



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

Admin Info: 19-04-CLIA

DATE: January 14, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Federal Monitoring Survey (FMS) and Assessment (FMSA) Process– **ACTION**

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) is providing highlights from the updated CLIA Federal Monitoring Survey and FMS Assessment Process and includes information on the following:
 - New CLIA FMS and FMS Assessment Process Standard Operating Procedure (SOP)
 - State Agency FMS Responsibilities
 - Updated fillable forms for the FMS Assessment Worksheet, Cover Letter & Summary Report
 - CLIA Training Database
 - Evaluation of the FMS Assessment Worksheets and Summary Reports
- **This memorandum supersedes all prior guidance regarding CLIA Federal Monitoring Survey.**

Background

The Regional Office (RO) is responsible for validating each State Agency (SA) Surveyor's use and performance of the CLIA Outcome-Oriented Survey Process (OOSP) and adherence to CLIA policies and procedures. This validation is achieved through the FMS process.

CLIA Central Office in collaboration with the ROs, examined each RO procedure to identify opportunities to establish a minimum set of policies and requirements to standardize the method for performing an FMS Assessment and improve the survey process nationwide.

This new process will allow the RO to focus efforts on SA surveyors that are new and still learning to ensure expertise and competency for the long term, utilize the FMS types effectively, ensure that the ROs can continue to meet their oversight responsibilities, and use their resources effectively.

Federal Monitoring Survey (FMS) and FMS Assessment Process Standard Operating Procedure (SOP)

The FMS and FMS Assessment Process SOP (Attachment 1) outlines the activities involved in the CLIA FMS and the FMS Assessment process. This new process standardizes the CLIA Federal Monitoring Survey and FMS Assessment process and provides the minimum requirements necessary for the RO process to:

- 1) Identify SA Surveyors requiring FMS assessment;
- 2) Select the appropriate type of FMS; and,
- 3) Document and provide feedback to the SA.

This documentation will be utilized by the RO and CO to evaluate the effectiveness of existing training, identify gaps in understanding, to design future training to support and improve survey process performance and develop future policy decisions.

An important element of the FMS process is providing timely feedback to the SA and the SA Surveyor. The RO will now be required to provide the FMS Assessment Cover Letter and Summary Report to the SA no later than 60 days after the exit date of the survey. This should allow sufficient time for the RO to review the majority of the CMS-2567 and all associated documents required for a CLIA survey. If there are instances when additional review time is necessary, the RO is expected to send an initial FMS Assessment Cover Letter and Summary Report within 60 days and follow up with an amended report once all final documents have been received and reviewed.

The policies and procedures described in this SOP are considered the minimum requirements for conducting a FMS and FMS assessment. The RO has the discretion to incorporate additional requirements into this procedure, as applicable, for their region.

State Agency Responsibilities

Three new SA responsibilities have been identified in the design of this new FMS process:

- 1. Written documentation for SA CLIA training not completed within 12 months**
Written documentation must be provided to the RO by the SA that explains the reasons for any delays in scheduling a FMS.
- 2. Written response to the Summary Report**
A written response to the FMS Assessment Cover Letter & Summary Report from the SA Manager/Representative must be received in the RO within 30 days after the FMS Assessment Cover Letter & Summary Report are received by the SA.
- 3. Documentation of remedial training**
All evidence and documentation of remedial training must be received in the RO within the timeframe provided in the FMS Assessment Cover Letter & Summary Report.

FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report

The mandatory FMS Assessment Worksheet (Attachment 2) and FMS Assessment Cover Letter & Summary Report (Attachment 3) will be used by the RO to formally document SA Surveyor compliance with the OOSP and CLIA policies and procedures and report findings to the SA.

- **FMS Assessment Worksheet** is a fillable form which is used by the RO Surveyor to document their verbal and written findings from the FMS. Technical Skills are divided into 4 primary sections: Pre-survey Activities, On-site Survey Activities, Post Survey Activities and Additional Skills. Comment boxes are provided for additional information.
- **FMS Assessment Cover Letter & Summary Report** is a fillable form to document findings from the FMS Assessment Worksheet. Using the information on the FMS Assessment Worksheet, the RO completes the Cover Letter & Summary Report.

CLIA Training database

FMS assessment documentation will be collected and stored using an existing database in SharePoint to document completion of CLIA training. The RO is required to upload all FMS assessment documents and any optional supporting documents to the CLIA Training Database within 15 days of the FMS Assessment Cover Letter and Summary Report being sent to the SA.

Evaluation of the FMS Assessment Worksheets and Summary Reports

The FMS Assessment Worksheets & Summary Reports will be evaluated by CLIA CO and RO to monitor the SA's use and performance of the CLIA OOSP and adherence to CLIA policies and procedures. This information will also be utilized to determine the effectiveness of existing training, identify gaps in understanding, to design future training to support and improve survey process performance and for developing future policy decisions.

This memorandum supersedes all prior guidance regarding CLIA-FMS, including previous forms/worksheets used for FMS assessment documentation.

Training for RO staff

The information contained in this memorandum and attachments will be shared with all appropriate survey and certification staff, their managers, and the State/RO training coordinators assigned to work with determinations involving compliance with CLIA. Training for RO staff will be announced and provided by CO and RO staff (via Webinar).

Contact: If you have any questions regarding this memorandum, please direct them to LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Karen Tritz
Acting Director

Attachment (s)

Attachment 1 – CLIA FMS and FMSA Process, Standard Operating Procedure

Attachment 2 – CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

Attachment 3 – CLIA FMS Assessment Cover Letter & Summary Report

cc: Survey and Certification Regional Office Management

CLIA Federal Monitoring Survey and FMS Assessment Process

I. PURPOSE

The Regional Office (RO) is responsible for validating each State Agency (SA) Surveyor's use and performance of the CLIA Outcome-Oriented Survey Process (OOSP) and adherence to CLIA policies and procedures. This Standard Operating Procedure (SOP) outlines the activities involved in the CLIA Federal Monitoring Survey (FMS) and the FMS assessment process. The purpose of this SOP is to provide the minimum requirements and policies required to standardize the Regional Office (RO) process for; identifying SA Surveyors that require a FMS assessment, selecting the appropriate type of FMS, and conducting, documenting and providing feedback to the SA. This process also seeks to establish an efficient and timely method for collection of FMS assessment documentation. This documentation will be utilized by the RO and Central Office (CO) to evaluate the effectiveness of existing training, identify gaps in understanding, to design future training to support and improve survey process performance and make future policy decisions.

II. RESPONSIBILITY

The CO, RO and SA are responsible for implementing this SOP. Communication between the CO, RO and the SA is instrumental throughout the FMS and FMS assessment process.

III. DEFINITION OF TERMS

<i>Term</i>	<i>Definition</i>
FMS assessment	A Federal Monitoring Survey Assessment (FMS assessment) includes all the activities performed by the RO to evaluate the SA Surveyor's use and performance of the CLIA Outcome Oriented Survey Process (OOSP) and adherence to CLIA policies and procedures. The SA Surveyor is assessed based upon a standardized list of technical skills. A summary report is prepared and sent to the SA Supervisor with a courtesy copy to the SA Surveyor.
CLIA-FMS	A CLIA Federal Monitoring Survey, FMS, is a type of survey in which the RO Surveyor accompanies the SA Surveyor or performs a separate laboratory survey. Laboratories under direct Federal jurisdiction are exempt from a CLIA-FMS.
Comparative FMS	A CLIA survey in which the RO Surveyor surveys the laboratory after the SA Surveyor, preferably within 30 days but no later than 60 days from when the SA Surveyor performs the survey. The deficiency citations of the RO Surveyor are compared to those of the SA Surveyor.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

<i>Term</i>	<i>Definition</i>
Observational FMS	A CLIA survey in which the RO Surveyor accompanies the SA Surveyor and acts as an observer of the OOSP. The RO Surveyor interacts as necessary during the survey process to provide guidance and education at the appropriate times during the survey process. The RO Surveyor serves as a resource to enable the SA Surveyor to strengthen skills, knowledge base, and adherence to the CLIA OOSP, regulations, and policies. The RO and SA Surveyor communicate findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.
Participatory FMS	A CLIA survey in which the RO Surveyor both observes and participates in the survey. The Participatory FMS facilitates a collaborative relationship between the RO and SA. As in the Observational FMS, the RO Surveyor serves as a resource to enable the SA Surveyor to strengthen skills, knowledge base, and adherence to the CLIA OOSP, regulations, and policies. The RO and SA Surveyor communicate findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.
Certification/Survey Kit	Information that is entered into the CMS/CLIA data system; the kit may consist of: Form CMS-116 , CLIA Application For Certification Form CMS-209 , Laboratory Personnel Report Form CMS-1539 , Certification and Transmittal; Form CMS-1557 , Survey Report Form (CLIA) - pages 1& 2 Form CMS-2567 , Statement of Deficiencies and Plan of Correction; Form CMS-2567B , Post Certification Revisit Report Form CMS-670 , Survey Team Composition and Workload Report, and Form CMS-2802A , Request for Complaint Investigation or Validation Survey of Accredited Laboratory
CMS/CLIA Data System/Database	Centers for Medicare & Medicaid Services National Data System
New SA Surveyor (< 1 year to 5 years of surveyor experience)	A SA Surveyor who has completed the required CMS CLIA and SA Surveyor training requirements and demonstrates sufficient proficiency and skills in the OOSP to survey independently; still continuing to gain experience/still in the learning process.
Experienced SA Surveyor (> 5 years of surveyor experience)	A SA Surveyor who has completed the required CMS CLIA and SA Surveyor training requirements and demonstrates continued proficiency in the OOSP knowledge of the CLIA regulations and policies.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

<i>Term</i>	<i>Definition</i>
RO Surveyor	A Regional Office subject matter expert who performs the FMS and FMS assessment.
CLIA Survey Contractor	A CLIA surveyor contracted by a SA to perform CLIA Surveys.

IV. POLICIES

- A. These policies and procedures are considered the minimum requirements for conducting a FMS and FMS assessment. The RO has the discretion to incorporate additional requirements into this procedure, as applicable, for their region.
- B. A copy of the FMS assessment worksheet will be provided to the SA (Surveyor) prior to the FMS.
- C. Surveyor Categories Based on Survey Experience (SA Surveyor FMS Algorithm)

1. New Surveyor – with < 1 year of survey experience.

NOTE: All new CLIA SA Surveyors with < 1 year of experience must have at least 2 Observational FMS assessments performed during the first year of employment.

- a. The RO has the discretion to determine if additional FMS assessments are needed as well as the type of FMS for the assessment.
- b. The first FMS assessment should occur after the training is complete, but no later than 12 months from the date of hire. If SA CLIA training is not completed within 12 months, written documentation must be provided to the RO by the SA that explains the reasons for any delays in scheduling a FMS.
- c. The SA notifies the RO that the SA Surveyor is ready for a FMS assessment.

IV. POLICIES, continued

- d. The RO confirms that all CLIA training is complete by reviewing all required documentation:
 - i. CLIA Orientation manual
 - ii. CLIA Virtual Basic training
 - iii. SA training. This activity may be completed by the RO in cases where the RO performs all of the training activities for the SA, i.e. a state

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

where there is no Training Coordinator or SA Supervisor who is able to perform these duties.

- iv. Other Regional Office training requirements, as applicable.
- e. The SA and RO agree that the SA Surveyor is ready for a FMS assessment.

2. New Surveyor – with 1 year, up to 5 years of survey experience.

NOTE: All CLIA SA Surveyors with 1 year, up to 5 years of survey experience must have at least one FMS assessment performed every year during the next 4 fiscal years (year 2, 3, 4 and 5).

- a. The RO has the discretion to determine if additional FMS assessments are needed as well as the type of FMS. This determination is made by the RO based on prior FMS assessments, ongoing surveyor performance and adherence to CLIA policies and procedures.
- b. Adherence to CLIA policies and procedures includes, but is not limited to:
 - i. OOSP
 - ii. Following requirements for Principles of Documentation (PoD), including writing Statement of Deficiencies (SoD);
 - iii. Acceptance criteria for Plan of Correction (PoC)/Allegation of Compliance (AoC);
 - iv. Notification requirements for receipt of complaints (if the reason for the survey was the result of a complaint);
 - v. Recommendations for enforcement and sanctions, etc. as applicable.
 - vi. As identified during a State Agency Performance Review (SAPR)

3. Experienced Surveyor – with > 5 years of survey experience and demonstrated proficiency.

NOTE: Experienced Surveyors with > 5 years of experience who demonstrate continued proficiency in the OOSP and knowledge of the CLIA regulations must have one FMS assessment at a minimum of every 3 years.

- a. The RO has the discretion to determine if additional FMS assessments are needed at a more frequent interval as well as the type of FMS. This determination is made by the RO based on prior FMS assessments, ongoing surveyor performance and adherence to CLIA policies and procedures.
- b. The RO monitors SA surveyors through the review of Immediate Jeopardy cases, review of flagged survey kits (per RO policy), proficiency testing cases, and phone calls and emails with the SA surveyors. Further monitoring is achieved through contact and feedback from laboratories.
- c. Adherence to CLIA policies and procedures includes, but is not limited to:
 - i. OOSP
 - ii. Following requirements for Principles of Documentation (PoD), including writing Statement of Deficiencies (SoD);

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- iii. Acceptance criteria for Plan of Correction (PoC)/Allegation of Compliance (AoC);
 - iv. Notification requirements for receipt of complaints (if the reason for the survey was the result of a complaint);
 - v. Recommendations for enforcement and sanctions, etc. as applicable.
 - vi. As identified during a State Agency Performance Review (SAPR)
- d. If the RO identifies SA Surveyor issues (i.e., non-adherence to CLIA policies) the RO will follow the policies provided in Section IV. Policies, Subpart C. 4 below.

4. Experienced Surveyor with >5 years of survey experience and who demonstrates performance concerns.

NOTE: Experienced Surveyors with > 5 years of experience who demonstrate performance concerns identified by the RO, must have a minimum of one FMS assessment for the next 2 consecutive years.

- a. The RO Surveyor has the discretion to determine the number (above the 1 required FMS assessment for 2 years), the type of FMS, and the frequency of FMS assessments required, to ensure performance concerns have been resolved. Additional instructions are provided below in Section V: Procedure, Subpart H: FMS assessment Follow Up by the RO.
- b. This determination is made by the RO based on the RO's review of the surveyor's survey package(s), discussions with the SA, previous or current FMS assessments and review of overall SA surveyor performance.
- c. Adherence to CLIA policies and procedures includes, but is not limited to:
 - i. OOSP
 - ii. Following requirements for Principles of Documentation (PoD), including writing Statement of Deficiencies (SoD);
 - iii. Acceptance criteria for Plan of Correction (PoC)/Allegation of Compliance (AoC);
 - iv. Notification requirements for receipt of complaints (if the reason for the survey was the result of a complaint);
 - v. Recommendations for enforcement and sanctions, etc. as applicable.

IV. POLICIES, continued

- vi. As identified during a State Agency Performance Review (SAPR)

D. Type of FMS

1. Observational FMS

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- a. Recommended for all new SA Surveyors and to determine if an experienced SA Surveyor continues to follow the CLIA OOSP.
 - b. The SA performs the survey while the RO Surveyor observes the survey process and reviews the same documents as the SA Surveyor.
2. **Participatory FMS**
- a. Typically performed to assist the SA Surveyor on a CLIA survey of a large facility or when it becomes apparent that an Observational FMS is no longer sufficient i.e. insufficient time to complete the survey, survey is scheduled for one day, observed surveyor performance.
 - b. A Participatory FMS is not recommended for an initial FMS assessment for a new surveyor.
 - c. The RO Surveyor and SA Surveyor will survey portions of the laboratory separately and jointly identify deficiencies.
3. **Comparative FMS**
- a. Performed to determine if the SA Surveyor is performing a thorough CLIA survey following the OOSP and to ascertain if the SA Surveyor is able to identify laboratory deficiencies.
 - b. A Comparative FMS is not recommended for an initial FMS assessment for a new surveyor. A Comparative FMS may be selected only after the required number of Observational FMS have been completed.
 - c. The RO Surveyor performs the onsite survey of the laboratory within 30 days but no later than 60 days from the date of the SA survey.
- E. Laboratory Survey Type
The following are laboratory survey types that are eligible for a FMS:
1. Initial;
 2. Recertification;
 3. Validation; and
 4. Complaint Investigations (Full Survey)
- F. All RO Surveyors that perform a FMS are required to complete the FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report.
- G. All optional tools utilized for review of the CMS-2567 must be submitted with the FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report to CO. See Section V. Procedure, Subpart D, 1, h. for more information about the use of optional tools available to document the RO review of the CMS 2567.
- H. The signature of the RO Manager or the designee is required on the FMS Assessment Cover Letter.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- I. All FMS documents are part of CMS' internal oversight processes for SAs. The FMS assessment is not a replacement for any individual staff performance evaluation(s), and should serve no other purpose. The FMS assessment should not be shared externally.
- J. CLIA Survey Contractor
 - 1. A FMS assessment must be performed on contracted surveyors as determined by the RO. When a FMS assessment is performed, all parts of this SOP must be followed.
 - 2. Active SA surveyors contracting with another state will have the FMS assessment process completed in their home state.
 - 3. Retired SA surveyors, contracted as CLIA surveyors, must be up to date on all CLIA training requirements and must have at least one FMS assessment each year of contracted service.
- K. There are two mandatory data fields in the CLIA System database that must be completed:
 - 1. The type of FMS and,
 - 2. The date when the FMS Assessment Cover Letter & Summary Report is sent to the SA.
- L. The RO Surveyor is required to send the FMS Assessment Cover Letter & Summary Report to the SA Supervisor, and a courtesy copy to the SA Surveyor, as soon as possible, but no later than 60 calendar days after the exit date of the survey.
NOTE: In a case where extenuating circumstances do not allow for a full FMS assessment review and there would be a delay in sending the FMS Assessment Cover Letter & Summary Report within 60 days, the RO surveyor is required to send a preliminary report. Complete all sections of the FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report using all information currently available. As soon as more information becomes available to complete their full assessment, the RO surveyor will send a final FMS Assessment Cover Letter & Summary Report. See Section V. Procedure, subsection F: Submitting the FMS Assessment Cover Letter & Summary Report, for instructions for sending a preliminary and final FMS Assessment Cover Letter & Summary Report to the SA.

IV. POLICIES, continued

- M. The RO Surveyor must upload all FMS assessment documents into the CLIA Training Database in SharePoint. This action must be completed no later than 15 calendar days after the FMS Assessment Cover Letter & Summary Report is sent to the SA.

V. PROCEDURE

A. Pre-FMS assessment Activities/Preparation

1. Observational or Participatory FMS

- a. The SA Surveyor and the RO Surveyor coordinate to select the type of laboratory (taking into consideration specialties/subspecialties, test complexity and test volumes).
- b. The RO Surveyor and SA Surveyor review the list of laboratories that are due for a survey using scheduling guidelines - geographic areas and timing, whether the survey is announced or unannounced, and agree on a specific laboratory (ies).
- c. The RO Surveyor and the SA Surveyor review the laboratory survey history (CLIA database information: CMS-2567, CMS-116, CMS-1557, CMS-209, CMS-670; fee status, complaints, enforcement actions, Proficiency Testing (PT) data, specialty and subspecialty services offered, and test volumes) prior to going into the laboratory

2. Comparative FMS

- a. The RO Surveyor identifies a laboratory to be surveyed within 30 calendar days but no later than 60 calendar days from the date of the SA survey.
- b. The RO Surveyor reviews the laboratory survey history (CLIA database information: CMS-2567, CMS-116, CMS-1557, CMS-209, CMS-670; fee status, complaints, enforcement actions, Proficiency Testing (PT) data, specialty and subspecialty services offered, and test volumes) prior to going into the laboratory.
- c. The RO Surveyor should not review the current SA CMS 2567 prior to or during the Comparative FMS.
- d. The RO Surveyor notifies the laboratory following CLIA survey protocols and processes.

NOTE: Refer to the State Operations Manual Chapter 6, Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services for the OOSP protocol and for additional procedures on Pre-Survey Preparation, Onsite Survey Activities, Post Onsite Survey Activities- Development of the Statement of Deficiencies, and Review of the Plan of Correction/Allegation of Compliance.

B. FMS assessment- Survey Activities

1. Observational or Participatory FMS

- a. The RO Surveyor provides verbal feedback during the onsite survey and/or immediately after the survey is completed.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- b. The RO Surveyor and SA Surveyor discuss the findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.
 - c. The Observational FMS may become a Participatory FMS based on the RO Surveyor's observations/assessment of SA Surveyor skills.
 - d. The RO Surveyor collects information from observations and verbal discussion to complete the FMS Assessment Worksheet.
2. **Comparative FMS**
- a. The RO performs the onsite survey of the laboratory.

C. Post-FMS assessment Activities

1. **Observational or Participatory FMS**

- a. The RO Surveyor verifies that the SA certification kit has successfully been entered into the CLIA database system and is available for review by the RO.
- b. No later than 45 days after the FMS, the RO Surveyor will review the:
 - i. CMS-2567: adherence to requirements for writing SoDs and following the Principles of Documentation
 - ii. CMS-209
 - iii. CMS-1557
 - iv. CMS-670: correct documentation of survey hours
 - v. PoC/AoC: adherence to requirements for determining that the laboratory has provided an acceptable PoC/AoC.

NOTE: The process for performing a review of the PoC/AoC may fall out of the above timeframe if extensions have been granted or extenuating circumstances exist to prolong this review.

2. **Comparative FMS**

- a. The RO Surveyor prepares the CMS-2567 and enters all survey information into the CLIA data system.
- b. The RO Surveyor verifies that the SA survey kit has successfully uploaded into the CLIA data system (e.g., timeliness).
- c. No later than 45 days after the FMS, the RO Surveyor will review:
 - i. Compares its CMS-2567 citations with the SA Surveyor's CMS-2567 citations for the FMS Assessment Worksheet.
 - ii. CMS-2567: adherence to requirements for writing SoDs and following the Principles of Documentation

V. PROCEDURE, continued

- iii. CMS-209
- iv. CMS-1557
- v. CMS-670: correct documentation of survey hours

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- vi. PoC/AoC: adherence to requirements for determining that the laboratory has provided an acceptable PoC/AoC.

NOTE: The process for performing a review of the PoC/AoC may fall out of the above timeframe if extensions have been granted or extenuating circumstances exist to prolong this review.

- d. When assessing comparability, the RO Surveyor must keep in mind the possibility that deficiencies may not have been present in the laboratory at the time of separate surveys. If an issue arises, the RO Surveyor must contact the SA Surveyor for clarification.

D. FMS Assessment: Documentation

<p>NOTE: It is mandatory for the RO Surveyor to complete an individual FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report to document each FMS performed.</p>

The RO assessment should be specific, objective, and constructive.

The FMS Assessment Worksheet and the FMS Assessment Cover Letter & Summary Report offer a hover help feature for instructions to complete the forms. When the mouse/pointer is positioned over a designated section or text on the form, a pop-up box will open. This window displays an example, or an explanation of the information that is required to complete the box, or a statement which describes a mandatory requirement or policy.

1. FMS Assessment Worksheet (six pages)

The FMS Assessment Worksheet is a fillable document which is used by the RO Surveyor to document their verbal and written findings from the FMS.

- a. The top box (header) is used to identify specific information about the FMS. Complete all boxes with the required information.
 - i. Date of Survey = the date the SA performed the survey.
 - ii. Type of Federal Monitoring Survey: use the comment box in this section to enter the date when the Comparative FMS was performed by the RO Surveyor.
- b. Radial buttons are provided to quickly select a response to the right of each Technical Skill. Select “Yes”, “No” or “NA” (not applicable).
- c. If there is a section on the worksheet that is not applicable, the RO Surveyor will note this section as “NA”
- d. Comment boxes next to each section allow for additional information.
- e. There is a comment box at the end of the form for additional information that does not fit in the comment fields next to each section.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

NOTE: The scroll feature for each of the comment boxes also allows for additional information to be entered. **Only the visible text in the comment fields will be on the printed form if a printed copy of the worksheet is generated;** a plus sign will appear on the bottom right corner of the form to indicate “hidden” additional information.

- f. The Technical Skills are divided into 4 primary sections.
 - i. **Pre-survey Activities**
 - Pre-survey Preparation
 - ii. **On-site Survey Activities**
 - Entrance Interview
 - Information Gathering
 - Assessing Laboratory Survey Outcome or Potential Outcome
 - Regulatory Compliance Decisions
 - Exit Conference
 - iii. **Post Survey Activities**
 - Development of the Statement of Deficiencies
 - Survey Report Documentation and Data Entry
 - Review of the Plan of Correction/Allegation of Compliance
 - iv. **Additional Skills**
- g. **Optional:** There is a signature box at the end of the FMS Assessment Worksheet for the signature of the RO Surveyor who performed the FMS and their RO Manager. **Digital signature** allows for the RO to sign and lock the document so that the information cannot be changed on the form (edits can be made only by the person who signed the document), click the box “Lock Document After Signing.”

NOTE: The RO Surveyor has to sign first in the designated space before the RO Manager/Designee signs, then the Lock Document after Signing option will appear. If changes/edits need to be made on the form, the person who signed the document can cancel the locked signature (right click over the digital signature and click “Clear Signature”).
- h. **Optional:** State Agency Performance Review (SAPR) review tools (Criteria #10 PoD and # 11 AoC, and Criteria #10, POD 3) may be used to document review of each D-tag on the CMS-2567 and review of the PoC/AoC. All optional tools utilized for review of the CMS-2567 must be submitted with the

V. PROCEDURE, continued

FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report to CO.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- i. **Supplemental Documents:** Supplemental worksheets may be used, i.e. forms, sheets, documents.
- j. **Links to Documents in [RO CLIA SOP](#) in SharePoint**
[CLIA FMS Assessment \(FMSA\) Worksheet](#)
[CLIA FMS Assessment Optional Documents](#)

2. FMS Assessment Cover Letter & Summary Report

The FMS Assessment Cover Letter & Summary Report are combined into one document. This document is fillable and is used by the RO Surveyor to document their findings from the FMS Assessment Worksheet, and to formally document SA Surveyor compliance with the OOSP and CLIA policies and procedures. There is a section at the bottom of the Summary Report, *Follow up Action & Monitoring*, for the RO Surveyor to request remedial training, the type of remedial training and a due date for the SA to send documentation to the RO, as applicable.

- a. Using the information on the FMS Assessment Worksheet, the RO Surveyor completes the Cover Letter & Summary Report.
 - i. **Cover Letter** (one page)
 - **Header:** at the top left, insert information specific to the RO, i.e. the address of the RO.
 - **Date box** is an auto-fill and defaults to the date that the document is opened.
 - **SA Supervisor Name:** open to insert the name of the official in the SA to whom the report will be sent
 - **Subject Line:** add the name of the SA Surveyor and either “Preliminary” or a “Final” report
 - **Body of the Letter:** customize the content of the message (a partial message is provided in the box) based on the FMS assessment; use your mouse to activate the box (the scroll feature allows you to scroll down to select and customize the content of your letter)
 - The signature of the RO Manager **or** the designee is required on the FMS Assessment Cover Letter.
 - **Digital signature** allows for the RO to lock the document so that the information cannot be changed. Click the box “Lock Document After Signing.”

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

NOTE: If changes/edits need to be made on the form, the person who signed the document can cancel the locked signature (right click over the digital signature and click “**Clear Signature**”).

SPECIAL NOTE: Remember to “**lock**” the document before the FMS Assessment Cover Letter and Summary Report is sent to the State Agency. Do not send the document to the State Agency without being locked.

- ii. **Summary Report** (four pages)
- The Header looks very similar to the FMS Assessment Worksheet. Complete all boxes with the required information.
 - Each section corresponds to the same Technical sections in the FMS Assessment Worksheet.
 - Hovering over the name of each section offers an **Example** of suggested narrative to assist the RO with completing that section.
 - The last section, *Follow up Action & Monitoring*, is for the RO Surveyor to request remedial training, the type of remedial training and a due date for the SA to send documentation to the RO, as applicable.

NOTE: The scroll feature for each of the comment boxes also allows for additional information to be entered. **Only the visible text in the comment fields will be on the printed form if a printed copy of the cover letter & summary report is generated;** a plus sign will appear on the bottom right corner of the form to indicate “hidden” additional information.

- b. In the absence of a PoC/AoC, the RO surveyor is expected to complete all sections of the FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report using all information available. A preliminary report may be sent, see Section V. Procedure, Letter F. *Submitting the FMS Assessment Cover Letter & Summary Report to the SA* for further guidance. As more information becomes available, the RO surveyor must send a final FMS Assessment Cover Letter & Summary Report.
- c. The RO Surveyor submits the completed FMS Assessment Worksheet and FMS Assessment Cover Letter & Summary Report to the RO Manager for review and signature. This responsibility may be delegated by the RO Manager to the RO designee.

V. PROCEDURE, continued

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- d. **Optional: Prior to the release of the FMS Assessment Cover Letter & Summary Report.** At the discretion of the RO, the RO Surveyor may have a verbal or face to face discussion with the SA Manager, SA Training Coordinator/Preceptor and SA Surveyor to discuss identified strengths and weaknesses (areas of concern) and the results of the FMS. Evidence of this conversation i.e. date, time and notes, should be documented in the FMS Assessment Worksheet in the Additional Comments section.
- e. **Links to Documents**
[*CLIA FMS Assessment \(FMSA\) Cover Letter and Summary Report*](#)

E. CLIA Data System: Documenting an Observational, Participatory or Comparative FMS in the CLIA Data System

- a. Guidance on how to enter a FMS (Observational FMS, Participatory FMS or Comparative FMS) survey into the CLIA Data System is available. Click on the “CLIA 116 and Certification Procedures” manual and search for “FMS”. ASPEN Central Office (ACO) Procedures Guide may be accessed here:
[*Aspen Manual Guide*](#)
- b. The CLIA Data system must be completed correctly to ensure that there is documentation to show when the FMS Assessment Cover Letter & Summary Report are sent to the SA Supervisor (courtesy copy to the SA Surveyor) to include.
 - i. Report was sent to State Agency: “Yes” or “No”;
 - ii. Date sent
- c. A Microsoft PowerPoint tutorial is offered as visual guidance and instructions for the following:
 - i. Creating & entering the FMS;
 - ii. How to link the FMS survey with the SA Surveyor Team;
 - iii. Verifying that the FMS was successfully uploaded;
 - iv. Viewing &/or printing a FMS tracking report
- d. **Links to Documents**
[*CO ARO Linking RO and SA FMS Surveys Tutorial*](#)

[*Participatory FMS Procedure*](#)

F. Submitting the FMS Assessment Cover Letter & Summary Report to the SA

The Cover Letter & Summary Report must be submitted to the SA Supervisor, with a courtesy copy to the SA Surveyor, no later than 60 calendar days after the exit date of the FMS.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

In a case where extenuating circumstances do not allow for a full FMS assessment to be completed within 60 days, the RO surveyor is expected to send a preliminary FMS Assessment Cover Letter & Summary Report.

a. Preliminary FMS Assessment Cover Letter & Summary Report

- i. Complete all sections of the FMS Assessment Cover Letter & Summary Report using all available information from the FMS Assessment Worksheet.
- ii. **Cover Letter:** In the Subject Line *RE: FMS ASSESSMENT (FMSA) SUMMARY REPORT FOR:* enter the name of the SA Surveyor and *Preliminary Report.*
- iii. **Summary Report:** In the section of the Summary Report identified as *Follow up Actions and Monitoring*, list all documentation that is outstanding that prevents a full FMS assessment. **Provide a notation that a final report will be sent when review of these documents have been completed in the RO.**
- iv. Recommendations for additional training, as applicable, and a date when documentation of training is expected to be received in the RO must be included for all sections that have been completed in this preliminary report.

b. Final FMS Assessment Cover Letter & Summary Report

Send a final report only after all final documentation required for a full FMS assessment is received and reviewed.

- i. Open the preliminary report and clear the digital signature to make changes to the FMS Assessment Cover Letter and Summary Report.
- ii. **Cover Letter:** Manually change the date to reflect the current date that the document is being modified.
- iii. Subject Line: change “Preliminary” to “Final”
- iv. **Summary Report:** Complete all sections of the FMS Assessment Cover Letter & Summary Report that still need to be completed from the preliminary report.
- v. In the final section of the Summary Report identified as *Follow up Actions and Monitoring*, provide additional recommendations for training, as applicable, and a date when documentation of training is expected to be received for review in the RO.
- vi. Digitally sign the document.
- vii. When prompted by the system to save the document to a file, change the date at the beginning of the document name to reflect the current date.
- viii. Update the FMS Assessment Worksheet with the results of the review of all final documents, i.e. PoC/AoC.

V. PROCEDURE, continued

G. CLIA Training Database

The CLIA Training Database (in SharePoint) will be used to **upload all** FMS Assessment Worksheets and FMS Assessment Cover Letters & Summary Reports, and optional documents, as applicable, from the RO.

1. The **CLIA Training Database SOP** is a step-by-step procedure on how to access, enter and edit information in the training database in SharePoint.
 - a. The following sections of this SOP are referenced below to quickly locate the sections that will be most helpful to the RO Surveyor.

Sections

- i. How to **enter** information in the training database (Section III Procedure, B.)
- ii. How to **attach** a file (for documentation) in the training database (Section III Procedure, F.)
- b. A naming convention is required for all documents to keep the FMS Assessment Worksheets and FMS Assessment Cover Letters & Summary Reports in the order they were conducted. Add the year, month, and day of the FMS exit date before the title of the documents, the name of the document, the CLIA Number and the Name of the SA Surveyor.

Examples:

2018.09.04 FMS Assessment Worksheet; CLIA Number, Name of SA Surveyor

2018.09.04 FMS ASSESSMENT CL_SR, CLIA Number, Name of SA Surveyor – Preliminary

2018.11.28 FMS ASSESSMENT CL_SR, CLIA Number, Name of SA Surveyor - Final

2. The RO Surveyor must upload all FMS Assessment documents into the CLIA Training Database. This action must be completed no later than 15 days after the FMS Assessment Cover Letter & Summary Report are sent to the SA.
3. **Links to the CLIA Training Database and CLIA Training Database SOP**

The CLIA Training Database and CLIA Training Database SOP can be accessed from:

[CMS Share](#) by going to >>>[COISCO](#) under **Centers & Consortia** and click [Division of Survey & Certification \(DSC\)](#)>>>[Providers & Suppliers](#) and then **CLIA** to get to the [CLIA RO Page](#) where the individual RO training

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

databases are located, and the >>>>[RO CLIA SOP](#) (these can be bookmarked/saved in your **Favorites/Favorites bar** to easily locate and access these links).

H. FMS Assessment Follow Up by the RO

1. New Surveyors (< 1 year)

a. The SA Surveyor is cleared to survey independently

No further action is required by the RO if the results of the FMS assessment(s) indicate(s) that the SA Surveyor has an established understanding and is able to apply the CLIA Outcome Oriented Survey Process (OOSP) and adherence to CLIA policies and procedures in the field.

b. The SA Surveyor requires remedial training

- i. The SA Manager/SA Representative will address any areas of concern that are stated in the FMS Assessment Cover Letter & Summary Report.
- ii. A written response to the FMS Assessment Cover Letter & Summary Report from the SA Manager/Representative must be received by RO within 30 calendar days after the FMS Assessment Cover Letter & Summary Report are received by the SA.
- iii. All evidence and documentation of remedial training must be received in the RO within the timeframe provided in the FMS Assessment Cover Letter & Summary Report.
- iv. A follow up FMS should be performed within 3-6 months (from when the SA's response is received by RO) to validate that all concerns identified in the FMS Assessment Cover Letter & Summary Report have been addressed.

2. New and Experienced Surveyors (All Surveyors) (> 1 year)

a. The SA Surveyor demonstrates proficiency in all technical skills

No further action is required by the RO if the results of the FMS assessment(s) indicate(s) that the SA Surveyor continues to demonstrate an understanding of the CLIA Outcome Oriented Survey Process (OOSP) and adherence to CLIA policies and procedures in the field.

b. The FMS assessment indicates areas of concern

- i. The SA Manager/SA Representative will address any areas of concern that are stated in the FMS Assessment Cover Letter & Summary Report.
- ii. A written response to the FMS Assessment Cover Letter & Summary Report from the SA Manager/Representative must be received by RO within 30 calendar days after the FMS Assessment Cover Letter & Summary Report are received by the SA.

**Centers for Medicare & Medicaid Services (CMS)
Clinical Laboratory Improvement Amendments (CLIA)**

- iii. All evidence and documentation of remedial training must be received in the RO within the timeframe provided in the FMS Assessment Cover Letter & Summary Report.
- iv. **Optional:** A follow up FMS assessment should be performed within 3-6 months (from when the SA’s response is received by the RO).

VI. EVALUATION OF THE FMS ASSESSMENT WORKSHEETS & FMS ASSESSMENT SUMMARY REPORTS

CLIA CO and RO will evaluate the FMS Assessment Worksheets and FMS Assessment Cover Letter & Summary Reports to evaluate the SA’s use and performance of the CLIA OOSP and adherence to CLIA policies and procedures. This information will also be utilized to determine the effectiveness of existing training, identify gaps in understanding, to design future training to support and improve survey process performance and for developing future policy decisions.

Monitoring includes the number and type of FMS assessments performed annually. Additional performance indicators may be identified over time and utilized to improve the FMS Assessment process.

VII. REFERENCES

1. [*State Operations Manual \(SOM\) Chapter 6 - Special Procedures for Laboratories*](#)
2. [*SOM Chapter 6 Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; \(Rev. 166, 02-03-17\)*](#)
3. ASPEN Manual Guide: [*Aspen Manual Guide*](#)

VIII. Reviewed/Approved by:

<i>Director</i>	<i>Date Mo/Day/Yr</i>	<i>Deputy Director</i>	<i>Date Mo/Day/ Yr</i>	<i>Author/ Change Author</i>	<i>Date/Description of Change</i>
Karen Dyer	10/23/2018	Regina Van Brakle	10/12/2018	AS/AL/ BP	10/9/2018: Original SOP; SOP Effective Date.
RO Manager					

<i>Staff Review First Name/Last Name</i>	<i>Date Month/Day/Year</i>



CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

State Agency (SA) Surveyor:	RO Surveyor:
Hire Date: <div style="display: flex; justify-content: space-around;"> Surveyor (<1 year to 5years) Surveyor (>5 years) </div>	Type of Federal Monitoring Survey Assessment (FMSA): <div style="display: flex; justify-content: space-around;"> Observational Participatory Comparative </div> Comments:
Date of Survey: <div style="display: flex; justify-content: space-around;"> SA RO BOTH </div>	Type of Survey: <div style="display: flex; justify-content: space-around;"> Initial Recertification Validation </div> Complaint (Full Survey)
Laboratory Name:	CLIA Number:

Technical Knowledge Skills	YES	NO	NA	Comment
PRE-SURVEY ACTIVITIES				
I. PRE-SURVEY PREPARATION				
a. Schedules survey using scheduling guidelines - geographic areas and appropriate survey timeframes.				
b. Provides forms (e.g., CMS-209, CMS-116) to the laboratory prior to or during the onsite survey.				
c. Reviews survey fee status, previous history and compliance, complaints, Proficiency Testing (PT) data, specialty and subspecialty services offered, and test volumes.				
d. Determines the size of the survey team and the expected time required for the survey and considers the number of sites under the certificate using the CLIA-database information.				
e. Requests records and documents be available, accessible and retrievable at time of survey.				





CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

Technical Knowledge Skills	YES	NO	NA	Comment
ONSITE-SURVEY ACTIVITIES				
II. ENTRANCE INTERVIEW				
a. Ensures proper identification and introductions.				
b. Explains purpose, time schedule, and survey process.				
c. Identifies a contact person and establishes a communication level based on the degree of technical knowledge of the contact person.				
d. If the laboratory consists of multiple testing sites, verifies all information concerning testing performed at each site.				
e. Requests that the laboratory collect any documents, records, or information that may be needed to complete the survey, and solicits and answers any questions the laboratory may have concerning the survey process.				
III. INFORMATION GATHERING				
a. Tours the laboratory, observes specimen collection/receiving area, verifies reagents, kits, equipment, space and staffing correlates with test menu, clients served, and test volume.				
b. Observes personnel performing specimen processing, testing, and reporting of results in each specialty/subspecialty of service. If direct observation is not possible, requests a verbal walk-through of the procedure.				
c. Demonstrates sensitivity to confidentiality of PHI (protected health information), laboratory records, and operations.				
d. Interviews staff to confirm observations and obtain necessary information.				
e. Reviews adequate and representative cross-section of information, procedure manuals, manufacturer's instructions, including records encompassing the time period since the previous survey.				
f. Evaluates Quality Assessment plan and documentation, including corrective action activities.				
g. Evaluates PT enrollment, performance, and corrective actions.				
h. Evaluates calibration, reagents, maintenance and function checks, and validation of new tests.				
i. Evaluates Quality Control (QC) protocols and performance (including outliers, shift, trends, and corrective actions)				



Technical Knowledge Skills	YES	NO	NA	Comment
j. Evaluates patient test results (particularly from periods of PT and QC failures).				
k. Reviews test records, reports, referrals, and turn-around times.				
l. Verifies all staff have written responsibilities and duties. The list of assigned duties must be current.				
m. Reviews CMS-209 and personnel records for education, training or experience of new staff and current state license or board certification of LD (if required).				
n. Reviews competency assessment records.				
o. Knows when to conclude the survey or continue a more in-depth review.				
IV. ASSESSING LABORATORY SURVEY OUTCOME OR POTENTIAL OUTCOME				
a. Assesses accurately, proficiently, and efficiently whether the identified problem “does or could negatively impact patient test results.”				
b. Uses the assessing outcome flow chart available from Appendix C of the State Operations Manual (SOM).				
c. Understands policy for citing the current mandatory Condition-level citations (available in Appendix C) (regardless of outcome).				
V. REGULATORY COMPLIANCE DECISIONS				
a. Determines whether problems identified are regulatory.				
b. Analyzes the findings for the degree of severity, pervasiveness, comparison with historical survey results and frequency of occurrence (Standard, Condition or Immediate Jeopardy (IJ)).				
c. Recognizes IJ and contacts (immediately) supervisor and/or RO in situations of IJ or serious problems, as necessary.				
d. Determines if the allegations are substantiated or unsubstantiated for a complaint survey.				



CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

Technical Knowledge Skills	YES	NO	NA	Comment
VI. EXIT CONFERENCE				
a. Conducts the Exit Conference with appropriate personnel.				
b. Describes the laboratory practices not in compliance with the regulatory requirements and the related findings.				
c. Provides laboratory personnel an opportunity to discuss and/or provide any additional information regarding the preliminary concerns noted.				
d. Informs the laboratory of compliance with CLIA or that they will receive a written statement of deficiencies (Form CMS-2567) with the final deficiencies cited.				
e. Provides the name of contact person, the instructions and time frame for submitting a plan of correction/allegation of compliance in response to final deficiencies.				
f. Understands it is the laboratory's responsibility to determine the corrective action(s) necessary to remedy the problem(s).				
g. Informs the laboratory that volume changes may result in fee changes.				
POST SURVEY ACTIVITIES				
VII. DEVELOPMENT OF THE STATEMENT OF DEFICIENCIES				
a. Selects the most appropriate regulatory citation and corresponding D-tag when documenting a deficiency.				
b. Follows the Principles of Documentation.				
c. Meets the required timeframe in sending the post survey letter with the CMS-2567, i.e. ten (10) days.				
VIII. SURVEY REPORT DOCUMENTATION AND DATA ENTRY				
a. Completes applicable survey forms accurately.				
b. Enters certification/survey kit(s) accurately and timely into CMS/CLIA data systems.				





CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

Technical Knowledge Skills	YES	NO	NA	Comment
IX. REVIEW OF THE PLAN OF CORRECTION/ALLEGATION OF COMPLIANCE				
a. Verifies the PoC is acceptable, AoC is credible, and evidence of correction is acceptable.				
b. Verifies that page 1 of the CMS-2567 is signed and dated by the LD or authorized official and correction dates are within acceptable timeframe. NOTE: The laboratory director or other authorized official (i.e. owner, operator and/or laboratory director) is not required to sign the CMS-2567 when there are no laboratory deficiencies cited.				
c. Makes recommendations to RO when enforcement actions are necessary.				
X. ADDITIONAL SKILLS				
a. The survey approach has been developed prior to conducting the survey. Well thought out survey plan (in an orderly and structured fashion).				
b. Follows survey plan. Understands when to broaden or narrow survey plan based on findings.				
c. Demonstrates efficient time management.				
d. All interview questions are clear, concise, open-ended, non-threatening and within the scope of the CLIA requirements.				
e. Demonstrates active listening skills. Differentiates facts or specific and relevant information from impressions, conclusions, judgments, etc.				
f. Handles difficult people and/or situations.				
g. Interacts with others in a professional and courteous manner; uses appropriate body language.				





CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet

OVERALL SURVEY EVALUATION AND GENERAL COMMENTS (OPTIONAL)

Empty box for overall survey evaluation and general comments.

RO SURVEYOR/DATE

RO MANAGER/DATE





RE: FMS ASSESSMENT (FMSA) SUMMARY REPORT FOR:

Dear

Sincerely,

RO MANAGER/DESIGNEE

Enclosure: CLIA FMS Assessment (FMSA) Summary Report

cc: CMS Central Office

III. INFORMATION GATHERING

IV. ASSESSING LABORATORY SURVEY OUTCOME OR POTENTIAL OUTCOME

V. REGULATORY COMPLIANCE DECISIONS

VI. EXIT CONFERENCE

VII. DEVELOPMENT OF THE STATEMENT OF DEFICIENCIES

VIII. SURVEY REPORT DOCUMENTATION AND DATA ENTRY

IX. REVIEW OF THE PLAN OF CORRECTION/ALLEGATION OF COMPLIANCE

X. ADDITIONAL SKILLS

FOLLOW UP ACTION & MONITORING