

Lab Audit Readiness Assessment

Clause-by-Clause Gap Matrix — ISO 9001:2015 (QC Lab Clauses)

Client: Acme Food Products	Assessment Date: February 2026
Lab Size: 6 analysts, 1 supervisor	Certifications: ISO 9001:2015, FSSC 22000
Location: Baton Rouge, LA	Next Audit: May 2026 (Surveillance)

Status: C = Conforming | MnG = Minor Gap | MjG = Major Gap | NA = Not Addressed **Priority:** H = High | M = Medium | L = Low

Clause	Requirement	Current State	Status	Priority
7.1.5.1	Monitoring & measuring resources	Calibration program exists but lacks documented acceptance criteria for 3 of 8 instruments.	MnG	M
7.1.5.2	Measurement traceability	NIST traceability certificates on file for reference standards. Balance calibration missing traceability chain.	MnG	H
7.1.6	Organizational knowledge	Tribal knowledge only. No documented method expertise or institutional knowledge transfer system.	MjG	M
7.2	Competence	Training records exist for 2 of 6 analysts. No competency assessments. No method-specific qualification protocols.	MjG	H
7.5.1	Documented information — General	SOPs exist for 4 of 9 test methods. Remaining methods rely on instrument manuals or informal notes.	MjG	H
7.5.2	Creating & updating documented info	No document numbering convention. No version control. SOPs stored in shared drive with no access controls.	MjG	H
7.5.3	Control of documented information	No controlled distribution. Multiple versions of same SOP in different folders. No review/approval workflow.	MjG	H
8.5.1	Control of production — monitoring	QC testing performed but release criteria not formally documented for all product lines.	MnG	M
8.6	Release of products and services	Batch release is verbal. No documented release authorization or sign-off process.	MjG	H
8.7	Control of nonconforming outputs	OOS results communicated verbally. No formal investigation procedure. No root cause framework.	MjG	H
9.1.1	Monitoring, measurement, analysis	Testing per customer specs. Results recorded in notebooks. No trend analysis.	MnG	L
9.2	Internal audit	No internal audit program for QC lab. Plant-level audits do not cover lab-specific clauses.	MjG	H
9.3	Management review	Lab not included in management review agenda. No lab performance metrics presented to leadership.	MjG	M
10.2	Nonconformity and corrective action	No CAPA system for the lab. Corrective actions informal and not tracked to closure or effectiveness.	MjG	H
10.3	Continual improvement	No structured improvement process. Ad hoc fixes only.	MnG	L

Summary: 8 Major Gaps | 5 Minor Gaps | 0 Conforming | 2 Not Fully Addressed

Audit Readiness Score: 38 / 100 — Significant exposure. Immediate remediation required prior to May 2026 surveillance audit.

This is a sample excerpt from the Lab Audit Readiness Assessment (\$997). The complete report includes detailed finding narratives, root cause analysis, and a prioritized 30/60/90-day remediation roadmap with owner assignments.

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