

Process Auditing Worksheet

Process Name: Calibration (PROC-11)

Output: Product (Tangible) or Service (Auto Repair, Calibration Service, etc). Under "Performance Measurement", specify how the performance (quality) of the product or service is measured. List what records are generated with the product or service

Product /Service	Performance Measure	Records Generated	Audit Item
<ul style="list-style-type: none"> Calibrated Equipment 	<ul style="list-style-type: none"> On-time calibration service Accuracy of results 	<ul style="list-style-type: none"> Sticker indicating status Calibration records availability / accuracy 	<p>For production processes audited, record measuring equipment id's & description then:</p> <ul style="list-style-type: none"> Verify that sticker on equipment correspond to calibration status / equipment ID Verify that calibration records show equipment ID, acceptable results, date corresponding to database, correct calibration frequency, etc.

Input / Process Activities: List applicable input elements with how they are controlled

Input Element	Identification / Control Criteria	Audit Item
<p>People</p> <ul style="list-style-type: none"> Qualifications? Any Required Training? Any Required Certification? 	<p>Quality Manager / Knowledge of responsibilities</p> <p>Associates who run the CMM / Qualifications</p>	<ul style="list-style-type: none"> Interview the Quality Manager about their responsibilities. Are they consistent w/ procedure PROC-11? Ask how these associates are qualified and/or their training / certification
<p>Materials / Information</p> <ul style="list-style-type: none"> Materials / components and/or information used as input? Suppliers or subcontractors used? 	<p>Calibration Status / Database information and previous calibration records</p> <p>Equipment to be calibrated / Masterlist</p>	<ul style="list-style-type: none"> How does the Quality Manager use the Database to schedule calibration? Ask for the masterlist of gages to be calibrated. Pick a sample and verify ID's and serial numbers / location / status. Do they match?
<p>Equipment / Measuring Devices</p> <ul style="list-style-type: none"> Process equipment Used? Measuring equipment & devices to measure the resulting product or service?? 	<p>Gage Blocks that gages are checked against / certification</p> <p>Outsourced calibration / Certification / Supplier Evaluation</p>	<ul style="list-style-type: none"> Verify that Gage Blocks are identified as on the masterlist Verify that the Outsourced Calibration Service is certified to acceptable standard (ISO 17025 or A2LA)? Verify that the Outsourced Calibration Service is on the Supplier Evaluation program
<p>Methods</p> <ul style="list-style-type: none"> List of documents and references used to get the job done (including external)? Documents accessible, followed? 	<p>Procedure / Document Control</p> <p>Calibration Work Instructions / Document Control</p> <p>Manufacturer's Manuals / Document Control</p>	<ul style="list-style-type: none"> Verify that PROC-11 rev. 2 and CA-01 Verification Work Instructions are consistent against document control masterlists Verify that Manufacturer's Manuals (user's guides) are available for calibrating a sample of employee-owned equipment
<p>Environment</p> <ul style="list-style-type: none"> Is work environment specified in process documentations? Safety requirements? Climate Control? Lighting? Clutter? 	<p>Protection of Equipment / Storage and protection requirements</p> <p>Temperature, Humidity & other limits / Lab</p>	<ul style="list-style-type: none"> Verify that equipment is protected against damage when not in use Observe that humidity and temperature limits are not violated