

Elements of ISO 9001 - 4.8 Product Identification and Traceability

- Are there unique identifications on raw materials and products?
- Are adequate records kept for traceability
- Are in-process material clearly identified?

Elements of ISO 9001 - 4.9

Process Control

- Are there procedures for how to run the process or perform a task?
- Are there standards for acceptability?
- Are the variables of the process which are important for quality known?
- Are these variables controlled and monitored?
- Is the equipment used capable of control?
- Is the capability of new equipment known prior to installation?
- Are special processes properly controlled?

Elements of ISO 9001 - 4.10

Inspection and Testing

- Is there a system for insuring the quality of raw materials?
- Does this system handle releasing, rejecting & quarantining?
- Are “in process” inspections & testing defined?
- Do the procedures cover the handling of rejects?
- Are customer requirements met before shipment?
- Are inspection and testing records maintained?

Elements of ISO 9001 - 4.11

Inspection, Measuring and Test Equipment

- Is all quality related equipment calibrated?
- Are there calibration records for equipment?
- Are there calibration procedures & specifications?
- Is calibration equipment traceable to a national standard?
- Is the frequency of calibration documented?
- Is the calibration status known to the person using the equipment?
- How is verification of calibration performed?

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Inspection and Test Status

- Do people using raw material know its quality acceptability?
- Is the quality status of “in-process” and finished goods known?
- Who has the authority to release nonconforming materials?

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Control of Non-Conforming Product

- Are non-conforming materials identified?
- Are non-conforming materials segregated?
- How are non-conforming materials dispositioned?
- Are reworked non-conforming materials reinspected?
- Are customers notified of non-conforming material shipments?

Elements of ISO 9001 - 4.14

Corrective Action

- Is the cause of non-conforming material determined?
- Are corrective actions taken to prevent recurrence?
- Is there a follow-up to insure they are effective?
- Are systems changed as a result of corrective actions?
- Is there a system to detect and prevent problem areas?

Elements of ISO 9001 - 4.15

Handling, Storage, Packaging and Delivery

- Are there procedures in place for raw materials & products?
- Do systems prevent damage or deterioration?
- Is it defined who removes product from storage areas?
- Are there systems to maintain packages :Fit-for-Use”?
- Is material protected after inspection to delivery?

Elements of ISO 9001 - 4.16

Quality Records

- Is there a system for maintaining quality records?
- Are records properly marked?
- Are the records retrievable?
- Is there a retention system?

Elements of ISO 9001 - 4.17

Internal Audits

- Are there independent audits of each department?
- Is there a documented audit schedule?
- Are the results of the audit communicated?
- Are there corrective actions as a result of the audit?

Elements of ISO 9001 - 4.18

Training

- Are training needs identified?
- Are people trained to perform their job?
- Are records maintained of the training?
- Who maintains the training records?
- Are there training materials?

Elements of ISO 9001 - 4.19

Servicing

- Are there procedures for performing servicing?
- Are there documented results indicating that servicing meets the specified requirements?
- Are corrective actions taken as a result of service calls?

Elements of ISO 9001 - 4.20

- Are appropriate statistical techniques used to determine process capability?
- Is it understood how the process variables affect the product quality, statistically?
- Are the statistical techniques used being used properly?