



*Kaiser Permanente Medical Center, San Francisco
Northern California Region*

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 Work Instruction		
Title: QS - Competency Assessment for Licensed Testing Personnel GEN.55500		WI Number SFOWI-0018 Revision: 13
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GEN.55500 - Competency Assessment

The competency of each person to perform his/her assigned duties is assessed.

NOTE: The competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing. Thereafter, during the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of employee competency must occur when problems are identified with employee performance. Elements of competency assessment include but are not limited to:

1. *Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing*
2. *Monitoring the recording and reporting of test results, including, as applicable, reporting critical results*
3. *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records*
4. *Direct observation of performance of instrument maintenance and function checks*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
6. *Evaluation of problem-solving skills*

Other elements of competency may be assessed, as applicable. A laboratory must evaluate and document the competency of all testing personnel for each test system. A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

The laboratory must identify the test systems that an employee uses to generate patient test results.

Many of the elements of competency assessment are performed during routine supervisory review of an employee. Documentation of these elements, including observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed by routine supervisory review, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment by routine supervisory review may be documented by a checklist. For nonwaived test systems, all the above six elements must be assessed annually (unless any are not applicable to the test system). For waived test systems, the laboratory may select which elements to assess.

1.0 Purpose:

The purpose of this procedure is to provide a step by step instruction on how to use the competency assessment templates to meet the Competency Assessment regulatory requirements.

2.0 Scope:

This procedure is to be followed by all department managers, assistant managers, and supervisors. (The CLIA position titles for these personnel are Technical Supervisors and General Supervisors) as delegated by and under the direction of the laboratory medical director ⁽¹⁾.

The competency of all employees is evaluated on an annual basis using the appropriate competency evaluation form template and instruction. If test methodology or instrumentation changes occur, competency of each person to perform the duties assigned is assessed following training before the employee is permitted to perform patient testing independently. The competency of new employees is evaluated at least twice during the first year. Retraining and reassessment of employee competency occurs when problems are identified with employee performance.

Appropriate training and technical assistance will be provided to employees who do not meet the competency requirements. These employees will be reassessed again after the re-training period as defined by the laboratory management and will be documented as remedial action taken. Each laboratory section must evaluate and document the competency of all testing personnel for each test system. Employees will be presented a list of test systems for which they will be evaluated. Employees can be asked to assist with their evaluations by providing examples of their work records and asking for direct observation review when work load allows.

A selection of representative tests from a automated multi-channel test system may be selected for yearly evaluation. Each unique automated platform (Manufacturer and/or Model) is considered a separate test system. Each manual test kit or manual method is considered a unique test system and must be included in competency assessment every year.

The mandatory elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills through practical bench case examples or written exam.

Each year the Supervisor of each laboratory section must verify all test systems and manual tests have been identified and included on the competency evaluation form. The competency form must include a direct observation check list for each test method assessed to define the critical steps that will be evaluated. When supervisor's record review is used to evaluate competency without a copy of the source document, a brief description of the type of record and elements evaluated will be noted.

As required by federal and California laboratory laws(1), the Laboratory Director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with applicable regulations therefore, the Laboratory Director has the overall oversight and final approval responsibility of the laboratory competency assessment program.

3.0 Definitions:

Test System:

A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Intermediate Test Results:

Patient result data used to calculate, interpret or evaluate accuracy of the final reportable parameter. Examples include body fluid worksheets, sample dilution records, raw data prior to final calculation, blood type or compatibility reaction results that support a final interpretation.

4.0 Procedure:

1. The General Supervisor (may be delegated to Technical Supervisor) completes the top portion of the Competency Assessment Summary form identifying the person assessed and the job title. Mark the appropriate response boxes to indicate the reason for competency assessment.
2. The General Supervisor (may be delegated to Technical Supervisor) prepares the Competency Assessment Summary form as follows:
 - a. List all automated and manual test methods on the top horizontal row of the grid. These

are the identified Test Systems. Review these systems annually and update as needed. See Example 1 below.

- b. Review, revise or develop performance expectations for each of the six competency assessment methods. Expectations of competency will be defined for direct observation of test performance, review of reported test results, completion of intermediate work records, direct observations of equipment maintenance, testing previously analyzed samples, and ability to problem-solve. See section 5 for details.

Example 1 - Test System Identification on Competency Summary Worksheet

Method of Assessment*	DXH800 CBCD	ESR (STRECK)	Manual ESR (Sediplast)	Body Fluid/ Cytospin	Hemata Stat II (HCT)	HIV Rapid	Manual DIFF/Slide Stainer	Binax (Malaria)
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- 3. The General Supervisor (may be delegated to Technical Supervisor) documents on the Competency Assessment Summary Worksheet the evaluation of competency for each of the six methods applicable to each Test System evaluated. Demonstration of competency must be based on all six methods of assessment listed in the first column of the form. (See Section 5 for details of the six elements).

Note: In some test methods not all six elements will apply; example - Instrument maintenance and Function Checks do not apply to a manual test such as the Monospot test kit method. When recording the assessment of the Test System identified on the Competency Assessment Summary worksheet enter N/A into the form when a method of assessment is not applicable. Compile copies of work records used to evaluate competency and maintain them behind the associated Competency Assessment Summary form.

Documentation of how competency assessment was evaluated must be maintained if copies of work records are not included with the summary page. Use the "Documentation of Competency - Records Reviewed". See Section 6.0, Example 5. Record the type of record reviewed (date/time/accession/ sample number). Either the use of hard copy evidence or written reference to specific work records must be maintained.

- 4. Assessment of testing personnel can be performed by a Senior Clinical Laboratory Scientist (CLS) designee who is qualified to be a General Supervisor, as long as the individual performing Direct Observation, or record review has been deemed competent in the previous competency cycle for the Test System being assessed and has been trained and competent in this work instruction and use of all associated forms.

Note: Based on CLIA requirements, any CLS who has at least 1 year experience in high-complexity testing is qualified to be a General Supervisor.

- 5. For each method of assessment under each test system, mark "YES" if competency was demonstrated successfully, "NO" if competency was not demonstrated during the period of assessment, or "N/A" if not applicable. Indicate date task was assessed. If "NO" is marked, specify the failure and actions to be taken for remedial training either on the Direct Observation checklist or on the bottom portion of the form addressed in Step 6 below.

6. The designated General Supervisor must complete a clerical check for completeness only, and is not responsible for rechecking all of the evidence provided.
7. The Technical Supervisor must provide his/her assessment summary by completing the bottom portion of page 1 of the Competency Assessment Summary form and the worksheet containing elements 2, 3, 5 and 6.
 - a. If competency for ALL applicable tasks was demonstrated successfully, mark the box “No Remedial Action Required”.
 - b. If the employee has not met competency, mark the box “Remedial Action Needed”.
 Proceed to Step 7 below.
 Sign the “Assessment Review Performed by” line and enter the date the assessment evaluation was made.
8. If the “Remedial Action Needed” box was marked, the Technical Supervisor must describe the remedial action plan. Upon completion of the plan, re-assess competency and document findings in the “Follow-up/Verification Report” area or on the Direct Observation form. Repeat Direct Observation steps as applicable.
9. The employee must review the approved policy or work instruction as applicable to the methods evaluated for competency. The supervisor must review the competency evaluation with the employee. To document that this step was done, the employee must mark the boxes indicating they have read/reviewed the procedures and that they have reviewed this competency assessment. The employee must sign the bottom of the form.

5.0 Methods Used to Assess Competency and Performance Expectations

For each method of assessment (1 through 6) (2), identify critical procedure steps that must be evaluated for competence.

1. Direct observation checklists should include pre-analytical, analytic and post analytical steps that can affect a analytical process or patient outcome. Example: specimen dilution, pretreatment, blood bank patient sample label history review. Whenever possible use specific temperature, units of measurement, analytical or reporting limits.

The observation checklist should be organized to follow the logical workflow and include key points on handling QC, specimen acceptance, integrity and post analytic reporting of typical and atypical patient results. Include relevant and specific key steps as defined in the approved policy or work instruction. The individual being evaluated is expected to perform work, answer questions and report QC and patient results per approved procedure.

2. Direct observation of routine patient test performance, including specimen handling, processing, and testing.
 Expected Performance Examples:
 - a. Knows how to handle QC material, how often QC must be performed and how to document it.

- b. Understands how to recognize, document and trouble shoot QC that is out of acceptable limits.
 - c. Understands accurate specimen, handling, collection and processing when applicable.
 - d. Maintains specimen integrity and traceability of sample ID throughout process/procedure
 - e. Adheres to correct technical steps as per approved procedure.
 - f. Accurate interpretation of test reactions and results
 - g. Thoroughness and accuracy in documenting preliminary, intermediate, and final results
 - h. Thoroughness and accuracy in computer functions (accessioning, generating preliminary and final reports, results retrieval)
 - i. Corrective action, documentation and resolution of aberrant results of patient and quality control procedures.
 - j. Adherence to universal precautions, safety and infection control policies
 - k. Appropriate disposal of used materials in appropriate containers.
- For low-volume and expensive to run tests, a walk-through or simulation may be used to evaluate direct observation and notate accordingly on the form.

3. Direct Observation checklists may be developed to evaluate specific technical key points specific to that test system. This level of a detailed observation checklist provides a strict standardized performance expectation and ensures evaluation by other qualified CLSs will be standardized. This also allows the Supervisor to specifically evaluate problem prone or technique critical procedural steps. See Example 2 below.

Example 2 - Customized Direct Observation Checklist

1. Direct Observation Automated Body Fluid

Y	N	NA	Critical Procedural Points
			Knows how often QC is performed and how to record performance (CBC)
			Knows how to document & troubleshoot out of control QC performance
			Understands specimen acceptance criteria, integrity, labeling.
			Performs background count as appropriate prior to BF cell count
			Performs patient BF cell count in correct mode.
			Understands upper and lower reporting limits.
			Understands which body fluids can be run on automation
			Understands automated dilution protocol.
			Results and reports patients results appropriately with regards to normal, abnormal, critical.
			Disposal of used materials in appropriate containers

Performance Record: _____ Competency Met _____ Competency NOT Met _____ Observed by: _____ Date: _____

Remedial Action Recommended: _____

Remedial Action Completed on _____ Trainer _____ Date _____

4. Direct Observation checklists pre-filled with generic performance expectations may be used however assessment by different competency observers may be inconsistent. The CLS being evaluated must demonstrate compliance with approved procedural steps through all phases of testing (pre-analytic, analytic, post analytic. See Example 3 below.

Example 3 - Generic Direct Observation Checklist

1. Direct Observation Manual Body Fluid & CSF test

Y	N	NA	Critical Procedure Points
			Knows how to handle QC material, how often QC must be performed and how to document it.
			Understands how to recognize, document and troubleshoot QC that is out of acceptable limits.
			Understands accurate specimen handling, collection and processing when applicable.
			Maintains specimen integrity and traceability of sample ID throughout process / procedure.
			Adheres to correct technical steps as per approved procedure.
			Accurate interpretation of test reactions and results.
			Thoroughness and accuracy in documenting preliminary, intermediate, and final results.
			Thoroughness and accuracy in computer functions (access online, generating preliminary and final results).
			Corrective action, documentation and resolution of aberrant patient results.
			Adherence to universal precautions, safety and infection control policies.
			Appropriate disposal of used materials in appropriate containers.

Performance Report: ___ Competency Met ___ Competency NOT Met Observed by: _____ Date: _____
 Remedial Action Recommended: _____
 Remedial Action Completed on: _____ Trainer: _____ Date: _____

- In this facility, a hybrid or a combination of the Customized and Generic Direct Observation Checklist will be used to incorporate the components of a detailed observation checklist which provides a strict standardized performance expectation along with common items in all test systems relating to quality control, sample handling, acceptance, labelling, safety, and infection control. These observation steps are considered "Critical Procedural Points" that the testing personnel must demonstrate to be deemed competent in the test system. As indicated in the example below, there will be up to 10 items in the form with the first 3 entries and the last one to be the common ones in all test systems. The remaining blank lines in the example are for "Critical Procedural Points" that are specific to each test system. See Example 4 below.

Example 4 - SFO Hybrid Direct Observation Checklist

1. Direct Observation of [enter test system here] Patient Testing			
Y	N	N/A	Critical Procedural Points
			Perform Quality Control using appropriated QC materials and according to established schedule and SOP.
			Troubleshoot unacceptable QC performance and document accordingly per SOP.
			Understand sample handling, acceptance criteria, integrity, and labelling requirements.
			Adherence to universal precautions, safety and infection control policies.

Critical procedural points specific to each test system listed in these 6 line spaces

Lines 1-3 and the last one are common critical procedural points to all test systems

Performance Report: ___ Competency Met ___ Competency NOT Met Observed by: _____ Date: _____
 Remedial Action Recommended: _____
 Remedial Action Completed on: _____ Trainer: _____ Date: _____

- Monitor the reporting of test results.

Expected Performance Examples:

- a. Accurate results reported upon review
- b. Notification of appropriate hospital personnel and physicians of significant results, followed by correct documentation
- c. Demonstration of critical value notification timeliness and “read-back” practice according to protocols if records are found. (This competency element may alternatively be added to a written quiz.)

7. Review of intermediate test results, worksheets, quality control, proficiency tests, and preventative maintenance records.

Expected Performance Examples:

- a. Accurate and legible transcription of QC, proficiency testing, or patient results.
- b. Complete, correct, calculations, interpretations, comments or follow up conclusions.

8. Direct observation of performance of instrument maintenance and function checks.

Performance Expectations:

- a. Performs and documents daily maintenance, if applicable, as per SOP and/or operator's manual.
- b. Performs and documents weekly maintenance, if applicable, as per SOP and/or operator's manual.
- c. Properly performs reassembly of analyzer for readiness to perform analytic testing.
- d. Properly adds, needed reagents, consumables and empties waste with required documentation.
- e. Performs performance/calibration checks, if applicable, as per SOP and/or operator's manual.
- f. Properly operates and obtains valid instrument function check results as per SOP and/or operator's manual.
- g. Recognizes aberrant patient or QC results, troubleshoots and documents problems/corrective action with the instrument according to SOP and/or operator's manual.
- h. Describes instrument corrective action / downtime process, including documentation of service, repair and when QC must be repeated prior to return to service.

9. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

Performance Expectations:

Results agree with previous results within 10% unless otherwise defined in test procedure.

Note: Do not use Proficiency Survey samples as competency material until the laboratory has received the CAP result report for the associated survey kit.

10. Assessment of problem solving skills.

- a. Written, oral or electronic open-book quiz format
 - i. An employee will have satisfactorily met competency on open book assessments by

- obtaining a minimum score of 80% or
- ii. Demonstration of 100% or alternative minimum standard for certain tasks where erroneous results can cause harm to the patient
- b. Correct response to instrument problems such as imprecision and alarm messages displayed by the instrument
- c. Recognition of shifts or trends in quality control results and ability to determine the causes and corrective actions
- d. Recognition and correction of erroneous patient results

6.0 Documentation of Competency Assessment Methods:

1. Direct Observation Assessments for either Patient Testing or Instrument Function Checks (Assessment Methods 1 and 4 on the Specific Test System Competency Assessment Checklist Form):
 - a. Identify the test system in the title of the checklist to make sure the correct form is used.
 - b. Following all the steps in the checklist which are considered "Critical Procedural Points", observe the employee performing the procedure.
 - c. Indicate with a √ (checkmark) in the appropriate box under the column "Yes" or "No" to indicate whether or not the competency was met and whether or not the employee followed the listed procedure or task as expected. For assessment method 4 "Instrument Function Checks", use "N/A" if the assessment does not apply based on the particular test system.
 - d. Record the date the observation was performed, initials of the individual making the observation
 - e. If competency performance expectations were not met identify why and recommend follow up action such as procedure review, retraining, and reassessment.
 - f. Once remedial action is complete and record the action taken, trainer and date.
 - g. Remedial action is to include re-evaluation of competency by using a new checklist to capture successful performance if needed. See Example 5 below..
 - h. Remedial action is to include re-evaluation of competency by using a new checklist to capture successful performance if needed.

Example 5 - Documentation of Direct Observation

KFH Lab Name Hematology - Coag Annual Competency Evaluation

4. Direct Observation of LH750 Instrument Maintenance / Function

Y	N	N/A	General Criteria for Direct Observation of Instrument Maintenance and Function Checks
<input checked="" type="checkbox"/>			Performs and documents daily maintenance, if applicable, as per SOP and/or operator's manual.
<input checked="" type="checkbox"/>			Performs and documents weekly maintenance, if applicable, as per SOP and/or operator's manual.
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Performs Startup / Shutdown appropriately <u>Performed only in night shift</u>
<input checked="" type="checkbox"/>			Properly performs reassembly of analyzer for readiness to perform analytic testing
<input checked="" type="checkbox"/>			Properly adds needed reagents, consumables and empties waste with required documentation
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Performs performance/calibration checks, if applicable, as per SOP and/or operator's manual
<input checked="" type="checkbox"/>			Properly operates and obtains valid instrument function check results as per SOP and/or operator's manual.
<input checked="" type="checkbox"/>			Performs scheduled preventive maintenance as stated in SOP and/or operator's manual.
<input checked="" type="checkbox"/>			Recognizes abnormal patient or QC results; troubleshoots and documents problem/infective action according to SOP and/or operator's manual.
<input checked="" type="checkbox"/>			Describes instrument corrective action / downtime process, repair record and when to perform QC following repair.

Performance Report: Competency Met Competency NOT Met Observed by: TD Date: 3/12/2012
 Remedial Action Recommended: None to review instrument corrective action procedure
 Remedial Action Completed on: 3/9/2012 Trainer: TD Date: 3/12/2012

2. Monitoring the Reporting of Test Results:

- a. Record outcome of record review on the Competency Assessment Summary form. Attach copies of test reports, worksheets or logs as supplemental documentation.

3. Review of Intermediate Test Results, Worksheets, Quality Control, Proficiency Tests, and Preventative Maintenance Records:

- a. List the procedure, QC, or Proficiency test and the accession# or QC level.
- b. Indicate whether or not intermediate results are in agreement with reported results.
- c. Record whether or not QC results were reported with acceptable ranges or if out of control results have been documented and reviewed.
- d. Provide appropriate comments if results(s) are found to be discrepant.

4. Assessment of Test Performance:

- a. Indicate specimen type (previously analyzed specimen, post CAP submitted sample, or inter-facility abnormal smear evaluation).
- b. Indicate specimen ID (ex. Cap D-1, etc).
- c. Attach copy of employee's test worksheet records and the correct result records.
- d. Provide appropriate comments if results(s) are found to be discrepant.

5. Problem Solving Skills Assessment:

Problem solving skills can be assessed through:

- a. Direct observation (incorporate verbal problem case scenarios into checklists).
- b. Record Review (look at all ad hoc problem solving documentation).
- c. On-line competency programs such as the University of Washington, College of the American Pathologists, etc.
- d. Regional written competency quizzes (these also incorporate questions from local problem prone areas of interest)
- e. Attempt to incorporate / identify problem solving challenges for each test system.
- f. If a local quiz is used, grade the quiz and attach the completed quiz.

7.0 Technical Supervisors, Technical Consultants, and General Supervisors:

According to the Centers for Medicaid and Medicare Services (CMS), "What Do I Need to Do to Assess Personnel Competency?", November 2012, brochure distributed to clinical laboratories, "Clinical Consultants, Technical Consultants, Technical Supervisors, and General Supervisors who perform testing on patient specimens are required to have the six required procedures in their competency assessment..." In this facility, Technical Supervisors, Technical Consultants, and General Supervisors who do not perform testing on patient specimens will use different forms for competency assessment purposes which can be found in the associated form control document.

8.0 Filing and Employee Competency Assessment Summary:

- A. CLS annual competency should be submitted at least three weeks prior to the month in which the employee's annual evaluation is due. It is recommended each CLS complete his/her competency assessment up to 3 months prior to their evaluation month. If the employee is scheduled for a vacation at or near the evaluation period, it is recommended that all documentation be provided at least three weeks prior to the vacation.
- B. Once CLS' annual competency had been signed off, he/she can start collecting evidence of compliance for next year's competency assessment.
- C. New employee will require initial and 6-month competency during the first year of employment.
- D. Completed competency assessment packets are to be retained on site at least 3 years total per California law, (5 years for Transfusion Medicine) for easy accessibility during laboratory surveys to verify appropriate results, result limits and review of Intermediate Test Results, Worksheets, Quality Control, Proficiency Tests, and Preventative Maintenance Records.

9.0 References:

1. Section 493.1445. Standard: Laboratory Director Responsibilities.
2. According to CLIA Section 490.1451 (98), the procedures for evaluating the competency of the testing personnel must include, but are not limited to:
 - a. Direct observations of routine patient testing performance, including patient preparation, if applicable, specimen handling, processing and testing.
 - b. Monitoring the recording and reporting of test results;
 - c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
 - d. Direct observation of performance of instrument maintenance and function checks;
 - e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - f. Assessment of problem solving skills; and evaluating and documenting the competency

of individuals semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's initial competency must be evaluated following training to include the use of the new test methodology or instrumentation.

3. College of American Pathologists, Lab General, GEN.55500, *CURRENT VERSION*.
4. Centers for Medicaid and Medicare Services (CMS), "What Do I Need to Do to Assess Personnel Competency?", November 2012

Associated Documents:

External Documents



CLIA_CompBrochure_508[1].pdf

Associated Documents:

SFOFCD-0005 -- QS - Competency Assessment Forms for Licensed Testing Personnel

[Click to Open an Associated Document](#)

Documents Generated:

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5	Procedure A2	Change name of instrument	1/22/2009
6	Procedure B.	Defined test system for competency assessment	1/21/2012
7	Entire Content	Updated to implement Region-wide competency policy and added CLIA requirements and CAP standards to References	5/17/2012
8	Approver	Changed approver to Junming Fang	2/5/2013
9	Section 7.0, References, and Associated Documents	Added Section 7.0 for Technical Supervisors, Technical Consultants, and General Supervisors; Added CMS document in References Section;	2/22/2013

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10	Section 5.0, 2	Added walk-through/simulation as acceptable for DO for low-volume, expensive to run tests	6/4/2013
11	Section 8.0 A-C	Added CLS competency due date per our current practice.	11/4/2015
12	Section 4.0, Part 4 Section 6.0, Part 2 Section 8.0 Approver	Defined "Supervisor" for the purposes of completing competency evaluations. Eliminated. Not in practice. Redefined due dates. Change of CLIA Director.	02/16/2016 10/7/2016
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Approvals:

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Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

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Jan 23, 2009 12:47:56 PM PST - Approved by: Harry Chima/CA/KAIPERM
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Feb 2, 2009 09:16:59 PM PST - Approved and Released Revision No.: 5
Jan 11, 2010 01:20:36 AM PST - First Review Escalation Sent to Richard Chui
DOCUMENT AUDITED FOR TIMELINESS -- Jan 13, 2010 09:45:52 AM PST by Deepty Bhansali
May 19, 2010 04:20:08 PM PDT - Author/Manager changed to Richard Chui/CA/KAIPERM by Richard Chui/CA/KAIPERM

May 19, 2010 04:20:45 PM PDT - Author/Manager changed to Richard Chui/CA/KAIPERM by Richard Chui/CA/KAIPERM
DOCUMENT AUDITED FOR TIMELINESS -- Dec 14, 2010 12:03:40 PM PST by Richard Chui
Nov 22, 2011 01:20:57 AM PST - First Review Escalation Sent to Richard Chui
Nov 22, 2011 08:50:37 AM PST - Document Modified by: Richard Chui
Jan 20, 2012 10:28:44 AM PST - Document submitted for Approval by: Richard Chui
Jan 20, 2012 05:50:35 PM PST - Approved by: Dean X Fong/CA/KAIPERM
Jan 20, 2012 05:50:38 PM PST - Approved and Released Revision No.: 6
Apr 27, 2012 09:51:47 AM PDT - Document Modified by: Armando P Tiong
Apr 27, 2012 03:14:33 PM PDT - Manager changed to Armando P Tiong/CA/KAIPERM by Armando P Tiong/CA/KAIPERM
May 29, 2012 10:00:15 AM PDT - Document submitted for Approval by: Armando P Tiong
Jun 5, 2012 01:11:03 AM PDT - First Backup Notification Sent to N
Jun 5, 2012 06:20:58 PM PDT - Resubmitted by: Dean X Fong/CA/KAIPERM For: Can you move the CAP Checklist to the top so that it can be easily referenced? Thanks.
Jun 6, 2012 08:38:42 AM PDT - Document submitted for Approval by: Armando P Tiong
Jun 7, 2012 12:48:42 PM PDT - Approved by: Dean X Fong/CA/KAIPERM
Jun 7, 2012 12:48:48 PM PDT - Approved and Released Revision No.: 7
Feb 5, 2013 11:40:06 AM PST - Document Modified by: Armando P Tiong
Feb 5, 2013 11:41:00 AM PST - Document submitted for Approval by: Armando P Tiong
Feb 11, 2013 01:22:13 PM PST - Approved by: Junming Fang/CA/KAIPERM
Feb 11, 2013 01:22:17 PM PST - Approved and Released Revision No.: 8
Feb 22, 2013 11:47:28 AM PST - Document Modified by: Armando P Tiong
Feb 22, 2013 12:14:37 PM PST - Document submitted for Approval by: Armando P Tiong
Feb 25, 2013 11:29:33 AM PST - Approved by: Junming Fang/CA/KAIPERM
Feb 25, 2013 11:29:38 AM PST - Approved and Released Revision No.: 9
Jun 4, 2013 11:17:20 AM PDT - Document Modified by: Armando P Tiong
Jul 16, 2013 10:46:47 AM PDT - Document submitted for Approval by: Armando P Tiong
Jul 16, 2013 12:16:46 PM PDT - Approved by: Junming Fang/CA/KAIPERM
Jul 16, 2013 12:16:52 PM PDT - Approved and Released Revision No.: 10
Jun 24, 2014 01:21:24 AM PDT - First Review Escalation Sent to Richard Chui
Jun 27, 2014 01:12:28 AM PDT - Second Review Escalation Sent to Richard Chui
Jul 1, 2014 01:12:30 AM PDT - Final Review Escalation Sent to Richard Chui
DOCUMENT AUDITED FOR TIMELINESS -- Jul 14, 2014 12:17:29 PM PDT by Richard Chui
DOCUMENT AUDITED FOR TIMELINESS -- Jun 15, 2015 08:51:59 AM PDT by Richard Chui
Aug 5, 2015 03:01:09 PM PDT - Manager changed to Maureen R Fitzgibbons/CA/KAIPERM by Richard Chui/CA/KAIPERM
Nov 4, 2015 01:39:05 PM PST - Document Modified by: Richard Chui
Nov 4, 2015 03:04:43 PM PST - Document submitted for Approval by: Richard Chui
Nov 12, 2015 12:56:07 PM PST - Approved by: Junming Fang/CA/KAIPERM
Nov 12, 2015 12:56:11 PM PST - Approved and Released Revision No.: 11
Feb 16, 2016 11:52:27 AM PST - Document Modified by: Maureen R Fitzgibbons
Oct 7, 2016 02:23:26 PM PDT - Document submitted for Approval by: Richard Chui
Oct 7, 2016 03:23:28 PM PDT - Approved by: Eric Suba/CA/KAIPERM
Oct 7, 2016 03:23:31 PM PDT - Approved and Released Revision No.: 12
Jul 6, 2017 10:03:03 AM PDT - Document Modified by: Maureen R Fitzgibbons
Apr 27, 2018 11:19:23 AM PDT - Document submitted for Approval by: Richard Chui
Apr 27, 2018 11:32:13 AM PDT - Approved by: Eric Suba/CA/KAIPERM
Apr 27, 2018 11:32:15 AM PDT - Approved and Released Revision No.: 13