

Examples of Quality System Scalability under § 21.137

Quality System Element	Large Company Quality System	Small Company Quality System
<p>(a) Design data control. Procedures for controlling design data and subsequent changes to ensure that only current, correct, and approved data is used.</p>	A large company may rely more on electronic systems for controlling design data.	A small company producing simple parts may rely on paper drawings and written procedures for controlling design data.
<p>(b) Document control. Procedures for controlling quality system documents and data and subsequent changes to ensure that only current, correct, and approved documents and data are used.</p>	Large companies may rely more on electronic systems for controlling quality system documents.	A small company may rely on paper documents and written procedures for controlling documents.
<p>(c) Supplier control. Procedures that—</p> <ol style="list-style-type: none"> (1) Ensure that each supplier-furnished product or article conforms to its approved design; and (2) Require each supplier to report to the production approval holder if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data. 	A large company may have dedicated staff for controlling its suppliers and for conducting source inspections at supplier facilities. Larger companies may have a larger quantity of suppliers and may rely more on electronically stored and transmitted data. Larger companies may also rely more on third party audits of suppliers.	<p>For a small company producing simple parts, supplier control may be a part-time responsibility for one employee.</p> <p>Also, a small company may conduct 100% inspections of articles upon receipt.</p>
<p>(d) Manufacturing process control. Procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.</p>	A large company may use controlled software to automate methods for measurement, analysis, monitoring, and reporting to control manufacturing processes. Electronic routing travelers may be used for recording completed tasks.	A small company may rely more on manual sampling inspections and analyses to control manufacturing processes. These tasks may be recorded on a simple paper router or traveler. Additionally, a small company may also rely on suppliers for special processes.

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<p>(e) Inspecting and testing. Procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures must include the following, as applicable:</p> <p>(1) A flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft.</p> <p>(2) A functional test of each aircraft engine and each propeller produced.</p>	<p>Inspection and testing at a large company may include complex procedures for: aircraft flight tests, functional tests of aircraft engines, functional tests of subsystems and equipment, and inspections of critical characteristics.</p> <p>Also, large companies may utilize software controlled acceptance methods.</p>	<p>Inspection and testing at a small company producing simple parts may be limited to bench tests of equipment or dimensional inspections of a part.</p>
<p>(f) Inspection, measuring, and test equipment control. Procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the FAA.</p>	<p>Large companies may have their own calibration laboratory responsible for the initial issuance, retrieval, calibration, and tracking of tools and gauges requiring a calibration cycle.</p>	<p>A small company may choose to send their tools and gauges to an independent calibration laboratory to perform the initial validation of new tools and gauges, and to control the retrieval, calibration, and tracking of tools and gauges in-service. A small company may also send its standards to an independent laboratory for periodic validation and use those standards to calibrate their tools and equipment.</p>
<p>(g) Inspection and test status. Procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.</p>	<p>Large companies may use routing or traveler documents to record the inspection and test status of a product or article. Larger companies may use electronic techniques to meet this requirement.</p>	<p>Small companies may also use routing or traveler documents to record the inspection and test status of a product or article. Status could also be indicated on boxes, carts, bins, etc.</p>

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<p>(h) Nonconforming product and article control. (1) Procedures to ensure that only products or articles that conform to their approved design are installed on a type-certificated product. These procedures must provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations. (2) Procedures to ensure that discarded articles are rendered unusable.</p>	<p>Large companies may tag, segregate, evaluate, and disposition nonconforming products or articles. Larger companies will typically use a materials review board to disposition nonconforming products or articles.</p> <p>Large companies may use software for documenting and tracking all MRB discussions.</p>	<p>Small companies may also tag, segregate, evaluate, and disposition nonconforming products or articles. A small company's materials review board may consist of just one individual within the company.</p>
<p>(i) Corrective and preventive actions. Procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.</p>	<p>A large company may have a dedicated staff performing these functions on a daily basis.</p>	<p>For a small company, this may be a part-time responsibility for one employee performed on a monthly or as needed basis.</p>
<p>(j) Handling and storage. Procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.</p>	<p>A large company may have dedicated staff and complex procedures for handling and storage of products and articles.</p>	<p>For a small company producing simple parts, this may be a part-time responsibility for one employee with basic procedures.</p>

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<p>(k) Control of quality records. Procedures for identifying, storing, protecting, retrieving, and retaining quality records. A production approval holder must retain these records for at least 5 years for the products and articles manufactured under the approval and at least 10 years for critical components identified under § 45.15(c) of this chapter.</p>	<p>Large companies may have a larger volume of quality records to control and may rely more on electronic systems for controlling this data. Additionally, large companies may solely use electronic records as opposed to paper records.</p>	<p>A small company producing simple parts may rely on paper records, standard filing techniques, and written procedures for controlling quality records.</p>
<p>(l) Internal audits. Procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures must include reporting results of internal audits to the manager responsible for implementing corrective and preventive actions.</p>	<p>Large companies may have a dedicated internal audit department responsible for scheduling, conducting, and reporting the results of internal audits. This might include the selection, training, and certification of industry qualified auditors.</p>	<p>A small company producing a non-complex article may appoint an individual (e.g., quality manager) to perform the internal audit function. The audit schedule could be as simple as randomly selecting a sample of completed work orders and reviewing the work orders for completeness and accuracy.</p>
<p>(m) In-service feedback. Procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must include a process for assisting the design approval holder to—</p> <ol style="list-style-type: none"> (1) Address any in-service problem involving design changes; and (2) Determine if any changes to the Instructions for Continued Airworthiness are necessary. 	<p>A large company may rely more on electronic methods for receiving and processing feedback and pass the information to their engineering organization.</p>	<p>A small company may rely more on manual techniques for receiving and processing feedback. This could be a part time employee or even the owner of the company, that is also the engineer for the company.</p>

Quality System Element	Large Company Quality System	Small Company Quality System
<p>(n) Quality escapes. Procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.</p>	<p>A large company may rely more on electronic systems for controlling quality escapes.</p> <p>The quality organization forwards quality escape information to the engineering group.</p>	<p>A small company producing simple parts may rely on written procedures for controlling quality escapes. This could be one person handling the escapes, determining the cause, and fixing the problem.</p>