

ISO 9001

▪ 4.2 Quality System

- What this means: The requirements may be seen as a four-stage process
 - Stage I quality system conformance to requirements
 - Ensure that your quality system conform with the requirements of the Standard
 - Stage II quality system documentation
 - Prepare appropriate quality system documentation
 - Stage III quality plan documentation
 - Prepare appropriate documented quality plans for products, processes, and/or projects within the quality system.
 - Stage IV implementation
 - Implements the quality system, its documentation, and appropriate quality plans.

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▪ 4.2 Quality System (cont'd)

– Required documents and records:

- Controlled documents
 - The quality manual;
 - Quality plans for products, processes, and/or projects;
 - Supporting procedures describing your processes; and
 - Supporting procedures describing work instructions and require records
- Quality records
 - Any records required by your documentation

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▪ 4.2 Quality System (cont'd)

– Auditor questions:

- Quality planning
 - How are control, processes, inspection equipment, and personnel resources identified and put in place to achieve required quality?
 - How is the need for changes in quality control determined?
 - How are standards of acceptability determined?
 - How are measurement requirement determined?
- Quality manual supporting documentation
 - Where is your documented quality manual?
 - Where does the quality manual contain: the quality policy, an outline of the document structure, reference to supporting documentation?
 - How is the need for additional procedures determined?

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▪ 4.2 Quality System (cont'd)

– Auditor questions:

- Quality plans
 - How do quality plans cover products, processes, and/or projects as appropriate?
- Implementation
 - How is the quality system being operated?
 - Is the quality system operated according to the documentation?

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- 4.5 Documentation and data control (cont'd)
 - Accessibility: includes
 - *A document reference index* (like a document master list) that is accessible to organization personnel and shows the most current revision of each controlled document or data sheet;
 - *Organization* for your control documents and data sheets in a structure allowing easy access to information;
 - Controlled documents and data sheets *formatted* to allow easy access to information;
 - Controlled documents and data sheets in *hard copy, electronic, or other media* accessible to those requiring them;
 - *Obsolete documents* and data sheet removed to preclude their accidental use

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- 4.5 Documentation and data control (cont'd)
 - Review, revision, approval, and disposition: includes
 - New and revised documents and data sheets *reviewed and approved* by authorized personnel
 - Reviewers and approver having access as necessary to *supporting reference material*;
 - *Immediate disposition* of all obsolete documents and data sheets;
 - Changes indicated in revised documents and data sheets or in some form of *change notice*
 - *Periodic review* of each document and data sheet

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- 4.5 Documentation and data control (cont'd)
 - Required documents and records:
 - Controlled documents
 - Document and data control process and procedures,
 - Document and data sheet master list or similar means of document indexing,
 - Lists of those approving documents and data sheets, and
 - Document and data sheet review schedule,
 - Quality records
 - Copy distribution lists,
 - Document and data sheet review results,
 - Individual document and data sheet background information, and
 - Identification of nature of changes.

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- 4.5 Documentation and data control (cont'd)
 - Auditor questions:
 - What is your process for controlling quality system documents and data sheets?
 - Who approves release of documents and data sheets?
 - How do personnel have access to documents and data sheets they require?
 - How are obsolete documents and data sheets accounted for?
 - How are changes identified?
 - What documents and data sheet master list or similar listing is readily available to personnel? Where is it?

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- 4.6 Purchasing
 - Requirement: your organization shall ensure that purchased product conforms to specified requirements.
 - What this means: you need to establish a purchasing process ensuring that purchased products coming into your quality system meet specified requirements. The purchasing process includes subcontractor evaluation, purchasing data, and verification at the subcontractor level.

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- 4.6 Purchasing (cont'd)
 - Subcontractor evaluation: included
 - Evaluation and selection of subcontractors based on their ability to meet your requirements, with selection criteria based on:
 - The type of product and
 - Previously demonstrated capability and performance;
 - Evaluation of subcontractor quality system effectiveness
 - Definition of type and extent of supplier control over the subcontractor
 - Maintaining a list of acceptable subcontractors.

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- 4.6 Purchasing (cont'd)
 - Purchasing data: included review and approval of purchase orders for
 - Identification and description of product ordered;
 - Inspection requirements;
 - Quantity and delivery;
 - Requirements for approval of product, process, and/or personnel;
 - The appropriate ISO Standard to be applied; and
 - Requirements for supplier or customer product verification and/or product release at the subcontractor's site.

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- 4.6 Purchasing (cont'd)
 - Required documents and records:
 - Controlled documents
 - Purchasing process and procedures;
 - List of acceptable subcontractors, and
 - Product specifications
 - Quality records
 - Subcontractors capability, including effectiveness of quality system controls,
 - Selection of subcontractors,
 - Periodic subcontractor review results,
 - Purchasing data and contract, and
 - Purchasing data review and approval.

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- 4.6 Purchasing (cont'd)
 - Auditor questions
 - What is the documented process for ensuring that incoming material conforms to specifications?
 - How are subcontractors selected?
 - How are acceptable subcontractors documented?
 - How is the performance of subcontractors reviewed?
 - Where on your purchase orders do you clearly describe
 - Product ordered,
 - Inspection requirements
 - Quantity and delivery requirement
 - Approval requirements

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- 4.7 Control of customer-supplied product
 - Requirement: your organization shall provide for verification, storage, and maintenance of customer-supplied product provided for incorporation into your product.
 - What this means: your customer becomes both your customer and your subcontractor when supplying you with product that is incorporated into your product.

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- 4.7 Control of customer-supplied product
 - Required documents and records:
 - Controlled documents:
 - Verification process and procedures
 - Storage process and procedures
 - Maintenance process and procedures, and
 - Nonconformance process and procedures.
 - Quality records:
 - Product lost, damaged, or unsuitable for use, and
 - Verification results.

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- 4.7 Control of customer-supplied product
 - Auditor questions:
 - What is the documented process for verification, storage and maintenance of customer-supplied product?
 - If customer-supplied product is lost, damaged, or unsuitable, how is this reported back to the customer?

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- 4.8 Product identification and traceability
 - Requirement: your organization shall provide any necessary identification and traceability of incoming materials, in-process product, and finished product.
 - Definition:
 - Identification = ability to separate two more materials or products, e.g., Product A, B, C
 - Traceability = ability to separate a material or product by individual batch, lot, or unit, e.g., Lot 1 of Product A

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- 4.8 Product identification and traceability
 - What this means: your need to be able to demonstrate an ability to identify each of your products. Traceability is required only if specified in the contract, but may be advisable if lot tracking is important to your process.
 - Required documents and records:
 - Controlled documents
 - Product and lot identification process and procedures, and
 - Product lists.
 - Quality records
 - Listings of incoming material batch, lots, or units, and
 - Listings of your product batches, lots, or units.

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- 4.8 Product identification and traceability
 - Auditor questions:
 - What is the documented process for identification and traceability?
 - How is product identified during all stages of production, delivery, and installation?
 - When required, how are individual products or batches uniquely identified to provide traceability?
 - What records are maintained for product identification and traceability?
 - How long are these records maintained?

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- 4.9 Process control
 - Requirement: your production, installation, and servicing processes are operated under controlled conditions.
 - What this means: ensure that your production, installation, and servicing processes are operated under control conditions,
 - necessary documented procedures,
 - Use of suitable equipment,
 - Suitable working environment,
 - Monitoring and control of process and product characteristics,
 - Approval of processes and equipment;
 - Standards of representative product or material samples,

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- 4.9 Process control
 - Required documents and records:
 - Controlled documents:
 - Process and procedures for product, control, monitoring, change approval, maintenance
 - Work instructions,
 - Reference standards, codes and quality plans
 - Representative material or product samples.
 - Quality records
 - Process change approvals,
 - Process maintenance
 - Process monitoring results

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- 4.9 Process control
 - Auditor questions
 - How are each of the following processes that after product quality controlled?
 - Production processes?
 - Installation processes?
 - Servicing processes?
 - What procedures are used to control each process?
 - How is the need for a procedure determined?
 - What is the equipment maintenance process used to ensure continuing process capability?
 - What ensures that process and installation equipment meet “fitness for use”?

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- 4.10 Inspection and testing
 - Requirements: your organization shall ensure that
 - Incoming product is verified for conformance to specified requirements,
 - In-process product is inspected and tested as necessary
 - Finished product is verified as conforming to specified requirements prior to release.
 - What this means: need to have an inspection and testing process that ensures quality of the product throughout your quality system, e.g., three stages
 - Stage I = receiving inspection and testing
 - Inspection or verification
 - Holding until verified, or controlling until verified

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- 4.10 Inspection and testing
 - Stage II = in-process inspection and testing
 - Identification and inspection of product
 - Monitoring of the process
 - Holding or positively controlling product until tests are completed
 - Stage III = final inspection and testing
 - Completing of all required tests and conformance to specified requirements,
 - Release of product only after tests are complete

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- 4.10 Inspection and testing
 - Required documents and records
 - Controlled documents
 - Incoming product tests or verification process and procedures,
 - Test process and procedures for in-process product
 - Test process and procedures for process monitoring,
 - Process and procedures for product final inspection.
 - Quality records
 - Incoming product test results or verification
 - In-process product test results
 - Results of process monitoring affecting product,
 - Final inspection and testing test results

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- 4.10 Inspection and testing
 - Auditor questions
 - What is the documented process for inspection and testing?
 - What are the documented test methods used in this process?
 - Where do inspection and test records clearly show that all tests were completed and released product met specified requirement?
 - Where do the final inspection records show the inspection authority responsible for release of product?
 - How is incoming product tested or verified to ensure conformance to specified requirement?
 - How does final inspection ensure product conforms to specified requirements?
 - How is in-process testing in conformance with quality system procedures?

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- 4.11 control of inspection, measuring and test equipment
 - Requirements: your organization shall
 - Control, calibrate, and maintain inspection, measuring, and test equipment and software used in your quality system to demonstrate the conformance of product to specified requirements
 - Ensure that measurement uncertainty is known and consistent with the required measurement capability.
 - What this means: need a calibrating process that ensures that your inspection, measuring, and test equipment and software have the capacity consistently to provided the specified measurement requirements.

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- 4.11 control of inspection, measuring and test equipment
 - Required documents and records:
 - Controlled documents:
 - Required measurements and their accuracy
 - Calibrating process and procedures
 - Software verification process and procedures
 - Verification and calibration schedule
 - The national standard or other basis for calibration
 - Quality records:
 - Equipment calibration and software verification results
 - Validity of previous inspection and test results when test equipment is found to be out of calibration or software is not verified.

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- 4.11 control of inspection, measuring and test equipment
 - Auditor questions:
 - How are required product measurement identified?
 - How are measurement accuracy requirements identified?
 - How is inspection equipment and software selected?
 - How is inspection equipment and software handled and stored?
 - How is inspection equipment and software affecting the quality of product identified?
 - How is verification status records?
 - Are all calibrations current?
 - How is inspection equipment identified as to calibration status?

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- 4.12 inspection and test status
 - Requirements: your organization shall
 - Ensure identification of inspection and test status of product throughout production, installation, and servicing.
 - What this means: need to be able to identify the inspection and test status of product throughout your production, installation, and servicing. This ensures that only the product passing the required inspections and tests or released under an authorized concession, is released.
 - Test status indicators: ways to indicate test status include:
 - Labels, tags, or stamps on individual product or batches
 - Production status cards
 - Storage in an identified location
 - Inspection and test records
 - Material management software programs

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- 4.12 inspection and test status
 - Required documents and records:
 - Controlled documents:
 - Responsibility for review and release of product
 - Inspection and test status process and procedures
 - Quality records:
 - Inspection and test results
 - Releasing authority for conforming product
 - Auditor questions
 - How is product inspection and test status shown?
 - How is this identification maintained throughout your quality system?
 - How is releasing authority identified and recorded?

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- 4.13 control of nonconforming product
 - Requirements: your organization shall
 - Ensure that nonconforming product is prevented from unintended use or installation.
 - What this means: need a process for controlling nonconforming incoming material, in-process product or finished product, e.g., five stages
 - Stage I identification: identifies nonconforming product
 - Stage II evaluation: see 4.14
 - Stage III notification: notifies all affected parties
 - Stage IV disposition: dispositions nonconforming product through
 - Rework to meet the specified requirements
 - Acceptance by concession with or without repairs
 - Re-grading for alternative applications or
 - Rejects or scrap

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- 4.13 control of nonconforming product
 - Required documents and records:
 - Controlled documents:
 - Responsibility for review and authority for disposition of nonconforming product
 - Control of nonconforming product process and procedures
 - Re-inspection procedures
 - Agreement in contract on need for concession on use or repair
 - Quality records:
 - Re-inspection of repaired or reworked product
 - Notification to interested parties
 - Any acceptances by concession agreements
 - Nonconformance investigation results and disposition action

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- 4.13 control of nonconforming product
 - Auditor questions:
 - How is nonconforming product identified?
 - Who is responsible for the evaluation of nonconforming product?
 - How is nonconforming product segregated?
 - How are affected parties notified promptly?
 - How is reworked or repaired product re-inspected?
 - What is the process for ensuring that nonconforming product is prevented from unintended use of installation?

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- 4.14 corrective and preventing action
 - Requirements: your organization shall
 - Investigate the cause of nonconforming product and consider corrective action needed to prevent recurrence
 - Analyze your quality system to detect and eliminate potential causes of nonconforming product.
 - What this means: it is not enough to control nonconforming product. You need a
 - *Corrective action process* to ensure that the cause of any nonconformity is eliminated to prevent recurrence
 - *Preventing action process* to detect and eliminate potential causes of nonconforming product *before* it occurs

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- 4.14 corrective and preventing action
 - Corrective action process: stages of the corrective action process
 - Stage I nonconformance identification
 - Identifies nonconformance through receipt of customer complaint or report of product nonconformity
 - Stage II cause investigation
 - Investigates the cause of the nonconformity relating to product, process, or quality system
 - Stage III corrective action
 - Determined the corrective action needed to eliminate the cause of the nonconformity
 - Stage IV control application
 - Applies controls to ensure that corrective action is implemented and effective.

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- 4.14 corrective and preventing action
 - Preventive action process: stages of the preventive action process
 - Stage I potential cause identification
 - Identifies process that affect product quality, concessions, audit results, quality records, service reports.
 - Stage II potential cause investigation
 - Investigates the potential cause of the nonconformities
 - Stage III preventive action
 - Determines the preventive action needed to eliminate the potential cause of the nonconformities
 - Stage IV control application
 - Reviews change with management
 - Revises documents
 - Trains personnel
 - Implements change

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- 4.14 corrective and preventing action
 - Required documents and records
 - Controlled documents
 - Corrective action process and procedures
 - Preventive action process and procedures
 - Customer complaint process and procedures
 - Quality records
 - Customer complaints
 - Customer concessions
 - Corrective action investigation results
 - Monitoring of corrective or preventive action for effectiveness

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- 4.14 corrective and preventing action
 - Auditor questions
 - What is the documented process for corrective action?
 - What is the documented process for preventive action?
 - How are corrective and preventive actions made?
 - How are corrective and preventive actions checked for effectiveness?
 - How do the corrective and preventive processes ensure that documents are changed as a results of corrective or preventive action?

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- 4.15 handling, storage, packaging preservation and delivery
 - Requirement: provide adequate handling, storage, preservation, packaging, and delivery of your product to ensure that it meets specified requirements.
 - What this means: handling, storage, preservation and packaging requirements apply to
 - Incoming materials to your process
 - In-process product
 - Finished product

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- 4.15 handling, storage, packaging preservation and delivery
 - Required documents and records:
 - Controlled documents:
 - Handling requirements, process and procedures
 - Storage requirements, process and procedures to include receipt and dispatch authorization
 - Delivery requirements, process and procedures
 - Packaging requirements, process, and procedures
 - Quality records:
 - Storage dates
 - Storage condition verification results
 - Results of calibration of storage control equipment
 - Expiration dating
 - Delivery dates
 - Verification results and mode of delivery

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- 4.15 handling, storage, packaging preservation and delivery
 - Auditor questions:
 - How is product handled to prevent damage?
 - How is product preserved during production?
 - How does packaging protect product in expected distribution?
 - How does packaging provide for any necessary expiration dating?
 - How are storage areas secured, and do they prevent damage and deterioration?
 - Where product shelf life dictates, is the first in, first out principle used?
 - How is product delivery a part of the contract?

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- 4.16 control of quality records
 - Requirements:
 - your quality system operates effectively
 - Required product quality is achieved
 - What this means:
 - You need a process for control of quality records. You make a record accessible to those who need them while minimizing deterioration and damage and preventing loss.

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- 4.16 control of quality records
 - Required documents and records:
 - Controlled documents:
 - Need for specific records (associated with other sections)
 - Process and procedures for control of quality records
 - Required records index and retention schedule.
 - Quality records:
 - Records management reviews
 - Records dispositions
 - Auditor questions:
 - What is the process for control of quality records?
 - Who is assigned responsibilities for the control of quality records process?
 - What subcontractor records are a part of the quality records?
 - How are retention times for each type of quality records?
 - Where called for in the contract, are records available for evaluation by the customer?
 - How do indexing and filing of records allow easy retrieval?

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- 4.17 internal quality audits
 - Requirement: internal audit plan shall verify that your quality activities and related results meet requirements, and determine the effectiveness of your quality system.
 - What this means: need to have internal audit plan that provides input to management on the conformance and effectiveness of your quality system. The output will serve as input to the corrective action process of Section 4.14 and 4.1
 - Internal audit process:
 - Stage I responsibility of quality system management
 - Develops audit plan.

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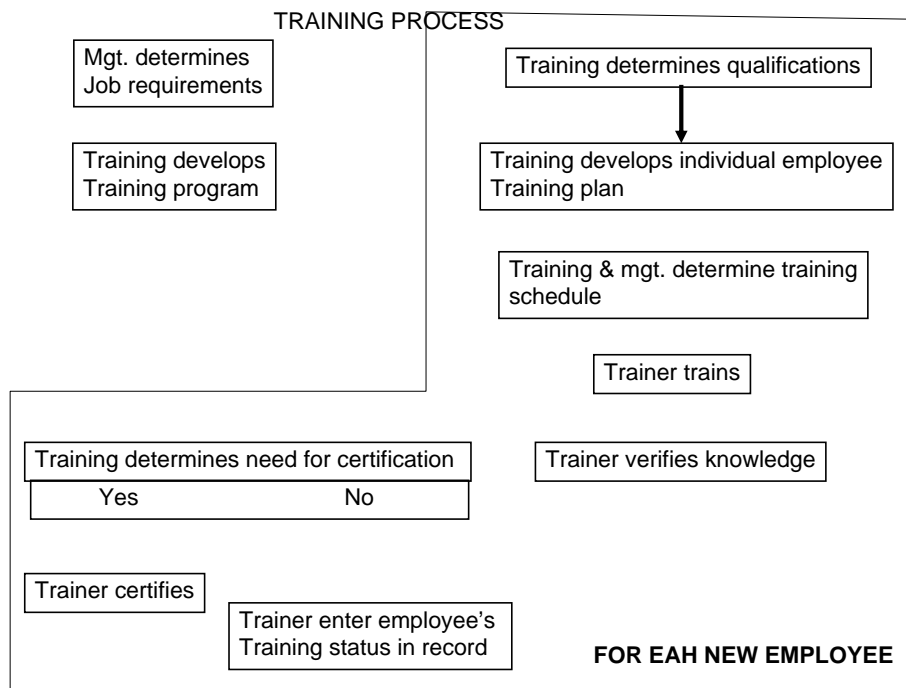
- 4.17 internal quality audits
 - Stage II responsibility of quality system management
 - Schedules audits on the basis of status and importance of the activity.
 - Stage III responsibility of auditor
 - Audits organization, including effectiveness of any previous corrective action
 - Stage IV responsibility of auditor
 - Submits audit report to management of the area audited
 - Stage V responsibility of quality system management
 - Review noncompliances
 - Stage VI responsibility of quality system management
 - Takes timely corrective action on noncompliances

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- 4.17 internal quality audits
 - Required documents and records:
 - Controlled documents
 - Annual internal audit plan, including audit schedule
 - Internal audit process and procedures
 - List of qualified auditors
 - Quality records
 - Audit reports
 - Management audit review and corrective action
 - Auditor questions
 - What is the internal quality audit plan?
 - How many internal quality audits are scheduled and conducted?
 - How are auditors qualified?
 - What corrective actions is taken on deficiencies found in the audit?
 - How are results of audits reports used in the management review?

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- 4.18 Training
 - Requirement: identify training needs and train personnel to meet these needs
 - What this means: employees need to know what to do in order to do their jobs effectively (need to develop a training process based on your quality system job needs and level of individual personnel knowledge)



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- 4.18 training
 - Required documents and records
 - Controlled documents
 - Quality system training needs identification
 - Training process and procedures
 - Training modules
 - List of qualified trainers
 - Quality records
 - Personnel qualifications
 - Individual training plans
 - Individual training results and necessary certifications

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- 4.18 training
 - Auditor questions
 - What is the training process?
 - How are personnel who perform specific tasks qualified to do so on the basis of education, training, and experience?
 - How are individual training schedules developed?
 - How are results of training verified by testing or examination of personnel?
 - Where necessary, how are personnel certified for specific tasks?
 - How are records of training maintained?

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- 4.19 servicing
 - Requirement: when servicing is a specified requirement in the contract, your organization shall control that servicing and verify that it meets specified requirement
 - What this means: servicing is the after-sale attention provided by you on your product, frequently at the customer's site

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- 4.19 servicing
 - Required documents and records
 - Controlled documents
 - Servicing requirements
 - Servicing processes and procedures
 - Training of servicing personnel
 - Calibration of any measuring equipment used for servicing
 - Verification methods
 - Quality records
 - Verification results
 - Calibration results on any measuring equipment
 - Personnel training results and certifications as necessary

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- 4.19 servicing
 - Auditor questions
 - How are servicing requirements determined?
 - What are the servicing process?
 - What are the procedures for performing and verifying service requirements specified in the contract?

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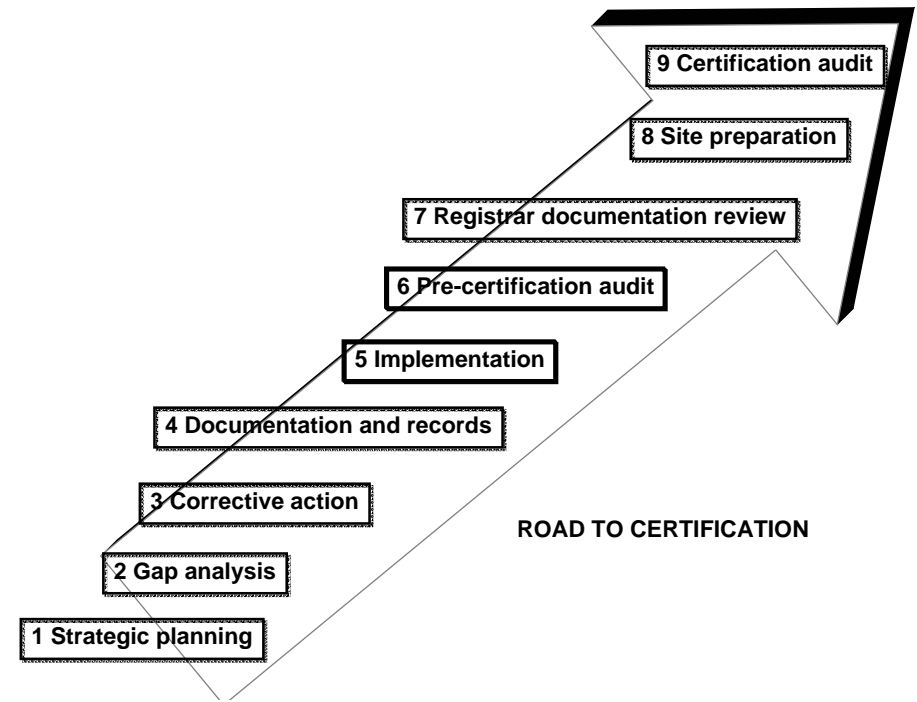
- 4.20 statistical techniques
 - Requirement: identify and use appropriate statistical techniques as necessary to verify that acceptability of process capability, product characteristics, and service.
 - What this means: you need to
 - Have a process for identifying any necessary statistical techniques
 - Use any statistical techniques you identify as necessary in your quality system

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- 4.20 statistical techniques
 - Using statistical techniques: depending on your process and product complexity, the probability of needing statistical techniques for your quality system is highest in these sections:
 - Design control
 - Process control
 - Inspection and testing
 - Control of inspection, measuring, and test equipment
 - Control of nonconforming product
 - Corrective and preventive action

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- 4.20 statistical techniques
 - Required documents and records:
 - Controlled documents:
 - Process for determining need for statistical techniques
 - Needed statistical techniques
 - Quality records:
 - Statistical results
 - Auditor questions:
 - What is the process for determining when statistical techniques are needed?
 - What statistical techniques have been identified and used?
 - How are test results of statistical techniques used?
 - How do you ensure that these techniques are used properly?



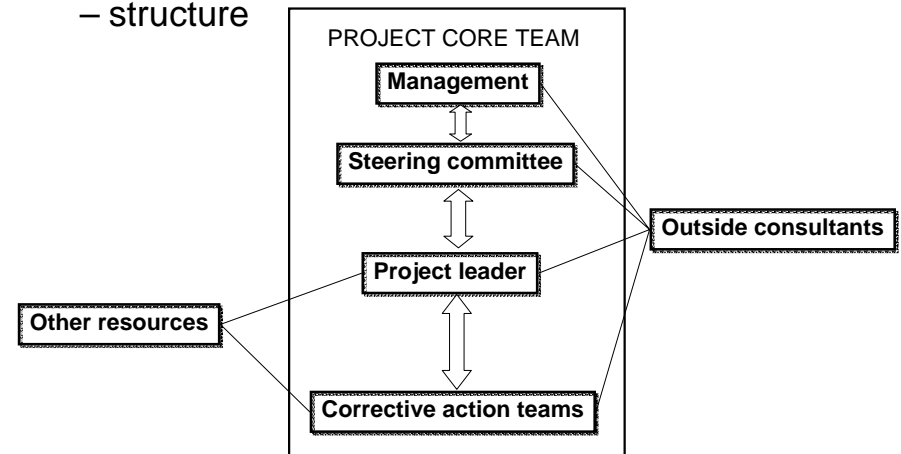
STRATEGIC PLANNING

- Management responsibilities
 - Management commitment
 - Assigning a project leader
 - Assigning a project team
 - Providing adequate resources
 - Establishing a timeline
 - Providing adequate training
- Selecting a registrar: asap, selection criteria (+ cost)
- Selecting a conformance model

STRATEGIC PLANNING

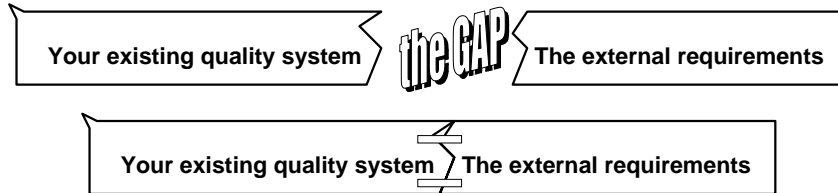
- Forming a project team

– structure



GAP ANALYSIS AND CORRECTIVE ACTION

- Gap analysis is the comparison of an existing quality system to one or more set of external requirements.
- Corrective action is the closure of gaps b/w the existing quality system and what is required in the external set of requirements



GAP ANALYSIS AND CORRECTIVE ACTION

- Corrective action team is a project team of personnel formed to the purpose of performing both the gap analysis and the corrective action.
- Process
 - Stage I Requirement identification
 - identifies the requirements of the selected conformance model
 - identifies any corporate, regulatory requirements
 - Stage II Resolution of requirements differences
 - Resolves any differences b/w the requirements and any regulatory, corporate requirements
 - State III Existing process evaluation
 - Identified the existing process in the quality system

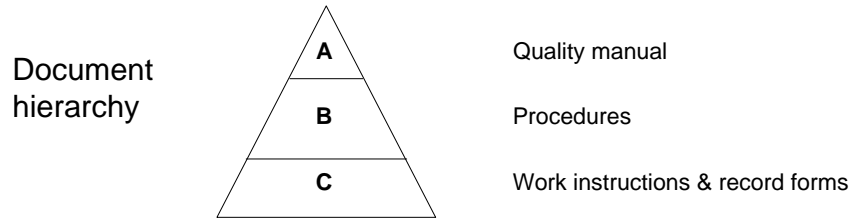
GAP ANALYSIS AND CORRECTIVE ACTION

- Stage IV Existing document compatibility
 - identifies the existing process supporting documents
 - Compares documents to the existing process
 - Resolves conflicts b/w process and documents
- Stage V Gap analysis
 - Compares the existing quality system to the external requirements to identify any gaps
- State VI Process corrective action
 - Develops any necessary changes to existing process to close the gaps and obtains approval from mgt.
- Stage VII Document corrective action
 - Develops new documents or changes existing documents as necessary and obtains approval from mgt.

GAP ANALYSIS AND CORRECTIVE ACTION

- Stage VIII Training and implementation
 - Assists mgt. in training of personnel and implementation of changes
- Stage IX Change effectiveness verification
 - Verifies effectiveness of any changes over time
 - Repeat Stage V – VIII as necessary to correct ineffective changes

IMPLEMENTING a DOCUMENT STRUCTURE



- Level A is the quality manual! The QM contains, for each section of the Standard,
 - Mgt. policy
 - a rationale for the policy
 - Primary responsibility
 - a document trail to Level B supporting documents

IMPLEMENTING a DOCUMENT STRUCTURE

- Level B describes what happens. It contains documents, identified in the Standard as procedures, describing each process in your quality system. A typical Level B document might contain:
 - Definitions of terms used in the process description
 - A description of the process
 - Process responsibilities
 - A document trail to Level C documents in support of the process

IMPLEMENTING a DOCUMENT STRUCTURE

- Level C tells how to do something. It contains documents, identified in the Standard as work instructions, telling the reader how to carry out specific operations or tasks. A typical Level C document might contain:
 - A reference data such as specifications, standards, or product lists
 - Training for specific operations
 - Hands-on directions such as instructions or checklists
 - Formats for forms
 - A document trail to any other supporting documents in Level C

DOCUMENT DEVELOPMENT

- Document development process may be used for creating or revising documents
- Process
 - Stage I need recognition
 - Document coordinator should be the focal point. Every document in the quality system should have owner responsible for its content.
 - Stage II preliminary planning
 - The document owner assess: audience, purpose, resource available of the document/data.
 - Stage III initial draft
 - Stage IV final draft: document coordinator ensures
 - Spell checking, grammar, format, page numbering, appropriate title, effective date of implementation
 - It is recommended that only one authorizer for each document

DOCUMENT DEVELOPMENT

- Stage V authorization
 - Authorizer reviews the document prior to distribution
- Stage VI distribution: document coordinator
 - Distributes copies of the document to designate copy holders
 - Retains the signed copy
 - Updated the “document master list”
- Stage VII individual copy
 - Holders of individual copies ensure
 - All concerned personnel are aware of content changes
 - Any necessary training is completed
 - The document is implemented on the effective date

SITE PREPARATION

- Noted: covers steps 6 – 9
- Pre-certification audit
 - This is an audit performed to ensure that your organization’s quality system and documentation conform to the ISO 9000 Standard.
 - It is done just prior to the official certification audit.
 - Trained internal auditors, an outside consultant or the registrar to perform the pre-certification audit
- The registrar document review
 - The registrar uses your documentation to review your organization’s quality system.
 - The registrar review to ensure that the quality system documents address all requirements of the ISO

CERTIFICATION AUDIT

- What happens: the registrar visit your site to
 - Meet with the upper mgt. to provide an overview of what will occur while they are there
 - Determine whether or not your quality system is implemented according to the selected conformance model

ข้อกำหนด ISO 9001: 2000

- 0. Introduction
- 1. Scope
- 2. Normative reference
- 3. Terms and definitions
- **4. Quality Management System***
- 5. Management responsibility
- **6. Resource management***
- **7. Product realization*** (การจัดทำผลิตภัณฑ์)
- 8 Measurement, **analysis**, and improvement**

* เนื้อหาเพิ่มเติม **เนื้อหาใหม่