

Public Health Laboratory Model Practices for
QMS18

Process Management: Test Menu Modifications



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SCOPE

The Clinical and Laboratory Standards Institute (CLSI) provides a broad framework for the approach to process management (Quality System Essentials [QSE] number 7). This document was developed as a tool for public health laboratories to utilize for any change in the process management.

Administration of the laboratory's technical and management processes through an organized approach of development and documentation of both the technical and management processes is critical to optimizing the effectiveness of a Quality Management System (QMS).

An established Process Management system will reduce errors, develop effective and efficient laboratory operations as well as a sustainable quality system, support accreditation and legal requirements, and have a transparent systematic process for meeting customer needs. Please note the specifics of this process rely heavily upon individual laboratory needs, such as accreditation, local legal and governance requirements.

PURPOSE

This document covers the procedures involved with any process changes within the laboratory. Included in this document is an example of applying the tool to test menu modifications within the laboratory through examples of model practices implemented throughout the Public Health Laboratory (PHL) community.

DEFINITIONS

Champion: Staff member who is responsible for advocacy of the change.

Change Management: Change management is defined as the method that describes and implements change within both its internal and external processes.

Collaborator: Any individual or entity with an interest in the final outcome.

Customer: Any user who may be using any part of the information generated. This includes but is not limited to, forms (paper and electronic), sample containers, results, and data.

Information Technology (IT): Entity supporting laboratory informatics.

Laboratory Information Management System (LIMS): Software system that manages samples from entry into the laboratory (pre-analytical) through testing process (analytical) to final reporting (post-analytical). There may be more functions depending on the system that was procured.

Nonconforming Event (NCE): A deviation from the standard operating procedure or conditions required to accurately complete testing and report an accurate test result.

Process Management: Process management is a systematic approach to ensure effective and efficient business processes. Process management addresses repetitive processes carried out on a regular basis and is used to align business with strategic goals.

Proficiency Test (PT): A specified sample tested by laboratory personnel for the purpose of comparison to an established result. PTs may be developed internally or through an external provider.

Standard Operating Procedure (SOP): Defined set of instructions that laboratory/testing personnel must follow for all phases of sample collection and preparation, testing and reporting.

Strengths, Weaknesses, Opportunities, Threats Analysis (SWOT): Process of identifying strengths, weaknesses, opportunities and threats for the laboratory, and, for this purpose, specifically how the addition, modification or removal of an analytical process will affect the laboratory.

Process Owner: Staff member with an understanding of the process details. This position is responsible for managing this process, as well as presenting ideas to entities (management, customers and vendors) who have resources that may be required.

WHEN ARE PROCESS CHANGES NEEDED

Processes may require changes due to both internal and external factors. External factors may include technology being modified or phased out, supply chains being compromised, customer requirements, regulatory requirements based on individual accreditation agencies or new analyses (organisms or compounds) being required. Internal factors may include need for cost savings through reagents, equipment or time, information technology upgrades for instrumentation, analysis or a laboratory information management system. Workflows may also require changes due to shifts in technology, workforce, physical space changes or demands from customers, accreditors, etc.

The following listing details examples of when process changes are needed based on QSE categories. Please note that this list can be expanded based on individual laboratory needs.

Organization:	New/revised regulatory/accreditation requirements Organizational required changes/mandates Strategic changes including quality/SWOT
Customer Focus:	Customer expectation changes, obtained through feedback or voice of the customer Communication algorithms with routine, non-compliant and emergency situations Patient and/or customer requirements
Facilities and Safety:	Physical laboratory changes due to new or modified site Pre-, analytical- and post-workflow and sample movement flow considerations Environmental or safety considerations, including risk assessment, waste stream needs and safe disposal
Personnel:	Staffing changes: routine (on-boarding, training, cross-training, transitional knowledge capture, such as succession planning, due to departures) High-demand situations (outbreak investigations, surge preparedness)
Purchasing/Inventory:	Supplier concerns-component availability/delivery, quality concerns, transportation costs, transportation regulatory requirements Referral laboratory costs/changes Organizational purchasing requirement changes Inventory management control
Equipment:	New or changed instrumentation/procedural platforms IT hardware/software requirements for current or new equipment Status/cost changes of instrument service maintenance agreements
Finance:	Ensure that budget changes are incorporated for current/future fiscal years. Reimbursement or funding source requirements
Process Management:	Regulatory/customer/accreditation/safety/etc., requirements are being addressed Test menu changes Instrument changes Facility changes Standardization of processes changes

Documents and

Records: Non-regulatory document retention requirement changes
Accreditation/regulatory document retention requirement changes
Changing from paper-based to electronic document management system

Information

Management: LIMS modifications
LIMS vendor changes
Organizational IT security requirements
Security/Confidentiality breaches
Data transfer requirement changes/challenges
Result reporting changes, including customer requirements

Nonconforming

Event Management

(NCE): Process to identify the issues as well as suggested improvements to address these issues.

Assessments: Audit/quality assessment finding change requirements – accreditation, regulatory, PTs (external, internal), critical indicators

Preliminary Considerations

The following items are to be completed *separate from and in advance of* initiation of the change process. This is an overview of *considerations that must be made by leadership prior to implementation of a process change*.

Alignment with Laboratory Mission, Vision and Scope of Services

In accordance with the strategic plan and business model, changes to the laboratory processes are to be assessed for alignment with the core mission.

Feasibility

Laboratory process changes are to be assessed for feasibility, including but not limited to:

- fiscal impact
- customer impact
- market demand
- market competition
- workforce capacity and retention
- instrumentation capacity and capabilities, and quality

Resource Requirements

Administration must assess the required resources prior to implementing a process change, including:

- personnel requirements (testing, IT, administrative and other personnel as identified)
- instrumentation
- supplies
- IT requirements
- facility requirements (space for testing, supplies storage, internal sample transport pathways)
- transportation needs (courier, shipping/transportation regulations)
- funding sources (federal/state grant funded, cooperative agreements, contract funded, fee for service), as well as documentation required for the various funding entities, and

- safety requirements determined by risk assessment

An example of resources/personnel/tasks checklist is in [Appendix B](#).

Timeline

Internal timeline: Upon determining the feasibility of a change to any process, a review is to be conducted to determine an appropriate timeline for the implementation. This includes the urgency of the need, while also allowing adequate time for any applicable customer communication and staff implementation (allow 6–8 weeks whenever possible). For sustainability, process monitoring after implementation should also be included in this timeline.

External timeline: If applicable, information about the change(s) should be communicated with internal staff and external customers at least four weeks in advance, unless otherwise approved by the applicable leadership. Notice of up to eight weeks is preferred.

The target deadline will be determined and documented. An example is shown in [Appendix B: Resource/Task Checklist](#). Each unit should make every effort to meet this deadline. If delays are encountered, all units should be notified due to the potential impact on the go-live date and client expectations.

Change Process

Collaborators

Collaborators are any individual or entity with an interest in the final outcome. This could include end users of the results or the data, such as customers and accreditation or regulatory agencies.

Based on the RACI matrix (Example within [Appendix A](#)), collaborators can be further categorized into one or more of the following:

Responsible: The individual(s) who completes the task, followed by the action/implementation. The responsibility can be shared.

Accountable: The individual who is making the decisions. Includes yes or no authority and veto power.

Consulted: The individual(s) or groups to be consulted prior to a final decision or action.

Informed: The individual(s) or groups who need to be informed after a decision or action is taken.

Documentation

The Process Definition Document, sometimes called Process Charter (Example in [Appendix C](#)), records the following aspects to serve as a resource document for potential accreditation protocols.

- Definition and introduction to the process (define the purpose of the process)
- Objectives (what goals will the process achieve? Refer to standard requirements)
- Scope (what the process manages, what is included in the process)
- Performance Indicators/Activities (measure the achievement of the process objective as compared to process performance)
- Inputs and Documents (procedures, work instructions, forms, tools, etc. used to perform the process)
- Outputs and Documents (procedures, work instructions, forms, tools, etc. used to generate the process outputs)
- Interfaces with other processes (upstream and downstream processes)
- Roles (roles that directly participate in performing process activities)
- Requirements (refer to requirements addressed by the process, regulations, accreditation, etc.)

Documentation of Existing and Proposed Process

The laboratory documents either the existing workflow or the proposed workflow using available tools, such as a flow charts, [Five Whys](#), [Kaizen](#) and other LEAN management tools.

This product is then used to determine non-value-added steps, wait times, record any deviations, suggested modifications, etc. The amended product will be used to develop the implementation plan for the new process.

Once the implementation plan has been developed, it is critical to review for any unintended consequences, both to the

laboratory as well as to existing processes or operations, and for the customers/collaborators. Additional costs should be considered at this time, as well as the time constraints.

Risk Management

Any process change should incorporate risk management to determine positive and negative effects of the change.

Risks are to be identified through a risk assessment, including a mitigation plan to minimize any issues that may arise.

Risk management tools include brainstorming within the team in anticipation of the intended outcome. Other tools include the [\(SWOT\) analysis](#), [Political, Economic, Social and Technological \(PEST\) analysis](#), etc. Another risk management tool also includes a checklist that can be tailored for either the entire process or a specific task ([Appendix B](#)).

These tools will help answer the following questions, which in turn, are used to prioritize the timeframe they need to be addressed:

- What risks are needed to be addressed before implementation?
- What risks are to be approached cautiously?
- What risks have minimal consequences to the project?
- What risks may terminate the project?

Implementation Plan

There are many components to implementing a process change. Each component should be assessed to determine the requirements and applicability to the specific process being changed. A useful tool is the [Plan, Do, Check, Act \(PDCA\) tool](#).

Collaborators should be convened for creating the implementation plan. This includes an assessment of each component. They should also be assigned action items according to the RACI matrix developed and the implementation timelines.

An implementation plan should be developed utilizing each applicable component to ensure a successful go-live date and may include, but is not limited to:

- Procedures
- Documentation
- Staff
- Environment
- Information technology
- Resources, equipment and consumables
- Training
- Communication (internal and external collaborators, as applicable)
- Approval chain
- Regulatory and accreditation considerations
- Safety
- Timeline and milestones including a go-live date
- RACI matrix of collaborators and action items

Process Monitoring

The new process should be monitored by quantifiable metrics for a pre-determined period of time to ensure successful implementation. Process monitoring will provide time for identification of unintended consequences or abnormalities. All collaborators are encouraged to report any concerns identified throughout the process. If applicable, external customers are also encouraged to report any issues or concerns identified.

Standardize the Process

Standardize the process change through documentation, communication and training. As the new process becomes part of the laboratory quality management system it should be incorporated into the existing continual improvement system.

APPENDIX A

Test Menu Modification Example

Preliminary Considerations

Convene your collaborators to perform a preliminary assessment of the proposed test menu modification. The initial meeting should include a discussion to understand whether the modification aligns with your laboratory core mission, strategic plan and business model.

Determine whether the modification is feasible. Addition of new testing services or the removal of testing services will have financial impacts, including the availability of trained and competent staff, instrumentation, reporting capabilities, turnaround times and more. Consider if modification of your test procedure changes the complexity of your laboratory from waived or moderate complexity to high complexity. High complexity testing considerations include additional types of personnel, higher levels of personnel qualifications, more stringent performance specifications, additional quality procedures and possibly even a new a CLIA classification for the laboratory.

Use the example of resources/personnel/tasks checklist in [Appendix B](#) to address the preliminary considerations, including the timeline for the modification.

Change Process

1. **The Testing Team consists of members who actively work with the system/samples.** The following members would be included within the testing team:
 - Testing area Managers
 - Quality assurance managers
 - Testing personnel
 - Specimen receiving personnel (if specimen pretesting will be affected)
 - Purchasing (if new or key components are to be purchased)
 - IT (if software configuration/validation is required)
 - Safety personnel, and, potentially
 - Customer representation—if the changes affect either sample collection or reporting

The Testing Team would be led by the “Champion” who is a staff member with an understanding of the process details and is likely the manager of the testing area or as assigned. This position is responsible for managing this process and may have the task of presenting the ideas to entities (management, customers, vendors) for additional resources and buy-in.

2. **Create a RACI matrix for your collaborators.** This group may be included in the planning stages to determine the variables needed to meet their requirements. They may be included in the final testing stages to verify that the process is successful. However, it may not be necessary for this group to be included in the planning process. This is dependent upon the specific requirements for the laboratory.

Figure: Sample RACI Chart

Deliverables	Test Manager	Tester/QA	Developer	Director
Test Execution	A	R	C	I
Unit Testing	A	C	R	I
Test Tool PoC	A	R	I	I
Tool License	R	C	I	A

■ Responsible ■ Accountable ■ Consulted ■ Informed

Documentation

Complete the Process Definition Document with your collaborators and ensure that existing test workflows are assessed against proposed modification workflows.

For testing, it may be helpful to incorporate additional tools and inputs:

- Gantt chart with itemized schedule
- work breakdown structure
- project management software

Testing personnel will use the tool to record any deviations, suggested modifications, etc. The amended change will be used to develop the implementation plan for the new process.

All procedures, including SOPs, job aids, forms, checklists and labels must have a review process prior to implementation that is recorded either as a paper document or in the LIMS. As processes are reviewed, and corrections are documented and incorporated into the implementation protocol, the documents are then ready for validation/verification. It should be noted that this review includes not only the testing process, but also the pre- and post-test processes.

If required, cost, time and staffing capacity information should be determined before final implementation.

All documents will be reviewed and signed off by the Champion, quality, testing personnel and leadership as designated by the facility. All documentation is to be saved into appropriate “files” (hard copy or electronic document management system).

Risk Management

The Process Definition Document should address exceptions, deviations or non-conforming events.

Document the following for the proposed test menu modifications:

- Situations that would lead to exceptions
- What needs to be done when an exception occurs
- Identify risks to further manage and address exceptions

Implementation

Staff Training

The quality managers will ensure that all staff have reviewed the documentation and completed the training and competency. All documentation will be maintained in the document control system for accreditation/certification purposes.

Appropriate proficiency testing analyte(s) will be obtained and tested if new testing has been implemented or if there has been incorporation of an alternate assessment plan.

Finalization of Documents

All documents (SOPs, intake forms, worksheets, etc.) will be approved by laboratory director and entered into the Document Control System as authorized documents.

Communication Plan

To ensure a seamless transition, a communication plan for both internal and external collaborators should be developed. While most components of the communication plan for internal staff will have been included in the operation procedure documentation and the go-live plan, it is important to have regular communication through meetings and/or email distributions to ensure that all staff are aware of the current status and any pending updates.

Components of the communication plan for external customers includes:

- Effective date (optimally, giving at least two weeks, and preferably a longer notice of four weeks)
- Changes in procedures (collection requirements, patient age group and other status, shipping requirements, changes in forms, test code change, changes in LIMS entry—if doing point-of-collection data entry)
- Changes in final reports, such as disclaimer
- Point of contact for questions/concerns/issues

Go-Live Plan

The Implementation Plan will have a Go-Live Plan, which will have a checklist of items that need to be ready for go-live, or “plan B” in case of sub-optimal implementation or failure of any step.

An example plan is below, adapted from the National Learning Consortium (NLC) Electronic Health Record (EHR) Implementation Go-Live planning checklist.

GO-LIVE PLANNING

Set a date with collaborators for go-live during a time that is the least busy as possible.

Use the go-live date to plan all aspects of the implementation, scheduling backwards from the go-live date. Allow for contingencies.

Determine your rollout strategy. Some facilities go-live with a portion of collaborators at a time or all collaborators using limited functionality. For go-live day and for a period of time after, schedules should be lightened.

Plan to notify other key individuals, third parties, and other vendors (e.g., physicians, labs, billing company) of go-live date when it appears certain and request their support.

SEVERAL DAYS PRIOR TO GO LIVE

Review evidence from testing:

Network: devices, connectivity, security

Hardware: computers, monitors, navigational devices, cables, printers, scanners, servers, universal power supply (UPS), storage, back-up server

Interfaces: lab, billing/clearinghouse, LIMS, as applicable

Software:

Unit testing to ensure all system build is complete for:

Screens

Templates

Reports

System testing to ensure data pass from one function to another:

Tasking

Ordering

Backup

Check workflow and process improvements

Ensure changes to workflows and processes are documented and practiced.

Ensure that the chart conversion and pre-load process has begun or is completed, depending on chosen process.

Distribute devices to staff and ensure they know how to use them. Issue a certificate for training completion or another process to document training

Obtain signatures from new user on each tasks including workflow and process map prior implementation. This reinforces the training provided to the new user.

Review policy for use and achievement of goals with key collaborators and reaffirm. Make any necessary changes if software precludes accomplishing goals. Also, set appropriate expectations that not everything will go perfectly on go-live day but that the office will be fully staffed, with the vendor standing by as applicable, to do everything possible to provide assistance.

Review staff schedules

Adjust schedules so those going live have a lighter test load than normal. Expect that each staff member will take a bit longer to use the new process for a period of time.

For the initial phase, you may assign a super user and/or vendor representative in a small group of initial users in the field for the first day or two.

Mid-morning and mid-afternoon check-ins and buffer-breaks should be provided for staff.

Plan a mid-day “huddle” to evaluate progress and to offer support.

Plan end-of-shift debriefing for new users to identify and address any issues and to celebrate getting through the first day!

As more users go-live, you may be able to handle more new users at a time. Scheduling may depend on distances, baseline user skills, etc.

Training

Every user has completed basic computer navigation, keyboarding and other applicable training; provide a refresher if necessary.

Every user has completed the training necessary to use the process; remedy immediately if not.

Every user has a user ID and password.

Plan with the support team to address any issues/gaps.

- Have paper process backup ready in the event of downtime or significant system issues.

- Identify situations or points where go-live needs to be stopped.

Notify collaborators of impending go-live a few weeks in advance of when go-live will occur.

DAY PRIOR TO GO-LIVE

To the extent feasible, provide something special for new users. This may be a coupon for a special cup of coffee or anything else that is affordable and demonstrates support and appreciation for their efforts.

Update the telephone message and post signs to say the organization is implementing a new process and request patience for any delays.

Verify schedule for go-live day, including calling each new user to check readiness, speak with the help desk staff, super users, etc.

Verify readiness.

Review escalation procedures to follow in the event of a problem.

- First-level support staff

- Second-level vendor staff

- Third-level organization management

- Fourth-level vendor management (only for designated individuals)

Review which staff within your organization has the authority to make/approve critical system changes.

Reinforce that time should be taken for buffer-breaks, huddles, debriefing, etc.

DAY OF GO-LIVE

Staff

Staff has been trained on any new policies and procedures and has signed off indicating that they understand the new policies and procedures.

Staff has completed applicable training (education session sign-in logs have been verified).

Staff has performed a “system walk through” of the process from beginning to end, allowing questions to be answered and minor glitches to be corrected.

Application

Everyone can log on and has the correct privileges.

The test menu modification build is complete and has been signed off.

The modification has been tested and has been signed off on.

Paper reports/forms that will be generated out of the modification have been tested.

Support

Support escalation procedures (procedures that define what actions will be taken in the event there is a problem, who will manage the problem internally, and if necessary, who will report the problem to the vendor) have been completed and are in place. The escalation plan has been communicated to all staff and collaborators.

The practice support team has been trained and is aware of their roles/functions for go-live.

Morning, noon and evening support team “huddles” have been established to check in and review issues.

A point person has been identified and will be available to make critical system changes.

Your LIMS vendor has been notified of your live event and is on site or on standby for support.

Backups and Downtime

System backups have been tested and validated. Offsite storage of backups has been arranged.

Downtime procedures have been established and are ready to go, if necessary.

Paper copies of all forms, templates, etc., have been made available in the event of a system failure.

Process Monitoring

The new process should be monitored for a pre-determined period of time as outlined in the Process Definition Document. Allow four to six weeks for monitoring as unintended consequences or abnormalities may take time to develop. Testing personnel, customers and all other collaborators should be provided a primary point of contact to report any deviations or issues.

Additionally, new metrics should be recorded and monitored to ensure the process performance of the test menu modification meets the process objective. These may include annual test volume changes, data reporting capabilities, fiscal impacts, training and proficiency time, etc.

Standardize the Process

Standardize the new process within the laboratory quality management system by ensuring all forms, SOPs, workflows, job aids, sample submission instructions, website and external communications, etc. have been updated accordingly and added to the internal review cycle.

APPENDIX B

Resource-Task Checklist Example

Unit	General Tasks	Attachment for workflow?	Number of weeks needed
Laboratory			
Lab Analyst	<ul style="list-style-type: none"> • Validation and verification studies, including instrumentation; use Validation & Verification SOP. Plan must be signed by CLIA Director prior to beginning study • Develop or amend SOP 	SOP name; validation or verification documents	6
Lab Supervisor	<ul style="list-style-type: none"> • Cost per test • Train staff and complete competency assessments (consult Quality Managers for accreditation requirements) • Determine impact to staffing and scheduling • Work with support services sections (see details below) • Work with IT (see details below) 	Costing worksheet; collection instructions	6
Lab Safety	<ul style="list-style-type: none"> • Risk Assessment 		6
Information Technology			
Information Technology	<ul style="list-style-type: none"> • First two weeks: update test request form (TRF), if necessary • First five weeks: OpenELIS (create test, add permissions, develop worksheets, trailers, results, test-specific QA events) • Last three weeks: electronic interface (all clinical tests and some environmental tests) and train staff as needed 	TRF; final report; worksheets	8
Support Services			
Billing	<ul style="list-style-type: none"> • Identify billing codes; notify IT • Validate first billing run • Verify consistency of test counts between staff and accounting system • Synchronize facility list between LIMS and accounting systems 	CPT or billing codes—add as comment	2
Central Accessioning	<ul style="list-style-type: none"> • Determine specimen requirements (temperature, sample type and size, and biosafety handling procedures) • Standard operating procedures • Train staff 		4
Central Services	<ul style="list-style-type: none"> • Adjust supply orders • Evaluate impact to supply inventory and storage • SOPs for collection kit assembly • Pre-assemble and mail out kits, as needed 		3

APPENDIX C

Process Definition Document Example

Process Charter for:

Defining the Process, Project Objective, Process Documentation Goal and Focus Areas	
<p>The Process Identify the process to be documented</p>	
<p>Project Objective Reason for this process</p>	
<p>Process Documentation Goal Reason for documenting this process/motivations behind process documentation</p>	
<p>Focus Areas State, in order of priority, particular areas on which the process documentation will focus</p>	
<p>Collaborator Key collaborators, responsibilities and contact numbers</p> <p style="padding-left: 20px;">Collaborator(s)</p> <p style="padding-left: 20px;">Responsibilities</p> <p style="padding-left: 20px;">Contact number</p>	
<p>Process Boundaries Process boundaries and activities included in the scope</p> <p style="padding-left: 20px;">When does the process start and when does it end?</p>	
<p>Process Activities List all activities that are within the scope of the process</p>	
<p>Process Inputs Process inputs, steps and outputs</p> <p style="padding-left: 20px;">What triggers the process or is needed for the process to start?</p>	
<p>Process Step Step</p>	
<p>Visual aid</p> <p style="padding-left: 20px;">Media</p> <p style="padding-left: 20px;">Description</p>	
<p>Process Outputs What is the result of the process, the expected outcome or product?</p>	

Defining the Process, Project Objective, Process Documentation Goal and Focus Areas

Exceptions

Not following the process steps in order or deviating from the intended process flow

Situations that would lead to deviations

What needs to be done when deviations occur

Risks to manage deviations

Approval, Challenges, and Revision Schedule

***Note:** To revise process documentation, duplicate the completed inspection and only edit the duplicate and not the original.

Process Documentation approved by:

Challenges to the Process

Expected

Actual

Learnings from challenges

Revision Schedule

Date process documentation was initially completed (date of approval)

Process documentation shall be reviewed on

Process documentation shall be reviewed by

Contact details of person who will be reviewing the process documentation

After review, will the process documentation be automatically revised?

Yes

No

Will the person who reviewed the process documentation also be the one to revise it?

Yes

No

Who will revise the process documentation?

Contact details of person who will be revising the process documentation

Steps that need to be taken before process documentation revision

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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