DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 19-10-CLIA

DATE: **September 30, 2019**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2019 (FY 2019)

Memorandum Summary

- **CLIA SAPR Review Protocol:** The FY 2019 review introduces a restructured, more streamlined, SAPR process.
- **Goal:** CLIA State Agency (SA) optimal performance, with support from the Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs), as necessary.
- **Summary Report for Each CLIA SA:** The aim of each report is a balanced picture of the CLIA SA's operations. **The CLIA SAPR review for FY 2019 is educational due to the new process; therefore, no SA "Performance Thresholds for Written Corrective Action Plan", "Quantified Performance Results" or "Written Corrective Action Plan" results will be reported on the Summary Report.**
- **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of Other Subject Areas:** CMS ROs have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR.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 2019 Review Criteria may also be reviewed at the RO's discretion.
- **Due Date**: Draft CLIA SAPR Summary Reports, Worksheets, Cover Letters and RO Review Tools are due in Central Office (CO) by **March 6, 2020.**

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.

A Regional Office/Central Office (CO) workgroup convened in 2017 to evaluate how the SAPR process could be restructured to be more streamlined and reduce burden for the SAs and ROs. All ten Regional Offices were represented on the workgroup. The 1864 Agreement, Budget Call Letter, State Operations Manual (SOM), and previous SAPR Administrative Memos were all reviewed. As a result, the workgroup met in Baltimore in June 2018 and identified seven specific areas that should be addressed in the process. These seven areas include:

- Personnel Qualifications, Training and Competency
- Data Management
- Proficiency Testing (PT) Desk Review
- Principles of Documentation (POD), Plan of Correction (POC), Allegation of Compliance (AOC)
- Survey Workload and Outcome-Oriented Survey Process (OSP)
- Complaints
- Quality Assessment

Objectives and Goal

The objectives of the SAPR 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.

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-laboratorian 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, and learning about best practices of other similarly-situated States. The SAPR process, including face-to-face conversations, is aimed at the goal of optimal CLIA SA performance and quality patient testing.

The restructured SAPR process will allow for more collaboration between the SA, RO, and CO. In addition, it will enable the SA to identify and correct issues related to their survey and certification duties in a more timely manner.

Please Note: The SAPR Summary report should not identify individual surveyors, laboratories, or CLIA numbers. Discussions regarding issues related to specific surveyors, laboratories, or CLIA numbers should occur at the on-site visit.

FY2019 Protocol

The CLIA SAPR review for FY 2019 is educational due to the new process; therefore, no SA no SA "Performance Thresholds for Written Corrective Action Plan", "Quantified Performance Results" or "Written Corrective Action Plan" results will be reported on the Summary Report. The FY 2019 standard review introduces the restructured 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 seven Criteria are:

Criterion #1—Personnel Qualifications, Training and Competency
Criterion #2 – Data Management
Criterion #3—Proficiency Testing (PT) Desk Review
Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5—Survey Workload and Outcome-Oriented Survey Process (OSP)
Criterion #6—Complaints
Criterion #7—Quality Assessment

Restructured SAPR Process Changes

Data Reports

The restructured process decreases the number of mandatory reports from 14 to 8 and allows the RO to pull all 8 reports as a package either by State or RO.

Criterion #1: Personnel Qualifications, Training, and Competency (Previous Criterion #1)

Goal: The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

This criterion includes previous performance indicators (PIs) related to personnel qualifications and training. However, it also includes a reconfigured PI related to training and competency to ensure all surveyors have an ongoing program to utilize feedback and focus on: interpreting regulations consistently, adhering to the State Operations Manual (SOM), and improving/maintaining surveyor skills.

Criterion #2: Data Management (Previous Criterion #4)

Goal: 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.

This criteria remains unchanged from the previous SAPR Criterion #4; however, the number of fields reviewed on the Form CMS-116, CLIA Application, was reduced to five rather than eight fields. The five fields include: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, and telephone number. The mailing address, fax number and email address were removed as they are optional fields in the CMS-116 database and are not required to generate a CLIA number; however, the expectation is that if this information is provided it should be accurately reflected in the database.

Criterion #3: Proficiency Testing (PT) Desk Review (Previous Criterion #8)

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

Criterion #3 was previously Criterion #8. The PIs are the same as the FY2018 SAPR; however, initial and non-initial PIs have been combined.

Criterion #4: Principles of Documentation (POD), Plan of Correction (POC), Allegation of Compliance (AOC) (Previous Criterion #10, #11)

Goal: 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).
- Accept only PoC/AoCs that meet the criteria for acceptability.

This criterion combines previous Criteria #10 (POD) and #11 (PoC/AoC). This criterion also includes the PI related to the utilization and understanding of mandatory citations which was moved from previous #9, Outcome-Oriented Survey Process (OSP).

Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP) (Previous Criterion #5, #6, #9)

Goal: The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process AND the SA has implemented a tracking system and ensures that the survey time frames are met.

This renamed criterion includes PIs from the previous Criterion #9, Outcome-Oriented Survey Proces (OSP). It also includes new PIs related to timeliness of survey upload.

Criterion #6: Complaints (Previous Criterion #13)

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

Criterion #7: Quality Assessment (QA) (New Criterion)

Goal: The SA had developed specific procedures related to SAPR AND the SA has an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

This is a completely new criterion. It requires the SA to have an overall QA program to identify and correct issues related to their certification and survey responsibilities throughout the year rather than annually. This criterion results in a more systemic look at process and procedures of the SA as related to their responsibilities; thus affecting a more proactive approach rather than reactive approach.

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 2019. 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 2019 review.

Attachments—Listing and Descriptions

Attachment #	Name
1	• **FY 2019 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets** • **FY2019 CLIA SAPR Criterion 2 Review Tool – Data Management *(required)*** • **FY2019 CLIA SAPR Criterion 4, POD Principle 3, Composition of a Deficiency Citation, Review Tool (with reference sheet) *(required)*** • **FY2019 CLIA SAPR Criteria 4 RO Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (PoC/AoC) (*optional*)**
2	• **FY 2019 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports**
3	• **FY 2019 CLIA SAPR—The Summary Report Template**
4	• **FY 2019 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA** • **FY 2019 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans**

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 "General & Specific Instructions". The Worksheets must be completed electronically. *Calculations are automated in Excel.*

- **Criterion 2 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 FY2019, the Review Tool for Criterion #2, Data Management, was updated to include the review of five (5) fields on the Form CMS-116. The 5 fields include: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, and telephone number.

- **Criterion 4, 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. This tool is **required** for FY2019.

- **Criteria 4 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 FY2019 review.

Attachment #2:

- **FY 2019 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports**
  The mandatory and optional reports have been reconfigured and consolidated, including removal of obsolete reports. The number of mandatory reports has been decreased from 15 to 8; and the optional reports have been decreased from 27 to 10. In additional, all mandatory reports are identified with a prefix related to the specific criterion (e.g., DM-A is related to data management). Optional reports will start with the prefix "OPT".

  These mandatory data reports are referenced in Criteria #2, 3, and 5. For consistency purposes, they must be used as indicated in the "General & Specific Instructions" for the respective Criterion. It is recommended that the report "ACTS Complaint/Incident Investigation Log" be used to identify complaints for Criterion #6, Complaints for the FY2019; 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.

These optional data reports are available for monitoring work, or RO optional review of subject areas not specifically addressed by the standard Criteria of the FY 2019 CLIA SAPR. CMS ROs have the overarching responsibility and authority for SA oversight, therefore, subject areas not specifically addressed by the FY 2019 Review Criteria may also be reviewed at the RO's discretion. The addendum report should indicate why the additional measure(s) are being reviewed.

Please note: Unless indicated as a CASPER report, all reports will now be found in the following QBIC Report Libraries: CLIA: SAPR Mandatory-FY19 or CLIA: SAPR Optional-FY19

Attachment #3:

- **FY 2019 CLIA SAPR Summary Report Template**
  For the FY2019 review, we have added a question on the Summary Report to include information related to implementation of a Corrective Action Plan (CAP), if required, from the FY2018 SAPR review. The response will be either Yes ("Y"), No ("N") or Not Applicable ("N/A"). We are also retaining the narrative section "Noteworthy Activities and Accomplishment". Due to the educational nature of the FY2019 SAPR review, the following two narrative sections will not appear on the Summary Report: "Findings" and "Special Circumstances Affecting Performance". It is very important to provide in the narrative the noteworthy accomplishments of SA's performance.

  Please note: The CLIA SAPR review for FY 2019 is educational due to the new process; therefore, no SA "Performance Thresholds for Written Corrective Action Plan", "Quantified Performance Results" or "Written Corrective Action Plan" results will be reported on the Summary Report.

Attachment #4:

- **FY 2019 CLIA SAPR Cover Letter Template—for Transmitting the Summary Report to the SA**

  The language in this model letter has been modified to address the educational nature of the FY 2019 review. 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 2019 CLIA SAPR Model Letter for Response to SA Corrective Action Plan**
  This model letter is not applicable for FY 2019.

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

Draft FY 2019 CLIA SAPR packages are due in CO by **March 6, 2020**. Please forward the **Summary Report,** along with the **Excel Worksheets, updated 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:

Sarah.Bennett1@cms.hhs.gov
Daniel.Cajigas@cms.hhs.gov
Rachel.Jacobs@cms.hhs.gov
Raelene.Perfetto@cms.hhs.gov
Ann.Snyder@cms.hhs.gov
Felicidad.Valcarcel@cms.hhs.gov

Effective Date: October 1, 2019. 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 5 for Listing and Descriptions

cc: Survey and Certification Regional Office Management

Attachment #1

CLIA SAPR Documents FY2019

Performance Review Criteria 1-7 with Performance Indicators

General Instructions, References, Worksheets and Review Tools

CLIA State Agency Performance Review FY2019
General and Specific Instructions for Completing Worksheets

General Instructions for all Worksheets

- Refer to the 1st page of each Worksheet for a list of all Performance Indicators (PI) for that Criterion.
- In general, the 2nd page of each Worksheet contains the specific PI(s) with a data field to enter the result of each finding.
- The 3rd page of each Worksheet (if needed) is where the RO consultant will enter the name of the State Agency reviewed, who in the Regional Office performed that specific review of that criterion, and the date of the review.

Instructions for Completing Data Fields associated with Performance Indicators

1. Complete data fields that require information (i.e. surveyor name, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.

2. For PI#1 in Criteria #1, #2, #3, #4 and #7, if "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

3. Complete data fields that require a "Yes", "No", "NA","Y' or "N" by entering a "1" into the space, with the exception of the "Yes" and "No" data fields located after "Written Corrective Action Plan Needed?" (not applicable for FY2019 SAPR).
Not applicable for FY 2019 SAPR: All of these data fields are used to calculate the Quantified Performance Result. Editing any of these associated data fields will cancel the formula in that data field and the Quantified Performance Result will not calculate correctly.

4. Not applicable for FY 2019 SAPR: In the box labelled "Written Corrective Action Plan Needed?", if "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.

5. Please see Attachment #2, "FY19 Data Rpt Info", for information related to both mandatory and optional reports.

Special Note: FY2019 is an educational year to allow the State Agency to become familiar with updated SAPR requirements and for the Regional Office and Central Office to obtain feedback from the State Agency. The following fields will not be displayed on the Excel spreadsheets for the FY2019 review: Performance Threshold, Quantified Performance Result. and Written Corrective Action Plan required.

Special Instructions for each Criterion

Criterion #1: Personnel Qualifications, Training & Competency

Personnel Qualifications

- Ask the SA to demonstrate how each new surveyor meets PI #2 & #3.
- Review surveyor personnel information (system, personnel files, etc.) to verify that the performance indicators are satisfied for each surveyor.

Ongoing Training & Annual Competency Programs

• Ask the SA to demonstrate how each surveyor meets PI #4. If any one of PI #4 a. → d. is not met, indicate which was not met in the "Comment" column.

Note for PI #5 In some instances, a SA surveyor will be unable to attend mandatory training for a variety of reasons (e.g., personal commitment 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.

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Criterion #2: Data Management

All information for PI #2- PI #7 should be collected from the Criterion #2 Review Tool.

CMS 116: Accuracy & Timeliness

For FY2019 only, the following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, telephone number. No other CMS-116 fields are required to be reviewed unless the RO determines an expanded review is warranted.

• Note for PI #2: When evaluating PI #2, the RO reviewer should compare the initial Form CMS-116 to the information entered into the CLIA 116 database. As long as the SA has requested additional information (e.g., laboratory director qualifications) prior to the 30 days, this PI is considered met as it is beyond the SA's control if a laboratory does not provide the requested information in a timely manner.

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Criterion #3: Proficiency Testing Desk Review

• Review the SA's PT tracking and frequency performed to determine whether Performance Indicator #1 is met.
• Select 10 laboratories and include a cross-section of initial and non-initial unsuccessful events.
• Indicate whether unsuccessful PT is either the initial unsuccessful or the non-initial unsuccessful.
• 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 line #1, PI #2 chart on this worksheet.

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Criterion #4: Principles of Documentation (PoD) & Plan of Correction (POC), Allegation of Compliance (AOC)

• Any CMS-2567s reviewed throughout the FY by the RO (e.g., FMS Assessments, Condition-level) may be incorporated into the RO review to meet this criterion.

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 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 POD and PoC/AoC review process.

- 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. 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.

- To quantify SA results for POD & PoC/AoC , the following formula must be used by the SA in its internal review process.
  POD: 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.
  PoC/AoC: 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 these calculations are used for SA's internal review only; it is not related to the performance threshold for this criterion.

ADDITIONAL REVIEW BY THE RO REVIEWER:

- Completion of the Criterion #4, 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 CMS-2567 reviewed, and record your findings for Criterion #4, 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' CMS-2567s in a subsequent year. If only 1 CLIA surveyor, select a minimum of TWO (2 CMS-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 #4, Principle 3 review tool, so the CMS-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 FY2019 SAPR review. Only the CMS-2567 should accompany the review tool. Use of the "CLIA SAPR Criterion #4 D-tag RO review tool" (the previous review tool utilized for Criterion #10 & #11) is <u>OPTIONAL</u> for FY2019.

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Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)

<u>Survey Workload</u>

NOTE for PI #1: 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.

NOTE for PI #2: 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.

NOTE for PI #3: 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 for PI #4:
- 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 certificates and has NOT generated the CASPER 850D report, enter a "2" in "No".

NOTE for PI #5:
- Ask the SA to demonstrate their system for uploading surveys. The format need not be elaborate or automated.

EXCEPTION: If the SA can demonstrate that survey kit uploads were due to circumstances beyond the CLIA SA's control (e.g., laboratory did not respond to a request for an AoC/PoC), do not hold the SA accountable and enter a "1" in "Yes." Document the exceptions in the Comments section of this worksheet.

Outcome Oriented Survey Process
- Any CMS-2567s reviewed throughout the FY by the RO (e.g., FMS Assessments, Condition-level) can be incorporated into the RO review to meet this criterion. For example, a sample of FMS Assessment surveys may be reviewed to ensure follow up actions and monitoring were completed as required.
- Interview surveyor and/or supervisor to ascertain how the SA utilizes FMS feedback, if any, for improving surveyor proficiency in OSP.
- Review the SA's mechanism for communicating SOM directives and changes to surveyors.
- Select a couple of major program directives or SOM issuances on the OSP and interview surveyors to determine whether they are familiar with them. 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 the OSP.
- If any one of PI #6 a. $\rightarrow$ d. or PI #7 a. $\rightarrow$ c. is not met, indicate which was not met in the "Comment" column.

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Criterion #6: Complaints

NOTE: All (i.e., CLIA and non-CLIA) complaints should be tracked in some way, not just CLIA-related complaints. Ask the SA to demonstrate how they track all complaints. The method of tracking non-CLIA complaints may be manual or electronic.

NOTE: If SA received no complaints, interview staff to ascertain their understanding of the complaints process and complete PI #2 -# 9 based upon the interview.

NOTE PI #1: Review the SA mechanism for logging in and tracking complaints and verify that all CLIA-related complaints are entered into ACTS.

NOTE PI #2: 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.

Performance Indicators #4 - #9:

Proceed to assess Performance Indicators #2 through #9.

- 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 the path of the complaint 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.

NOTE for PI #4: Many of the complaints that are received are anonymous and cannot be acknowledged, mark "N/A" as applicable.

NOTE for PI #8: 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.

NOTE for PI #9: 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."

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Criterion # 7: Quality Assessment

Ensure that the SA has, and is following, their five required SAPR procedures. The procedures may be either written or electronic.

NOTE for PI #2: If any one of SOs for PI 2 are missing, indicate which was missing in the "Comment" column.

NOTE for PI #3: If any one of PI 3 a. → h. is not met, indicate which was not met in the "Comment" column.

CLIA State Agency Performance Review FY2019
References for each Criterion

Criterion #1 Personnel Qualifications, Training & Competency
SOM §§4003.2, 4009A-E, 4018. 6234.2, 6410, 6434
Budget Call Letter
1864 Agreement – Article IV-A, B; Article V–C
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Criterion #2: Data Management
SOM §6135
Budget Call Letter
1864 Agreement – Article V-C
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Criterion #3: Proficiency Testing Desk Review
SOM §§6052-6058
Budget Call Letter
1864 Agreement – Article II-E
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Criterion #4: POD/POC, AOC
SOM §6130
Appendix C
Laboratory Principles of Documentation
1864 Agreement – Article II-A, E; Article V-C
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Criterion #5: Survey Process & Workload
SOM §6102
1864 Agreement, Article II-A-C, E; Article V-C
Validation Survey Protocol
Appendix C, I.-A.
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Criterion #6: Complaints
SOM: Chapter 5, sections for CLIA;
ACTS Procedure Guide
1864 Agreement, Article II-E; Article V-C
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Criterion #7: Quality Assessment
1864 Agreement – Article II-A, E, I-J; Article IV-A, B; Article

Overall Goal:

The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

Performance Indicators (PIs): Personnel Qualifications

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. For new surveyors, completion of a CMS-developed Basic Surveyor Training Course within the first three (3) months of employment (4009-C) AND the individual has completed sufficient orientation for RO to evaluate their survey skills (Federal Monitoring Survey Assessment) within one year.

Performance Indicators (PIs): Ongoing Training & Annual Competency Programs

4. For all surveyors, the SA's ongoing training and annual competency program utilizes feedback or information from and focuses on:
   a. SA orientation, FMS, RO review of any CMS-2567s and PoC/AoCs to improve surveyor skills;
   b. Consistency in interpretation of the regulations;
   c. Ensuring surveyor adherence to the SOM;
   d. Improving individual surveyor skills, as needed;
5. All SA surveyors attend CMS-funded mandatory training, including those budgeted for in the annual SA budget apportionment (e.g., Consortium/Division meetings).
6. All SA surveyors participate in mandatory online training, as applicable.

***EXCEPTION:** Performance Indicator #3 and 4 may not be applicable to an individual who was hired shortly before the time of review.

CLIA State Agency Performance Review FY2019
Criterion #1: Personnel Qualifications Training and Competency

Performance Indicator 1:	Yes	No
The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.		

Personnel Qualifications: New Surveyors Hired During FY2019

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

Ongoing Training and Annual Competency Programs: All Surveyors

	Performance Indicators							
	PI 4			PI 5		PI 6		
	Y	N	NA	Y	N	Y	N	Comments
PI 4: For all surveyors, the SA's ongoing training and annual competency program utilizes feedback and focuses on improving/maintaining surveyor skills.								
PI 5: Attend CMS-funded mandatory training								
PI 6: Participate in mandatory online training, as applicable								

State Agency:	
Date:	
Evaluator:	

Overall Goal:

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

1. The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

Performance Indicators (PIs): CMS 116: Accuracy & Timeliness

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.)
Note: See Review Tool 4 for the list of fields that are reviewed.
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.)**

Performance Indicators (PIs): Certificate Changes & Timeliness

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.

Performance Indicators (PIs): Demographic Updates & Timeliness

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.

CLIA State Agency Performance Review FY2019
Criterion #2: 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:	

CLIA State Agency Performance Review FY2019
Criterion #3: Proficiency Testing Desk Review

Overall Goal:

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

Performance Indicators (PIs)

1. The SA has implemented a mechanism to track PT scores every 30 - 45 days.
2. **Unsuccessful Participation:**
   a. 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.
   b. Prepares CMS-2567, including appropriate D-Tags.
   c. Notifies the laboratory to seek training/technical assistance for initial unsuccessful participation, as appropriate.
   d. Notifies the RO for all non-initial unsuccessful participation.
   e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated).

CLIA State Agency Performance Review FY2019
Criterion #3: Proficiency Testing Desk Review

Performance Indicator 1:	Yes	No
The SA has implemented a mechanism to track PT scores every 30 - 45 days.		

			Performance Indicators														
			Unsuccessful Participation														
PT Desk Reviews	Initial Unsuccessful	Non-Initial (Subsequent) Unsuccessful	PI 2a			PI 2b			PI 2c			PI 2d			PI 2e		
CLIA #			Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

State Agency:	
Date:	
Evaluator:	

CLIA State Agency Performance Review FY2019
Criterion 4: Principles of Documentation(PoD) and Plan of Correction(PoC)/Allegation of Compliance(AoC)

Overall Goal:

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).
- Accept only PoC/AoCs that meet the criteria for acceptability.

Performance Indicators (PIs):

1. The SA utilizes and understands mandatory citations.
2. The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the PoD on an on-going basis.
3. The SA reviews the PoC/AoCs for consistency with SOM 6130.
4. The SA reviews at least 10 of each surveyor's CMS-2567s prepared during the federal fiscal year (FFY) under review for both POD and acceptability of PoC/AoCs.
5. The SA review process includes participation by all surveyors as an opportunity for skill improvement.
6. The review process must include at least quarterly review and must track progress of surveyor improvement or document sustained proficiency.
7. Specific area(s) of improvement identified in RO feedback (FMS Assessment and other RO reviews), if any, are incorporated by the SA into their review process.
8. The SA 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 review process.** *POD*: 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. *PoC/AoC*: 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.

CLIA State Agency Performance Review FY2019
Criterion 4: Principles of Documentation(PoD) and Plan of Correction(PoC)/Allegation of Compliance(AoC)

Performance Indicator #1	Yes	No
The SA utilizes and understands mandatory citations.		

P.I. 9 Results of SA Internal Review:

Performance Indicators	Yes	No
2		
3		
4		
5		
6		
7		
8		

show calculation # D-tags meeting PoD / Total # D-tags reviewed = enter a calc

P.I. 9 Results of SA Internal Review:

show calculation # D-tags PoC/AoC was acceptable / Total # D-tags reviewed = enter a calc

Comments

State Agency:	
Date:	
Evaluator:	

CLIA State Agency Performance Review FY2019
Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)

Overall Goal:

- The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.
- The SA has implemented a tracking system and ensures that the survey time frames are met.

Performance Indicators: Survey Workload

1. The SA completes all initial surveys within 3-12 months.
2. The SA completes all recertification surveys timely so that no Certificates of Compliance expire.
3. The SA completes budgeted validation surveys within 90 days of the AO survey date.
4. The SA has generated and utilized the CASPER 850D quarterly reports to address expired certificates (CoR, CoC).
5. All surveys are uploaded in a timely manner (within 45 days).

Please note: If the laboratory does not provide an acceptable POD/credible AOC within 45 days, the SA will not be able to upload the kit within 45 days. If they SA has documentation to show this is the case (i.e., extenuating circumstances), the SA will not be held to the 45 day upload timeframe.

Please note: SA can upload condition-level noncompliant survey kits and the system will register the upload by the SA even though L32 and L33 error messages are received.

Performance Indicators: OSP

6. 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
7. 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.
8. All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OSP are implemented by all surveyors.
9. SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the RO.

CLIA State Agency Performance Review FY2019
Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)

Performance Indicators	Yes	No	Comments
PI 1: All initial surveys (CoR) completed within 3-12 months			
PI 2: All recertification of CoC laboratories are completed timely			
PI 3: All budgeted validation surveys are completed within 90 days of the AO survey date			
PI 4: The SA generated and utilized the CASPER 850D quarterly reports			
PI 5: All surveys are uploaded in a timely manner (w/i 45 days).			
PI6: All surveyors conduct surveys using the OSP			
PI 7. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems.			
PI 8: All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OSP are implemented by all surveyors			
PI 9: SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the RO			

State Agency:	
Date:	
Evaluator:	

CLIA State Agency Performance Review FY2019
Criterion #6: Complaints

Overall Goal:

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

Performance Indicators:

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 has a mechanism to track all complaints received by the SA.
3. The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.
4. The SA acknowledges and notifies complainant.
5. 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 (NOCN).
    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.
6. Complaints are scheduled in accordance with established procedures/priorities.
7. Complaint investigations are:
    a. Conducted in accordance with established time-frames.
    b. Unannounced.
8. The SA adheres to the SOM instructions for post-investigation actions.
9. There is resolution and closeout of each complaint (completion of all actions required by SOM, including follow-up to complaint, if not anonymous).

CLIA State Agency Performance Review FY2019
Criterion #6: Complaints

Performance Indicator	Y	N	Comments
PI1: The SA utilize ACTS for all complaints in accordance with the current ACTS Procedure Guide.			
PI 2:The SA has a mechanism to track all complaints received by the SA.			
PI 3: The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.			

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

State Agency:	
Date:	
Evaluator:	

CLIA State Agency Performance Review FY2019
Criterion #7: Quality Assessment

Overall Goal:

- The SA has developed specific procedures related to SAPR.
- The SA has an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

Performance Indicators:

1. The SA has documented evidence of the implementation of CAP and/or QIP.
2. The SA must establish and follow a standard operating procedure (SOP) for:
    a. Surveyor and clerical orientation, training, and annual competency;
    b. Entry of initial application, certificate changes, and demographic information updates;
    c. Performing PT desk review every 30-45 days;
    d. Handling and triaging all complaints; and
    e. Quality Assessment, including quality indicators.
3. The SA QA must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity, and must include:
    a. Identification of areas needing improvement for surveyors;
    b. Utilization of FMS Assessments and other RO feedback when identifying areas for surveyor improvement;
    c. Measuring progress in improving surveyor skills when needed (data from SoD review, PoC/AOC review or other SA internal measurement);
    d. Tracking of errors in data management
    e. Interval between running CASPER 153 and 155 and review of information for PT desk review;
    f. Timeliness of sending letters and CMS 2567s for unsuccessful participation in PT;
    g. Identification of issues in the overall process;
    h. All activities related to QA must be documented.

CLIA State Agency Performance Review FY2019
Criterion #7: Quality Assessment

CAP and/or QIP

Performance Indicator	Yes	No	NA	Comments
PI 1: The SA has documented evidence of the implementation of a CAP and/or QIP.				

SA Standard Operating Procedures

Performance Indicator	Yes	No	NA	Comments
PI 2: The SA must establish and follow a standard operating procedure (SOP).				

SA Quality Assessment Program

Performance Indicator	Yes	No	NA	Comments
PI 3: The SA QA must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity.				

State Agency:	
Date:	
Evaluator:	

FY 2019 CLIA SAPR CRITERIA 2, 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 FY2019 only the following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, and telephone 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 2019 CLIA SAPR CRITERIA 2, 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	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 4, POD Principle 3, Composition of a Deficiency Citation
RO Review Tool FY2019

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 2019 CLIA SAPR CRITERIA 4 D-TAG RO REVIEW TOOL

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

CRITERION 4, PI #4, POD			CRITERION 4, PI #4, PoC/AoC				
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 #4: % D-tags which meet PoD	#DIV/0!	CRITERION #4: % D-tags which meet requirements for PoC or AoC	#DIV/0!

FY 2019 CLIA SAPR CRITERIA 4 D-TAG RO REVIEW TOOL

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

CRITERION 4, PI #4, POD			**CRITERION 4, PI #4, PoC/AoC**				
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 4: % D-tags which meet PoD		88%	**CRITERION 4:** % D-tags which meet requirements for PoC or AoC		100%		

Reference Sheet for RO REVIEW TOOL, Criterion #4
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, Criterion #4 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

Mandatory SAPR Reports

Report Name	Description	Cr	PIs	Replacement Report Name
DM-A: 116 Entry	A DETAIL report, sorted by application type, identifies the labs that applied and entered into the CLIA program in the FY under review.	2	2,3	SAPR 2
DM-B: Cert Changes	A DETAIL report listing all Certificate changes made during the fiscal year under review with a run time parameter for Geography.	2	4,5	SAPR 9A→10C
CASPER 0104D CLIA 116 Activity	A DETAIL report identifying the names of labs that had specific demographic fields updated during the FY under review. The report also displays the date the change was made, the user ID of the person who made the change, and fields changed.	2	6,7	CASPER 0104D CLIA 116 Activity
PT-A: PT Desk Rvw	A DETAIL report listing all PT Desk Reviews performed during the fiscal year under review with a run time parameter for Geography	3	All	New
SVY-A: Initial Surveys	A DETAIL report identifying the labs that had early/late initial surveys in the fiscal year under review.	5	1	SAPR 17-20
SVY-B: Expired CoC	A DETAIL report identifying the labs that had Recertification Surveys after the certificate expired.	5	2	SAPR 23
SVY-C: Validation	A DETAIL report identifying the accredited labs (ap type 3) that had Validation surveys during the fiscal year under review and showing the number of days between the AO survey date and the Validation date. Note: The report displays the labs by AO, so a lab accredited by both ASHI and AABB would display (and be counted) on 2 lines.	5	3	New
SVY-D: Survey Upload	A DETAIL report showing labs surveyed during the FY under review, and first uploaded into the ACO system more than 45 days after the survey date. Note: 'Survey Transaction Date' is a date generated at the time the State first attempts to upload certification kit in ACO.	5	8	SAPR 6

Optional SAPR Reports

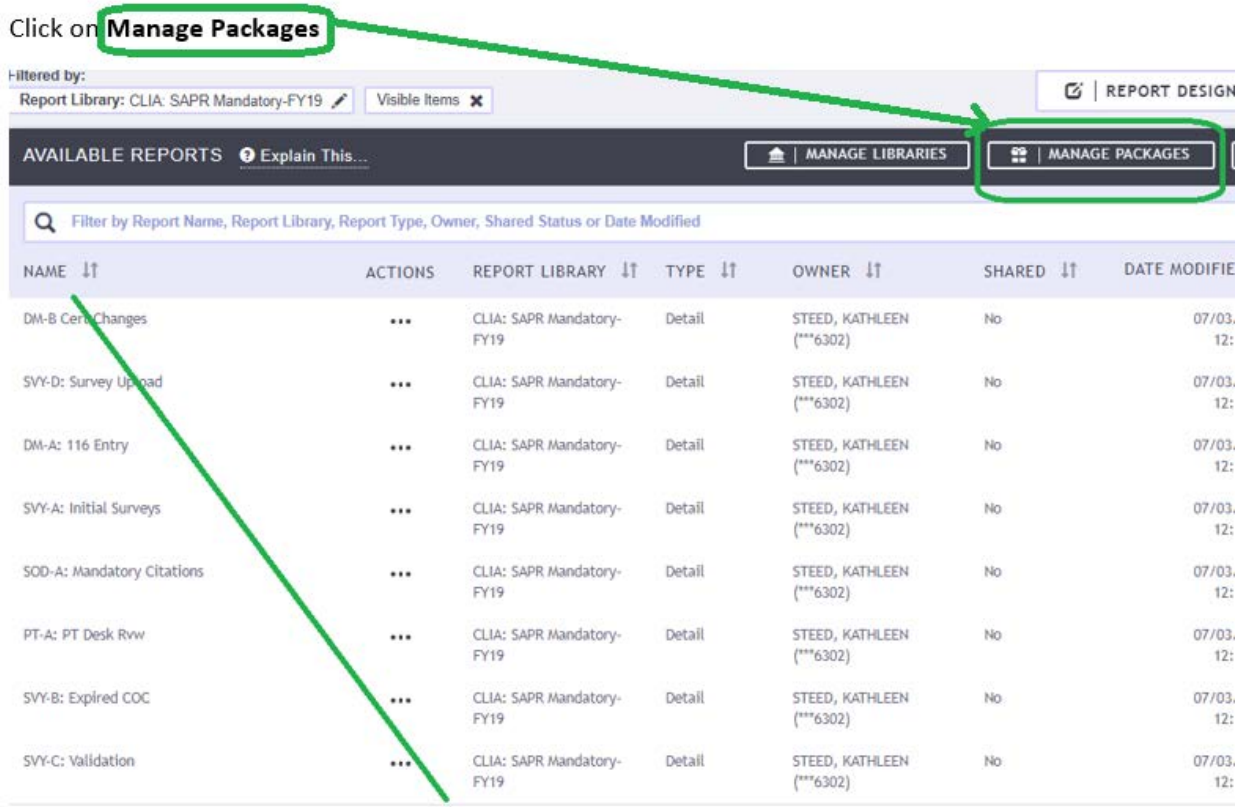
Report Name	Description	PIs	Old Report Name
OPT-A: 116 Entry, Total	A SUMMARY report providing totals on the number of 116s entered in FY. Note: Used 'ap received date', a system-generated date based on date user enters CMS-116 into CLIA data base.	n/a	SAPR 1
OPT-B: 116 Entry, Outliers	A DETAIL report showing the outlier records, i.e., States entering the CMS-116 more than 30 days after receipt of the CMS-116 form in the State agency, designated by the date stamp on the form. Notes Report compares 'state agency receipt date' to 'app received date'	n/a	SAPR 3
OPT-C: Total Surveys	A SUMMARY report provides totals on the number of labs surveyed during FY.	n/a	SAPR 4
OPT-D: Surveyed Labs	A DETAIL report identifies the labs that were surveyed during FY.	n/a	SAPR 5
OPT-E: Recert	A SUMMARY report providing totals on the number of labs that had recertification surveys accepted into the data system during FY.	n/a	SAPR 11
OPT-F: Uploaded Recerts	A DETAIL report identifying the labs that had recertification surveys accepted into the data system during FY.	n/a	SAPR 12
OPT-G: Initials	A SUMMARY report providing totals on the number of labs that had initial surveys accepted into the data system during FY.	n/a	SAPR 15
OPT-H: Uploaded Initials	A DETAIL report identifies the labs that had initial surveys accepted into the data system during FY.	n/a	SAPR 16
OPT-I: Follow-ups, Total	A DETAIL report identifying the compliance labs, surveyed during FY, that had follow-up surveys (including onsite and 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.	n/a	SAPR 25
OPT-J: Mandatory Citations	A DETAIL report listing surveys in which mandatory citations were cited during the fiscal year under review with a run time parameter for Geography. Does not include PT Desk Review.	n/a	New
CASPER 157D: PT Excused Nonparticipation	This DETAIL report identifies the laboratories that have been given a pass for failure to participate in proficiency testing for one or more analytes/events.	n/a	CASPER 157D

SAPR FY2019 Mandatory Reports

The mandatory reports can be pulled as a package:

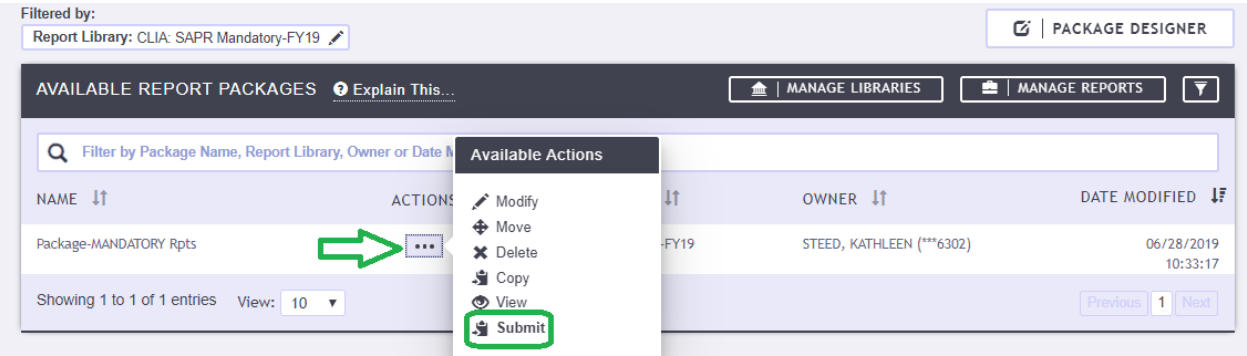
Log into QBIC, find the **CLIA: SAPR Mandatory-FY19** library.

Instead of running each report one at a time, Use the Package feature.

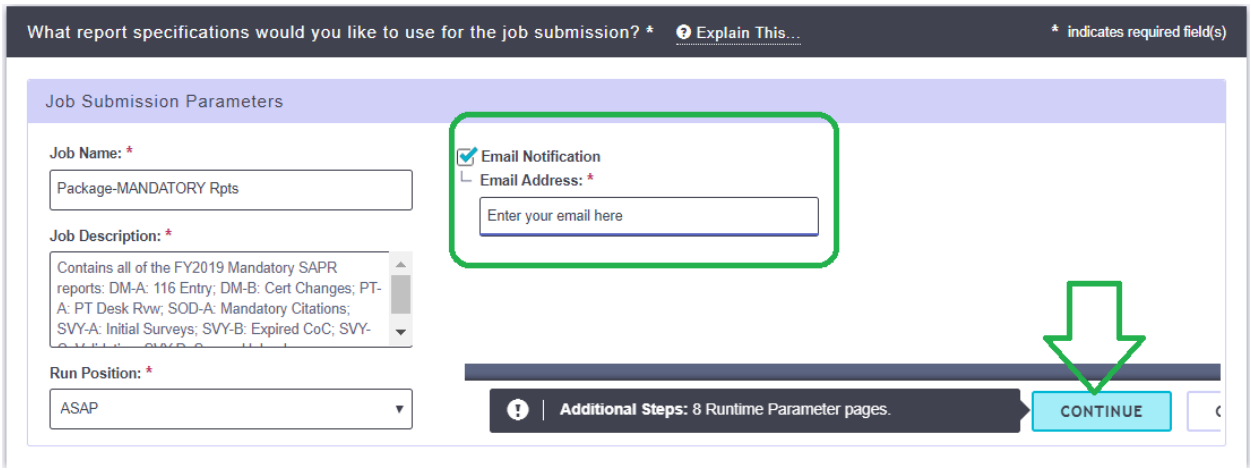


Running the Mandatory SAPR reports as a package saves time!

Clicking on Manage Packages brings up:

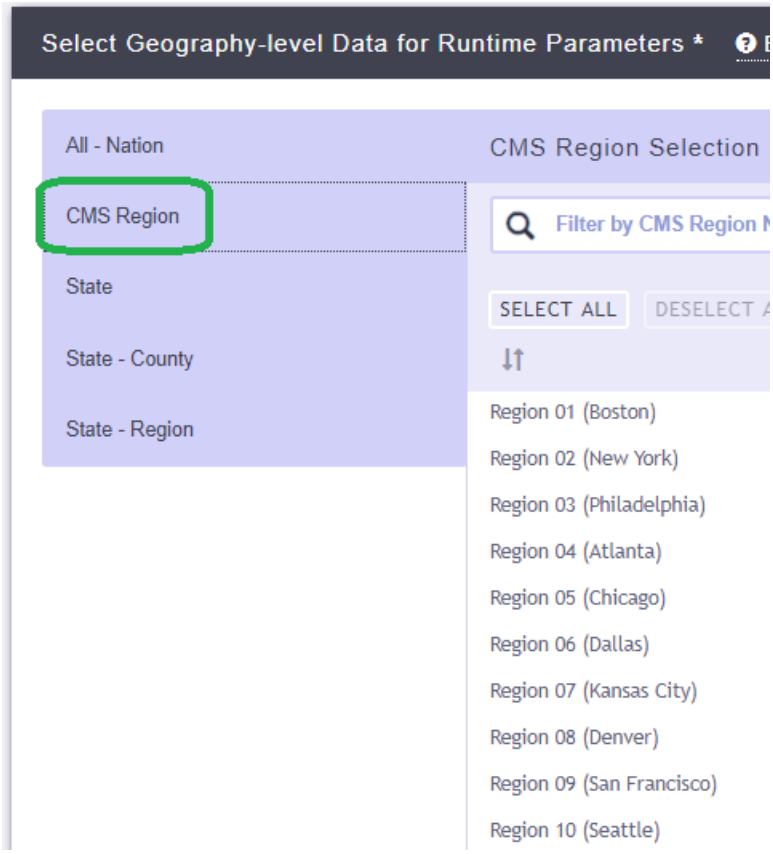


Click on the ellipses and choose Submit



Using the Email Notification function allows you to submit the package and move on to other things. The email will tell you when the package is complete!

Check the Email Notification, enter your email, and continue.

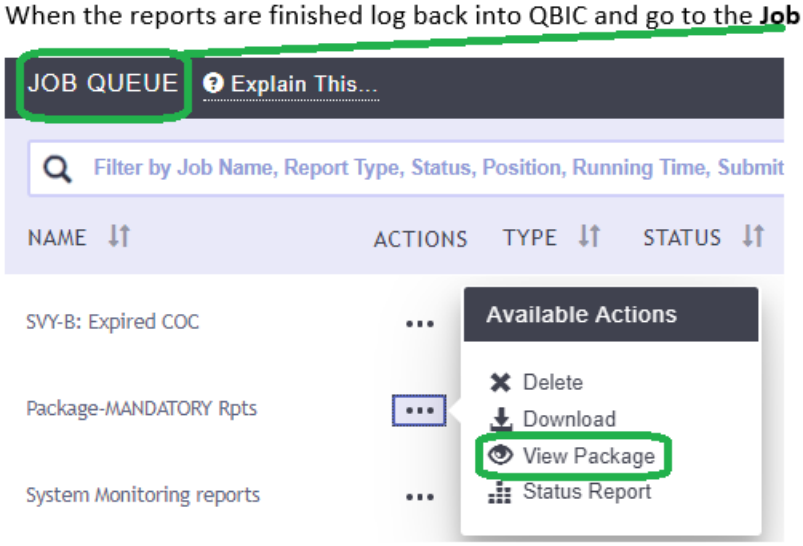


Enter the Geographical selection you desire – 8 times. Here I pause to repeat, **yes I said 8 times**. I apologize but this is a system requirement and beyond my control.

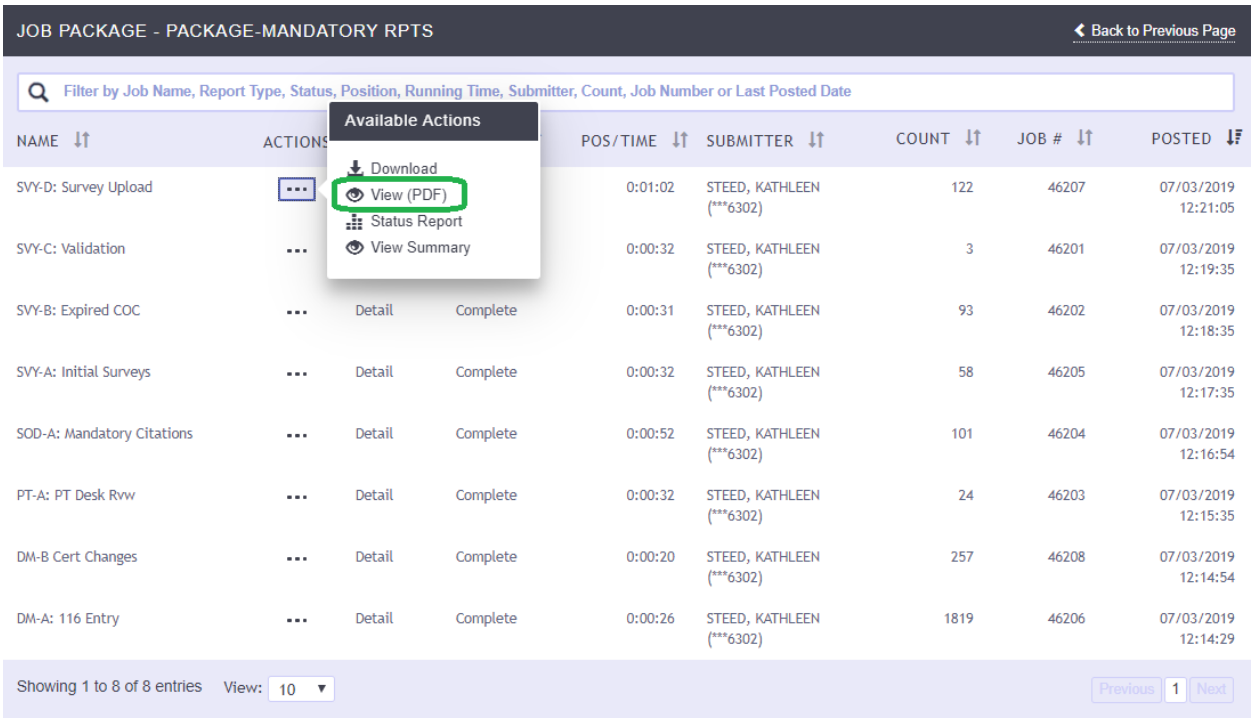
Note: the individual reports inside the package are set to give a page break after each state. Run the report for your Region and you will get all your states. You won't have to come back later to run it again.

You can log out of QBIC now and wait for the email that tells you the reports are finished.

When the reports are finished log back into QBIC and go to the **Job Queue** to 'View Package':



Then all 8 of the Mandatory reports will display and you can 'View (PDF)' on each and go from there.

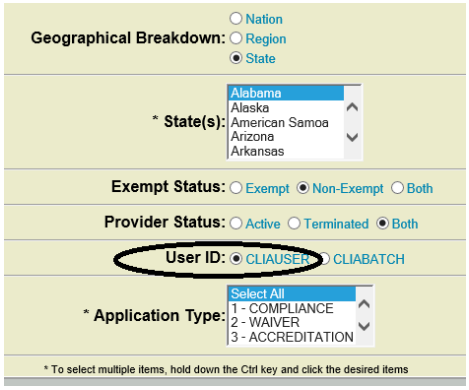


Instructions for Printing CASPER 0104D CLIA 116 Activity (Criterion 2 Data Management PI 6,7)

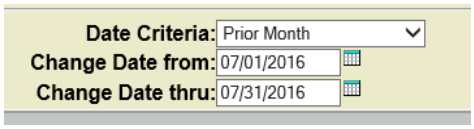
[Use "DM-B: Cert Changes" for Status changes] [104 is just for Demographic changes]

1. Log into CASPER Reporting and locate CASPER report 0104D CLIA 116 Activity.
2. Select the following criteria:

Geographic Breakdown: the state on which you are performing the SAPR.
Exempt Status: Non-Exempt
Provider Status: Both
User ID: CLIAUSER [Note: CLIAUSER sets the filter to Humans, not the system]
Application Type: Select All

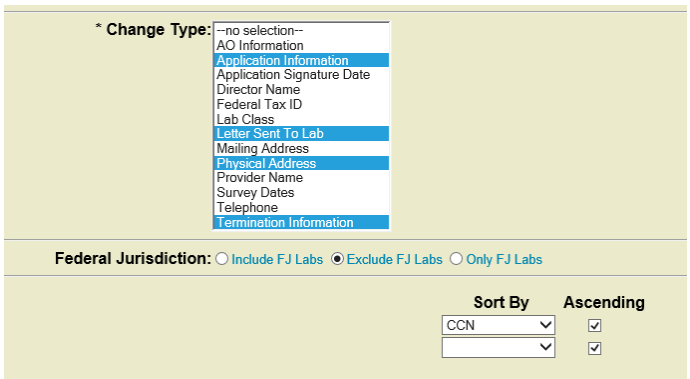


3. Note: The RO may choose to run one Report or multiple Reports based on varying time frames. Then, use the listing to ask the State agency to pull a representative sample of lab records and, as part of the review process, compare and assess the accuracy of the ASPEN data with the associated written notifications (email, letter, CMS-116).
4. 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

5. 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

- **This year the Regional Offices should not use CASPER 104D to find labs with certificate type changes. Instead use the new SAPR report: DM-B: Cert 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.

6. 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.
7. 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 – User IDs 1004651 and 1004731.

Clinical Laboratory Improvement Amendments (CLIA) Program

State: [name]

CLIA State Agency Performance Review

SUMMARY REPORT*

***The CLIA SAPR review for FY 2019 is educational due to the new process; therefore, no SA "Performance Thresholds for Written Corrective Action Plan", "Quantified Performance Results" or "Written Corrective Action Plan" results will be reported on the Summary Report.**

Review Period: Fiscal Year 2019

(October 1, 2018 to September 30, 2018)

CLIA STATE AGENCY PERFORMANCE REVIEW FISCAL YEAR 2018

REVIEW CRITERIA

Criterion # 1:	Personnel Qualifications, Training and Competency
Criterion # 2:	Data Management
Criterion # 3:	Proficiency Testing Desk Review
Criterion # 4:	Principles of Documentation (POD), Plans of Correction (PoC), Allegations of Compliance (AoC)
Criterion # 5:	Survey Workload and Outcome-Oriented Survey Process (OSP)
Criterion # 6:	Complaints
Criterion # 7:	Quality Assessment

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2018 SA:

Performance Review Criterion #1: Personnel Qualifications, Training and Competency

The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

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

Performance Thresholds for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Results

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #2: 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

N/A for FY 2019 SAPR review.

SA Performance Results

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #3: Proficiency Testing (PT) Desk Review

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

Performance Thresholds for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Results

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion # 4: Principles of Documentation (POD), Plan of Correction (PoC)/Allegation of Compliance (AoC)

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).
- Accept only PoC/AoCs that meet the criteria for acceptability.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Results

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

CLIA STATE AGENCY PERFORMANCE REVIEW FY 2018 SA:

Performance Review Criterion # 5: Survey Workload and Outcome-oriented Survey Process (OSP)

- The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.
- The SA has implemented a tracking system and ensures that the survey time frames are met.

PERFORMANCE MEASUREMENT:

Performance Thresholds for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Results

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #6: Complaints

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

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Result

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Performance Review Criterion #7: Quality Assessment

- The SA has developed specific procedures related to SAPR.
- The SA has an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

N/A for FY 2019 SAPR review.

SA Performance Result

N/A for FY 2019 SAPR review.

WRITTEN CORRECTIVE ACTION PLAN:

N/A for FY 2019 SAPR review.

WAS THE CORRECTIVE ACTION PLAN (CAP) FOR FY 2018 IMPLEMENTED: YES NO N/A

IF NO, PLEASE EXPLAIN.

NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:

Attachment #4

COVER LETTER TEMPLATE FOR FY2019 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 2019 (FY 2019)

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 FY2019 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 2019 review was restructuring of the original CLIA SAPR Criteria. As this is a transitional year, the CLIA SAPR review for FY 2019 is educational; therefore, no SA "Quantified Performance Results" will be reported on the Summary Report. The following are the seven Criteria included in the restructured SAPR:

Criterion #1—Personnel Qualifications, Training and Competency
Criterion #2 – Data Management
Criterion #3—Proficiency Testing (PT) Desk Review
Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5—Survey Process and Workload
Criterion #6—Complaints
Criterion #7—Quality Assessment

We encourage you to communicate any feedback regarding the new SAPR process to your Regional Office.

The subject areas of the other Criteria from the previous version of the SAPR, 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. Performance measurement consists of gathering 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

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.

(***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.***

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 2019

STANDARD REVIEW

The CLIA SAPR review for FY 2019 is educational due to the new process; therefore, no SA "Quantified Performance Results" will be reported on the Summary Report.

Criterion #1—Personnel Qualifications, Training and Competency
Criterion #2 – Data Management
Criterion #3—Proficiency Testing (PT) Desk Review
Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
Criterion #5—Survey Process and Workload
Criterion #6—Complaints
Criterion #7—Quality Assessment

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

***Please Note: This should not be used for the FY2019 SAPR**

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 2019 (FY 2019)—***(State)*** Corrective Action Plan

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

Thank you for the corrective action plan submitted in response to the FY 2019 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,