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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Admin Info: 19-20-CLIA

DATE: **September 28, 2018**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2018 (FY2018)

Memorandum Summary

- **CLIA SAPR Review Protocol:** The FY 2018 review is limited to **eight** criteria.
- **Summary Report for Each CLIA SA:** The aim of each report is a balanced picture of the CLIA SA's operations, including activities the SA performs well, area(s) where improvement may be needed, noteworthy accomplishments, and any special circumstances affecting performance.
- **Review of Other Subject Areas:** CMS ROs have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR. Subject areas not specifically addressed by the FY 2018 Review Criteria may also be reviewed at the RO's discretion.
- **Review of CLIA SAPR Criterion 4:** The RO Review Tool has been updated based on RO reviewer feedback (See Attachment #1).
- **Review of CLIA SAPR Criterion 10:** The RO Review Tool for Criterion 10, POD Principle 3 is utilized again this year, with slight modification, based on RO reviewer feedback. (See Attachment #1).
- **Due Date**: Draft CLIA SAPR Summary Reports, Worksheets, Cover Letters and RO Review Tools are due in Central Office (CO) by **March 8, 2019.**

Background

The CLIA SAPR is a mandated annual evaluation of each SA's performance of its survey and certification responsibilities under the CLIA program. The evaluation is performed by the CMS RO CLIA program personnel.

Objectives and Goal

The objectives are to document CLIA program oversight of SA performance and to support and facilitate SA performance improvement, as needed. The goal is optimal SA performance to further quality in patient testing.

State Agencies are encouraged to utilize the SAPR reports enclosed in Attachment 2 throughout the entire fiscal year in order to identify any areas which may need to be addressed prior to each annual SAPR review.

FY2018 Protocol

The FY 2018 standard review is limited to eight of the original CLIA SAPR Criteria. CMS ROs have the option to expand the review to include additional areas of CLIA SA responsibilities which, in their judgment, merit evaluation or monitoring. (Also see "Relationship to Other RO Oversight Responsibilities"). The eight Criteria are:

Criterion #1—Personnel Qualifications/Training
Criterion #4 – Data Management
Criterion #6—Survey Time Frames
Criterion #8—Proficiency Testing (PT) Desk Review
Criterion #9—Outcome-Oriented Survey Process
Criterion #10—Principles of Documentation (POD)
Criterion #11—Acceptable Plan of Correction (POC)
Criterion #13—Complaints

RO Collaborative Support

RO collaborative support is an integral part of the CLIA SAPR. This includes assistance with CLIA SA internal reviews of Statements of Deficiencies and POCs, where circumstances warrant, such as States with less than 1.0 CLIA surveyor full-time equivalent, or non-laboratorial supervisors. This activity can double as an onsite training opportunity. Collaboration also provides further opportunities for mutual understanding of obstacles to optimal CLIA SA performance, brainstorming for solutions, learning about best practices of other similarly-situated States, additional face-to-face conversations about application of POD and acceptability of laboratory POCs and Allegations of Compliance (AOC), as well as further enhancing RO/SA communication—all aimed at the goal of optimal CLIA SA performance and quality patient testing. The SAPR Summary report should not identify individual surveyors, labs, or CLIA numbers. Discussions regarding issues related to specific surveyors, labs, or CLIA numbers should occur at the on-site visit.

Relationship to Other RO Oversight Responsibilities

ROs, as always, have the overarching responsibility and authority for CLIA SA oversight, which is neither superseded nor limited by the CLIA SAPR. Thus, the RO may review a State's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard protocol for FY 2018. Any review conducted in addition to the standard protocol should be documented in a separate section of the CLIA SAPR Summary Report, and presented separately from the review outcomes of the standard Criteria designated for the FY 2018 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	• FY 2018 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets • FY2018 CLIA SAPR Criterion 4 Review Tool – Data Management (with example) • FY2018 CLIA SAPR Criterion 10, POD Principle 3, Composition of a Deficiency Citation, Review Tool (with reference sheet) • FY2018 CLIA SAPR Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC) (*optional*)
2	• FY 2018 CLIA SAPR Data Reports for Standard Review Protocol—Instructions and Description • CLIA Data Reports—Optional Review of Additional Subject Areas
3	• FY 2018 CLIA SAPR—The Summary Report Template
4	• FY 2018 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA • FY 2018 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans
5	• Instructions for Printing CASPER 850D– CLIA SAPR Current Certificates Expiring Before Survey Upload • Special Instructions for Accessing CASPER Report 104 during FY18 • Step-by-Step Instructions: Accessing SAPR data reports in QW

Attachment #1:

- **Document: Performance Review Criteria, Performance Indicators, and Worksheets**
  The Review Criteria, Performance Indicators, and instructions for completing the Worksheets are consolidated into one Excel document, for ease of reference. Instructions for completion are contained in the section entitled "Criterion Review Procedures." The Worksheets must be completed electronically. Calculations are automated in Excel.

- **Criterion 4 RO Review Tool—Data Management**
  This tool is used by the RO Reviewer to review accuracy and timeliness of input into the database for initial Form CMS-116, certificate type changes, and updated demographic information. For FY2018, the Review Tool for Criterion #4, Data Management, was updated to include the review of eight (8) fields on the Form CMS-116. The 8 fields include: Facility Name, Federal Tax Identification (TIN), Facility Address, Mailing Address, Name of Director, email address, telephone number, and fax number.

- **Criterion 10, POD Principle 3, Composition of a Deficiency Citation, Review Tool**
  This tool is used by the RO Reviewer to review CMS-2567 Statements of Deficiency for adherence to POD Principle 3, Composition of a Deficiency Citation. Based on review of data from FY2012 through FY2016, 60-70% of the reviews from "Criteria 10 and 11 RO Review Tool" had identified issues with POD Principle 3. Outcomes from this review will be used for year-to-year comparisons and monitoring for improvement, and assessment for national training needs, as needed. This tool is **required** for FY2018. This Review Tool was updated for FY2018 in order to make it easier to utilize for multiple D-Tags.

- **Criteria 10 and 11 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC)**
  This tool is used by the RO Reviewer to review CMS-2567 Statements of Deficiency and Plan of Correction for adherence to POD and proper acceptance of PoC/AoC. Outcomes from this review will be used for year-to-year comparisons, monitoring for improvement, and assessment for national training, as needed. This tool is **optional** for the FY2018 review.

Attachment #2:

- **SAPR Data Reports for Standard Review Protocol—Instructions and Description**
  These data reports are referenced in Criteria #4, 6, 8, 9, 10, 11 or 13. For consistency purposes, they must be used as indicated in the Criterion Review Procedures for the respective Criterion. It is recommended that the report "ACTS Complaint/Incident Investigation Log" be used to identify complaints for Criterion #13, Complaints for the FY2018; however, details regarding timeline should be verified onsite at the SA as the documentation is a true indication of whether timelines have been met. In addition, tracking sheets developed and implemented at the RO may be used.

- **CLIA Data Reports—Optional Review of Additional Subject Areas**
  These data reports are available for monitoring work, or RO optional review of subject areas not specifically addressed by the eight standard Criteria of the FY 2018 CLIA SAPR. These reports were developed for the CLIA SAPR in previous years, and have been updated with FY 2018 data. Please note they are accessible for CLIA SA as well as RO use. CMS ROs have the overarching responsibility and authority for SA oversight, therefore, subject areas not specifically addressed by the FY 2018 Review Criteria may also be reviewed at the RO's discretion. The addendum report should indicate why the additional measure(s) are being reviewed.

- **FY 2018 CLIA SAPR Summary Report Template—Completion Instructions**
  This template has been updated for FY 2018.

Attachment #3:

- **FY 2018 CLIA SAPR Summary Report Template**
  It is very important to provide in the narrative a balanced picture of activities that the CLIA SA performs well, any areas where improvement is needed, noteworthy

accomplishments, and any special circumstances positively or negatively affecting the SA's performance.

Attachment #4:

- **FY 2018 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA**

  Model language is included for instances where the RO has exercised the option to review additional subject areas. Instructions for the associated narrative are now more specific.

- **FY 2018 CLIA SAPR Model Letter for Response to SA Corrective Action Plan**
  No changes were made to this model letter for FY 2018.

Attachment #5:

- **Step-by-Step Instructions: CASPER 104**
  This attachment includes step-by-stem instructions for accessing the CASPER 104 report for Criterion 4, Data Management.

- **Instructions for Printing CASPER 850D – CLIA SAPR Current Certificates Expiring Before Survey Upload**
  This report replaces OSCAR reports 30 through 33.

- **Step-by-Step Instructions: Accessing SAPR data reports in QW**
  This attachment includes the step-by-step instructions for accessing the SAPR reports in QW.

Due-Date for Draft Summary Reports, Worksheets and Cover Letters and RO Review Tools

Draft FY 2018 CLIA SAPR packages are due in CO by **March 8, 2019**. Please forward the **Summary Report,** along with the **Excel Worksheets, undated Cover Letter, RO Review Tool for Criterion 4, RO Review Tool for POD Principle 3, Composition of a Deficiency Citation and associated CMS-2567s.**

When e-mailing messages regarding CLIA SAPR matters, including the draft CLIA SAPR packages, please include the entire SAPR team:

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Effective Date: October 1, 2018. This information should be shared with all CLIA Program survey and certification staff and their managers within 30 days of this memorandum.

/s/
David R. Wright

Attachments: See Table on Page 3 for Listing and Descriptions

cc: Survey and Certification Regional Office Management

CLIA State Agency Performance Review FY2018
Criterion #11: Acceptable Plan of Correction (PoC) or Allegation of Compliance (AOC)

Performance Review Criterion # 11: Acceptable Plan of Correction (PoC)

The SA has a review system to ensure that all CLIA surveyors accept only PoCs that meet the Criteria for Acceptability.

Performance Indicators (PI):

1. The SA reviews the PoCs for consistency with SOM 6130. The SA reviews at least 10 PoCs accepted by each surveyor during the federal fiscal year (FFY) under review.
2. The SA PoC review process includes participation by all surveyors, as an opportunity for skill improvement.
3. Specific area(s) of improvement identified in RO feedback (FMS and other RO review of PoC), if any, are incorporated by the SA into its PoC review process.
4. The SA PoC review compares results periodically (e.g. quarterly, annually) to track progress of surveyor improvement or to document sustained proficiency in PoC acceptance.
5. The SA PoC review identifies the areas of improvement for each surveyor, as needed.
6. The SA PoC review process quantifies* and documents the state-wide results annually so the State can compare results across federal fiscal years (FFY)--October 1 to September 30

** To quantify results, the following formula must be used by SA in its internal PoC review process. Divide the total number of D-tags on the PoC that meet the Criteria for Acceptability by the total number of D-tags cited on the CMS-2567s reviewed during the FFY under review.* ***NOTE: The result of this calculation is used for SA's internal review only; it is not related to the Performance Threshold listed below.***

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #11: Acceptable Plan of Correction (PoC) or Allegation of Compliance (AOC)

Performance Indicators	Yes	No	Comments
1			P.I. 6 Results of SA Internal Review:
2			
3			show calculation # D-tags POC was acceptable / Total # D-tags reviewed =
4			
5			
6			Comments:

State Agency:		
Date:		
Evaluator:		
Performance Threshold:	**100%**	
Quantified Performance Result:	**#DIV/0!**	
	Yes	**No**
Written Corrective Action Plan required?		

Performance Measurement:
Performance Threshold: 100% (100 percent = the SA has a review process in place that includes all activities described in Performance Indicators #1-6. It does NOT refer to the % outcome of the SA's internal review specified in Performance Indicator 6.)

A Written Corrective Action Plan is required if the quantified performance result is less than 100 percent.

Criterion Review Procedures

See additional review item for RO Reviewer on next page.

Performance Indicators #1 - #5

NOTE: In States with few surveyors, particularly those with fewer than 2 FTEs, the RO staff may need to be more directly involved in the PoC review activities and should apply the performance indicators in a manner that is reasonable for the particular SA administrative and operational set-up. This may include RO participation in the SA PoC review process.

1. Ask the SA for an overview of their review system and/or other review activities they may use, and documentation of their review findings during the past year. Seek sufficient information about the review system to determine whether the performance indicators are met.
2. Indicate whether or not the SA fulfills the requirements of each Performance Indicator by inserting a "1" (number one) in the "Yes" or "No" box as applicable.
3. If the SA internal review finds that no improvements are warranted (i.e., full consistency with PoC Criteria for Acceptability), mark the cells as "Yes" for PI # 3 and # 5.

Criterion Review Procedures--continue to next page.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #11: Acceptable Plan of Correction (PoC) or Allegation of Compliance (AOC)

Performance Indicator #6										
1. Indicate in the Comments section of this worksheet only (not the SAPR Summary Report)										
• the number of D-tags that met the PoC Criteria for Acceptability,										
• the total number of D-tags reviewed, and										
• the outcome expressed as a %.										
NOTE: The result of this calculation is used for the SA's internal review only; it is not related to the Performance Threshold.										
The RO collaborates with the SA to ensure completion of PoC review.										
ADDITIONAL REVIEW BY THE RO REVIEWER: See information on Criterion #10.										
CALCULATION:										
Excel will automatically calculate the Quantified Performance Result and a value will appear in the cell.										
Type an "X" in the "Yes" or "No" box to indicate whether a written corrective action plan is required.										
Reference(s):										
SOM 6130; Appendix C										
Total # of "Yes" PI 1 - 6	0									
Total # of "Yes"/"No" PI 1 - 6	0									

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Attachment #1

FY 18 CLIA SAPR Document:
Performance Review Criteria, Performance Indicators, and Worksheets

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Performance Review Criterion # 1: Personnel Qualifications and Training

The SA has an effective system in place to ensure that all CLIA surveys are conducted by qualified individuals. Individuals are qualified to conduct CLIA surveys if they meet all of the performance indicators.* The SA has an ongoing training program to improve survey skills.

Performance Indicators (PI):

1. The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.
2. Health Professional Qualifications as set forth in the SOM at 4009B.
3. Education, Training, and Experience as set forth in the SOM at 4009C.
4. Completion of SA orientation program based on a CMS-developed orientation program, as in SOM 4009-C.
5. Completion of a CMS-developed Basic Surveyor Training Course within the first 12 months of employment (4009-C) , if available, AND the individual has completed sufficient orientation for RO to evaluate their survey skills.
6. For all surveyors, the SA's ongoing training program utilizes feedback or information from the SA orientation, FMS, and RO review of any CMS-2567s to improve survey skills.
7. The SA's process has on-going activities for each surveyor that are focused on:
    a. Consistency in interpretation of the regulations;
    b. Ensuring surveyor adherence to the SOM;
    c. Improving individual surveyor skills, as needed;
    d. Measuring progress in improving surveyor skills when needed (data from SoD review, PoC review or other SA internal measurement).
8. All SA surveyors attend CMS-funded mandatory training, including those budgeted for in the annual SA budget apportionment (e.g., Consortium/Division meetings).

***EXCEPTION:** Performance Indicator 4 or 5 may not be applicable to an individual who was hired shortly before the time of review.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #1: Personnel Qualifications and Training

Performance Indicator 1:	Yes	No
Are all staff positions (professional and clerical) filled as reported on the CMS-1465A?		

Personnel Qualifications: New Surveyors Hired During FY2018

		Performance Indicators										
New Surveyor Name or ID #	Date of Hire	PI 2		PI 3		PI 4			PI 5			Comments
		Y	N	Y	N	Y	N	NA	Y	N	NA	

Training: All Surveyors

	Performance Indicators												
	PI 6		PI 7								PI 8		Comments
			a		b		c		d				
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
PI 6: On-going training program for surveyors													
PI 7a: Consistency in interpretation of regulations													
PI 7b: Adherence to the SOM													
PI 7c: Improving surveyor skills													
PI 7d: Measuring improvement of surveyor skills													
PI 8: Attendance at mandatory training													

State Agency:	
Date:	
Evaluator:	
Performance Threshold:	**100%**
Quantified Performance Result:	**#DIV/0!**

	YES	NO
Written Corrective Action Plan required?		

Performance Measurement:
Performance Threshold: 100%
A Written Corrective Action Plan is required if the performance result is less than 100% or if Performance Indicator 1 is not met.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #1: Personnel Qualifications and Training

Criterion Review Procedures:

1. PI1 - Verify CLIA SA staff positions, as listed on CMS-1465A, are occupied as reported. If "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.
List all new surveyor names or ID# hired in FY2017.

2. Ask the SA to demonstrate how each surveyor meets PI 2 – 5.

3. Review surveyor personnel information (system, personnel files, etc.) to verify that the performance indicators are satisfied for each surveyor.

4. Proceed to assess Performance Indicators 2 through 5 inserting a "1" (number one) in the "Y" or "N" cell as applicable.

NOTE: Performance Indicator 4 and 5 may not be applicable to an individual hired shortly before the time of this review. If this is the case, enter a "1" in the "NA" box and also enter the reason in the "Comment" column.

5. PI6. Enter a "1" in the "Yes" column if the SA has an ongoing training program for surveyors and a "1" in the "No" column if the SA does not have a training program for surveyors

6. PI7a. Insert a "1" in the "Y" if the SA can demonstrate that ongoing training includes consistency in interpreting the regulations and a "1" in the "No" if the SA does not include this in their training program.

7. PI7b. Insert a "1" in the "Y" if the SA surveyors adhere to the SOM and a "1" in the "No" if the SA surveyors do not adhere to the SOM.

8. PI7c. Insert a "1" in the "Y" if the SA's training program includes a mechanism to improve surveyor skills and a "1" in the "No" if the SA training program does not include this in their training program.

9. PI7d. Insert a "1" in the "Y" if the SA's training program includes a mechanism to measure improvement in surveyor skills and a "1" in the "No" if the SA training program does not include this measurement.

10. PI8. Insert a "1" in the "Y" if all of the SA surveyors attended mandatory training and a "1" in the "No" if some or all surveyors did not attend CMS-funded mantatory training.
Please note: In some instances, a SA surveyor will be unable to attend mandatory training for a variety of reasons (e.g., personal committment or medical issue); however, the intent is that if CMS funds a mandatory training, all SA surveyors must attend unless a staff member is given an approved exception. Denial by the SA to approve CMS-funded training is not an acceptable exception.

CALCULATION

Excel will automatically calculate the performance result based on the number of cells marked "1" for "Yes" divided by the total sum of cells marked "1" for "Yes" and "No". NA is not included in the count.
Type an “X” in the “Yes” or “No” box to indicate whether a written corrective action plan is required.

Reference(s):

SOM: 4003.2; 4009 A-E; 4018; 6234.2; 6410; 6434
Budget Call Letter; 1864 Agreement: Article IV; Parts A - Organization, B – Personnel; Article V - C; Evaluation, form CMS-1465A.

Total of all "Yes" PI 2-8	0
Total of all "Yes" & "No"PI 2-8	0

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion # 4: Data Management

Performance Review Criterion #4: Data Management

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

Performance Indicators (PI):

1. The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.
2. The SA has entered all reviewed initial applications (Form CMS-116) information accurately into the CMS-116 database. **(Note: The name of the laboratory only allows for 50 characters to be entered, so the SA may use abbreviations in order to meet this requirement. The abbreviations must be reflective of information on the CMS-116.)**
3. The SA has entered all reviewed initial applications (Form CMS-116) information into the CMS-116 database within 30 calendar days of receipt by the SA. (**Note: This performance indicator is met if the SA has requested from the laboratory any additional information which is needed to approve the initial Form CMS-116 within 30 days of receipt by the SA.)**
4. The SA has entered all reviewed certificate changes accurately into the CMS-116 database. **(Note: If, when reviewing for certificate changes, it is noted that the demographic information does not match, further investigation should be done to ensure that the demographic information is correct, e.g., check for later CMS-116 submissions with demographic changes.)**
5. The SA has entered all reviewed certificate changes into the CMS-116 database within 45 calendar days of receipt by the SA.
6. The SA has entered all reviewed demographic updates into the CMS-116 database accurately.
7. The SA has entered all reviewed demographic updates into the CMS-116 database within 45 calendar days of receipt by the SA.
8. All personnel responsible for data entry have been trained to enter the information into the CMS data systems in accordance with their responsibilities.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion # 4: Data Management

Performance Indicator 1:	Yes	No
The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates		

	PI 2		PI 3		PI 4		PI 5		PI 6		PI 7		PI 8		
	CMS-116		CMS-116		Cert Changes		Cert Changes		Updates		Updates		Data Entry		
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Comments
PI 2: CMS-116 Accuracy															
PI 3: CMS-116 Timeliness															
PI 4: Certificate Changes: Accuracy															
PI 5: Certificate Changes: Timeliness															
PI 6: Demographic Updates: Accuracy															
PI 7: Demographic Updates: Timeliness															
PI 8: Data Entry Personnel: Training and Data Entry															

State Agency:	
Date:	
Evaluator:	
Performance Threshold:	100%
Quantified Performance Result:	#DIV/0!

Performance Measurement:
Performance Threshold: 100%
A Written Corrective Action Plan is required if the performance result is less than 100% or if Performance Indicator 1 is not met.

	YES	NO
Written Corrective Action Plan required?		

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion # 4: Data Management

Criterion Review Procedures:
1. PI1: If the the SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates, mark an "X" in the "Yes" or, if the SA does not have a tracking mechanism mark an "X" in the"No".
All information for PI 2-PI 7 should be collected from the Criterion #4 Review Tool.
2. When evaluating PI 2, the RO reviewer should compare the initial Form CMS-116 to the information entered into the CLIA 116 database. **SAPR18** should be used for PI 3 and **CASPER 104** should be used for PI4 through PI7.
3. PI2: Enter a "1" in the "Yes" if the SA has entered all reviewed initial applications (Form CMS-116) accurately and a "1" in the "No" if the SA has not accurately entered the data. For FY2018 only the following 8 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Mailing Address, Name of Director, email address, telephone number, fax number. No other CMS-116 fields are required to be reviewed unless the RO determines an expanded review is warranted.
4. PI3: Enter a "1" in the "Yes" if the SA has entered all reviewed initial applications (Form CMS-116) within 30 days and a "1" in the "No" if the SA has not entered the data within 30 calendar days.
5. PI4: Enter a "1" in the "Yes" if the SA has entered all reviewed certificate changes accurately and a "1" in the "No" if the SA has not entered the certificate changes accurately.
6. PI5: Enter a "1" in the "Yes" if the SA has entered all reviewed certificate changes within 45 days and a "1" in the "No" if the SA has not entered certificate changes within 45 calendar days.
7. Enter a "1" in the "Yes" if the SA has entered all reviewed demographic updates accurately and a "1" in the "No" if the SA has not entered the demographic updates accurately.
8. PI7: Enter a "1" in the "Yes" if the SA has entered all reviewed demographic updates within 45 days and a "1" in the "No" if the SA has not entered demographic updates within 45 calendar days.
9. PI8: Enter a "1" in the "Yes" if the data entry personnel have been trained to enter the information into the CMS data systems in accordance with their responsibilities and a "1" in the "No" if this is not the case.
SOM 6135
Budget Call Letter; 1864 Agreement

Total of all "Yes" PI 2-8	0
Total of all "Yes" & "No"PI 2-8	0

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Performance Review Criterion #6: Survey Time Frames

The SA has implemented a tracking system and ensures that the survey time frames are met.

Performance Indicators (PI):

1. Initial Surveys:
   The SA completes all surveys and data entry activities timely so that no Certificates of Registration expire.

2. Recertification Surveys:
   The SA completes all surveys and data entry activities timely so that no Certificates of Compliance expire.

Note: Performance Indicators 3 and 4 are reserved.

3. Reserved

4. Reserved

5. Validation Surveys:
   The SA conducts all validation surveys no later than 90 days after the accreditation inspection.

6. Tracking System:
   The SA has a system in place for tracking survey timeliness.

7. Tracking System for 850D:
   The SA has generated and utilized the CASPER 850D quarterly reports to address expired certificates (CoR, CoC).

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #6: Survey Time Frames

Performance Indicators	Yes	No	Comments
PI 1: Zero Expired CoR			
PI 2: Zero Expired CoC			
PI 3: Reserved			
PI 4: Reserved			
PI 5: Zero or 1 Validation Survey More than 90 Days after AO Survey			
PI 6: Tracking System Implemented for CoR, CoC and CoA			
PI 7: Addressed Expired Certificates on CASPER 850D			

State Agency:		
Date:		
Evaluator:		
Performance Threshold:	**85%**	
Quantified Performance Result:	**#DIV/0!**	
	Yes	**No**
Written Corrective Action Plan required?		

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #6: Survey Time Frames

Criterion Review Procedures

Performance Indicator 1:
Utilize **CASPER Report 850D (aka SAPR Reports 30 and 31).** If there were zero expired CoR, enter a "1" in "Yes"; if there were one or more expired CoR, enter a "1" in "No".

EXCEPTION: If the SA can demonstrate that all expired CoR listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.

Performance Indicator 2:
Utilize **CASPER Report 850D (aka SAPR Reports 32 and 33).** If there were zero expired CoC, enter a "1" in "Yes"; if there were one or more expired CoC, enter a "1" in "No".

EXCEPTION: If all expired CoC listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.

Performance Indicators 3 and 4:
Reserved

Performance Indicator 5:
1. Obtain SAPR Data Reports"**SAPR 13 FY18"** (CRIT 6 PI5 VALSUM) and "**SAPR 14 FY18**" ("CRIT 6 PI5 VALDET).
2. Give copies of these reports to the SA with a request to indicate for each CLIA #:
   -- date of AO survey
   -- date of validation survey
   -- time interval between AO & CLIA surveys, in # of days.
3. If the SA is unable to provide the information requested in 2. above within a reasonable time frame, enter a "1" in "No" for this Performance Indicator as well as PI #6, as this is an indication of inability to track validation survey timeliness.
4. If zero or one of the time intervals between AO and CLIA surveys exceeded 90 days, enter a "1" in "Yes." If two or more of the time intervals exceeded 90 days enter a "1" in "No".

EXCEPTION: If the SA can demonstrate that all of the intervals which exceeded 90 days were due to scheduling changes by the laboratory or accreditation organization, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.
NOTE: Postponing a validation survey more than once, at the request of the laboratory, is contrary to SOM instructions, and is not considered an exception for SAPR purposes.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #6: Survey Time Frames

Performance Indicator 6:
Ask the SA to demonstrate their system for tracking survey timeliness. The format need not be elaborate or automated. If SA's system tracks for survey timeliness of all types of certificates--CoR, CoC and CoA--enter a "1" in "Yes"; if not enter a "1" in "No." If there were zero expired CoR, enter a "1" in "Yes"; if there were one or more expired CoR, enter a "1" in "No."

EXCEPTION: If the SA can demonstrate that all expired CoR listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable and enter a "1" in "Yes." Document the exceptions in the Comments section of this worksheet.

Performance Indicator 7: Ask the SA to demonstrate that they have generated, evaluated and acted on the CASPER 850D reports each quarter of the FY. Enter a " 1" in "Yes"; if not, enter a "1" in "No." If the State has no expired certificates (CoR, CoC) on the CASPER 850D report, enter "1" in "Yes." If there are mitigating circumstances beyond the SA control as to why certificates expired, enter a "1" in "Yes."
NOTE: The SA should be able to show that they have generated the 850D reports each quarter even if the reports show that the State has no expired certificates. If the SA has generated the CASPER 850D report and has no expired certificates, enter a "1" in "Yes"; however, if the State has no expired

CALCULATION

Excel will automatically calculate the Quantified Performance Result based on the number of cells marked "1" for "Yes" divided by the total of cells marked "1" for "Yes" and "No".

Type an "X" in the "Yes" or "No" box to indicate whether a written corrective action plan is required.

Reference(s):

1864 Agreement, Article V, Section C; Validation Survey Protocol; SOM 6102.1; Appendix C, I.-A.

Total # of "Yes" PI 1 - 6	0
Total # of "Yes"/"No" PI 1 - 6	0

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Performance Review Criterion # 8: Proficiency Testing Desk Review

The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation.

Performance Indicators (PI):

1. The SA has implemented a mechanism to track PT scores every 30 - 45 days.

2. **Initial Unsuccessful Participation**

   the SA:

   a. Reserved (Timeliness was incorporated into Performance Indicator 1)
   b. Verifies the scores using information from the PT provider and/or the laboratory prior to recommending an action, and takes any necessary follow-up actions based on their collaboration with their RO.
   c. Prepares CMS-2567
   d. Notifies the laboratory to seek training/technical assistance, as appropriate
   e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated)

3. **Non-initial Unsuccessful Participation**

   the SA:

   a. Reserved (Timeliness was incorporated into Performance Indicator 1)
   b. Verifies the scores using information from the PT provider and/or the laboratory prior to recommending an action, and takes any necessary follow-up actions based on their collaboration with their RO.
   c. Prepares CMS-2567
   d. **Refers to RO for sanction**.
   e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated)

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #8: Proficiency Testing Desk Review

Performance Indicator 1:	Yes	No
Does the SA conduct PT reviews every 30 - 45 days?		

Performance Indicators

PT Desk Reviews	Initial Unsuccessful															Non-Initial (Subsequent) Unsuccessful												
	PI 2a			PI 2b			PI 2c			PI 2d			PI 2e			PI 3a			PI 3b			PI 3c			PI 3d		PI 3e		
CLIA # /ANALYTE-SPEC-SUBS/EVENT	Reserved			Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Reserved			Y	N	NA	Y	N	NA	Y	N	Y	N	NA
1																													
2																													
3																													
4																													
5																													
6																													
7																													
8																													
9																													
10																													

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #8: Proficiency Testing Desk Review

State Agency:	
Date:	
Evaluator:	

Performance Threshold:	**85%**	
Quantified Performance Result:	**#DIV/0!**	
	YES	**NO**
Written Corrective Action Plan required?		

Performance Measurement:
Performance Threshold: 85 percent
A Written Corrective Action Plan is required if **the SA has not reviewed PT scores every 30 - 45 days** **or** the performance result is less than 85 percent.

Criterion Review Procedures

Performance Indicator 1:

1. Review the SA's PT tracking and frequency performed. Determine whether Performance Indicator #1 is met. If it is not met, a Written Corrective Action Plan is required.

Type an "**X**" in the "Yes" or "No box to indicate if PI #1 is met.

Performance Indicators 2 and 3:

2. Proceed to assess Performance Indicators 2b, c, d, e and 3b, c, d, e using the following information outlined in #3 of this section.

Insert a "1" (number one) in the cells for the "Y", "N" or "N/A", as applicable.

Extra lines below each CLIA # provide space to annotate analytes/specialties/subspecialties and events.

3. Use CASPER Report #153 and obtain a listing for "Unsuccessful PT Report" for the test years under review. Also use CASPER Reports #155 and #157.

Use #157 to confirm valid non-participation events.

- Select 10 laboratories and include a cross-section of Initial and Non-initial unsuccessful events. Each laboratory selected for the worksheet can be used to review either the Initial unsuccessful or the Non-initial unsuccessful, or both, depending on whether the Initial and/or Non-initial unsuccessful occur during the FY under review.
- If either the Initial or Non-initial unsuccessful history applies to the lab selected, but not both, mark the non-applicable cells as "NA."
- If no Non-initial unsuccessful events occurred during the FY under review, select 10 Initial unsuccessful events or all, whichever is fewer.

NOTE: If no unsuccessful events appear on CASPER 153, interview SA personnel to ascertain their understanding of proper procedure in the case of Initial or non-initial unsuccessful events. Treat the criterion as met and note the interview and any related comments in the "Comments" section of this worksheet.

CALCULATION

Excel will automatically calculate the performance result based on the number of cells marked "1" for "Yes" for PI#2 & PI#3, divided by the total sum of cells marked "1" for "Yes" or "No". NA is not included in the calculation.

The Quantified Performance Result will automatically calculate and a value will appear in the cell. Type an "X" in the "Yes" or "No" box to indicate whether a written corrective action plan is required.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #8: Proficiency Testing Desk Review

Comments:

Reference(s):
1864 Agreement Article II, Section E; SOM 6054 – 6058; Budget Call Letter

Total # of "Yes" PI2 & PI3	0
Total # of "Yes"/"No" PI2 & PI3	0

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #9: Outcome-Oriented Survey Process (OSP)

Performance Review Criterion # 9: Outcome-oriented Survey Process (OSP)

The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.

Performance Indicators (PI):

1. All surveyors conduct surveys using the OSP and focus on the:
   a. overall performance of the laboratory;
   b. laboratory's ongoing mechanisms to monitor and evaluate its practices and solve its problems; and
   c. interconnectedness of the laboratory's system(s) to ensure accurate, reliable and timely test results, rather than a methodical evaluation of each standard-level requirement standing alone
2. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems which:
   a. relate to laboratory testing;
   b. cause or have a potential to cause a negative impact on patient test results; and
   c. are regulatory under CLIA.
3. The SA utilizes FMS feedback when identifying each surveyor's area(s) for improvement, if any, in conducting outcome-oriented surveys, and takes action for improvement.
4. All surveyors have access to the SOM and other CMS directives related to OSP.
5. The SA ensures SOM directives and/or changes related to OSP are implemented by all surveyors, **including the policy of "Mandatory Citations.**"

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #9: Outcome-Oriented Survey Process (OSP)

Performance Indicator 1:		
	Yes	No
Does the SA utilize mandatory citations?		

			Performance Indicators																				
CLIA #	Laboratory Name	Indicate "O", "P", "C"	PI 1a		PI 1b		PI 1c		PI 2a		PI 2b		PI 2c		PI 3			PI 4			PI 5		
			Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	NA	Y	N	NA	Y	N	NA
1																							
2																							
3																							
4																							
5																							
6																							
7																							
8																							
9																							
10																							

State Agency:		Comments
Date:		
Evaluator:		
Performance Threshold:	**95%**	
Quantified Performance Result:	**#DIV/0!**	

	Yes	No
Written Corrective Action Plan required:		

Performance Measurement:
Performance Threshold: 95%
A Written Corrective Action Plan is required if:

- the combined performance results for performance indicators 1 through 5 is less than 95% percent

OR

- one or more surveyors did not implement the policy of "mandatory citations."

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #9: Outcome-Oriented Survey Process (OSP)

Criterion Review Procedure:

1. Select a sample of 10 FMS surveys. To compile the sample:

- Choose first, any FMS surveys which indicated improvement needed for OSP. Review the written feedback for those FMS along with the corresponding Checklists.
- Then, as necessary to achieve the sample size of 10, select about 1/2 from Observational ("O") and/or Participatory ("P") and 1/2 from Comparative ("C").

If less than 10 FMS' were performed, select all.

2. List the CLIA # and lab name for all FMS surveys in the sample and note whether ("O"), ("P") or ("C").

Performance Indicators 1a, b, c:

3. Review, for each CLIA # listed, FMS feedback & corresponding checklist to ascertain whether each surveyor demonstrated proficiency for items a, b, c.

Insert a "1" (number one) in "Y" (yes) or "N" (no), accordingly.

Performance Indicators 2a, b, c:

4. Review, for each CLIA # listed, the FMS feedback & the respective SoD (Form 2567) to ascertain whether each surveyor demonstrated proficiency for items a - c.

Insert a "1" (number one) in "Y" (yes) or "N" (no), accordingly.

Performance Indicator 3:

5. Interview surveyor and/or supervisor to ascertain how the SA utilizes FMS feedback, if any, for improving surveyor proficiency in OSP, i**ncluding mandatory citations.**

Insert a "1" (number one) in "Y" (yes) or "N" (no), accordingly.

"NA" applies if there was no FMS feedback related to OSP, (**including mandatory citations.**)

Performance Indicators 4-5:

6. Review the SA's mechanism for communicating SOM directives and changes to surveyors.

7. Select a couple of major program directives or SOM issuances on OSP and interview surveyors to determine whether they are familiar with them.

Insert a "1" (number one) in "Y" (yes) or "N" (no), accordingly.

If, during the year under review, no new directives or changes were issued, interview any newly hired surveyors to ascertain their familiarity with SOM directives on OSP.

Insert a "1" (number one) in "Y" (yes) or "N" (no), accordingly. If "N", augment their understanding. If there were no new directives and no new surveyors, insert a "1" (number one) in "NA."

CALCULATION

Excel will automatically calculate the performance result, based on the following formulas:

PI#1-5: the number of "Yes" cells in 1-5 marked "1" divided by the total sum of "Yes" and "No" cells in 1-5 marked "1".

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #9: Outcome-Oriented Survey Process (OSP)

Reference(s):		
SOM Section 4018: Regulatory Role of Surveyor & Consultation		
1864 Agreement		
• Article V- Evaluation; Section C		
• Article II – Functions to Be Performed by the State; Sections A-1; C; E		
SOM Appendix C: Survey Procedures & Interpretive Guidelines for Laboratories & Laboratory Services		
SOM 6100 - 6108		
Total # of "Yes" PI 1 - 5	0	
Total # of "Yes"/"No" PI 1 - 5	0	

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #10: Principles of Documentation (PoD)

Performance Review Criterion # 10: Principles of Documentation (PoD)

The SA has a review system/process to ensure that all CLIA surveyors write clear, concise, and legally defensible Statements of Deficiencies (SoD) (CMS-2567) that are consistent with the CLIA Principles of Documentation (PoD).

Performance Indicators (PI):

1. The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the PoD on an on-going basis. The SA reviews at least 10 of each surveyor's SoD prepared during the federal fiscal year (FFY) under review.
2. The SA SoD review process includes participation by all surveyors, as an opportunity for skill improvement.
3. Specific area(s) of improvement identified in RO feedback (FMS and other RO reviews of SoD), if any, are incorporated by the SA into their SoD review process.
4. The SA SoD review compares results periodically (e.g., quarterly, annually) to track progress of surveyor improvement or to document sustained proficiency in SoD.
5. The SA SoD review identifies the areas of improvement for each surveyor, as needed.
6. The SA SoD review process quantifies* and documents the state-wide results annually so that the State can compare results across federal fiscal years (FFY) (October 1 to September 30).

*To quantify results, the following formula **must be used by the SA in its internal SoD review process.** Divide the total number of D-tags that meet the Principles of Documentation by the total number of D-tags cited on the CMS-2567s reviewed during the FFY under review. ***NOTE: The result of this calculation is used for SA's internal review only; it is not related to the performance threshold listed below.***

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #10: Principles of Documentation (PoD)

Performance Indicators	Yes	No
1		
2		
3		
4		
5		
6		
State Agency:		
Date:		
Evaluator:		
Performance Threshold:	**100%**	
Quantified Performance Result:	**#DIV/0!**	
	Yes	**No**
Written Corrective Action Plan required?		

P.I. 6 Results of SA Internal Review:

show calculation **# D-tags meeting PoD** / **Total # D-tags reviewed** **=**

Comments:

Performance Measurement:
Performance Threshold: 100% (100 percent = the SA has a review process in place that includes all activities described in Performance Indicators #1-6. It does NOT refer to the % outcome of the SA's internal review specified in Performance Indicator 6.)

A Written Corrective Action Plan is required if the quantified performance result is less than 100 percent.

Criterion Review Procedures

See additional review item for RO Reviewer on next page

NOTE: In States with few surveyors, particularly those with fewer than 2 FTEs, the RO staff may need to be more directly involved in the SoD review activities and should apply the performance indicators in a manner that is reasonable for the particular SA administrative and operational set-up. This may include RO participation in the SA SoD review process.

Performance Indicators 1 – 5:

1. Ask the SA for an overview of their review system and/or other review activities they may use, and documentation of their review findings during the past year. Seek sufficient information about the review system to determine whether the performance indicators are met.
2. Indicate whether or not the SA fulfills the requirements of each Performance Indicator by inserting a "1" (number one) in the "Yes" or "No" box as applicable.
3. If the SA internal review finds that no improvements are warranted (i.e., full consistency with PoD), mark the cells as "Yes" for PI # 3 and # 5.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #10: Principles of Documentation (PoD)

Performance Indicator #6:										
The SoD review **MUST** be quantified using the formula shown in Criterion #10.										
1. Indicate in the Comments section of this worksheet only (not the SAPR Summary Report):										
• the number of D-tags that met the PoD										
• the total number of D-tags reviewed and										
• the outcome expressed as a %.										
NOTE: The result of this calculation is used for the SA's internal review only, it is not related to the Performance Threshold.										
The RO collaborates with the SA to ensure completion of SoD review.										
ADDITIONAL REVIEW BY THE RO REVIEWER: COMPLETION OF THE Criterion 10, POC Principle 3, Composition of a Deficiency Citation REVIEW TOOL is required (see Attachment #1 of the CLIA SAPR Admin Info). **Select one CMS-2567 for each CLIA surveyor in the SA. Use a separate RO Review Tool for each 2567 reviewed, and record your findings for Criterion 10, Principle 3 on the review tool. If all D-Tags in the CMS-2567 being reviewed meet POD, enter an "X" in column C, "All D-Tags Meet POD. Or, if one or more D-Tags do not meet POD, enter the applicable D-Tag that does not meet POD and the reason in column E, "D-Tag Not Meeting POD + Reason". Leave the "All D-Tags Meet POD" column blank if 1 or more D-Tags do not meet POD.** **If more than 5 CLIA surveyors in the SA, review other surveyors' 2567s in a subsequent year. If only 1 CLIA surveyor, select a minimum of TWO (2) 2567s. *Refer, as needed, to the CLIA Principles of Documentation , when you discuss the outcome of Principle 3 with the SA.* The outcomes of the RO Review Tool are for year-to-year comparison and monitoring for improvement, and assessment for national training, as needed.** ***Note:*** **SCAN OR OTHERWISE ELECTRONICALLY SAVE THE CMS-2567 WITH THE Criterion 10, Principle 3 REVIEW TOOL, SO THECMS-2567 ACCOMPANIES THE RO REVIEW TOOL WHENEVER FORWARDED TO THE SA OR TO CMS CO. THERE IS NO NEED TO SUBMIT THE POC/AOC FOR THE FY2018 SAPR REVIEW. ONLY THE CMS-2567 SHOULD ACCOMPANY THE REVIEW TOOL. USE OF THE REVIEW "CLIA SAPR CRITERIA 10 & 11 D-TAG RO REVIEW TOOL" (previous review tool utilized for Criteria 10 & 11) IS OPTIONAL FOR FY2018.**										
CALCULATION:										
Excel will automatically calculate the Quantified Performance Result and a value will appear in the cell.										
Type an "X" in the "Yes" or "No" box to indicate whether a written corrective action plan is required.										
Reference(s):										
SOM: 6130; Appendix C; Laboratory Principles of Documentation										
Total # of "Yes" PI 1 - 6	0									
Total # of "Yes"/"No" PI 1 - 6	0									

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Performance Review Criterion # 13: Complaints

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

Performance Indicators (PI):

1. The SA utilizes the Automated Complaints Tracking Systems (ACTS) in Aspen, in accordance with the current ACTS Procedure Guide.
   NOTE: The guide is kept current at the following website: *https://qtso.cms.gov/software/aspen/reference-manuals*
2. The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.
3. The SA acknowledges and notifies complainant.
4. The SA triages/evaluates complaints for proper disposition.
   a. SA conducts investigations for the following only when authorized by the RO:
      CoW, PPMP, CoA, Facilities testing w/out a certificate
   b. Forwards via ACTS all CoA complaints received in the SA to the RO for disposition.
   c. Forwards to another agency (OIG, FDA, OSHA, another SA as required by law, etc), as necessary.
5. Complaints are scheduled in accordance with established procedures/priorities.
6. Complaint investigations are:
   a. Conducted in accordance with established time-frames.
   b. Unannounced.
7. The SA adheres to the SOM instructions for post-investigation actions.
8. There is resolution and closeout of each complaint (completion of all actions required by SOM, including follow-up to complaint, if not anonymous).

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #13: Complaints

Performance Indicator 1	Y	N
Does the SA utilize ACTS for all complaints ?		

CLIA # or SA Complaint ID # (if no complaints, indicate here results based on interview)	Performance Indicators																								Comments
	PI 2		PI 3			PI 4a			PI 4b			PI 4c			PI 5			PI 6a			PI 6b			PI 7		PI 8		
	Y	N	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	Y	N	
1																												
2																												
3																												
4																												
5																												
6																												
7																												
8																												
9																												
10																												

State Agency:	
Date:	
Evaluator:	
Performance Threshold:	**90%**
Quantified Performance Result:	**#DIV/0!**

	YES	NO
Written Corrective Action Plan Required?		

Performance Measurement:
Performance Threshold: 90 percent
A Written Corrective Action Plan is required if either of the following applies:
Performance indicator #1 is not met
Performance results were less than 90 percent

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

CLIA State Agency Performance Review FY2018
Criterion #13: Complaints

Criterion Review Procedures

NOTE: If SA received no complaints, interview staff to ascertain their understanding of the complaints process and complete PI 2 -8 based upon the interview.

Enter "No complaints received" on line 1.

Performance Indicator #1

1. Determine whether Performance Indicator # 1 is met. If not met, a Written Corrective Action Plan is required.

Review the SA mechanism for logging in and tracking complaints and verify that all complaints are entered into ACTS.

Interview staff to determine how complaints are handled. Verify their understanding that ALL CoA complaints must be forwarded via ACTS to the RO for disposition.

Also verify that all staff would closely coordinate with the RO when the SA is delegated the complaint for action, especially when issues have attracted media attention.

Type an "X" in the "Yes" or "No box to indicate if PI #1 is met.

Performance Indicator #2 - #8 (except 4a)

2. Proceed to assess Performance Indicators 2 through 8.

Randomly select some complaints. If the total number of complaints is 1 -10, review all. If the total number is more than 10, review 10.

Follow their paths through ACTS and determine if the applicable performance indicators are met. Verify that each complaint was entered into the ACTS system, all associated actions fulfilled, and ACTS data screens completed, as appropriate.

If complaint was forwarded to AO, note in comments section.

Insert a "1" (number one) in the "Y", "N" or "NA" in the box as applicable. "NA" is shown as an option only where appropriate.

Note: For PI #7, if the SA has followed the SOM and has forwarded the complaint to the RO for investigation and the SA is not required to perform the post-investigation, enter "1" in the "Yes" box. For PI #8, if the SA has followed the SOM and has forwarded the complaint to the RO for disposition or if the complaint is anonymous, the SA is not responsible for the resolution or close out of the complaint. Enter a "1" in "Yes."

CALCULATION:

The Quantified Performance Result will automatically calculate and a value will appear in the cell.

Type an "X" in the "Yes" or "No" box to indicate whether a written corrective action plan is required.

Reference(s):

1864 Agreement, Article II, Section E; Article V- Section C

SOM: Chapter 5, sections for CLIA; ACTS Procedure Guide at https://www.qtso.com/aspenmanguide.html

Total # of "Yes" PI 2 - 8	0
Total # of "Yes"/"No" PI 2 - 8	0

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

Note to RO Reviewer: Discuss with SA the data recorded on these worksheets.

FY 2018 CLIA SAPR CRITERIA 4, Data Management

RO Review Date:			**State:**
RO Reviewer:			

Initial CLIA Applications (Form CMS-116), PI2 + PI3

CLIA Number	Selected* Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	Comments List All Fields Not Accurately Entered AND/OR Entered > 30 Days
			*For FY2018 only the following 8 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Mailing Address, Name of Director, email address, telephone number, fax number. No other CMS-116 fields are required to be reviewed unless the RO determines an expanded review is warranted.
1			
2			
3			
4			
5			
6			
7			
8			

Certificate Changes, PI4 + PI5

CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	Comments List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

Demographic Updates, PI 6 + PI7

CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	Comments List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

FY 2018 CLIA SAPR CRITERIA 4, Data Management

RO Review Date:			**State:**
RO Reviewer:			

Initial CLIA Applications (Form CMS-116), PI2 + PI3

CLIA Number	All Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	Comments List All Fields Not Accurately Entered AND/OR Entered > 30 Days
1 21D0000000	Y	Y	
2 21D1111111	N	Y	Facility Address, LD name mispelled
3 21D2222222	Y	N	43 days - backlog for entry
4 21D3333333	N	N	Mailing address not entered, 48 days - no reason given
5			
6			
7			SAMPLE
8			

Certificate Changes, PI4 + PI5

CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	Comments List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1 21D4444444	N	Y	PPM entered instead of CoW
2 21D5555555	Y	N	57 days - data entry person out on medical leave, no back up
3			SAMPLE
4			

Demographic Updates, PI 6 + PI7

CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	Comments List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1 21D6666666	N	Y	Facility address - street address #
2 21D7777777	Y	N	61 days - data entry position vacant
3			SAMPLE
4			

Criterion 10, POD Principle 3, Composition of a Deficiency Citation
RO Review Tool FY2018

CLIA Number:	Facility Name:	
State:	RO Reviewer:	Review Date:
Total Number of D-Tags on CMS-2567:		

Principle Requirement	All D-Tags Meet POD	D-Tag Not Meeting POD + Reason
Statement of Deficient Practice aka Deficient Practice Statement (DPS)		
The specific violation of regulations stated clearly, e.g., Specific action(s), error(s), lack of action (i.e., deficient practice)		
The DPS does not simply restate regulation.		
Extent		
Extent of deficient practice is stated in DPS		
Extent is expressed in a numerical value		
Sources of Evidence		
DPS contains the source(s) of evidence		
At least 2 sources, if possible?		
Identifiers		
Identifiers are included		
Individual's names/titles are referred to by a coding system so they remain confidential		
Findings/Facts		
Findings support the DPS		
Findings/facts are organized in a concise, chronological and logical order		
The questions who, what, when, where, and how are answered		
Sources of Evidence		
All sources of evidence in the DPS are also reflected in the findings		
Observations: date, time, location		
Interviews: date, time, identifier		
Record/Document review: record name/type		
Identifiers		
Iindividual's names are referred to by a coding system so they remain confidential		
Uunique patient identifers are used so patients cannot be identified		
General		
The D-Tag applicable to the requirement cited		
The deficiency citation is free of extraneous remarks and advice		

Reference Sheet, Principle #3, Composition of a Deficiency Citation

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A. Regulatory Reference:

A Regulatory Reference includes the following components:
1. A survey data tag (D-Tag) number,
2. The CFR (Code of Federal Regulations),
3. The language from that regulatory reference which specifies the aspect(s) of the requirement with which the laboratory was non-compliant, and
4. An explicit statement that the requirement was "NOT MET".

B. Deficient Practice Statement (DPS)

The statement of deficient practice is one component of the evidence. It includes:
1. The specific action(s), error(s), or lack of action (deficient practice),
2. Outcome(s) relative to the deficient practice, when possible,
3. A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4. The identifier of the individuals or situations referenced in the extent of the deficient practice; and
5. The source(s) of the information through which the evidence was obtained.

C. Relevant Facts and Findings
The facts and findings relevant to the deficient practice answer the questions: who, what, where, when, and how. They illustrate the laboratory's noncompliance with the requirement or regulation.

How the deficiency was determined and how the evidence relates to the requirement.
What laboratory practice was non-compliant?
Who were the patients of the failed practice or the laboratory staff involved?
Where the deficient practice occurred, e.g., specific locations in the laboratory documents; and
When the problem occurred and for how long. Include the number of records or observations and the duration of the records or observations. Include the specific dates or time period for the noncompliance.

FY 2018 CLIA SAPR CRITERIA 10 & 11 D-TAG RO REVIEW TOOL

CLIA Number:		**Facility Name:**		**State:**
Survey Date:		**RO Reviewer:**		**RO Review Date:**

CRITERION 10			**CRITERION 11**				
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Identify D-tag(s) which do not meet POD	**Identify principle(s) of POD not met**	**Total # of D-tags which meet POD**	**PoC: Is the POC acceptable? (Y, N, N/A)**	**AoC: Is the AOC credible? (Y, N, N/A)**	**Total # of acceptable and/or credible D-tag(s)**	**Total # D-tags cited in CMS-2567**	**Additional Comments, Reason why D-tag does not meet POD OR Why POC/AOC was not acceptable/credible**
CRITERION 10: % D-tags which meet PoD		#DIV/0!	**CRITERION 11:** % D-tags which meet requirements for Poc or AoC		#DIV/0!		

FY 2018 CLIA SAPR CRITERIA 10 & 11 D-TAG RO REVIEW TOOL

CLIA Number:		**Facility Name:**		**State:**
Survey Date:		**RO Reviewer:**		**RO Review Date:**

CRITERION 10			**CRITERION 11**				
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Identify D-tag(s) which do not meet POD	**Identify principle(s) of POD not met**	**Total # of D-tags which meet POD**	**PoC: Is the POC acceptable? (Y, N, N/A)**	**AoC: Is the AOC credible? (Y, N, N/A)**	**Total # of acceptable and/or credible D-tag(s)**	**Total # D-tags cited in CMS-2567**	**Additional Comments, Reason why D-tag does not meet POD OR Why POC/AOC was not acceptable/credible**
			Y				
D5411							missing impact on patients
		7			**8**	**8**	

CRITERION 10: % D-tags which meet PoD	88%	**CRITERION 11:** % D-tags which meet requirements for Poc or AoC	100%

Reference Sheet for RO REVIEW TOOL, Criteria 11
Required Elements for acceptable POC and credible AOC

Acceptable Plan of Correction

Evaluation

Does it address:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and applicable corrective action (s)?
3. What measure has been put into place or what systemic changes will be made to ensure that the deficient practice does not recur?
4. How the corrective action(s) will be monitored to ensure the deficient practice does not recur?

Credible Allegation of Compliance

Evaluation

Lab's Statement or documentation:

a. Is it made by a representative of a laboratory with a history of commitment to compliance and taking action when required?
b. Is it realistic; is it possible to accomplish corrective action(s) by date of AOC?
c. Does it indicate that the problem has been resolved?

Lab's AOC must include acceptable evidence of correction with documentation. Does the evidence show:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken?
3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur?
4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur?

Reference Sheet for RO REVIEW TOOL, Criteria 10 Principles of Documentation (POD) - Key Points	
POD Principle	**Key Points**
1, Lab Compliance and Noncompliance	◊ Compliance → D0000 (only used for compliance when all requirements met, not for addl info) ◊ Noncompliance → includes specific citations
2, Using Plain Language	◊ Written clearly, objectively in active voice and in layman's terms ◊ Avoid words such as: *seems, appears, inadequate, unnecessary* ◊ No extraneous advice, comments, directions, slang ◊ Should contain only evidence to support noncompliance ◊ Define acronyms, abbreviations 1st time used ◊ Ensure accuracy of cited/quoted material
3, Composition of Deficiency Statement	◊ Deficient Practice Statement: ◦ Clearly states what lab did/did not do to cause noncompliance ◦ Do not merely repeat the regulation ◦ Includes: specific action(s) or lack of action(s), outcome(s) when possible, extent, sources (2) ◦ Name of individuals/patients should never be used ◊ Findings Statement: ◦ Supports/illustrates lab's noncompliance ◦ Who, what, where, when, how ◦ Citations specific to lab, in concise and chronological or logical order ◦ Date and time for observations
4, Relevance of Onsite Correction Findings	◊ Must be documented on CMS-2567 as "NOT MET"
5, Interpretive Guidelines (IG)	◊ May not be used as a basis for citation(s) ◊ IGs do not replace/supercede statute or regs
6, Citation of State/Local Code Violation	◊ Only used for 2 reasons, see POD
7, Cross References	◊ Applicable and provides additional strength to linked citation(s) ◊ Must support noncompliance with requirement
8, Condition Deficiencies	◊ Includes only requiremements to be corrected to achieve condition-level compliance ◊ May stand alone as single cite or include accompanying standards ◊ Condition statement is written as a practice statement. Findings are listed or cress-referenced

Attachment #2

SAPR reports for FY 2018 - Mandatory reports 2018

Criteria 4 PI3:

SAPR 2 FY18*: See SAPR Report #1. A detail report, sorted by application type, identifies the labs that applied and entered into the CLIA program in FY18.

Criteria 5 and 6 PI5:

SAPR 13 FY18*: A summary report providing totals on the number of accredited labs (ap type 3) that had validation surveys during FY18.

SAPR 14 FY18*: See SAPR report #13. A detail report identifying the accredited labs (ap type 3) that had validation surveys during FY18.

SAPR 14 FY18 AO DETAIL*: See SAPR report #13. A detail report identifying the accredited labs (ap type 3) that had Validation surveys during FY18. Note: The report displays the labs by accreditation organization, so a lab accredited by both ASHI and AABB would display (and be counted) on 2 lines.

Criteria 6 PI1 and PI2:

CASPER report 850D: Run this report for Certificates Expiring within 6 Months for Certificate Type: Registration (PI 1) and then again for Certificates Expiring within 6 Months for Certificate Type: Compliance (PI 2). (Details in Attachment)

OR

SAPR 30 FY18*: A detail report identifying compliance labs that have registration certificates due to expire within 6 months, or, have actually expired, and there is no evidence of any survey activity in Aspen Central Office (ACO). (PI 1)

SAPR 31 FY18*: A detail report identifying compliance labs that have registration certificates due to expire within 6 months, or have actually expired, and the initial certification kits are in ACO and have not yet been uploaded to the national system. (PI 1)

SAPR 32 FY18*: A detail report identifying labs that have compliance certificates due to expire within 6 months, or have actually expired, and there is no evidence of any survey activity in Aspen Central Office (ACO). (PI 2)

SAPR 33 FY18*: A detail report identifying compliance labs that have compliance certificates due to expire, or have actually expired, and the recertification kits are in ACO, but have not yet been uploaded to the national system. (PI 2)

Access the CASPER reporting system for the following reports:

Criteria 4 PI4-PI7:

CASPER Report 0104D (aka SAPR 8): Identifies the names of labs that had specific fields updated during FY18, including, but not limited to: lab director name, address of lab, app type, etc. The report also displays the date the change was made, the user ID of the person who made the change, and fields changed. (Details in attachment)

Criteria 8:

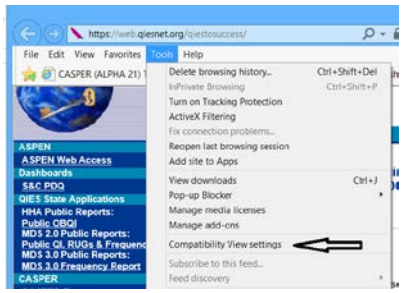
CASPER Report 0153D: A detail report that displays unsatisfactory (failed) score and/or unsuccessful (two failures in three events or two consecutive failures) proficiency testing performance.

CASPER Report 0155D: A detail report that displays a profile of a laboratory's proficiency testing performance by listing the most recent twelve events for each analyte.

CASPER Report 0157D: A detail report identifies the laboratories that have been given a pass for failure to participate in proficiency testing for one or more analytes/events.

***** These reports are found in QIES Workbench (QW) in the folder: CLIA: SAPR Mandatory-2018. Note: if QW doesn't appear to be working correctly, please check your QIES compatibility settings.

Compatibility Settings for QIES when using QIES Workbench (QW)



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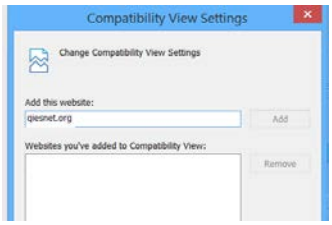
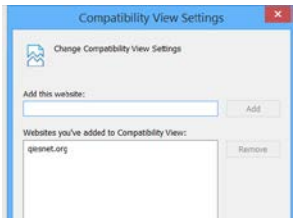


click Add



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QIES to Success needs to be added to compatibility View Settings in IE 11. Open QIES to success webpage and click on Tools, choose Compatibility View Settings, qiesnet.org should be listed as above; click add and it moves down into the second box. Click close and now QW should work.

Attachment #2

SAPR reports for FY 2018 - Optional reports 2018

Criteria 4 PI5:

SAPR 1 FY18*: A summary report providing totals on the number of 116s entered in FY18.

SAPR 3 FY18*: A detail report showing the outliers records, i.e., States entering the CMS-116 >30 days after receipt of the CMS-116 form in the State Agency, designated by the date stamp on the form.

SAPR 4 FY18*: A summary report provides totals on the number of labs surveyed during FY18.

SAPR 5 FY18*: See SAPR Report #4. A detail report identifies the labs that were surveyed during FY18.

SAPR 6 FY18*: A detail report showing labs surveyed during FY18 and first uploaded into the ACO system more than 45 days after the survey date**.**

CASPER Report 104: identifies the names of labs that had specific fields updated during the selected timeframe, including, but not limited to: lab director name, address of lab, app type, etc. The report also displays the date the change was made, the user ID of the person who made the change, and fields changed. (Details in attachment).

Criteria 5 PI1:

SAPR 9A FY18*: A summary report provides totals on the number of compliance labs (ap type1) that applied for a CLIA certificate (for the first time) during FY18.

SAPR 9B FY18*: A summary report provides totals on the number of laboratories that have been in CLIA prior to FY18 (as an ap type other than a 1), but changed to a Compliance lab (ap type 1) in FY18 and are currently under a Registration certificate.

SAPR 9C FY18*: A summary report provides totals on the number of laboratories that have been in CLIA prior to FY18 (as an ap type other than a '1'), but changed to a Compliance lab (ap type 1) in FY18 [paid 01/02 fees quickly, became a cert type 9, had a good survey, uploaded quickly and paid their Compliance certificate (04) fee quickly, so their cert type 9 went to 1st history and their CoC became current, all in FY18] and are currently under a Compliance certificate (cert type 1).

SAPR 10A FY18*: See SAPR Report #9A. A detail report provides totals on the number of labs applying to CLIA for the first time in FY18 and the application was for a Certificate of Compliance (ap type 1).

SAPR 10B FY18*: See SAPR Report #9B. A detail report provides totals on the number of laboratories that have been in CLIA prior to FY18 (as an ap type other than a '1'), but changed to a Compliance lab (ap type 1) in FY18 and are currently under a Registration certificate.

SAPR 10C FY18*: See SAPR Report #9C. A detail report provides totals on the number of laboratories that have been in CLIA prior to FY18 (as an ap type other than a '1'), but changed to a Compliance lab (ap type 1) in FY18 [paid 01/02 fees quickly, became a cert type 9, had a good survey, uploaded quickly and paid their Compliance certificate (04) fee quickly, so their cert type 9 went to 1st history and their CoC became current, all in FY18] and are currently under a Compliance certificate (cert type 1).

Criteria 5 and 6 PI2:

SAPR 11 FY18*: A summary report providing totals on the number of labs that had recertification surveys accepted into the data system during FY18.

SAPR 12 FY18*: See SAPR Report #11. A detail report identifying the labs that had recertification surveys accepted into the data system during FY18.

Criteria 6 PI1:

SAPR 15 FY18*: A summary report providing totals on the number of labs that had initial surveys accepted into the database system during FY18.

SAPR 16 FY18*: A detail report identifying the labs that had initial surveys accepted into the data system during FY18.

SAPR 17A FY18*: A detail report identifying labs that had initial surveys that were performed within 90 days of the registration certificate effective date. The report selects labs that have current registration certificates, then compares the certificate effective date with associated survey date.
SAPR 17B FY18*: A detail report identifying labs that had initial surveys that were performed within 90 days of the registration certificate effective date. The report selects labs that have current compliance certificates, then compares the first history (i.e., the registration) certificate effective date with associated survey date.
SAPR 18A FY18*: A detail report identifying labs that had initial surveys that were performed more than 12 months from the registration certificate effective date. The report selects labs that have current registration certificates, then compares the certificate effective date with associated survey date.
SAPR 18B FY18*: A detail report identifying labs that had initial surveys that were performed more than 12 months from the registration certificate effective date. The report selects labs that have current compliance certificates, then compares the first history (i.e., the registration) certificate effective date with associated survey date.
SAPR 19 FY18*: A detail report identifying initial surveys completed after the lab's registration certificate had expired. (Current certificate is a registration).
SAPR 20 FY18*: A detail report identifying registration labs surveyed after certificate expired. Current certificate equals compliance. Initial survey added during FY18.

Criteria 6 PI2:

SAPR 21A FY18*: A detail report identifying labs that were accepted into the data system during FY18 and the survey done within 6 months of the current certificate's expiration date.
SAPR 21B FY18*: A detail report identifying labs that were accepted into the data system during FY18 and the survey done within 6 months of the current certificate's expiration date. Selected records where resurvey was done for next 2 year certificate (shown as current certificate) and then compared with the first history certificate's expiration date.
SAPR 22 FY18*: A detail report identifying labs that were accepted into the data system during FY18 or the prior FY and survey was done more than 12 months earlier than the current certificate's expiration date.
SAPR 23 FY18*: A detail report identifying labs that were accepted into the data system during FY18, and the resurveys were completed after the certificate expired.
SAPR 24 FY18*: A detail report identifying labs that were accepted into the data system during FY18 and the survey was after the certificate expired.

Criteria 7 PI2 and PI3:

SAPR 25 FY18*: A detail report identifying the compliance labs surveyed during FY18 that had follow-up surveys (including onsite & offsite revisits).
Note: The report is sorted by a counter that totals the number of onsite hours spent in the lab. So, the offsite revisits are identified with '00' in the 'Total Onsite Teamhrs' column. The report also displays 4 deficiency counters: 1) 'Curr Tot Defs' counts the total number of D tags cited on the CMS-2567; 2) 'Cur Def Nocor' counts the number of D tags that have not been corrected; 3) 'Curr std all' counts the number of D tags deficiencies at the standard level; and 4) 'Curr cop all' counts the number of D tags deficiencies at the condition level.

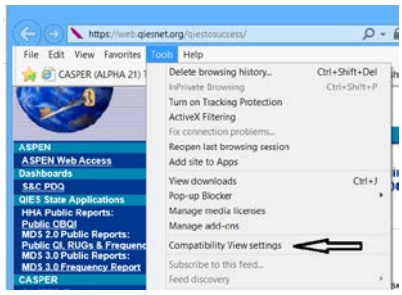
Criteria 12:

CASPER Report 17D: This CASPER report lists the CCN, lab name and address, survey date, approval date, and the deficiency data (tag number, description, correction date, and status) for labs with specific requirements of groups (conditions, standards) out of compliance on the selected survey.

***** These reports are found in QIES Workbench (QW) in the folder: CLIA: SAPR Optional-2018. Note: if QW doesn't appear to be working correctly, please check your QIES compatibility settings.

Attachment #2

Compatibility Settings for QIES when using QIES Workbench (QW)



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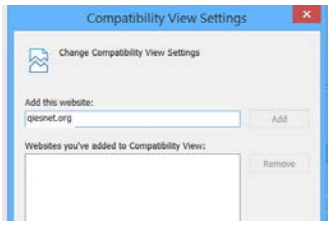

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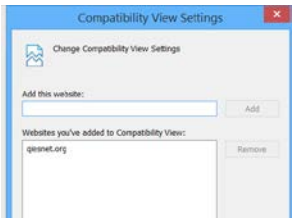

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Clinical Laboratory Improvement Amendments (CLIA) Program

State: [name]

CLIA State Agency Performance Review

SUMMARY REPORT

Review Period: Fiscal Year 2018

(October 1, 2017 to September 30, 2018)

CLIA STATE AGENCY PERFORMANCE REVIEW
FISCAL YEAR 2018

REVIEW CRITERIA

Criterion # 1: Personnel Qualifications/Training

Criterion # 4: Data Management

Criterion # 6: Survey Time Frames

Criterion # 8: Proficiency Testing Desk Review

Criterion # 9: Outcome-Oriented Survey Process

Criterion # 10: Principles of Documentation

Criterion # 11: Acceptable Plan of Correction, Credible Allegation of Compliance

Criterion # 13: Complaints

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2018 SA:

Performance Review Criterion #1: Personnel Qualifications/Training

The SA has an effective system in place to ensure that all CLIA surveys are conducted by qualified individuals (§SOM 4009-E). Individuals are qualified to conduct CLIA surveys if they meet all of the performance indicators. The SA has an ongoing training program to improve survey skills.

DID THE SA HIRE ANY NEW SURVEYORS IN FY2018? YES NO*

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:

- Written Corrective Action Plan Required if quantified performance results are less than 100%; OR
- The staff positions (professional and clerical) listed on CMS-1465A are not occupied as reported

SA Performance Results

Quantified Performance Results %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #4: Data Management

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

Performance Thresholds for Written Corrective Action Plan

A written corrective action plan is required if:

- Written Corrective Action Plan Required if quantified performance results are less than 100%; OR

Performance Thresholds for Written Corrective Action Plan
Written Corrective Action Plan Required if quantified performance results are less than 100%

SA Performance Results

Quantified Performance Results %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #6: Survey Timeframes

The SA implemented a tracking system and ensures that the survey timeframes are met.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

Written Corrective Action Plan Required if quantified performance results are less than 85%

SA Performance Results

One or more initial surveys completed after registration period expired? Yes No
One or more recertification surveys completed after compliance certificate expired? Yes No
SA has implemented a tracking system? Yes No
Quantified Performance Results %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion # 8: Proficiency Testing Desk Review

The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

Written Corrective Action Plan Required if*:*

- SA has not implemented a mechanism to track PT scores every 30 – 45 days OR
- Quantified Performance Results are less than 85%

SA Performance Results

SA has implemented a mechanism to track PT scores every 30 – 45 days? Yes No

Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2018 SA:

Performance Review Criterion # 9: Outcome-oriented Survey Process (OSP)

The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

Written Corrective Action Plan Required if:

- One or more surveyors did not implement the policy of "mandatory citations", or
- Quantified Performance Results are less than 95%

SA Performance Results

Surveyors have implemented the policy of "mandatory citations"? YES NO

Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2018 SA:

Performance Review Criterion # 10: Principles of Documentation (PoD)

The SA has a review system/process to ensure that all surveyors write clear, concise, and legally defensible Statements of Deficiencies (SoD) (CMS-2567) that are consistent with the Principles of Documentation (PoD).

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

Written Corrective Action Plan Required if quantified performance results are less than 100%. (Note: This pertains to whether or not the SA has a review process in place that includes all activities described in Performance Indicators #1-6. It does not refer to the outcome of the standardized calculation used by all SA's to quantify their internal reviews per Performance Indicator #6.)

SA Performance Result

Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion # 11: Acceptable Plan Of Correction (PoC), Credible Allegation of Compliance (AOC)

The SA has a review system to ensure that all surveyors accept only PoCs and AOCs that meet the Criteria for acceptability/credibility.

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

Written Corrective Action Plan Required if quantified performance results are less than 100%. (Note: This pertains to whether or not the SA has a review process in place that includes all activities described in Performance Indicators #1-6. It does not refer to the outcome of the standardized calculation used by all SA's to quantify their internal reviews per Performance Indicator #6.)

SA Performance Result

Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion # 13: Complaints

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

Written Corrective Action Plan Required if*:*

- SA does not utilize ACTS for all complaints, or
- Quantified Performance Results are less than 90%

SA Performance Results

SA utilizes ACTS for all complaints? Yes No

Quantified Performance Results: %

WRITTEN CORRECTIVE ACTION PLAN:

Written Corrective Action Plan Required? YES NO

FINDINGS:

SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Attachment #4

COVER LETTER TEMPLATE FOR FY2018 CLIA SAPR SUMMARY REPORTS

(**Date**)

(**Name & Address of SA Official**)

Dear (**SA Official**):

Re: Clinical Laboratory Improvement Amendments State Agency Performance Review (CLIA SAPR) Summary Report—Fiscal Year 2018 (FY 2018)

Thank you for your cooperation and the courtesies extended to ***[Name of RO SAPR Reviewer]*** during the CLIA SAPR visit to ***[name of SA]*** conducted on ***[Dates]***. Enclosed is the Summary Report for the FY2018 review.

The performance evaluation of each State Agency performing CLIA survey and certification activities is mandated by the Section 1864 Agreement. The CLIA SAPR was structured to accomplish this end in a manner consistent with the performance improvement model employed throughout the CLIA Program. Thus, the goal of the CLIA SAPR is to promote optimal performance by the State Agency, as our partner in ensuring quality in laboratory practices and testing, using an effective mechanism that is efficient, recognizes State-specific circumstances, and fosters a positive performance incentive. This office stands ready to provide educational assistance, information, and support, whenever needed.

The FY 2018 review was limited to eight of the original CLIA SAPR Criteria, due to the time needed for the extensive activities related to CMS' adoption and implementation of changes to CLIA quality control policy. Every CLIA SA was reviewed for the following Criteria:

Criterion #1 – Personnel Qualifications/Training
Criterion #4 – Data Management
Criterion #6—Survey Time Frames
Criterion #8—Proficiency Testing Desk Review
Criterion #9—Outcome-Oriented Survey Process
Criterion #10—Principles of Documentation
Criterion #11—Acceptable Plan of Correction, Credible Allegation of Compliance
Criterion #13—Complaints

The subject areas of the other five Criteria, however, could be examined separately at each CMS RO's discretion, under our overarching authority for SA oversight, and reported in addition to the outcomes of the standardized review.

While the CLIA SAPR addresses major CLIA survey and certification responsibilities, it is not an exhaustive evaluation, nor an exact measurement of state agency performance. Therefore, we do not issue an overall score or grade. Performance measurement consists of gathering and quantifying a snapshot of data in standardized fashion:

- to ascertain objectively whether your agency has fulfilled the expectations of each CLIA SAPR Performance Criterion, as delineated in the Performance Indicators; and
- to determine whether your agency must submit any written corrective action plans.

As you examine the summary report, please keep in mind that the Performance Threshold is neither a score nor a pass/fail rating. It serves as a demarcation point for this office to request a written corrective action plan. And be assured, as well, that the Performance Threshold also serves to ensure nationwide consistency among the CMS regional offices for requesting the plans.

The CLIA SAPR Summary Report recognizes your agency's strengths and accomplishments in meeting your CLIA program responsibilities, as well as any areas that may need improvement. If your agency has experienced special circumstances that affected your performance, they are also indicated, in the interest of providing a balanced view of your state's operations.

(***Add the following paragraph if NO written CAP is needed***)
We are pleased to report that your agency's performance exceeded the Performance Threshold for all of the Criteria, thus no written corrective action plan is requested. Your agency is to be commended for the fine performance. **(*Add the following sentence to this paragraph or at other suitable placement if optimal performance outcome has been sustained over multiple years*).** We note that your agency has sustained optimal performance outcomes for **(Criterion # /Criteria ##)** for several years. With your permission, we would like to share the "best practices" employed by your SA with other states.

(***Add the following paragraphs if one or more CAP's are needed***)
A written corrective action plan is required for the following:

(***list Number and Name for each Criterion)***

The corrective action plan should be received in this office no later than 30 days from your receipt of this letter, and should contain the following information:

- name of your State
- name and number of the Criterion needing corrective action and the action that will be taken
- how it will be monitored and evaluated to verify that it was successful and complete
- name of the individual responsible for completion of the corrective action
- expected dates of institution and completion of the corrective action
- any other information as may be necessary to show that correction can be achieved or has already been achieved.

(***If other subject areas were reviewed, add the following language in this cover letter)***

Other Subject Areas Reviewed

This office exercised the option to review the following subject ***(area) (areas)*** under our overarching authority for SA oversight:
List each subject area by Name (without Criterion # to maintain separation from the standard protocol, e.g. "Financial Management" rather than "Criterion #3"), and add the following information in a narrative:

- ***For each subject area, indicate what was reviewed, including a description of the data gathered, the specific findings and the overall outcome.***
- ***Request written corrective action, if needed. (If more than one subject area was reviewed, request an individual CAP for each one.)***
- ***If CAP is requested ,***
  - ***indicate the information to be included (same items as bulleted above for CAPs for the Standard Criteria)***
  - ***indicate time frame for submission to your office***

Again, we commend you and your staff for all of your efforts related to the CLIA Program, and we appreciate your commitment to quality improvement. If you have any questions, comments or concerns about this letter or the Summary Report, please contact **[*Name of RO Reviewer*]** at **[*phone #*].**

Sincerely,

RO Official

Also, see next page: use or delete optional language

CLIA STATE AGENCY PERFORMANCE REVIEW

FISCAL YEAR 2018

STANDARD REVIEW

Criterion #1—Personnel Qualifications/Training
Criterion #4 – Data Management
Criterion #6—Survey Time Frames
Criterion #8—Proficiency Testing Desk Review
Criterion #9—Outcome-Oriented Survey Process
Criterion #10—Principles of Documentation
Criterion #11—Acceptable Plan of Correction
Criterion #13—Complaints

Use or delete the following, as appropriate:

OTHER SUBJECT AREAS REVIEWED

If other subject areas were reviewed, list each by name rather than Criterion#, as shown by the following example:

- Financial Management

Attachment # 4

CLIA SAPR

MODEL LETTER
For
RESPONSE TO SA CORRECTIVE ACTION PLAN

(Date)

Name of CLIA State Agency official
CLIA State Agency name
Address
City, State, ZIP code

Re: CLIA State Agency Performance Review (SAPR), fiscal year 2018 (FY 2018)—***(State)*** Corrective Action Plan

Dear ***(CLIA SA official)*****:**

Thank you for the corrective action plan submitted in response to the FY 2018 CLIA SAPR. We have reviewed the plan and find that it ***(includes)*** ***(does not include)*** all the items, as specified in our cover letter to the CLIA SAPR summary report, dated ***(date)*****.**

If the corrective action plan does NOT include all the specified items, add the following paragraph, individualized for each Criterion:
Following is the information that should be ***(added to)(clarified in)*** your corrective action plan.

CRITERION ***(number and name)***

Informational Item(s) **:** ***(refer to bullets listed on model cover letter of the SAPR Summary Report, for example… "How corrective action will be monitored and evaluated to verify that it was successful and complete".)***

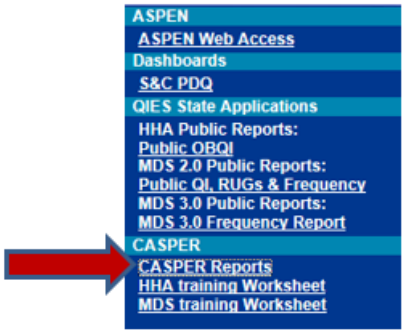
Comments: ***(for example… "Your plan indicates how the action will be monitored. Please also indicate how the action will be evaluated to verify that is was successful")***
Please re-submit your corrective action plan with the requested modifications no later than 30 days from your receipt of this letter.

Finish each letter with the following paragraph:
As always, we appreciate your efforts in the CLIA Program and your commitment to laboratory quality improvement. If you have any questions or comments about this letter, please call ***(name)*** at (***telephone number)*****.**

Sincerely,

Instructions for Printing **CASPER 104D**

1. Go to "QIES to Success" icon on your desktop.
2. Under "CASPER" choose "CASPER Reports".

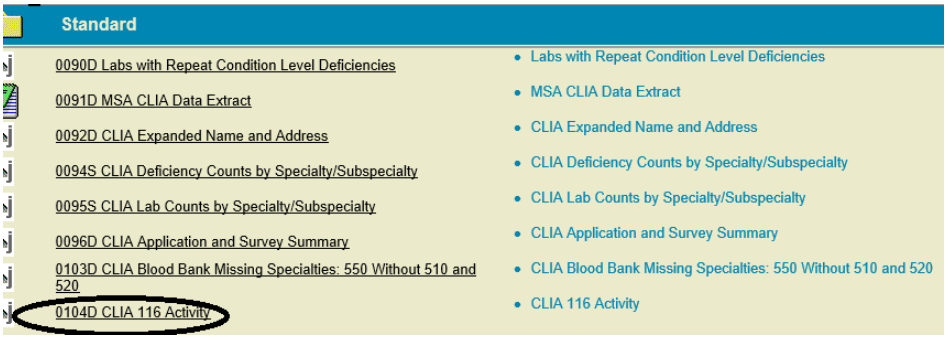


3. Log into CASPER Reporting

4. Choose "Reports".

5. Enter "104D" into Search box. Hit "search".

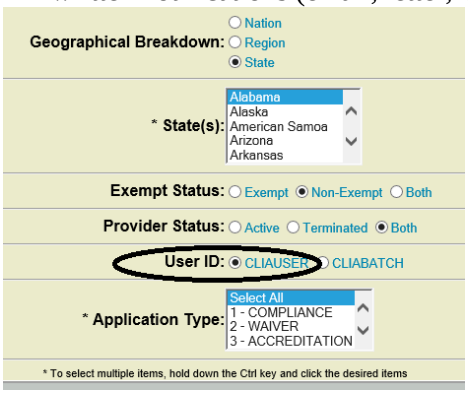
6. The following CASPER Report Find screen will appear and show the report "0104D CLIA 116 Activity".



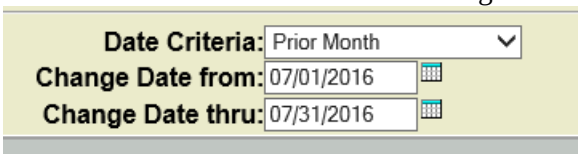
7. Make the necessary selections for **GEOGRAPHIC BREAKDOWN, EXEMPT STATUS, PROVIDER STATUS, USER ID and APPLICATION TYPE**. Note: Selecting User ID: CLIAUSER will include only additions or update changes made directly by the ASPEN CLIA users, and exclude the automated changes from the weekly batch program User ID: CLIABATCH.

8. Note: The RO may choose to run one Report or multiple Reports based on varying time frames. Then, use the listing to ask the State agency to pull a representative sample of lab records and, as part

of the review process, compare and assess the accuracy of the ASPEN data with the associated written notifications (email, letter, CMS-116).

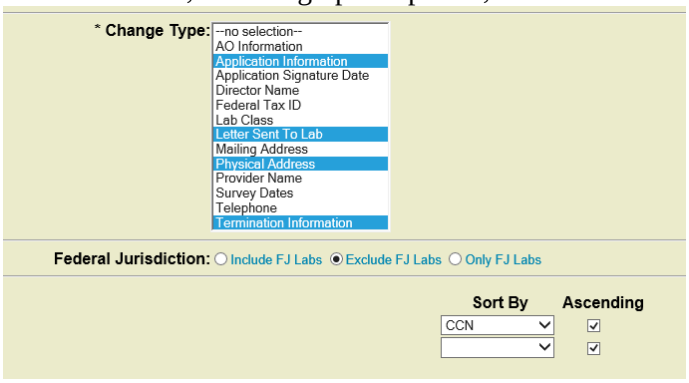


9. Using a time period that falls within the fiscal year SAPR under review, complete the DATE CRITERIA as illustrated below using the dates for this review period:



Press NEXT

10. Leave default either as NO SELECTION, or select change types that represent application, termination, or demographic updates, as shown below:



Press SAVE AND SUBMIT

Important Notes

- When searching for certificate type changes, only highlight "Application Information". This will result in a report being generated which only identifies these type of changes.
- When searching for demographic updates, we would recommend highlighting all fields, but only selecting 4-5 separate weeks, not 4-5 continuous weeks, throughout the FY rather than the entire FY. If you choose the entire FY, the report may be very long.

11. Once submitted, you can go into the "Folders" then to "My Inbox" to see the report. Double click on the 104D report in the inbox.
12. Below is an excerpt of CASPER Report 104 that identifies the labs that had specific fields updated during the time period selected. On the bottom left side of the report you will see some total numbers. You can use these to determine how many changes were made in the state, region and nation for the changes requested in the report.

CASPER Report 0104D
CLIA 116 Activity
Change Dates from 05/01/2018 thru 05/31/2018
Connecticut - Exclude FJ Labs
USER ID - CLIAUSER

Run Date: 06/26/2018
Job # 70539853
Last Update: 06/25/2018
Page 1 of 7

CCN	Provider Name	App Type Code	Term Code	Change Date	User ID	Data Changed	Cert Exp Date
07D0094149	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	02/02/2019
07D0094385	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	08/11/2018
07D0095024	HARTFORD HEALTHCARE MEDICAL	2	00	05/02/2018	1004731	Director Name, Provider Name, Mailing Address	07/22/2018
07D0098549	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Generate Replacement Certificate, Mailing Address	10/13/2019
07D2003939	LABORATORY - HARTFORD LIFE	2	00	05/02/2018	1004731	Generate Replacement Certificate, Mailing Address	02/21/2020
07D2092236	HARTFORD HEALTHCARE CANCER I	3	00	05/16/2018	1004651	Application Information, Application Signature Date, Mailing Address	08/11/2019

Total Selected Criteria Changes for Connecticut = 6
Total Selected Criteria Changes for Boston Regional Office = 31
Total Selected Criteria Changes for Nation = 1,289

This 104 report was for Region 1 and mailing address changes. One page of the report displays the mailing address changes in Connecticut for the time period chosen (Change Dates from 05/01/2018 thru 05/31/2018 – see the third line in the report header).

The report lists the labs with mailing address changes – and if that lab had other changes made at the same time those are listed also.

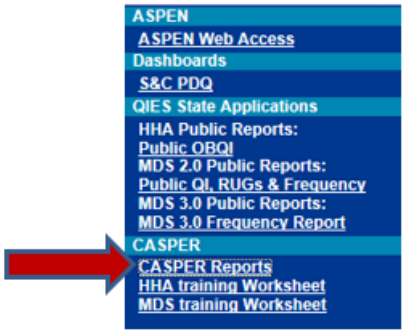
The statistics do not count the other changes, just the number of labs with mailing address changes. In this case for the month of May 2018 Connecticut had 6 labs with mailing address changes – and those 6 labs are listed. The entire Region for May had 31 mailing address changes entered and the nation had 1,289 mailing address changes for the same timeframe.

You can also see that two different people were making these changes in Connecticut.

Instructions for Printing **CASPER 850D**

This report should be printed each fiscal year (FY) in October, January, April, and July.

1. Go to "QIES to Success" icon on your desktop.
2. Under "CASPER" choose "CASPER Reports".

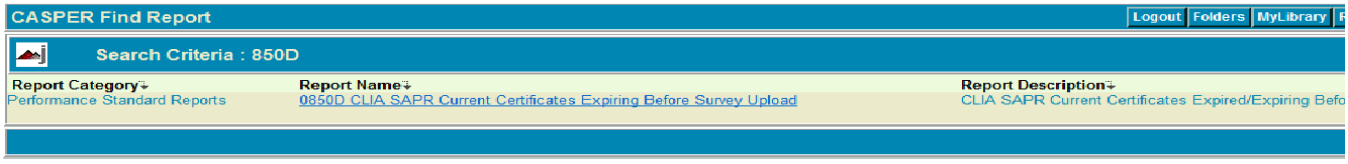


3a. Log into CASPER Reporting

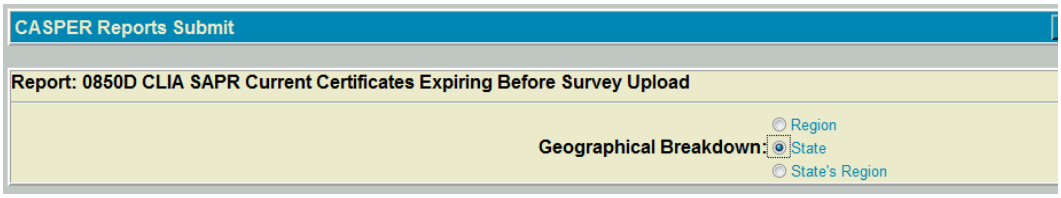
3b. Choose "Reports".

4. Enter "850D" into Search box. Hit "search".

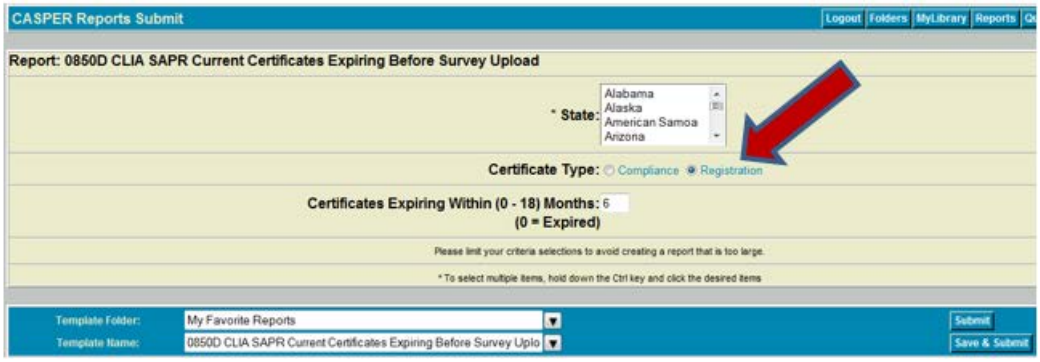
5. The following CASPER Report Find screen will appear and show the report "0850D CLIA SAPR Current Certificates Expiring Before Survey Upload". This is the correct report.

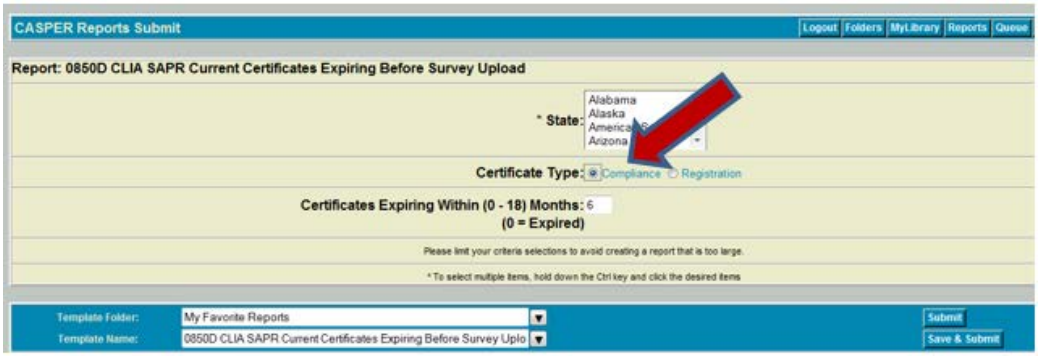


6. Double click on report. Choose "State" then choose "Next".

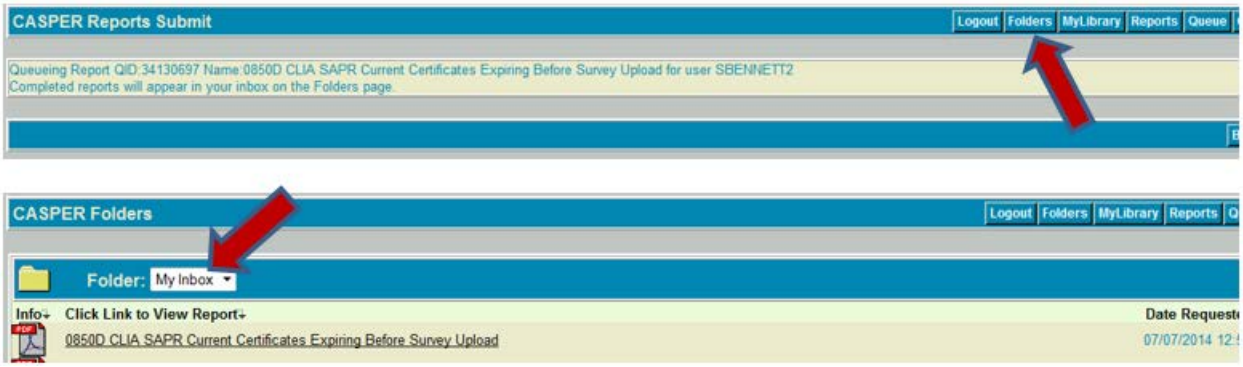


7. Select the appropriate State. Select Certificate Type (Compliance or Registration). Please note that an 850D report must be run separately for both CoCs and CoRs. Leave the "6": in the field after certificate type. Select "Submit" in the lower right corner.





8. Once submitted, you can go into the "Folders" then to "My Inbox" to see the report. Double click on the 850D report in the inbox.



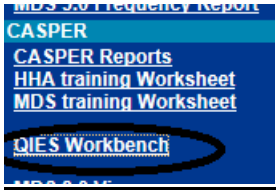
9. Print the report twice. Once for CoCs and once for CoRs.

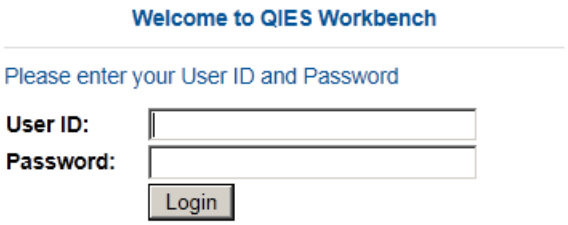
Step-by-Step Instructions: **Accessing SAPR data reports in QW**

You will use QIES Workbench (QW) in CASPER to run CLIA reports, including the SAPR reports. If you need to obtain QIES access to QW, refer to the QTSO (https://qtso.cms.gov/reference-manuals) website for instructions on **completing the *QIES National Data Access Request* form**. Once you obtain proper QIES access, you will be able to create, update and run the SAPR reports in QIES Workbench (QW).

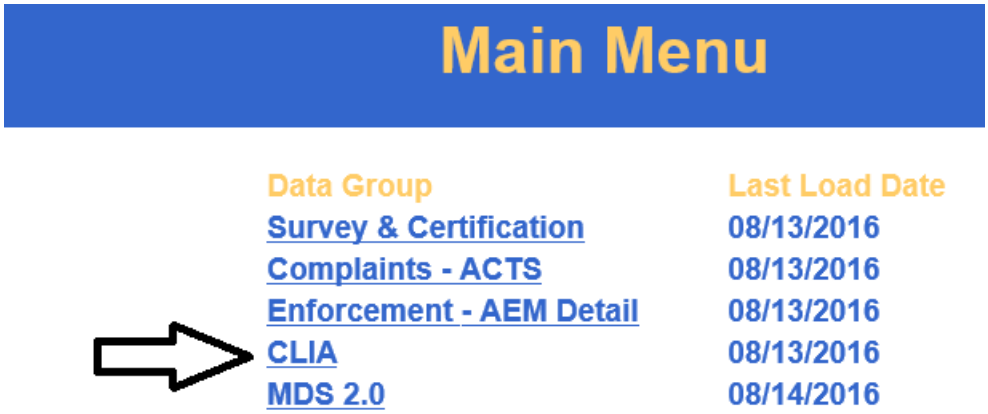
Provided below are detailed instructions on running the SAPR reports using QW for CLIA.

1. Go to QIES to Success website at: https://web.qiesnet.org/qiestosuccess/ and select QIES Workbench and sign in.

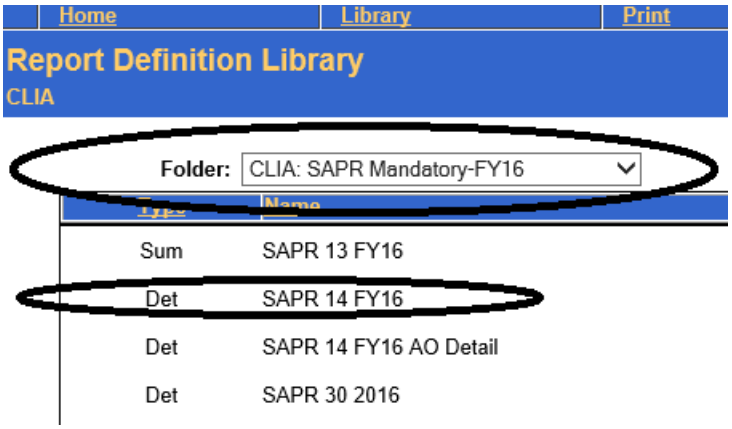




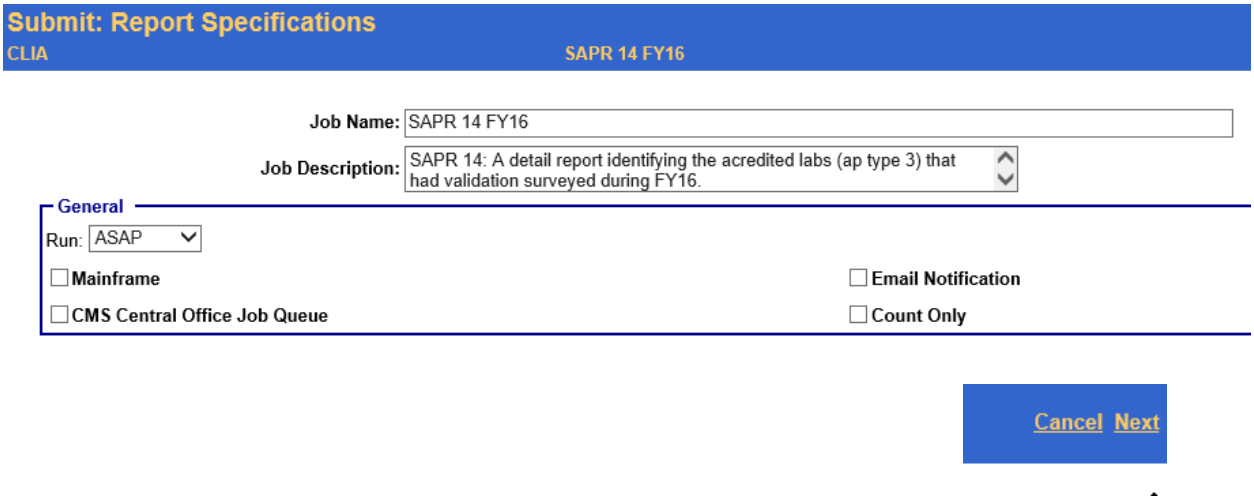
2. From the QW Main Menu, select the **CLIA Group**.



3. Once in QW, select **LIBRARY**, then **FOLDER** drop-down menu, select **CLIA:SAPR Mandatory-FY18**, highlight report, and press **SUBMIT**

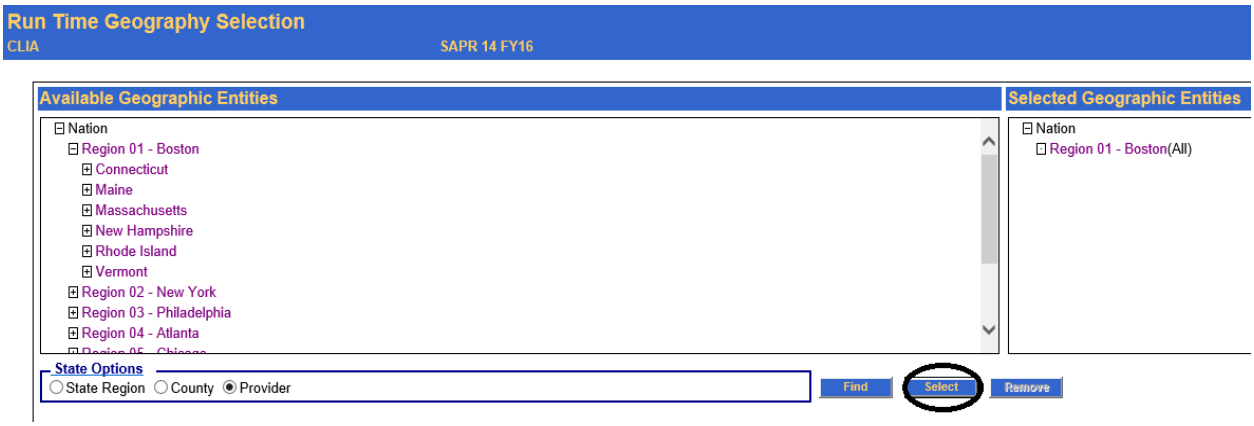


4. Press **Submit** at the bottom of the screen and you will now see the Report Specifications screen; Press **NEXT** on upper left of the screen**.**

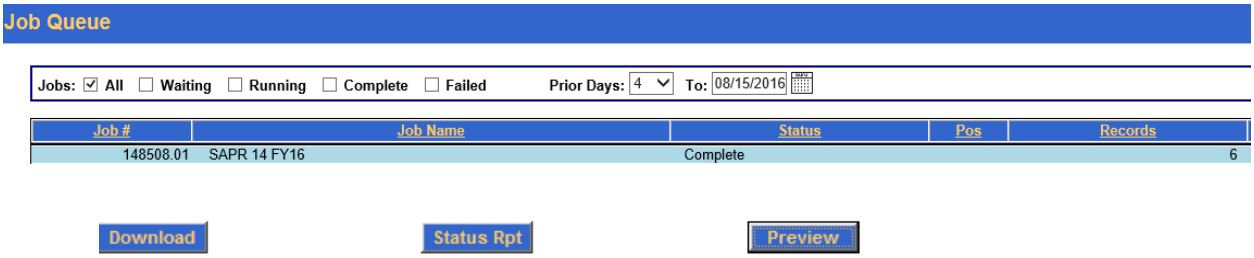


5. There are run-time parameters set on the QW SAPR reports to direct user to specify **REGION** and/or **STATE**. To choose a **STATE** within the **REGION**, click the + sign by **REGION** and the **STATES** will display. To select a particular **STATE**, either double click on the **STATE** or

highlight the **STATE** and press **SELECT** or select all the States within the Region. The selections will display on the right side of the screen. Then press **SUBMIT TO QUEUE**.



6. You will then go to the **Job Queue** where you will receive a status of the job you submitted to run. Press the **REFRESH** button to update its status; when completed it will also tell you the number of records that are contained in the pdf report. You can then select **DOWNLOAD** (view, save, print), view **STATUS RPT** (reports stats), or **PREVIEW** (view the report and print) the report.



Report Date: 08/15/2016

SAPR 14 AO Detail: Criterion 6 PI 5 - Detail report displaying accredited labs that had validation surveys conducted during FY16.
(Labs with multiple AO accreditation will display on separate lines

CCN	#1 TRM CD	NAME	#1 APP CD	SIM IND	CRTN DT (SURVEY DATE)	AO SURV DT CURRNT	AO THAT SURV LAB	AABB Y	AOA Y	CAP Y	ASHI Y	COLA Y	JC Y
D0096355	00	MIDDLESEX HOSPITAL SHORELINE MEDICAL CENTER LAB	3	N	06/06/2016	04/22/2016	CAP	N	N	Y	N	N	N
D1066908	00	PAIN & SPINE SPECIALISTS OF CT, LLC	3	N	06/15/2016	04/20/2016	COLA	N	N	N	N	Y	N
D0067543	00	MERCY HOSPITAL BLOOD BANK LABORATORY	3	N	12/30/2015	11/02/2015	CAP	N	N	Y	N	N	N
D0068584	00	UMASS HEALTHALLIANCE HOSPITAL-BURBANK CAMPUS	3	N	02/16/2016	12/17/2015	CAP	N	N	Y	N	N	N
D0872040	00	PATTIE GROVES HEALTH CENTER	3	N	04/20/2016	03/31/2016	COLA	N	N	N	N	Y	N
D0089961	00	CARY MEDICAL CENTER	3	N	06/30/2016	05/23/2016	CAP	N	N	Y	N	N	N

QW Features

- QW can display code value and/or description. (Prints CAP, instead of '04'.)
- QW can display calculated fields on a report. Example: if report selects labs that were surveyed within 6 months of the expiration dates, QW can also print this derived date on the report.
  Note: we do not print the calculated dates on the QW SAPR FY18 reports.

- QW provides run time parameters, such as, region, state, survey date ranges, etc. When submitting a report from your QW library, user only needs to insert these parameters before submitting.
- QW allows user to modify field length for print fields, such as laboratory name, to allow for data to fit on one page.
- QW allows user to modify column heading for a printed field.
- QW reports can be easily downloaded and saved; extract reports can be downloaded to be imported to Excel spreadsheets.
- QW user can package (or group) reports to run all at once, instead of submitting one at a time.
  Note: we did not package the SAPR reports.

- QW user can schedule QW reports to run on a regular basis, e.g., daily, weekly, monthly.
- QW allows for use of Public Folders so that CLIA users can easily access reports for general use.
  Note: We are making the CLIA FY18 SAPR reports available in Public Folders.

Special Notes about QW SAPR Reports

- The SAPR reports in QW are stored in 2 Public Folders:
  1. CLIA: SAPR Mandatory- FY18 and
  2. CLIA: SAPR Optional-FY18.
- The SAPR reports are sorted in a standard way: Region, State Abbreviation (not State code), and CCN (CLIA Provider Number).
- SAPR 14 has 2 versions: 1) displays labs with validation surveys, 2) displays, by AO, labs with validation surveys – so a lab multiply accredited by ASHI and AABB would display on report (and be counted) on 2 lines.

QW for CLIA Training

- Monthly CLIA Technical calls (first Tuesday of the month) have provided demonstrations of the QW for CLIA reporting system.

- Recorded Webinars describing QW features are available on the QTSO Website:
  1. Log in to new QTSO website: https://qtso.cms.gov.
  2. Click on Training in the menu line.
  3. Choose either CMS (Regional/Central) or State Agency.
  4. Click on training in the menu line.
  5. Do not choose the QW 2016 training. Instead scroll down to CLIA and click on CLIA.
  6. On the right there are several QW training modules:
     QIES Workbench Job Queue (recording)
     QIES Workbench Scheduling Jobs (recording)
     QIES Workbench Training Introduction to the Search Criteria Page (recording)
     Introduction to Extracts (recording)
     Download Extract Output and Import into Microsoft Excel
     Importing Extracts Into Microsoft Excel (recording)
     Download Extract Output and Import into Microsoft Excel
     Introduction to Detail Reports (recording)
     QIES Workbench for CLIA Users Detail Reports - Example #1
     Navigating the Report Definition Workflow (recording)
     QIES Workbench Main Menu Options (recording)
     QIES Workbench Report Definition Library (recording)
     QW Submit Report with Run Time Parameter (recording)
     Accessing QIES Workbench (recording)
- For guidance in using QW, you may contact the QTSO Help Desk at 1.888.477.7876 or help@qtso.com, or
- Contact one of the members of the CLIA DLS team that developed the SAPR reports in QW: Daniel Cajigas (Daniel.cajigas@cms.hhs.gov), Scott Stacy (scott.stacy@cms.hhs.gov), Kathleen Steed (Kathleen.steed@cms.hhs.gov)

Revised 08/14/2018