective action most likely to deal with this root cause must be identified. It might be necessary to produce, change, or improve one or more of the following: documented procedures and instructions, equipment checks, process controls, training, subcontractor evaluations, contract reviews, or even the quality system itself.

The identified corrective action must be implemented in a controlled way and its effectiveness monitored. If ineffective, alternative corrective action must be considered.

4.13.3 Preventive Action

The procedures for preventive action are basically the same as those for corrective action. The process begins with the use of appropriate sources of information to detect and analyze potential sources of nonconformity. The preventive action necessary to eliminate the cause of the potential nonconformity must be identified and implemented in a controlled manner. The effectiveness of the preventive action must be monitored and determination made of the effectiveness of that action. Relevant information on the preventive actions taken must be submitted for management review.

Element 15 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

4.15.1 General

To prevent the damage or deterioration of conforming product between processes, or between final inspection and receipt by the customer, the company must plan, control, and document the procedures for handling, storage, packaging, preservation and delivery. This includes incoming materials, in-process materials, and finished goods.

4.15.2 Handling

The company's methods of handling product must consider provisions for the appropriate transportation units such as pallets, containers, conveyors, vessels, tanks, pipelines, and vehicles to prevent damage, deterioration, or contamination, from vibration, shock, abrasion, corrosion, temperature, moisture, radiation, or any other conditions occurring during handling and storage. If

particular equipment is necessary for the effective handling of goods, it must be provided and maintained.

4.15.3 Storage

The supply of goods and material to and from designated storage areas must be controlled and authorized. The company must plan for the use of suitable storage facilities, considering not only physical security but also safety and environmental conditions ' (e.g., temperature and humidity). Depending on the nature of the materials being stored, it may be necessary to check items periodically for deterioration. Consideration may also need to be given to procedures for assigning, monitoring and controlling expiration dates and stock rotation.

The packaging procedures, materials, and designs used by a company must provide appropriate protection against damage, deterioration, or contamination during storage and transportation or at any later period until the company's responsibility ends. It is important, therefore, that the planning of packaging procedures accounts for all the available packaging materials appropriate to providing the degree of preservation required, as well as all the various forms of storage and the types of transportation involved in getting conforming product to the customer.

Where either regulations or the contract require these, the packaging must provide a clear description of the contents and/or the ingredients. The methods for the marking and labelling of goods in storage must give legible, durable, accurate information in accordance with the specifications (e.g., identification, inspection, test status).

4.15.5 Preservation

The company must apply appropriate methods for the preservation of the product when the product is under the supplier's control.

4.15.6 Delivery

The company must provide for the protection of the quality of the product or service during shipping and other phases of delivery where this is a contractually specified requirement. For some products, including services, delivery time is a critical factor. For others, the environmental conditions maintained during transportation may be more critical. Consideration must be given to the various options available for delivery and variations in environmental conditions that may be encountered during delivery. If the company uses subcontractors to provide delivery, it is the company's responsibility to evaluate the subcontractors to ensure all of these requirements are still met.

Element 4.16 CONTROL OF QUALITY RECORDS

ISO 9000 requires a supplier to establish and maintain documented procedures for controlling quality records. This control covers the identification, collection, indexing, access, filing, storage, maintenance, and disposition of records. Quality records provide evidence that the product meets requirements and that a quality system complying with the requirements of the Standard has been effectively implemented. Sometimes, quality records provided by subcontractors will form part of the supplier's quality records.

The company must ensure that quality records are legibly completed, as well as safely and securely stored and maintained. They may be stored in any suitable form (e.g., hard copy or electronic media), provided they are readily retrievable when needed. If records are summarized, then the summaries must accurately contain all the relevant information from the original quality records that demonstrated compliance to specification. The supplier is expected to establish and record the retention times for the various kinds of quality records. When agreed contractually, quality records must be made available for evaluation by the customer for an agreed-period.

Element 4.17 INTERNAL QUALITY AUDITS

Internal quality audits must be carried out by the company to verify whether the various elements within its quality system are implemented effectively and are achieving the quality objectives defined by the company's management. Audits are planned and carried out following documented procedures and in accordance with an established program that establishes the frequency of the audits. This frequency, which may differ from department to department, is based on status and importance. Therefore, in areas where major problems exist, or in areas which are more critical to the quality of the company's output, more frequent audits are likely to be carried out.

The findings of the audit must be documented and brought to the attention of the management of the audited area. It is the responsibility of that manager to ensure that effective corrective action is taken. However, target dates for the correction of nonconformities raised by the audit must be established, and the audit is not completed until the effectiveness of the corrective action taken for every identified nonconformity has been verified.

Element 4.18 TRAINING

This clause of the Standard requires the company to establish and maintain documented procedures for determining the training needs of all people whose work affects quality and for ensuring that the necessary training is carried out. Appropriate records of this training must be maintained. Since the training of an organization's personnel is central to the achievement of quality, both specific training to perform assigned tasks and general training to heighten quality awareness and to build incentives is necessary.

To achieve and maintain proficiency a number of steps can periodically be taken by the company:

- Evaluate the general education, experience, and proficiency of the personnel for the activities to be performed
- Identify the individual training needs against those required for satisfactory performance of particular tasks or functions
- Plan, organize, and carry out appropriate training programs either in-house or through the use of an outside body
- Record training and achievement so that records can be updated and gaps in training can be readily identified.

Element 4.19 SERVICING

When servicing is a specified requirement (e.g., under a product warranty), the supplier has to establish and maintain documented procedures to ensure that the performance, verification, and reporting of servicing activities meets specified requirements.

When the functionality of products and services depends on regular maintenance, the following activities must be considered:

- Clarification of servicing responsibilities among supplier, distributors, and users
- Planning of service activities, whether carried out by the supplier or by a separate agent
- Validation of the design and function of special-purpose tools or equipment for handling and servicing products after installation
- Control of the measuring and test equipment used in field servicing and tests
- Provision and suitability of documentation, including instructions for use in dealing with the spares or parts lists, and in servicing of the product
- Provision for adequate back-up, to include technical advice and support, and spares or parts supply
- Provision of competent servicing personnel
- Training of servicing personnel

Even when not specified in the contract, the guidance provided here may be helpful to a company that offers service contracts or agreements to customers after the expiration of the warranty period.

Element 20 STATISTICAL TECHNIQUES

The company must identify where the use of statistical techniques is needed to establish, control, and verify process capability and product characteristics. Once such a need is established, the company must establish documented procedures to ensure that the identified techniques are implemented and controlled.

The use of statistical methods can be beneficial to the company in a wide range of circumstances, including the collection, analysis, and application of data. They assist in deciding what data to obtain and in making best use of the data, both of which help a firm gain a better understanding of customer requirements and expectations.

Statistical methods are useful in product, service, and process design; controlling processes; avoiding nonconformities; analyzing problems, determining risks; finding root causes; establishing product and process limits; forecasting; verification; and the measurement or assessment of quality characteristics.

2. How the Audit Fits into Your Quality System

- * What is a quality system?**
- * Documentation of the system**
- * What is an audit?**
- * Why do we audit?**
- * Management's role**

What is a Quality System?

A **quality system** is a strategy to provide a structure or process of how you will operate.

In learning about or forming a quality system, you will need to take the following four items into consideration:

- **Quality Policy**

The company's quality policy is a statement of its organization's philosophy and emphasizes the values that are important in its operations. The quality policy is initiated, and usually written, by top management.

In the quality policy, the company will make specific commitments to their customers, their employees, and to itself. When a company establishes a quality policy and communicates it to all employees, it becomes a commitment to quality decisions and work emphasis.

- * **System Elements**

The quality system must integrate all functional areas of the organization that may have an impact on product quality if it is to be successful. Therefore, it is important not to think of quality as limited to the Quality Assurance Department, but as a part of operations that everyone is concerned with.

- * **Best Practices**

Having a quality system means that the company must define how things are going to be done (the defined activities are known as "procedures"). It makes sense to build procedures based on the best, most efficient practices in place. In that way, the company is communicating to all employees the best, most efficient ways to get the job done.

- * **Types of standards**

Businesses have to take many types of standards into consideration, which fall into one of two categories: **contractual** or **voluntary**. Contractual standards must be adhered to due

to a legal requirement; examples of these requirements can be found in contractual agreements and in government regulations. Voluntary standards are those which are not legally required; examples are the ISO 9000 standards, and standards from industry associations.

Documentation of the System

Why document a quality system?

* **Guidance**

Documentation provides a structure on which employees can get dependable information concerning their work place and work functions. Quality system documentation explains such things as the company organization, company objectives and goals (related to quality), the skills and experience required for work positions/functions, and work activities performed to produce product.

* **Consistency**

When employees perform work according to documented best practices, the end result is that activities are performed in the same manner every time. This produces consistency in work performance, and in turn, in the way product is produced.

* **Compliance**

Documentation is a vehicle to communicate adherence to the requirements of applicable standards.

* **Basis for auditing**

Because documentation is used to communicate how organizations fulfill the requirements of applicable standards, it can be used as a basis for auditing the quality system against the standards.

What is an Audit?

*An **audit** is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.*

The above definition outlines some important characteristics of audits. The following list is of characteristics that should be built into quality system audits to maximize audit credibility and effectivity:

*** Planned**

Audits must be planned in accordance to a defined objective. To be effective, auditors should prepare for an audit by considering questions such as:

What is the purpose of this audit? **Define what needs to be accomplished.**

What is the scope of this audit? **Define what/who will be audited.**

Who will perform the audit? **Define which person(s) will carry out activities.**

When will the audit be performed? **Define the day(s) and time(s) for the audit.**

What information sources will be utilized? **Define a strategy for investigation by identifying what information is available/appropriate for review.**

*** Independent**

Audits must be performed by persons who are independent of the functions audited in order to eliminate potential bias. For example, auditors cannot be completely objective when auditing their own work, and managers may question the motives behind findings when auditors review processes within their own departments.

*** Management Driven**

The success of any audit program depends on the support of management. Quality system audits are a source of information to management with regard to how well the company has established and implemented an effective quality system, and an integral part of continuous improvement.

*** Compliance Orientation**

Quality system audits to ISO standards are conducted such that the auditors *look for compliance* to the requirements set forth by the standards. This means that quality system audits will review documentation for **intent** to comply with the applicable standard, as well as records and processes to determine **implementation** of the documented quality system and how **effective** the quality system is.

Why do we audit?

Audits are an information gathering and reporting process which provides management with factual input for making decisions, and therefore are

considered a valuable tool. Internal audits are also a requirement of ISO 9000, and must be performed to satisfy element 4.17 of the standard.

The benefits to performing audits include, but are not limited to:

* **Identification of opportunities for improvement.**

Audit reports provide management with information about where the quality system is working and where it is not working. Management then has the opportunity to determine what causes the problem identified and implement appropriate corrective action.

* **Quality system implementation check.**

Internal audits provide an objective view of how well the documented processes/procedures have been implemented.

* **Quality system effectiveness check.**

Information generated from internal audits provide an objective view of whether or not the quality system is accomplishing what was intended. Are the results what the company expected?

* **Improve communications and motivation.**

Regular internal audits facilitate the company's awareness of processes, on a company wide as well as departmental level. Communications improve within departments, between departments, and on a managerial level. A clear understanding of what improvements are needed is a motivator for action.

Management's Role

Management has an active role in an internal audit program, and is charged with the responsibility of:

- * **Initiation of the audit program.**
The audit program must be initiated and supported by management if it is to be viable.
- * **Assurance of auditor independence.**
Provisions must be made to ensure that auditors have no responsibilities in the areas audited so as to eliminate the possibility of any bias with respect to audit findings.
- * **Provide resources.**
Managers must ensure that there are an adequate number of trained auditors available to administer the audit program, and that employees are made available during audits.
- * **Assure corrective action.**
Managers must consider and take actions necessary when the results of an audit show that corrective action is required.

3. Types of Audits

Traditionally when we think of audits, we think of the kind of audit most people have been exposed to - - a financial audit. Although the principle is the same for all audits (a review of the actual activity performed against an established requirement), audits performed in quality have distinctly different categories and types that we need to be aware of.

*** Internal and External Audits**

*** Quality System Audits**

*** Other Types of Audits**

Internal and External Audits

Audits performed in quality, particularly quality system audits, fall into one of two categories: internal or external audits.

*** Internal Audits**

Internal audits are audits that are carried out by an organization on itself to confirm to management that the quality system is in good working order. As has already been discussed, internal audits are a requirement of the ISO 9000 standards, but organizations which are not registered to ISO 9000 utilize internal audits as a functional tool as well. Internal audits can also be used as a control mechanism by management, a source of meaningful information by which management makes business decisions, or a requirement of an outside regulating body.

* **External Audits**

There are two different types of **external audits: second party** and **third party**. Second party audits are audits that are carried out by one company on another company, and is also commonly known as a *vendor audit*. These audits are performed when the purchasing company has a vested interest in the results of the audit; for example, if the purchasing company needs assurance that any chosen vendor can supply a specific amount of product within a specific amount of time, second party (vendor) audits can be performed investigating potential vendors' capability to deliver. A decision to utilize a particular vendor can be made based on audit findings.

Third party audits are audits that are carried out on a company by an independent organization. In other words, the organization that performs the audit represents an interest that is separate from a direct business relationship. Examples of third party audits are ISO 9000 assessment audits (performed by a **registrar**), Good Manufacturing Practices audits (performed by **FDA**), financial audits (performed by the **IRS**), and safety audits (performed by **OSHA**).

Quality System Audits

A **quality system audit** is an evaluation of the whole quality system, and will include all processes that affect quality. As you can see, thorough audits of this nature can be time consuming, and therefore expensive, to conduct.

An example of a quality system audit is the *assessment audit* for the purpose of ISO 9000 registration, which differs from most internal audit programs. Internal audits tend to be relatively short, reviewing the quality system in segments over an established period of time. An assessment audit will be more concentrated in that it is intended to accomplish a similar quality system review over a much shorter period of time.

Since we are looking at the ISO 9000 assessment audit as an example of a quality system audit, let's discuss what the auditors will look at and try to establish:

Intent

The first order of business in a quality system audit is to determine that a quality system is in place. The initial proof of the existence of the quality system is documentation, and the auditor will commonly look at the quality manual. The quality manual should provide the auditor with assurance that (1) the quality system in place considers all of the requirements of the applicable standard and (2) the quality system is supported by management.

Implementation

The second order of business in a quality system audit is to determine that the documented quality system is in practice, or in other words, is implemented. Auditors may choose several avenues of investigation, including: Are all of the processes affecting quality documented? Is the documentation of processes affecting quality accessible to employees who need it? Are employees familiar with quality system documentation, and are they utilizing it in their job functions? Are records produced as proof that employees are following the prescribed quality system?

Effectiveness

The third order of business in a quality system audit is to determine that the quality system is producing the results intended, or in other words, is effective. The auditor reviews all processes to see if the processes are working *for* the organization. For example, if a company's purchasing procedure does not take into consideration problems with vendors that are shown to consistently interfere with business, then the documented purchasing process is ineffective.

Other Types of Audits

There are other types of audits that are performed for the purpose of evaluating quality. Consider the following examples:

*** Product Audits**

A product audit is performed for the purpose of verifying that the product meets the required specifications.

*** Process Audits**

A process audit is performed for the purpose of verifying that the process enables a product (that meets specified requirements) to be produced consistently. In other words, the auditor will be looking to confirm that the process is stable. Process audits are typically utilized to assure confidence, not to investigate problems.

*** Problem or Spot Audits**

A problem (or “spot”) audit is performed for the purpose of verifying continued stability in an area where a problem has been identified. These audits are usually focused, of short duration, and assess whether procedures/work instructions are being followed.

*** Self Audits**

A self audit is performed when a manager audits his/her own area, or when an employee audits his/her own work processes. This particular type of audit lacks independence (is considered *biased*), but is considered useful in the identification of (1) problems that may be found in documented processes or (2) areas that could be improved.

4. Parts of the Internal Audit System

*** Who are the people involved?**

*** Which procedures/documentation will be used?**

- * What are the goals of the audit?**

- * What are the audit results?**

- * What kind of follow up activities will be performed?**

Who are the People Involved?

- * Management**

Management provides for the establishment of an internal audit program and is responsible for approving an internal audit schedule, providing for adequate resources to carry out the internal audit program, and receiving/considering internal audit reports and requests for corrective action. For quality systems that are compliant with an ISO 9000 standard, much of these responsibilities can be carried out by the Management Representative, who reports to management.

- * Internal Audit Team**

The internal audit team is composed of people representing multiple areas or functions such that independence in audits can be assured. These individuals are qualified by formal training/experience in performing quality system audits.

While internal auditors must possess an appropriate level of training/experience, they should also be appointed based on important personal attributes, including (but not limited to):

Open minded	Fair	Dedicated	Sensitive
Analytical	Tenacious	Skilled communicator	Mature
Good listener	Attentive	Sound judgment	Dependable
Consistent	Friendly	Organized	Supportive
Handles stress	Assertive	Good concentration	Professional manner

*** Department Personnel**

All personnel in departments who have responsibilities that affect quality are subject to internal audits. Department personnel are expected to be available for audit participation, answer auditor questions honestly and fairly, and to participate in the implementation of corrective action when necessary.

Which Procedures/Documentation Will be Used?

*** ISO 9000 Standard**

For quality system audits performed based on an ISO 9000 standard, the standard should serve as a reference for requirements which must be addressed/met by the quality system.

*** Procedures**

To be in compliance with ISO 9000, organizations must document the functions/processes of the internal audit system by procedure(s) or work

instruction(s). To be effective, the procedure(s) or work instruction(s) should address the following items:

Auditor Qualifications

Auditor qualifications should be established in terms of training and/or experience such that employees performing internal audits are ensured to be effective.

Audit Tools

There are tools commonly used by auditors such as checklists, nonconformity reports, and various other forms that help to standardize audit format as well as ensure that minimum audit criteria are achieved.

Audit Process

The audit process itself should be established for the benefit of all audit participants. Steps in the audit process should include (but not be limited to) audit preparation, the opening meeting, execution of the audit, the closing meeting, requests for corrective action, and follow up to corrective action.

What are the Goals of the Audit?

What you are trying to accomplish by performing an audit must be established prior to the audit during the audit planning stage. Audits will vary according to **purpose** (why is the audit being performed?) and **scope** (which processes/documentation will be audited?). Internal auditors of quality systems which are based on an ISO 9000 standard audit for the purpose of confirming compliance to both the standard and other documented requirements within a scope defined by the schedule or the internal audit program administrator. Once compliance is demonstrated, auditors look for evidence that the quality system is beneficial to the organization (is effective).

An important concept in quality that is central to quality auditing is *continuous improvement*. The idea is to utilize audits as a tool for identification of areas that are either weak or could be improved upon. Continuous improvement is helpful to companies who wish remain competitive in an ever changing market place, as well as potentially beneficial in terms of cost control.

With these points in mind, the overall goal of internal quality auditors is to provide management with information that is needed to help **build a better company**. This goal should be in the front of an auditor's mind even while operating within the limits of any one audit's purpose and scope.

What are the Audit Results?

Audit results are very simply a communication of what the auditors found during the audit. The audit results are communicated verbally during the audit closing meeting, and summarized in writing in a final report to management.

It's important to remember that while most of us think of an audit as a way to find what's *wrong*, it's also a way to find out what's *right*. Information with regard to what is going well can sometimes be as important/useful as information concerning areas where improvement is needed.

What's *wrong* can be classified as an **observation** or **nonconformity**. An *observation* is a situation which relates to existing conditions which, in an auditor's judgment, warrants clarification or investigation. A *nonconformity*, by contrast, in which nonfulfillment of a requirement can be clearly demonstrated by objective evidence.

Nonconformities are classified as either **major** or **minor**. A *major nonconformity* can be described as the absence of a requirement, or the total breakdown of a process/system (such that the requirement is not met). An example of a major nonconformity would be the absence of documented procedure(s) for contract review. A *minor nonconformity* can be described as a single observed lapse with respect to meeting a requirement. An example of a minor nonconformity would be a finding that an employee forgot to fill out a form as required by procedure. **NOTE:** A number of minor nonconformities made against one requirement may be judged to indicate the total breakdown of a system, and therefore be collectively considered a major nonconformity.

Corrective action taken as the result of audit findings should be proportional to the significance of each of finding.

What Kind of Follow Up Activities Will be Performed?

Internal auditors have a responsibility to **follow up**, or review, the corrective action associated with audit observations and nonconformities for the purpose of ensuring adequacy and effectiveness of the corrective action.

Follow up activities include:

- * Review of a written response made by management to each observation/nonconformity. The response should include a cause analysis (*why* the problem existed) and a commitment to an outlined plan for corrective action.

During this part of follow up, the auditor should gain confidence that the root of the problem has been identified, and that corrective action addresses the problem adequately. Temporary (often called “band aid”) fixes are acceptable provided that a long term fix is identified and under implementation.

- * Review of the corrective action in the field must be performed for final verification of effective implementation.

During this part of follow up, the auditor should return to the area(s) affected by the nonconformity and gather objective evidence that the corrective action has been implemented, and if implemented, has been effective in eliminating the problem.

Until corrective action has been found to be both implemented and effective, an audit may not be closed.

5. How to Plan an Audit

The key to the success of any audit is proper planning. The planning stage itself takes time, which is particularly dependent upon the experience and knowledge of the auditor(s) involved.

A well defined audit plan is the best insurance that the audit will be smoothly executed and provide comprehensive information. Several activities should take place during the planning stage to develop a well defined plan, which we will go over in detail.

* **Pre-audit Review**

* **People/Departments Involved**

*** Development of Audit Checklist**

*** Auditing Methods to be Used**

Pre-audit Review

A review should be performed prior to the audit for auditor orientation. The review must include documentation, but may also involve a visit to the area being audited.

The review should result in the following questions being answered:

What is the purpose and scope of the audit?

When is the audit scheduled to take place? Who should be contacted prior to the scheduled date for appropriate arrangements/notification?

What processes will be covered during the audit? Is there information that can be obtained in advance that would help to prepare the auditors?

Which department(s) will be affected by the audit? Who are the key people to speak to within the department(s)?

Have there been previous audits addressing the same purpose and scope? If so, what were the findings?

Are there any open corrective action issues which could be followed up during the audit?

These questions are not all inclusive, but are representative of information that is relevant in preparation for most internal audits.

People/Departments Involved

Audit team members should be chosen considering both audit content and auditor background.

When forming the audit team, the following should be addressed:

*** Technical/functional expertise needed for the audit.**

Audits are always more productive when auditors are familiar with the processes being audited. In cases where processes are highly technical or specialized, it is best to assign at least one auditor to the team that has knowledge/experience in that area to ensure a fair and accurate review.

*** Experience of auditors.**

Auditors without an appropriate level of training/experience should not perform an audit alone. Audits are most productive when performed utilizing at least one person who has experience in the audit process.

Audits performed by a team may (and should) utilize auditors with varying levels of auditing experience. This can function to strengthen the team; experienced auditors can draw off of the technical/functional knowledge of the inexperienced audits, and inexperienced auditors will gain valuable auditing experience.

*** Independence of departments.**

It is a requirement that auditors *may not* audit departments/work functions for which they have *direct responsibility*. This is important in the control of auditor bias (real or implied), and therefore in the general acceptability of audit results.

* **Need for orientation.**

Situations may arise when one or all members of the audit team will benefit from an orientation to the audit process, the facility in which the audit will take place, or the processes being audited. The need for orientation should be assessed and orientation performed prior to the audit.

Development of Audit Checklist

One of the most important tools for auditors is the **checklist**. The audit checklist is exactly what the name implies - - a reference form for the auditor that guides him/her through the audit in accordance to the audit plan.

The checklist helps to reduce the auditor's "thinking time" because it both serves as a reminder of what is to be covered and provides information that otherwise may require a search. In other words, the checklist functions to speed up the audit process, help the auditor keep track, and ensure that (as a minimum) the amount of review prescribed by the audit plan is accomplished.

What should a checklist look like? There's many more than one acceptable format, but the checklist should contain at least the following:

* **Departments/processes/records targeted for review.**

This information can be formatted many ways to guide the auditor, such as questions that may be asked or a simple list of what is to be covered where.

* **A cross reference to the (ISO 9000) requirement to which the review is against.**

Each part of the audit should speak to the fulfillment of one or more requirement.

* **Space for notes.**

Recording what is observed is one of the most important activities an auditor performs. Notes document the audit trail followed, audit findings, and point out possible audit trails that may be relevant for other audits.

Audit Methods to be Used

There are several approaches to performing an audit, and auditors should understand which method (or combination of methods) of investigation are to be used prior to audit execution.

* Vertical

Auditors using this method follow a trail of specific records through relevant departments.

Vertical audits can be performed *upstream* (with the normal flow of business) or *downstream* (backwards from the normal flow of business).

Example of upstream vertical auditing: _____

Example of downstream vertical auditing: _____

* Horizontal

Auditors using this method review the processes within a particular department and how the department interfaces with other departments.

Example of horizontal auditing: _____

* By ISO Element

Auditors using this method review all processes related to a particular ISO element.

Example of auditing by ISO element: _____

No one method of auditing is better than another. A clearer, more accurate picture of the quality system is gained by varying and combining these methods over the course of the audit schedule.

6. How to Conduct an Audit

Although internal audits will not be conducted exactly the same way from company to company, there are some basics that all auditors should utilize in conducting an audit. We will discuss the basics as follows:

- * Opening Meeting**

- * Performing the Audit**

- * Collecting Objective Evidence**

- * Observations and Nonconformities**

- * Closing Meeting**

Opening Meeting

An **opening meeting** is conducted to introduce the audit plan to the auditees, allow for any questions the auditees might have concerning the audit, and to make any last minute adjustments to the audit plan.

The opening meeting is conducted by the **lead auditor**, is attended by the audit team and auditees, and is typically informal (for internal audits). The format of the opening meeting should include the following:

A description of the audit plan. The lead auditor should define the scope and purpose of the audit, and the schedule (estimated time table) the audit will follow.

An introduction of the audit team members. The lead auditor introduces him/her self and the audit team members who will perform the audit.

Discuss confidentiality. Auditors sometimes review records that contain proprietary company information, and auditees should be assured that this type of information is protected. It is also helpful for auditees to know that audit findings are presented and discussed only with authorized personnel.

Discuss the logistics of the audit. If the audit team is unfamiliar with the facility, the lead auditor may arrange for a brief tour as well as inquire about areas/departments which may have special requirements for safety or production related issues. Auditors may be asked to wear special garments/equipment or be asked to avoid the area altogether. Guides also may be provided to the auditors, and if so, should be identified at this time.

Make any necessary changes to the audit plan. Auditors must stay sensitive to the fact that business does not stop due to an audit and allow for requested changes to schedule that do not threaten the integrity of the audit.

Performing the Audit

Effective auditors are those people who become good at formulating questions and researching the answers through either reviewing documentation or interviewing employees.

Your job as an internal auditor will be to look *for* objective evidence of compliance with the ISO 9000 standard. This means that you thoroughly research the quality system to see that the requirements of the standard are being fulfilled. When you are at the end of the **audit trail** (i.e., you have no other resource available for research) and cannot confirm that a requirement is being fulfilled, *or* when you have confirmation that a requirement is not being fulfilled, then you have uncovered a **nonconformity**.

Auditing is most productive when you are able to work well with auditees. There are several ways in which auditors can foster a helpful attitude among auditees as well as encourage auditees to provide useful information:

Always be professional and courteous. When you behave in a respectful, cooperative manner, auditees will typically reciprocate. Ask for records instead of demanding them, be open about concerns you may have during the audit with respect to what you are finding (nonconformities should never be a surprise to the auditee!), and refuse to be pulled in to a confrontation.

Think about your interviewing techniques. When you are looking for a simple “yes” or “no” answer, ask a *closed-ended* question (for example, “Do you file this record once it is complete?”). When you are looking for an explanation, ask an *open-ended* question (for example, “What do you do with the record once it is complete?”), or simply be silent. *Never prompt an answer*, as this tends to bias auditee response.

Cross check your findings. A number of circumstances may lead you to the wrong conclusion (for example, differences in terminology or an employee who “fills in” what he/she doesn’t know) if left unconfirmed by cross check. Once you get into the habit of making sure your finding is accurate, you will minimize your errors as well as increase auditee confidence in your objectivity.

Collecting Objective Evidence

The integrity of the audit depends on the auditor's ability to base findings on objective evidence. **Objective evidence** is evidence that is first hand, factual, and gathered during direct observation by the auditor; it is proof that stands up to scrutiny that the finding is accurate and true.

Look at the following examples and see if you can pick out evidence that is objective:

Evidence	Objective? (Y or N)
Statements made by the Receiving Supervisor about Customer Service Department activities.	_____
Statements made by Customer Service Employees about customer complaints with the product.	_____
Customer Service complaint records.	_____
Statements made by the Quality Control Supervisor about quality control activities.	_____
Statements made by shipping personnel about receiving work instructions.	_____
Purchase orders.	_____
Master list of controlled documents.	_____
A hand written addition to procedure on a sticky note.	_____
Statements made by the Production Supervisor about the ethics of the Production Manager.	_____
An explanation of the company Quality Policy a production employee.	_____

Observations and Nonconformities

We have already discussed *observations* and *nonconformities* as classifications for what is found wrong during the quality system audit (refer to **What are the Audit Results?**). Nonconformities can be further classified as *major* or *minor*. The classification of findings can be somewhat subjective, but there are a few useful rules of thumb to follow:

Observations and nonconformities are based on objective evidence. An auditor's findings are never based on hunches, suspicion, or any other incomplete information. Findings should always be clearly documented by detailing the facts: note what was observed, where it was observed, and who (job title) verified the finding.

Observations and nonconformities are written clearly against a requirement of the standard to which the quality system is audited. Auditors must provide a clear case for nonfulfillment of a requirement by referencing the standard.

Always give the auditee the benefit of the doubt. If you question whether to classify the nonconformity as major or minor, classify it as minor.

Provide the auditee with as much useful information as possible. If you feel strongly about something that does not clearly demonstrate a failure to meet a requirement, report it as an observation. And remember, observations can be negative *or* positive. It is as important to give credit where it is due in the audit report such that the audit will have a clear understanding of what is going **well**, not just what is going wrong.

As an exercise, try to classify the following as a nonconformity or observation. If you find that it is a nonconformity, classify it as major or minor:

The quality system does not include a procedure for the controlled distribution of documentation.

The quality system includes a mechanism for indexing quality records that is cumbersome and reported to be difficult to keep up with.

The quality system includes a procedure for indexing quality records that is not consistently being followed.

Closing Meeting

Like the opening meeting, the **closing meeting** of an internal audit is conducted by the lead auditor, but is usually more formal than the opening meeting. It ends the audit with a presentation of findings to managers and so requires the lead auditor to establish a professional atmosphere so that he/she can maintain control of the meeting agenda.

The format of the closing meeting should include:

An introduction of audit team members and thanks to the auditees. Possibly not all employees attending the closing meeting were present at the opening meeting, so a reintroduction may be in order. Expressing gratitude for hospitality is always in order; auditing activity takes away from the time employees have to perform job duties.

Scope and purpose of the audit. A repeat of the scope and purpose will provide a framework for the audit results.

Presentation of findings. Link all nonconformities to the appropriate requirement, and indicate how the nonconformities were classified. End the presentation of findings with general impressions, indicating areas of strength and weakness (positive and negative observations).

Presentation of corrective action requests. This is in written form, and should address all nonconformities.

Final report contents and schedule. Cover in detail what the final report will include and when it will be delivered to management.

7. How to Write the Final Report

The **final report** is intended to provide a balanced picture of the entire audit. It is not intended to be a “stand alone” document, but rather as a summary of the audit that ties the audit records together. Written by the lead auditor, the final report should be kept short, to the point, and in line with the purpose of the audit.

Include in the report format information such as: the **scope and purpose of the audit**, **auditee information**, **auditor information**, the **audit basis** (standard to which the quality system was audited against), and the **audit results/conclusions** (including the nonconformities found and supporting evidence). Auditor recommendations may be included in the report if requested by management, but as a general rule *auditors should not offer suggestions for fixes to nonconformities*. If the auditor returns to the area to reaudit, review of the fix will put the auditor in the position of auditing his/her own work, producing possible *bias*.

The final report for internal audits is usually routed to the managers of the departments audited, and may be distributed further to upper management depending upon the requirements of the documented quality system.

8. How to Follow-up the Audit

The audit is not closed upon distribution of the final report; it is closed once corrective action to nonconformities have been implemented by management, and **followed up** and found to be effective by an auditor. This provides a *closed loop* system for auditing, which ensures that the auditing program is effective.

Corrective action isn't sufficient if it is administered as a "bandaid" or a "patch." The root cause of the problem must be identified and attacked for the fix to have real meaning. If the root cause is not readily apparent or if planned corrective action will take a long amount of time to implement, an interim corrective action may be taken but is not reviewed by an auditor for the purpose of closure.

Similar to writing nonconformities, objective evidence is gathered during follow-up to demonstrate the implementation and effectiveness of corrective action. In other words, the auditor is responsible for documenting objective evidence that corrective action was initiated and is working. This constitutes a "mini-audit" of sorts, with a very limited scope and performed for the sole purpose of closing the nonconformity. Auditors therefore should avoid the temptation of "springboarding" into new findings.

Once all nonconformities associated with an audit are followed up and verified to be effective, the audit can be formally closed. The official closing of the audit is generally routed to the managers who received the final report, and may include a summary of corrective action.

Glossary of Key Terms

The following definitions relate to terms used in the ISO 9000 standards. These are terms that are frequently affiliated with the process a company undertakes to achieve ISO 9000 compliance.

Accreditation	Procedure by which an authoritative body formally recognizes that a body or person is competent to carry out specific tasks.
Assessment	An estimate or determination of the significance, importance, or value of something.
Audit	A planned, independent assessment to determine whether agreed-upon requirements are being met.
Auditee	An organization being audited.
Auditor	(Quality Auditor) A person qualified to perform quality audits.
Certification	Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.
Client	A person or organization requesting the audit.
Compliance	An affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant specifications, contract or regulation; also, the state of meeting the requirements.
Configuration	The functional and physical characteristics of a product as set forth in technical documentation and achieved in the product.
Configuration Management	The technical and organizational activities of configuration identification and configuration control.
Conformity	The fulfillment of specified requirements.
Concession	An approved alternative to original agreement/specification.
Contract Review	The systematic activities carried out by the supplier before signing the contract to ensure that requirements for quality are adequately defined, free from ambiguity, documented, and can be realized by the supplier.
Corrective Action	An action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situations in order to prevent recurrence.
Defect	The nonfulfillment of intended usage requirements.
Design Review	A formal documented, comprehensive and systematic examination of a

design to evaluate the design requirements and the capability of the design to meet these requirements and to identify problems and propose solutions.

Finding	A conclusion of importance based on observation(s).
Follow-up	An audit whose purpose and scope are limited to verifying that corrective action has been accomplished as scheduled and to determination that the action effectively prevented recurrence.
Inspection	Activities such as measuring, examining, testing, or gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.
ISO	Adopted from the Greek word “isos” meaning “equal,” this term is often used to refer to the International Organization for Standardization based in Geneva.
Lead Auditor	An auditor designated to manage a quality audit.
Management Review	A formal evaluation by top management of the status and adequacy of the quality system in relation to the company’s quality policy and objectives.
Nonconformity	The nonfulfillment of specified requirements.
Objective Evidence	Information which can be proved true, based on facts obtained through observation, measurement, test, or other means.
Observation	A statement of fact made during a quality audit and substantiated by objective evidence.
Preventive Action	An action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence.
Procedure	A specified way to perform an activity.
Process	A set of interrelated resources and activities which transform inputs to outputs.
Product	The result of activities or processes.
Product Liability	(Service Liability) A generic term used to describe the duty of a producer or others to make restitution for loss related to personal injury, property damage or other harm caused by a product or service.
Production Permit	(Deviation Permit) Written authorization, prior to production or before provision of a service, to depart from specified requirements for a specified quantity or time.
Purchaser	The recipient of a product provided by the supplier in a contractual situation.

Quality	The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.
Quality Assurance	All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.
Quality Audit	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Quality Control	The operational techniques and activities that are used to fulfill requirements for quality.
Quality Management	That aspect of the overall management function that determines and implements the quality policy.
Quality Manual	A document describing the quality system of an organization. The Quality Policy is also included in this document.
Quality Plan	A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, service, contract or project.
Quality Policy	The overall quality intentions and direction of an organization in regard to quality, formally expressed by top management.
Quality Surveillance	The continuing monitoring and verification of the status of procedures, methods, conditions, processes, products and services, and analysis of records in relation to stated references to ensure that specified requirements for quality are being met.
Quality System	The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.
Quality System Review	A formal evaluation by top management of the status and adequacy of the quality system in relation to the company's quality policy and new objectives resulting from changing circumstances.
Record	A document which furnishes objective evidence of activities performed and results obtained.
Registration	Procedure by which a body indicates relevant characteristics of a product, process or service, or particulars of a body or person, and then includes or registers the product, process or service in an appropriate list which is available to the public.

Reliability	The ability of an item to perform a required function under stated conditions for a stated period of time.
Rework	The action taken on a nonconforming product so that it will fulfill the specified requirements.
Root Cause	A fundamental deficiency that results in a nonconformance and must be corrected to prevent recurrence of the same or similar nonconformance.
Service	The results generated, by activities at the interface between the supplier and the customer and by supplier internal activities, to meet customer needs.
Specification	The document that prescribes the requirements with which the product or a service to a customer.
Subcontractor	The organization that provides a product to a supplier.
Supplier	An organization that provides a product or service to a customer.
Survey carefully;	An examination for some specific purpose; to inspect or consider to review in detail.
Tender	Offer made by a supplier in response to an invitation to satisfy a contract to provide product.
Total Quality Management	A systems approach to continuous improvement, centered on quality, based employee empowerment, and aiming at long term success through customer satisfaction and benefits to the organization and society.
Traceability	The ability to trace the history, application or location of an item or activity, or similar items or activities, by means of recorded identification.
Validation	The process of evaluating a product or process to ensure compliance with specified requirements.
Verification	The process of confirming that product or process output meets the input.