▶ **Indicator Tracking Data** — Quality indicators established as part of a facility's QMS are measurements to monitor processes and specific activities. There are several different types of indicators that an organization may track. These indicators can provide useful information regarding the solution's success without necessarily being part of the solution implementation. The organization's quality indicators may provide additional insight that the process or outcome indicators may not provide and should therefore be considered for inclusion in the evaluation. See CLSI document QMS12[28] for additional information on laboratory quality indicators.

▶ **Customer and Stakeholder Feedback** — Stakeholders are an important source of information for determining the effectiveness of the solution that was implemented. Often, stakeholders have a unique perspective and valuable information on whether the change worked as expected. Soliciting stakeholder feedback is an important component of data collection. The special considerations outlined in Section 4.7.2 apply to obtaining feedback at this stage, and can be used as a guide.

▶ **Direct Observation** — This can provide useful input into the status of a solution implementation. This method allows the team to gather accurate information about how a solution implementation operates. Potential challenges with this method are the difficulty in interpreting observed behaviors, the complexity of categorizing behaviors, the potential of influencing the behaviors of participants, and the cost of using the method.[38,43]

▶ **Audit Results** — Both internal and external audits can provide useful information regarding a particular solution implementation. Findings from an audit may indicate the effectiveness of and potentially reveal flaws in the process that were not identified by the individuals performing the implementation and evaluation.

▶ **Analysis and Synthesis of Data** — The review of an evaluation's findings might detect patterns in performance, either by isolating important findings (analysis) or by combining sources of information to reach a larger understanding (synthesis). Evaluations require separate analysis of each data group and a synthesis for examining patterns of agreement, convergence, or complexity of the analyses. How the information is organized, classified, interrelated, compared, and displayed is guided by the questions asked, the types of data available, and input from customers and stakeholders.[31,32,38,45]

5.5.3　Justify Conclusions

The evaluation conclusions can be considered justified only if they are linked to the evidence gathered and judged against agreed-on values

Based on the data, justify the conclusions by:

▶ **Interpreting** the practical significance of the data

▶ **Judging** the merit, worth, or significance of the solution implementation

▶ **Recommending** actions for consideration

ⓘ **REMINDER:**

. . . .

See **CLSI document QMS12[28]** for additional information on laboratory quality indicators.

or standards set by the stakeholders. Stakeholders must agree that conclusions are justified before they use or support the evaluation's results. Justifying conclusions on the basis of evidence includes interpreting the data, making judgments, and making recommendations.

▶ **Interpretation** is the effort of figuring out what the evaluation findings mean. Evaluation findings need interpretation to determine their practical significance. Interpretations are based on information and perspectives of stakeholders and can be strengthened through stakeholders' active participation in the evaluation process.

▶ **Judgments** are statements concerning the merit, worth, or significance of the solution implementation, and are formed by comparing the findings and interpretations against one or more standards. Stakeholders might reach different or even conflicting judgments when multiple standards apply to the solution implementation.

▶ **Recommendations** are actions for consideration resulting from the evaluation. Forming recommendations requires information beyond what is needed to form judgments. Recommendations that lack sufficient evidence or those that are not aligned with stakeholders' values or standards can undermine an evaluation's credibility. Sharing draft recommendations, soliciting feedback from multiple stakeholders, and presenting options instead of directive advice increases the likelihood that the recommendations will be relevant and well-received.[31]

⚠ **NOTE:**

Stakeholders must **agree that conclusions are justified** before they use or support the evaluation's results.

Recommendations based on the evaluation evidence may be to stop continued implementation of the solution, try an alternative solution, make adjustments to the current solution, continue with the complete implementation, or expand the implementation efforts. If the evidence shows that the solution implementation was unsuccessful, another solution may be identified by going back to the Generating Solution(s) process discussed in Section 5.3.

Additional components of justifying the conclusions may include team review, customer review, review of requirements, and planned follow-up:

▶ **Team Review** — The individual(s) performing the evaluation is tasked with writing, reviewing, editing, updating, and disseminating the results of the evaluation.

▶ **Customer Review** — Open communication with customers is often recommended but not always necessary or prudent. Customer review considers both internal and external customers and all stakeholders, when applicable. An evaluation report or communication for internal and external stakeholders may be used to support management decisions about ongoing or future program efforts, and often focuses on findings instead of evaluation methods.

▶ **Review of Requirements** — This varies depending on the type of project and its findings. The solution implementation and evaluation individual(s) or team may need to consider regulatory and compliance issues throughout the process. This report or communication may consist of a summary of the solution implementation, outcome objectives, and a discussion of the relationships between applicable regulatory and compliance standards and the achieved outcomes. The

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regulatory or accrediting agency(s) may require records of the CI initiative in response to a previous deficiency or in an effort to demonstrate the organization's intent of continual quality improvement.

▶ **Follow-up** – Reaching conclusions in an evaluation can seem like an end in itself. However, additional action might be necessary. Follow-up might be necessary to remind intended users of their planned use. Follow-up might be required to prevent lessons learned from becoming lost or ignored in the process of making complex or sensitive decisions. Active follow-up might help prevent evidence from being misinterpreted and applied to questions other than those that were considered in the evaluation.[31,34]

5.5.4 Common Supporting Elements

Table 26 provides examples of how the common supporting elements can be applied to the Evaluating Effect of Solution(s) fundamental process.

Table 26. Common Supporting Elements Applied to Evaluating Effects of Solution(s)

Management Review	Teamwork	Models and Tools (commonly used)	Documents and Records
• Periodic review of team's progress, with focus on: – Results achieved – Unintended or undesired impact	• Team evaluates effects of solution	• PDCA • Lean Six Sigma • RCA • C-E diagram • Checksheet • Decision matrix • FMEA • Flow chart • Histogram • Pareto chart • Risk severity matrix • Scatter plot • SPC/control chart • Survey	• Management review meeting records – Progress reports • Evaluation team meeting records • Evaluation plan • Risk management plan • Communication plan
Change Management	**Risk Management**	**Communication**	
• Analyzing • Monitoring • Mitigating	• Monitoring and reviewing risks	• Informing – Progress/status of initiative – Results achieved – Risk identification and response • Recommending – Implementing solution on a larger scale • Recording – Meeting records – Implementation plan – Data	

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5.5.5 Summary of Evaluating Effect of Solution(s)

Evaluating the outcomes of a solution implementation is an important process for the ultimate success of the CI initiative. Once the data are compiled, analyzed, and synthesized and conclusions are justified, the results should be communicated to key stakeholders. If the results of the evaluation indicate that the CI initiative is successful, widespread implementation (if applicable) may be considered as well as strategies for sustaining the improvement effort(s).

5.6 Integrating and Sustaining Improvement(s)

The basic question answered in this CI fundamental process is, *"Is the change fully implemented and continuing to work as expected?"*

A CI initiative should be considered successful only when the organization is able to integrate the improvement into the organization and sustain it. To celebrate a success and prevent deterioration, an organization should monitor and measure the change and offer the necessary infrastructure to support the initiative.

? QUESTIONS TO ANSWER:

Is the change fully implemented and continuing to work as expected?

5.6.1 Integrating Improvements

By monitoring the primary process measurements established during the CI initiative, an ongoing assessment of the success of the improvement may be made. Integrating the improvement into the organization may involve the following key activities:

- ☑ Assigning an individual (process owner) accountable to ensure improvements are monitored

- ☑ Keeping the operational documents and protocols up-to-date

- ☑ Providing and maintaining equipment required for intended work

- ☑ Establishing purchasing and inventory systems to support the improvement

- ☑ Continuing attention to orientation and training activities (see CLSI document QMS03[46] for information on training and competence assessment)

- ☑ Communicating with staff members, stakeholders, and management

- ☑ Gathering customer feedback and satisfaction

Ensuring the improvement is fully operational may require attention to the culture of the organization and its staff members, along with continued frequent communication by the leaders of the improvement initiative. Occasionally, some resistance to change is encountered and needs attention.

Removing the old ways of operation such as equipment, documentation, supplies, and signage may assist with adoption of the new process.

When measuring success, the question of how long one should monitor and measure arises. A properly executed improvement plan includes key measures or indicators designed to monitor the improved process and signal the operational lead staff when performance may change. Designing the measures to detect the early stages of performance change provides a more proactive and corrective effort. These measures, in combination with already established measures, are routinely reported to management. As the measures become stable and predictable, the need for some measures may no longer be necessary.

Less-than-expected performance may indicate issues with the selection and application of models and/or tools, engagement of the people involved in the process, lack of communication, operational failure to ensure long-term implementation of the solution, or possibly lack of management support for the change.

One method for integration of improvements is a postimplementation review where team members who were involved meet to review the improvement close-out plan, discuss what lessons were learned from the CI effort, and explore ways in which the learning could be shared in the organization. Some key outputs of a postimplementation review could be determined by asking the following questions:

- ☑ What did we learn from this improvement activity?

- ☑ Can the lessons be applied to other areas of the system or organization?

- ☑ How could the lessons be modified to improve other areas?

- ☑ Could a standard of practice be developed from this improvement?

Depending on the system or organization, the potential is great to bring these lessons learned to other areas and reap the benefits of its success. Sharing of ideas may generate further ideas on other improvement projects to consider, expand understanding of operations, and/or develop a greater connection to other areas within the organization.

5.6.2 Sustaining Improvements—Holding the Gains

In keeping with the QSEs and requirements of ISO, organizations need defined methods for gathering performance measures, including customer satisfaction surveys, internal and external assessments, and corrective and preventive action plans. Careful development of measures provides sufficient information to effectively monitor the sustainability of the

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⚠ **NOTE:**

Remove the old process (ie, equipment, documents, supplies, and signs) to help in adopting the **new or changed solution process.**

---

improvement initiative. Setting and reviewing performance targets for the measures with ranges of performance acceptability and setting triggers for intervention in the process are activities contributing to the establishment of ongoing performance specifications for the improved process. Depending on the CI initiative, a formal control plan may be used. Refer to Appendix Z for a sample template. It is recommended that a validation check of the improvement be scheduled for six and 12 months after the initiative is considered "closed."

A control plan may be a useful tool for keeping the improvement process success on track and being ready to respond to new process performance issues. Key components of a control plan may include:

- ☑ A process map or explanation of the process, including any important linkages to other processes

- ☑ A description of the goals and expected outcomes

- ☑ A list of process monitors or measures and the expected performance values

- ☑ A description of how the process monitors will be collected and by whom

- ☑ A prospective list of potential issues that may arise

- ☑ How and who would respond to the issues

An algorithm or map for contingency measures to address issues may be useful. If measures indicate the process is out of control, even after follow-up plans were initiated, a return to the solutions generated in the planning phase of the improvement can be helpful to determine if modification of the process is needed.

The control plan and records of any control activities are essential for closing the process management loop and may assist with future quality planning.

Communication is important in both integrating and sustaining an improvement. Using newsletters, memos, and articles in the organization's general communication publications may be advantageous. A storyboard concept in which laboratory staff and others can review performance serves as a communication tool to maintain focus on the improvement efforts and ability to sustain the improvement. A storyboard can be a bulletin board or large cardboard on a free-standing easel or countertop that is accessible to the staff. Content of a storyboard could include:

! IMPORTANT NOTE:

Communication is important **in both integrating and sustaining** an improvement.

☑ Project title

☑ Goals and key information about the project

☑ List of solutions and key decision points

☑ Names of the team members and sponsors, if applicable

☑ Implementation plan

☑ Current activities with progress and measures underway

☑ Summary of outcomes

☑ Ongoing monitoring of performance

Including a place on the storyboard for viewers to add comments provides an interactive mechanism to acknowledge team and staff efforts, and allows for posting and feedback of questions and answers. This interaction may support the change and communicate issues throughout the improvement process. Sharing both the good and bad experiences of the CI activities produces a learning effect within the organization.

Celebrate. Success of the improvement initiative is a cause for celebration by the planning and implementation teams, the staff involved in the process, and management. Sharing success transfers key learnings to colleagues, to subsequent projects, and to other organizations, enabling continuation of good practices. Organizations can highlight the CI program efforts in many different ways. Some may have articles in a newsletter,

CI program efforts can be highlighted using:

▶ Storyboards   ▶ Formal presentations

▶ Newsletter articles   ▶ Quality events

▶ Bulletin board displays   ▶ Contests, with categories for prizes

display efforts on bulletin boards, or provide formal presentations in meetings such as an annual quality event that showcases all the CI initiatives, with some organizations even awarding prizes for various categories such as "improved patient care," "productivity gains," "customer satisfaction," and "cost reduction."

5.6.3 Closing the Continual Improvement Initiative

As the implementation concludes and the effects of the solution(s) are evaluated, the next step is closure. Defining closure of the work is important

for several reasons. The most obvious is releasing resources, especially people, to pursue other work. Closure also provides the team and stakeholders with satisfaction of completing the work and attaining the objectives.

Some important considerations for determining how to successfully achieve closure are:

▶ Meet with all stakeholders to describe the closure process and gain their acceptance.

▶ Establish the closure criteria with the key stakeholders and customer(s) and create a closure checklist based on the criteria, if complexity warrants it.

▶ Prepare a plan for the transfer of responsibilities, including documentation.

▶ Release resources, such as people, equipment, and materials.

▶ Complete and audit the implementation activities.

▶ Finalize and compile the records.

▶ Prepare a final summary report of the achievements and performance.

▶ Conduct a "close-out" meeting with the key stakeholders.

Final approval for closure of the CI initiative can be effectively achieved in a "close-out" meeting involving the main stakeholders. The meeting can take various forms based on the magnitude, importance, and complexity of the improvement initiative. It is important to match the meeting content and format to the stakeholder audience, while considering the characteristics of the change that was implemented.

Suggested content for a close-out meeting for the team members and key stakeholders to review is:

- [✓] Scope

- [✓] Timeline (high level)

- [✓] Milestones achieved

- [✓] Objectives (met and not met)

- [✓] Risks identified and mitigated

- [✓] Plan for monitoring and evaluating the effectiveness of the change over time

- [✓] Lessons learned

Following the "close-out" meeting, documents and records related to the improvement initiative are organized and maintained according to the laboratory's defined recordkeeping system. Appendix AA provides a template for a close-out report.

⚠ **NOTE:**

Formal closure provides the team and stakeholders with the opportunity to:

▶ Transfer responsibility

▶ Release resources

▶ Close out records and reports

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5.6.4 Common Supporting Elements

Table 27 provides examples of how the common supporting elements can be applied to the Integrating and Sustaining Improvement(s) fundamental process.

Table 27. Common Supporting Elements Applied to Integrating and Sustaining Improvement(s)

Management Review	Teamwork	Models and Tools (commonly used)	Documents and Records
• Review of recommendations to fully operationalize the solution • Review of the improvement initiative's results through periodic assessment of performance indicators	• Team selected for fully operationalizing the solution—may be an intact workgroup (eg, laboratory department)	• PDCA • Lean Six Sigma • RCA • Checksheet • Histogram • Scatter plot • SPC/control chart • Survey	• Management review meeting records • Quality report • Integration team meeting records • Integration plan • Risk management plan • Communication plan • Control plan
Change Management	**Risk Management**	**Communication**	

• Analyzing
• Planning
• Monitoring
• Mitigating
• Integrating
	• Monitoring and reviewing risks	• Informing
		  – Progress/status of initiative
		  – Ongoing performance indicators (ie, information and/or data)
		  – Risk identification and response
		• Aligning
		  – Planned action for integration
		• Recommending
		  – Integration plan for review
		• Requesting
		  – Approval to proceed with defined plan
		• Recording
		  – Meeting records
		  – Integration plan
		  – Data	

5.6.5 Summary of Integrating and Sustaining Improvement(s)

When integrating and sustaining the improvement solutions implemented, it is critical to continue to establish acceptable limits of performance to monitor over time. When performance falls outside the acceptable limits, one or more of the processes described in this guideline may need repeating. Assigning accountability to an individual to "own the improvements" is critical to ensure the gains are maintained. Many improvement initiatives can be replicated within the organization; this is an important opportunity that should be explored. Communicating and celebrating the CI team's success throughout the organization provides recognition to the team and creates momentum for the next CI initiative.

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Chapter 6

Conclusion

6 Conclusion

CI is achieved through the development and implementation of a program that integrates and coordinates key processes and common supporting elements. With a focus on meeting customer expectations, CI efforts should result in improved quality.

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