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Example audit evidence for ISO/FDIS 9001:2000 Quality management systems – Requirements standard. The audit evidence list came for students at the J.P. Russell & Associates ISO 9001:2K Delta training course.

### 5.2: Customer focus

- Proactive customer surveys
- Solicit input from customers for potential improvement
- Documentation of repeat business
- Documentation and awareness of customer complaints
- Customer awards received by the organization
- Customer quality ratings
- Has satisfaction been determined
- Do surveys determine needs (or is it marketing demographic data).
- Internal and external customer surveys
- Results of interviews with top management awareness
- Linkage of customer requirements to goals to documents
- Evidence that customer satisfaction is a quality goal/objective, or part of quality policy

#### 5.4.1: Quality Objectives

- Department key indicators (measurable) that align with overall quality objectives.
- Trend charts, periodic performance reports by department or function
- Product related key indicators such as scrap, capability indices, test results.
- Measures of customer satisfaction and continual improvement
- Functional managers/ supervisors demonstrating they have objectives (on file, posted on board) and that they are measuring them. e, g, Objective versus % of goal
- Identification of relevant functions. i.e. organizational chart, quality manual, job descriptions
- Determine how goals are measured. i.e. control chart, tally sheets, pareto charts, other documentation.
- Organization is able to demonstrate that the objectives are linked to product requirements. Ask managers to explain

#### **5.4.2: Quality planning**

- Business plan or annual operating plan, resource plan
- Career plans for succession planning
- Agendas and meeting minutes (quality planning meetings, management review)
- Interview personnel about QMS plans and their awareness

#### **5.4.2: Quality planning [changes]**

- management of change documentation
- documented change plan or minutes from planning meetings
- timeline plan or chart
- project management charts changes
- interviewing functions that had changes (per corrective action, management review)
- Review causes of corrective actions to determine if changes caused subsequent corrective actions

#### **6.2.2 c) & d): Training, awareness and competency**

##### *Effectiveness of actions*

- evidence that training met learning objectives (student evaluations, survey, assessment tools, testing, quiz, workshop results)
- training certificates from CEU provider registered program. Registered with ASQ, IACET (Intern'l Assoc. for Continuing Ed. and Training), RAB, or other organization.
- evidence that *actions* were effective such as output measures, observations, check out progress, progress reports, process audits
- performance plans and job descriptions
- improvement of process output
- verify new employee orientation; reporting system to show employee progress
- verify how and what records maintained and review a sample
- identify core competence requirements and assess how organization determines effectiveness.
- Ask for evidence of meeting competence requirements
- training records
- peer review and verification
- Demonstrations of skills by audit or observation

##### *Awareness*

- verbal conformation from employees and management
- management methods for communicating importance employee activities
- training records
- review of training materials and instructor guide
- learning objectives contain need for student to understand importance of activity.

### **7.2.1a) & b): Determination of requirement related to the product**

- Orders include delivery requirements, dates, location, circumstances
- Special requirements listed such as certificate of compliance or certificate of analysis, Kosher, special approvals, packaging, markings
- Order include post delivery such as set up, tech service requirements
- Identify customer service not specified by part of internal requirements
- Compare customer complaints to internal requirements
- results of customer surveys included as internal requirements (not specified by the customer)
- requirements recorded by some means
- Examples of unspecified requirements
  - cleanliness of hotel room not specified in price negotiations
  - traceability not specified but customer expects organization to resolve complaint and eliminate cause
  - parts are in spec but rusty
  - software functional but requires all new equipment

### **7.5.2: Validation of processes for production and service provisions** *achieve planned results*

- comparison of targets to actuals/ revisions made
- quality targets included in quality plans, route cards, travelers
- review measurement trends versus plans
- control charts
- check design (performance) versus output
- records of rework

arrangements for validation

- procedure for validation
- quality plan
- records of people and process validation (check training records)
- maintenance plan
- process approval (stamp, sign off, etc.)
- process certificate
- Identification of processes that need validation
- are records defined, manual, procedures, quality plans,
- training conducted, is frequency established
- maintenance records
- SPC charts, measures
- process flow diagrams

### **8.2.1: Customer Satisfaction**

- competitor comparison reports (product performance and service)
- repeat customer complaints, review of complaint log
- corrective actions as a result of a customer complaint
- Corrective action follow up reports
- market and industry reports

- cost of poor quality
- late delivery and premium freight charges
- parts per million reports (PPM)
- customer satisfaction trends
- returned goods
- number customer referrals
- method or procedure for monitor customer satisfaction
- customer survey (independent and in-house)

### **8.2.3: Monitoring and Measurement and of Processes**

- See methods used and perhaps a procedure
- Reports or minutes of meeting where action was taken to correct nonconforming processes.
- examples of the identification of nonconforming processes
- list of devices and data collect (trend charts) on process conformance
- Target and range values for acceptable process operation (delivering, painting, finishing, packaging, filling, instructing, and so on).
- SPC or similar charts, CpK
- R&R studies
- Test plans, quality plans

### **8.4: Analysis of Data**

- customer satisfaction measures, returns, referrals, repeat business, vs competitor, rebates, discounts, no charge sales, etc.
- Customer complaint satisfaction
- customer audit results
- Meeting customer requirements vs goal, trend charts, tracking
- record of preventive action projects/ programs
- SPC data
- supplier defects
- suppliers notified of nonconformances/ defects/ short of goal
- supplier rating vs performance
- possible procedure
- supplier audit results
- product audit results
- process audit results
- customer feedback, forum, survey cards,
- management review actions based on data
- available records and charts
- proof of follow up actions based on data

### **8.5.1: Continual Improvement**

- Organization is able to demonstrate how continual improvement is achieved.
- Has there been a decrease in undesirable results or an increase in desirable results. See data.

- regular meetings (minutes, agenda) where continual improvement results are discussed.
- Processes have improved: faster, better quality, more reliable, costs controlled, worker efficiency up,.
- Output have improved: higher levels of meeting product or service requirements, higher percentage and meeting more requirements (specifications).
- Overall cost of quality going down
- Cost of quality studies show improved effectiveness of the QMS