

The CLSI Standards Practice Check

Use this shared first step to identify where the conversation needs to go.

We know which CLSI standards support our priority work.

☐

YES

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Somewhat

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NO

The right people can readily access current versions.

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YES

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Somewhat

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NO

Someone is responsible for reviewing changes.

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YES

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Somewhat

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NO

Standards are incorporated into procedures, validation, or development plans.

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YES

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Somewhat

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NO

Staff can explain the basis for methods or decisions they own.

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YES

☐

Somewhat

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NO

Access and use are consistent across teams, shifts, sites, or functions.

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YES

☐

Somewhat

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NO

The goal is not a perfect score. It is a clear next conversation.

How Do I Get the Guidance to Do the Job Right?

Use individually or with a shift, discipline, or technical team.

I can identify the standard behind the methods I perform.

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YES

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Somewhat

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NO

I can access current guidance when I need it.

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YES

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Somewhat

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NO

I know how I would learn that guidance changed.

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YES

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Somewhat

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NO

Our procedures connect clearly to recognized standards.

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YES

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Somewhat

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NO

I could explain why we perform the method this way.

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YES

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Somewhat

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NO

New staff receive the same standards-based foundation.

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YES

☐

Somewhat

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NO

One “No” is enough to ask what would help the team work with greater confidence.

Is Standards-based Practice Sustainable?

Use with laboratory directors, managers, supervisors, and operational leaders.

Priority CLSI standards and users are mapped.

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YES

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Somewhat

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NO

Access is appropriate across sites, shifts, and departments.

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YES

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Somewhat

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NO

Ownership for updates, onboarding, and adoption is clear.

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YES

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Somewhat

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NO

Guidance informs validation, procedures, training, and competency.

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YES

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Somewhat

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NO

Practice can be sustained through staffing or technology change.

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YES

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Somewhat

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NO

Future standards needs are considered in planning and budgeting.

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YES

☐

Somewhat

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NO

Look for patterns, not just scores.
Turn the top three gaps into a recommendation.

How defensible is our standards-based practice?

Use with quality, compliance, accreditation, and regulatory stakeholders.

Procedures can be traced to the guidance used to develop or review them.

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YES

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Somewhat

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NO

Revisions are identified, evaluated, and incorporated through a defined process.

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YES

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Somewhat

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NO

Implementation decisions are documented.

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YES

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Somewhat

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NO

Application is consistent across relevant departments and locations.

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YES

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Somewhat

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NO

Teams can produce the current source when practice is questioned.

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YES

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Somewhat

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NO

Standards use is included in quality planning and improvement work.

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YES

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Somewhat

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NO

Prioritize items that weaken traceability, consistent implementation, or readiness.

Is Recognized Guidance Built into Development?

Use with R&D, medical and scientific affairs, quality, regulatory, and product teams.

Relevant CLSI standards are identified early in development.

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YES

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Somewhat

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NO

Development, validation, quality, and regulatory teams use aligned references.

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YES

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Somewhat

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NO

Current versions are accessible to study planners and reviewers.

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YES

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Somewhat

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NO

Changes are evaluated for product and documentation impact.

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YES

☐

Somewhat

☐

NO

Validation plans identify the basis for key decisions.

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YES

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Somewhat

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NO

Standards ownership is assigned across the product lifecycle.

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YES

☐

Somewhat

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NO

**Treat uncertainty as a cross-functional alignment need,
not an individual knowledge gap.**