ISO 9001:2015 · AUDIT PREPARATION COMPANION

Audit Preparation Companion

Example LLC

Independent calibration and measurement laboratory serving manufacturers in Greenville, South Carolina; specialized in NIST-traceable calibrations for industries with stringent documentation and turnaround demands.

Locale	en-US
Prepared for	Dana Whitfield
Companion to	Quality Management System Manual — Example LLC v1.0

This companion document supports the audit readiness of Example LLC’s ISO 9001:2015 quality management system. The following section-by-section checklist is tailored to your calibration laboratory, referencing your processes, roles, and objectives as documented in your QMS manual. Use each section to prepare relevant records and to rehearse your responses with your named staff before the Stage 2 or surveillance audit.

ISO 9001 · CHAPTER 4

Context of the Organization

AUDITOR QUESTIONS

- [ ] Example LLC serves ISO-certified clients in the automotive and aerospace supply chains—what external compliance or audit demands have shaped your documented procedures?
- [ ] How do you identify and review the needs and expectations of interested parties—such as clients requiring NIST traceability and suppliers providing reference standard calibrations?
- [ ] Describe how Marcus Bell (Lab Manager) and Dana Whitfield (Owner) evaluate risks like certificate errors or overdue reference standards. How are these risks documented and reviewed?
- [ ] Show how Example LLC ensures the consistent application of procedures among experienced and newly trained technicians.
- [ ] How are changes in regulations—for example, new OSHA or NIST requirements—captured and fed into your quality management processes?

EVIDENCE REQUIRED

- [ ] Documented context/organization analysis showing identification of relevant stakeholders (customers, suppliers, staff, regulators), including a copy of the interested parties table from your manual.
- [ ] Risk and opportunity register with owner assignments—covering items like certificate error risk, turnaround delays, overdue standards, and procedural inconsistency.
- [ ] Evidence of periodic review of these risks (e.g., management meeting minutes, risk review logs).
- [ ] Examples of communicated and signed-off procedures for both experienced and new technicians; technician sign-off or training records.
- [ ] Documentation showing how changes from NIST or OSHA are communicated internally (e.g. update memos, revised SOPs, training logs).

TIMING & FREQUENCY

- [ ] Context, interested parties, and risks should be reviewed at least annually or when significant changes arise (new customer requirements, regulatory updates).
- [ ] Training and procedure sign-off should be updated when roles shift, new staff are hired, or procedures are revised.
- [ ] Records and reviews should be available from live QMS operation (not just recent creations) and cover the last 3–12 months where feasible.
- [ ] Evidence retention: as per applicable national requirements for calibration labs in the US, or as set forth by customer/regulatory contracts; typically no less than 5 years for calibration records and traceability documentation.

PREPARATION ROADMAP

- [ ] Gather current context and risk overview as documented in your QMS manual; verify all stakeholder lists reflect your present key clients and suppliers.
- [ ] Ensure the most recent risk and opportunity register is available, showing Marcus Bell and Dana Whitfield’s reviews and action plans.
- [ ] Review procedure sign-off logs for onboarding and recent procedure changes—verify signatures for all current technicians.
- [ ] Prepare at least one example of how a new regulatory requirement or customer expectation led to a documented procedure change in your lab.

ISO 9001 · CHAPTERS 5–6

Leadership, Planning & Support

AUDITOR QUESTIONS

- [ ] Dana Whitfield sets the quality policy for Example LLC—where is this policy displayed and how do you ensure all staff understand and implement it?
- [ ] The manual specifies a strict certificate correction rate target. What is your process for tracking, reviewing, and responding to certificate corrections as they arise?
- [ ] Show how documented procedures for calibration, reference standard management, and complaints are maintained, controlled, and communicated to technicians (including how obsolete versions are managed).
- [ ] How does Example LLC ensure supplier reliability, especially with a small number of accredited external calibration providers? What happens if a provider fails to deliver on time?
- [ ] How are document retention periods determined for calibration records, certificates, and corrective actions? Who is responsible for authorizing the disposal of obsolete documents?

EVIDENCE REQUIRED

- [ ] Signed copy of the quality policy, including date and review/release signature by Dana Whitfield.
- [ ] KPI summary (e.g. for certificate correction rate, on-time delivery, overdue standards) including monthly or quarterly tracking data and meeting notes showing review and action decisions.
- [ ] Controlled document register, examples of current/recent and obsolete procedures for calibration execution, complaints handling, and reference standard management; communication logs or training sign-off sheets.
- [ ] Supplier evaluation records (e.g. external calibration provider assessments, delivery/ turnaround monitoring, and actions for missed deadlines).
- [ ] Copies of procedures or logs stating retention periods, document disposal authorization records, and evidence of restricted access control for archived/obsolete records.

TIMING & FREQUENCY

- [ ] Quality policy should be reviewed at least annually and signed as evidence of this process.
- [ ] KPIs (certificate corrections, on-time delivery, overdue standards) are measured monthly and discussed at quarterly and annual reviews.
- [ ] Document control records and supplier evaluations should demonstrate ongoing and recent use (with at least several months of activity and at least one current cycle completed).
- [ ] Retention periods: for calibration records, certificates, and corrective actions, retain for at least 5 years or as required by customer/regulatory contract; disposal must be documented and authorized.

PREPARATION ROADMAP

- [ ] Obtain a signed, current copy of your quality policy and check that all staff are aware of its key points.
- [ ] Review your latest KPI tracking data—prepare to explain your reaction to any missed targets, especially the certificate correction and reference standard KPIs.
- [ ] Verify your document control register is up to date and all obsolete procedures are removed from active use and archived securely.
- [ ] Prepare supplier evaluation records showing at least one recent monitoring cycle for your main external calibration services provider.

ISO 9001 · CHAPTERS 7–8

Operation & Performance Evaluation

AUDITOR QUESTIONS

- [ ] How does Theresa Nguyen record and track customer calibration jobs, and how is traceability from request to certificate ensured?
- [ ] Show the process Marcus Bell follows when assigning calibration tasks and verifying technician competence, including onboarding of new staff.
- [ ] How does Kevin Park ensure all in-house reference standards are recalibrated before due date? What happens if a standard comes back out of tolerance?
- [ ] Walk through the process for responding to a customer complaint involving certificate errors: who logs the complaint, who investigates, and how is corrective action documented?
- [ ] Present an example calibration job, including all traceability records (request, technician assignment, reference standards used, certificate, and shipment).

EVIDENCE REQUIRED

- [ ] Job logs/tracking records in lab management software showing customer request, technician assignment, calibration execution, and certificate generation/release.
- [ ] Technician onboarding records and competence checks (signed-off procedure training, pairing/oversight logs for trainees).
- [ ] Reference standard calibration schedules, tracking logs, and escalation records showing timely send-out by Kevin Park and review by Marcus Bell/Dana Whitfield (in event of out-of-tolerance result).
- [ ] Corrective action logs with links to root cause analysis, showing complaint input (by Theresa Nguyen), investigation (Marcus Bell), review (Dana Whitfield), and closure evidence.
- [ ] Sample job file showing all traceable documentation for a single calibration project.

TIMING & FREQUENCY

- [ ] Evidence from at least 3 months of live QMS operation prior to Stage 2 audit should be available. Prefer job and complaint records that span more than one month.
- [ ] Technician competence and onboarding updated for new staff and reviewed on each procedure change.
- [ ] Reference standard calibration logs and actions should demonstrate continual/rolling operation, with due-date monitoring evident for current and prior periods.
- [ ] Complaint handling and corrective action log must evidence every recent case, with action tracked to closure and demonstrated trend review at management meetings.

PREPARATION ROADMAP

- [ ] Export a small sample of job records from your lab management software, with end-to-end documentation from request to shipment.
- [ ] Review technician training logs and ensure all staff (including trainee) have recent competence sign-offs.
- [ ] Prepare records showing both proactive and escalated reference standard status cases (e.g. a standard was not overdue, and a case where a standard came back out of tolerance).
- [ ] Make sure your complaint/corrective action log is current and every recent case documents the full investigation and resolution process.

ISO 9001 · CHAPTERS 9–10

Improvement, Internal Audit & Management Review

AUDITOR QUESTIONS

- [ ] Provide details of your last internal audit—who conducted it, which processes were sampled, and how were findings documented and tracked to closure?
- [ ] In the 2026 audit cycle, certificate corrections and overdue standards were both identified as risks. What evidence can you provide that these trends were addressed through management review and improvement actions?
- [ ] How are customer complaints and corrective actions tracked, and what is your process for performing root cause analysis and verifying that corrective actions are effective?
- [ ] Describe the format and content of your annual management review: who participates, what data is discussed (e.g., KPIs, complaints, supplier performance), and how are actions assigned and tracked?
- [ ] What is your process for evaluating the effectiveness of improvements implemented after audits or reviews (e.g., retraining, procedure updates)?

EVIDENCE REQUIRED

- [ ] Internal audit plan, schedule, auditor assignment record (showing impartiality), audit checklists, list of sample jobs/processes reviewed, and complete internal audit report including follow-up actions.
- [ ] Corrective action log for any audit or management review findings (relating specifically to certificate corrections or overdue reference standards), with status showing closure or ongoing monitoring.
- [ ] Records of customer complaints, root cause analyses, improvement actions, and evidence confirming the effectiveness of these actions (e.g., reduction in repeat errors).
- [ ] Management review agenda, minutes signed by Dana Whitfield, KPI trend charts, supplier performance summaries, and status lists of past corrective actions with assigned owners.
- [ ] Evidence of implemented improvements and their measured effectiveness (e.g., before/after KPI graphs, feedback results, training attendance).

TIMING & FREQUENCY

- [ ] Internal audits: at least annually and before the management review, with each process (calibration, reference standard management, complaint handling) sampled at least once per cycle.
- [ ] Management reviews: held annually, or when major nonconformities or customer escalations occur; minutes and actions must be available for the most recent cycle.
- [ ] Corrective action and complaint trend reviews should reference findings across at least the prior 12 months.
- [ ] Evidence retention: per national/legal or customer-specific requirements in the US, typically at least 5 years for audit, corrective action, and management review records.

PREPARATION ROADMAP

- [ ] Schedule and complete an internal audit covering all core QMS processes; compile the report and record actions taken (or planned).
- [ ] Hold a management review led by Dana Whitfield, using real data from corrective actions, KPIs, and supplier evaluations; produce and sign review minutes showing owner assignments.
- [ ] Summarize all improvement actions implemented as a result of the last internal audit or management review. Prepare evidence of their measured effectiveness as requested.
- [ ] Ensure the corrective action log is current and that closed actions have supporting evidence of effectiveness review (such as KPI improvement or reduced findings).

For questions about this Audit Preparation Companion or for support with evidence gathering, contact your AlignedDocs consultant.