Quality Management System Manual

Example LLC

Quality Management System per ISO 9001:2015

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ISO 9001:2015 · Stage 1 Foundation

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1. Quality Policy

At Example LLC, every calibration service delivered is backed by rigorous adherence to NIST-traceable reference standards, forming the foundation of our quality management approach. Every piece of equipment that leaves our laboratory is calibrated against these traceable standards, and the corresponding certificate is generated based on the exact data measured during the calibration process. We uphold a non-negotiable requirement for complete and transparent documentation: if the calibration results or documentation cannot be guaranteed without reservation, we withhold certification until all requirements are met.

Ensuring the accuracy and clarity of our calibration certificates is not only a lab policy but a customer expectation. We understand that many of our clients, particularly those in automotive and aerospace supply chains, operate under stringent compliance and audit demands. Therefore, our procedures are crafted so that any auditor—ours or the customer's—can trace the process and underlying data for any issued certificate at any time.

We also recognize that our customers' operations are often dependent on the prompt return of their measurement and test tools. Turnaround times are closely monitored, and job scheduling incorporates daily reviews of incoming work and due dates to prevent backlogs. Each project's progress is transparent to the team, and urgent jobs are given priority when necessary, based on customer production needs.

We select our external calibration providers for reference standards with care, requiring them to maintain their accreditation and demonstrate reliability with documented turnarounds and up-to-date certificates. Incoming and outgoing shipments are checked for completeness and transit damage before and after calibration. Our laboratory safety practices follow OSHA guidelines, with designated work zones, equipment-specific safety procedures, and required staff training to ensure a safe environment for both personnel and equipment.

When issues are discovered—whether a certificate error or an overdue reference standard—we act promptly. Corrections are documented, affected customers are notified, and root causes are investigated to determine if procedural updates or staff training are needed. Our continual improvement cycle draws on customer feedback, complaint analysis, and team debriefs, seeking not only to rectify errors but to prevent their recurrence and raise the standard of our service.

This policy is implemented throughout the organization and reviewed annually by management to ensure continuing suitability, taking into account changing customer, regulatory, and internal requirements. This manual addresses the requirements of ISO 9001:2015, chapters 4 to 10.

2. Quality Objectives

QUALITY OBJECTIVES BY END OF 2026

Certificate correction rate	6 → 2 per year
On-time delivery rate	88 % → 95 %
Reference standards past due for recalibration	2 → 0

Maintaining a low certificate correction rate is a top operational priority. Every time a customer reports a correction, the original records are retrieved, and a thorough review is conducted before a corrected certificate is generated. The objective is to reduce certificate corrections from last year's 6 to 2 or fewer per year by the end of 2026. This goal is pursued by thorough spot-checks prior to certificate release and periodic individual training to clarify any persistent errors.

Consistent on-time delivery of calibrated equipment is essential to building customer trust and meeting their production scheduling needs. Our present on-time rate is approximately 88%; the objective is to achieve a minimum 95% on-time delivery rate by the end of 2026. Daily work queues in our lab management software, proactive communication with customers, and resource adjustments during peak periods are used to identify and resolve delays before they impact delivery.

Another core objective is to keep the number of overdue in-house reference standards at zero. Currently, two reference items were overdue in 2025, which is unacceptable for a laboratory promising full traceability. With Kevin Park responsible for ongoing monitoring, the target is zero overdue reference standards at any time, effective from Q1 2026 forward. A restructured scheduling and reminder system is in place so that recalibration is initiated 60 days prior to due date, and any deviation is escalated immediately to both the Lab Manager and Owner.

These objectives are measured monthly and discussed quarterly in review meetings, ensuring that progress is tracked and the targets remain central to the day-to-day operation of the lab.

3. Scope of the Quality Management System

This quality management system (QMS) covers all calibration services provided by Example LLC at the Greenville, South Carolina laboratory and at customer sites as scheduled. The scope includes the management and execution of calibrations for dimensional, pressure, temperature, and electrical measuring equipment used by manufacturing clients, as well as all associated certificate generation and documentation practices. The QMS further encompasses the management of in-house reference standards, customer and supplier interactions, incoming and outgoing shipments, complaint processing, and the overall handling of documentation and controlled records.

Excluded from this scope are any manufacturing or repair activities not directly related to the calibration and certification of measuring equipment. The QMS applies to all staff, including technicians, management, and administrative personnel, and is binding for any subcontracted calibration services performed under Example LLC's name.

3.1 Context of the Organisation

Example LLC operates in a sector defined by high customer expectations around measurement traceability, particularly from ISO-certified manufacturers in automotive and aerospace supply chains. External factors greatly impacting our operations include customer-driven regulatory requirements, reliance on a limited number of accredited external calibration providers for our reference standards, and ongoing changes in customer compliance expectations. Internally, the consistency of procedural execution across experienced and newly trained technicians is a key challenge, requiring ongoing attention to documentation and knowledge sharing.

3.2 Interested Parties

The requirements and expectations of all relevant interested parties are summarized below.

INTERESTED PARTY	KEY REQUIREMENTS	HOW THE COMPANY MEETS THEM
Customers	Fully traceable, error-free calibration with prompt turnaround and robust documentation	All calibrations are traceable to NIST; certificates are reviewed before release; strict documentation; delivery performance monitored daily
Suppliers	Clear purchase orders, prompt payment, notification of nonconformance or scheduling issues	Orders specify due dates and requirements; suppliers' certificates and accreditations reviewed; payments processed promptly
Employees	Safe working environment, clear procedures, fair workload distribution, opportunities for growth	OSHA guidelines followed; lab safety reviewed regularly; job training and documented procedures provided; workload tracked and redistributed as needed
Authorities / Regulators	Compliance with NIST traceability, lab safety according to OSHA, readiness for audit, response to inquiries	All records maintained as per requirements; calibration certificates archived; staff trained in compliance areas; audits supported as requested

3.3 Risks and Opportunities

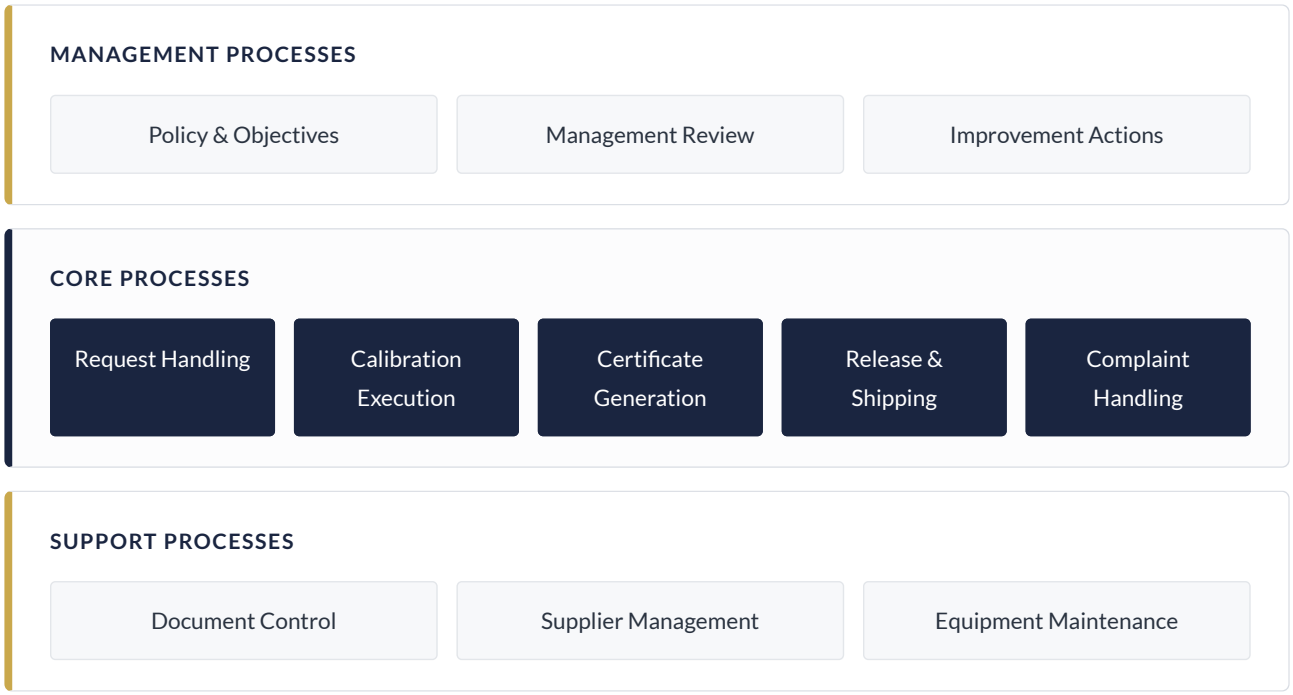
The following table lists the principal risks identified and how they are addressed.

RISK	RATING	MEASURE	OWNER
Certificate errors not detected before release	high	Review and spot-check by Lab Manager before certificate release; retraining on recurring issues	Marcus Bell
Turnaround times slipping in peak periods	medium	Daily monitoring of work queues; adjust staffing and overtime as needed	Dana Whitfield
Overdue in-house reference standards	high	Automated reminder system and monthly reconciliation; escalate overdue status to management	Kevin Park
Inconsistent procedures among technicians	medium	Expanded documentation; structured onboarding and technician sign-off on procedures	Marcus Bell
Supplier delays affecting standard turnaround	medium	Track supplier turnaround times; dual-source critical standards where feasible; escalate delays	Dana Whitfield

Additionally, the QMS presents opportunities such as deepening collaboration with customers via feedback on documentation, and providing regular cross-training to strengthen team flexibility and reduce reliance on specific individuals.

4. Process Overview

Example LLC structures its operations through a combination of oversight, technical workflow, and essential support processes. Management establishes policy and carries out review and improvement actions; the core team executes calibration workflows, maintains reference standards, and handles customer interactions. Supporting activities include document control, lab equipment maintenance, purchasing, and onboarding. This process architecture ensures that calibration results are reliable, errors and backlogs are minimized, and compliance is demonstrable at all times.



Customer requirements flow through the core processes, supported by management and support activities.

4.1 Leadership Processes

Management oversight is carried out primarily by Dana Whitfield, Owner, who initiates an annual review of the entire QMS. This review is scheduled near the anniversary of the management system's introduction or following any major nonconformity or customer escalation. Dana collects performance data, including certificate correction rates, on-time delivery statistics, and overdue reference standard counts, and prepares a management review agenda that is circulated to Marcus Bell and other relevant staff in advance.

During the review meeting, Dana works through the objectives: for each, performance is measured against numeric targets. Where metrics fall short, root causes are sought by reviewing process histories and customer feedback. Policy or resource changes are authorized if required, and any process deficiencies are actioned with deadlines assigned and responsible parties designated. Supplier reliability, particularly for external calibration services, is also reviewed at this meeting, including an analysis of any delays or inconsistencies that occurred over the prior year.

Between annual reviews, monthly alignment meetings are held between Dana Whitfield and Marcus Bell to address operational and strategic questions, such as resource constraints, technician training needs, or new customer requirements. If significant deviations or new risks are identified, such as missed calibration deadlines or a rise in customer complaints, the management team escalates the issue for immediate intervention—ranging from reprioritizing the lab's workload to seeking alternative suppliers.

4.2 Core Processes

Customer calibration projects begin when Theresa Nguyen, handling the front office, receives a request by phone, email, or via the website form. She logs the request in the lab management software, clarifies the specific calibration scopes required, and confirms the desired turnaround with the customer. Upon receipt of the customer's equipment—checked for completeness and damage on arrival—Theresa organizes either the on-site visit or internal handling.

Marcus Bell assigns the project to a bench technician with the corresponding technical specialization (dimensional, electrical, pressure, or temperature). The technician retrieves the applicable NIST-traceable reference standards and verifies their current calibration status before beginning. All measurement results are recorded both in the software and as bench notes, ensuring full traceability. Each instrument is given a unique calibration label and is not released until the data is confirmed.

Upon calibration completion, certificates are generated by the lab management software. Dana Whitfield (or Marcus for critical or unusual jobs) reviews or spot-checks each certificate before release to catch any discrepancies in values, units, or missing data. When approved, Theresa packages the equipment and certificate and prepares outbound shipment—checking again for transit suitability, particularly for sensitive items—or hands them to the customer in the case of onsite work.

Customer complaints arising after receipt of their certificates are logged immediately by Theresa. Dana pulls the original bench records and checks the full workflow. If an error is confirmed, a revised certificate is issued and the correction is documented. Marcus investigates the cause and, when patterns emerge, leads procedural update or targeted technician training. Repeat nonconformities trigger written corrective actions tracked to closure.

Reference standard management is coordinated by Kevin Park, who uses the tracking log to monitor calibration due dates. Some 60 days before each is due, Kevin initiates shipment to our accredited calibration provider and maintains contact for status updates. Returned standards and their certificates are logged, new due dates are updated immediately, and if any result is out of tolerance, Marcus Bell and Dana Whitfield decide whether to review completed jobs for possible customer impact. All actions are documented, and affected customers are contacted when necessary.

4.3 Support Processes

Support activities at Example LLC are closely integrated into the daily workflow to safeguard both process continuity and compliance. All documentation, including calibration procedures, bench records, and certificates, is managed via the lab's management software. The current version of each procedure and template is released to technicians only after management review and approval. When revisions are made—often in response to process improvements or observed deviations—Dana Whitfield ensures obsolete versions are withdrawn and only the current one is active. Soft copies are archived, and historic revisions can be retrieved as necessary for audit or review.

Procurement and supplier monitoring processes are managed collaboratively by Theresa Nguyen and Dana Whitfield. Purchase orders for external calibration services or consumables are issued based on monthly review of inventory levels and upcoming due dates. Supplier performance is monitored by recording actual delivery or turnaround times against purchase requirements, and instances of late delivery are formally tracked in the lab management software. Persistent supplier-related issues are escalated at monthly management meetings to decide whether alternative sources need to be identified.

Lab equipment and reference standards are systematically maintained according to scheduled intervals. Kevin Park monitors all calibration and maintenance logs, and initiates preventive maintenance actions in advance of any due dates. In the case of equipment malfunction, affected items are removed from service and marked "quarantined" in the system until full repair and recertification are completed. In the event that new equipment is introduced or a calibration discipline is expanded, Marcus Bell updates or drafts new procedures, and technicians receive structured onboarding. New staff—including apprentices—are integrated by pairing them with experienced technicians, with procedural checks and sign-off requirements built into their workflow so that operational knowledge is not dependent solely on individual experience.

Organizational knowledge is preserved through this systematic onboarding and documented knowledge, anchored in workflow checks and frequent review to prevent loss of critical techniques or procedural drift over time.

5. Roles and Responsibilities

The quality management system at Example LLC is grounded in clear, operational roles, each with defined responsibilities in daily execution and compliance monitoring.

Dana Whitfield, Owner, serves as the managing director and final authority for all policy, resource, and review activities. Dana conducts the annual management review, ensures resources are aligned to customer and compliance requirements, approves critical customer communications and decisions on corrective action, and authorizes process changes.

Marcus Bell, Lab Manager, acts as the quality manager and is responsible for the day-to-day control of all technical calibration work. He oversees technician performance and training, assigns individual jobs, performs certificate spot-checks, participates in complaint investigation, and leads corrective actions for recurring process problems. Marcus is consulted by Dana Whitfield on all quality-related management decisions and provides a monthly summary on key metrics such as delivery performance and certificate correction rates.

Theresa Nguyen, handling the front office, is responsible for customer inquiries, receiving and dispatching equipment, invoicing, and logging jobs into the workflow system. She tracks turnaround schedules, enters complaint and correction requests, and ensures documentation packets for each shipment are complete before release.

Kevin Park manages the inventory and calibration schedule for all in-house reference standards. He issues purchase and recalibration orders and monitors supplier performance and calibration due dates daily, escalating overdue cases or supplier delays directly to Marcus and Dana for action.

Bench technicians, numbering nine, are responsible for executing calibrations to procedure in their assigned discipline. Each technician maintains their own workbench records, follows released procedures, and applies calibration labels as part of workflow sign-off. Technicians are responsible for flagging unclear requirements or equipment issues to Marcus. The trainee technician currently works under the supervision of Marcus Bell, with all work double-checked and documented as part of their onboarding.

Organizational knowledge is safeguarded by structured onboarding led by experienced staff, written procedures, and mandatory workflow checks, so critical process knowledge is retained even as personnel or roles change.

6. Document Control Procedure

All documentation related to calibration processes, certificates, bench notes, and reference standard records is maintained in a central lab management software system. Each procedure or template introduced to the system is first reviewed and approved by Dana Whitfield. Release of new or revised documents is communicated directly to all technicians before use, and any older versions in use are withdrawn by Marcus Bell to avoid confusion. Obsolete document versions are archived in a restricted folder accessible only to management for possible audit or reference.

When procedural updates are necessary—due to process changes, audit findings, or recurring certificate corrections—Marcus Bell drafts proposed changes and circulates them for review to Dana Whitfield. Affected technicians are briefed on the revisions, required to sign off on understanding, and implementation is logged. Lab management software access permissions are set so that only current, approved documents are available at the bench.

Documented records (work orders, certificates, supplier calibrations) are kept in both digital and physical formats, with retention periods determined by regulatory and customer requirements, typically a minimum of 5 years. Any modification or correction to a record is stamped with the date, the author of the change, and a summary note. In case of loss or corruption of an electronic record, the master database backup is restored under Marcus Bell's supervision, and affected partners are notified.

7. Internal Audit Procedure

Internal audits are scheduled at least annually, typically 4 to 6 weeks prior to the full management review. Dana Whitfield appoints an auditor not directly involved in the daily calibration workflow for impartiality—often drawing on a technician from a different discipline or involving external support if required. The audit covers process adherence, documentation completeness, certificate traceability, equipment maintenance logs, and compliance with NIST and OSHA requirements where applicable.

The auditor reviews randomly selected calibration jobs from the previous quarter, checks the reference standard tracking logs, and examines complaints and corrective actions. Deviations are briefly discussed with the responsible staff at the time of discovery. Upon completion, a written audit report details all findings, segregated by severity. The number and severity of findings are recorded for each audit, and these statistics are compared across years to monitor improvement.

Any major nonconformity triggers immediate escalation to Dana Whitfield and Marcus Bell, with corrective actions initiated and tracked until closure. Root causes for recurring issues are investigated jointly by the management and technical leads.

8. Management Review Procedure

The annual management review, led by Dana Whitfield, includes a comprehensive review of QMS effectiveness against objectives and compliance requirements. Agenda items include certificate correction rates, on-time deliveries, overdue reference standard instances, customer complaints, supplier performance analysis, and completion status of previous corrective actions.

Customer feedback is consolidated not just from complaints, but also from direct communications during equipment handover, routine commissioning calls, and post-delivery surveys. This feedback is summarized as a measure of customer satisfaction and analyzed for patterns that warrant improvement actions.

The outcomes of the management review can include setting new or revised quality objectives, resource reallocations, updates to procedures, and—where needed—the introduction of new training or documentation requirements. Formal meeting minutes are recorded, signed by Dana Whitfield, and distributed to all participants. Actions are tracked with assigned owners and deadlines.

9. Continuous Improvement Procedure

Continuous improvement is embedded into job execution and management routines at Example LLC. Staff are encouraged to identify and report process issues at any point; such reports are logged by Theresa Nguyen or Marcus Bell and reviewed at weekly team meetings for patterns. Recurring or severe issues are escalated to Dana Whitfield for root cause analysis.

Corrective and preventive actions (CAPA) are documented and tracked through closure in the lab management software. In cases of certificate corrections or supplier problems, causes are mapped to procedural or training gaps. Improvements are trialed and then formalized into procedures, with staff briefings and documented sign-offs to confirm implementation.

Improvements are not limited to error reduction but also target operational efficiency and robustness—such as streamlining certificate generation or implementing additional supplier checks—to ensure quality standards not only meet but exceed customer and regulatory expectations.

Appendix A: Sample Inspection Record

The following table outlines the main steps for final inspection before releasing calibrated equipment.

INSPECTION STEP	RESULT	REMARKS
Visual check of equipment condition		
Verification of correct calibration label attached		
Review of recorded measurement data		
Certificate matches measurements and standard traceability		
Shipment packaging checked for shipment type		
Final approval by authorized reviewer		

Appendix B: Supplier Evaluation

Key suppliers and their evaluation metrics are monitored as shown below.

SUPPLIER	QUALITY	DELIVERY RELIABILITY	STATUS
Accredited external calibration provider (reference standards)	NIST-traceable, valid certificates	98 %	approved
Consumables distributor (lab supplies)	Consistent	95 %	approved
Shipping carrier	Damage-free delivery	97 %	approved