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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-39

DATE: **August 12, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) State Agency Performance Review (SAPR)—Fiscal Year 2004 (FY2004)

Letter Summary

- This letter transmits the FY 2004 CLIA SAPR package. This is the first official review under this review mechanism.
- The FY 2004 CLIA SAPR Criteria are identical to the Criteria in the Introductory Version, issued for the FY 2003 preparatory activities.
- The Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) maintains its overarching responsibility for program oversight, however, its primary role in the CLIA SAPR is to provide education and support for optimal SA performance.

The purpose of this memorandum is to transmit the SAPR package for the review of CLIA SA performance for FY 2004, the first official review under the SAPR mechanism. The CLIA SAPR is an annual evaluation and summary report by the CMS (RO) of the SA's performance of its survey and certification responsibilities under the CLIA program.

The FY 2004 CLIA SAPR consists of 13 Review Criteria, based on the SA responsibilities prescribed in the State Operations Manual, CLIA Budget Call Letter, and the 1864 Agreement. The CLIA SAPR is structured for consistency among RO reviewers nationwide; yet it provides flexibility for realistic application to several States with relatively few laboratories and small staffing (less than 1.0 FTE). The RO maintains its overarching responsibility for program oversight; however, its primary role in the CLIA SAPR is to provide education and support for SA optimal performance.

The FY 2004 SAPR Criteria are identical to those of the Introductory Version issued in FY 2003, for preparatory activities. That time period was designated for orientation and familiarity with the SAPR mechanism so that the expectations are clearly understood by all parties. States were encouraged to assess their internal operations in relation to the performance indicators of the Review Criteria, and to proactively make the changes that would obviate, or at least minimize, the need for corrective action as a consequence to the actual review in FY 2004.

Performance evaluation of each SA is mandated by the 1864 Agreement; however, the methodology of the evaluation is not prescribed. Thus, we have structured the SAPR according to the performance-improvement model that characterizes much of the administration of the CLIA program. In an effort to promote optimal performance by the SA, sustained proficiency is recognized, and areas needing improvement are identified to the SA for further, more in-depth assessment and corrective action. The SA is expected to have systems in place for monitoring and evaluating the efficiency of its corrective actions, so that positive outcomes can be demonstrated.

At the completion of the fiscal year we plan to convey a written report to the SA that summarizes the results of the CLIA SAPR. A copy of each report will be kept in CO. The report will include the strengths and weaknesses found for each state, summary information about the state's action plans for further improvement, and their timeframes for and status of such improvements.

Effective Date: October 1, 2004

Training: This information should be shared with all CLIA Program survey and certification staff, their managers, State/RO training coordinators, State/RO CLIA budget personnel, State/RO CLIA data entry/data management personnel, and state human resources personnel (hiring of CLIA SA surveyors).

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments - Excel Zipped File 14KB

CLIA State Agency Performance Review (SAPR)
FY 2004

The FY 2004 CLIA SAPR package consists of 3 sections:

- **Overview and Guidance**
- **Review Criteria**
- **Review Worksheets**

Please note: FY2004 changes in language from the FY 2003 Introductory Version are in Arial font.

OVERVIEW AND GUIDANCE

Introduction

The CLIA State Agency Performance Review (SAPR) is an annual evaluation by the RO of each SA's ability to carry out the survey and certification responsibilities, as specified by the Section 1864 Agreement. The CLIA SAPR consists of 13 Review Criteria that are based on the SA responsibilities prescribed in the State Operations Manual (SOM), the CLIA Budget Call Letter, and the 1864 Agreement.

Implementing the CLIA SAPR and maintaining basic information about state performance has a dual value for program administration purposes. This annual evaluation:

documents fulfillment of our CLIA program oversight responsibilities for Congress and our other external oversight entities; and

provides nationwide data from which we can identify needs and develop training or other initiatives aimed at professional development or performance improvement.

While State agency performance evaluation is a mandated program administration responsibility for CMS, we have designed the SAPR to also serve as additional opportunity to further our educational and supportive efforts of the CLIA SA's, as we partner to ensure quality laboratory testing across the nation.

Goal and Intent of the CLIA SAPR

The goal of the CLIA SAPR is to promote optimal performance by SAs in carrying out their CLIA survey and certification responsibilities. One intent of the SAPR is to encourage states to have quality systems in place for enhancing performance and sustaining proficiency in their performance. The systems need not be complex, just suitable for organizing, tracking and completing the work in a manner consistent with the SOM, CLIA Budget Call Letter, and the 1864 Agreement.

The SAPR has been structured according to the performance-improvement model that characterizes much of the administration of the CLIA Program. In an effort to promote optimal performance by the SA, sustained proficiency is recognized, and areas needing improvement are identified to the SA for further, more in-depth assessment of its internal systems and corrective action. The SA is expected to monitor and evaluate the effectiveness of its corrective actions, so that positive outcomes can be demonstrated.

The SAPR has been structured for objective measurement and consistency among RO reviewers nationwide, yet flexibility is built-in for realistic application to each state's CLIA program operations. In other words, it is intended to "fit" each SA, whether it has .3 FTE staff or 8.0 FTE staff assigned to the CLIA program.

The primary focus of the RO under SAPR is on education and support for improvement. The SAPR is not intended to limit or supersede the RO's overarching responsibility for program oversight.

Relationship of the SAPR to the Federal Monitoring Survey (FMS) Program

The SAPR and the FMS are distinct CLIA Program oversight activities with separate reporting avenues, however, the SAPR follows-up FMS and brings improvement full-circle. Through FMS, the RO gives the SA feedback for improvement, in addition to noting the SA's strengths. The SA reviews the feedback, incorporates it into its ongoing activities—notably training, outcome-oriented survey process (OSP), review of Statements of Deficiencies (SoD), review of Plans of Correction (PoC), and perhaps others—and should be able to demonstrate to the RO, for documentation in the SAPR, its survey-related improvement efforts and the outcomes achieved. Thus both SAPR and FMS are critical to the overall mission: optimal performance of survey and certification responsibilities to ensure quality laboratory testing.

One can distinguish the FMS from the SAPR by recognizing that the focus of the FMS is more limited (performance of surveys) than the comprehensive focus of the SAPR (surveys as well as all the other SA responsibilities, such as financial management, data entry, and enforcement).

Following is a comparison of CLIA FMS and CLIA SAPR:

FMS	SAPR
1) limited to reviews of survey performance	1) comprehensive review of all SA responsibilities
2) focus: on surveys individually	2) focus: on surveys in the aggregate
3) gives feedback to SA about each survey	3) reviews how the SA utilized the FMS feedback
4) onsite verbal feedback(except look-behinds) and written feedback for each FMS	4) written summary report—annually
5) performed by CMS RO	5) performed by CMS RO
6) goal: well-performed surveys	6) goal: optimal performance of every S&C responsibility
7) where performed: onsite in lab	7) where performed: in SA and RO (via OSCAR reports or other data)
8) characteristics: recognize strengths, identify areas for improvement. RO support through educational and technical assistance, as needed. Not punitive. SA takes corrective actions in response to areas identified by the RO for improvement.	8) characteristics: same as FMS

Format and Protocol of the SAPR

The format of each criterion is identical:

- topic sentence summarizing the overall expected performance outcome
- Performance Indicators
- Method of Evaluation

- Performance Measurement
- Reference (e.g., SOM citations for the particular SA responsibilities)

Following is a step-by-step discussion of each task in the SAPR protocol.

Note: It may help the reader to refer to one of the Criteria while reading this section.

The SAPR has capsulated the major SA responsibilities into the following 13 **"Criteria":**

Personnel Qualifications	Ongoing Training Activities
Financial Management	Data Management
Completion of Workload Targets	Survey Time Frames
Survey Selection and Scheduling	Proficiency Testing Desk Review
Outcome-Oriented Survey Process	Principles of Documentation
Acceptable Plan of Correction	Enforcement
Complaints	

Each **"Criterion"** has a topic sentence that summarizes the overall expected performance outcome. Within each Criterion are **"Performance Indicators,"** which break down the overall performance outcome into manageable elements for review and correction, if needed. The Performance Indicators *en toto* equate to the overall expected performance outcome. Thus, if all the Performance Indicators are met, the overall expected performance outcome is achieved. For consistency in review, each Criterion specifies the **"Method of Evaluation,"** which lists various tasks for the CMS RO reviewer to complete, and probes (in the form of a question) for the reviewer to ponder in the course of reviewing the SA performance for that Criterion.

The next section is "**Performance Measurement.**"

PLEASE NOTE:

The SAPR is not an exhaustive evaluation and measurement of CLIA SA performance. Therefore, it is not the intent of the CLIA SAPR to treat the Performance Measurement (specifically, the "Performance Result") as a "score" or "grade." The purpose of performance measurement in the SAPR is to ascertain objectively:

- **whether the SA has fulfilled the expectations of the Criterion, as delineated in the performance indicators; and**
- **whether the SA must submit a written corrective action plan.**

The SAPR Performance Measurement has been designed for nationwide consistency in quantifying the data gathered about the SA performance, through the use of **Worksheets,** which have been tailored to each Criterion. (FY 2004 changes to the worksheets are in **Arial bold font**.) Some worksheets are quite simple to complete. The worksheet for Principles of Documentation, for example, can be completed in a short time because the Performance Indicators address whether and how the SA reviews Deficiency Statements. The RO reviewer does not make any computation regarding the quality of the individual Deficiency Statements. That computation is made by the SA, using a standardized formula, in the course of its internal review. Completion of the worksheet results in the **"Performance Result"** expressed as a percentage (%). Again, please keep in mind that the CLIA SAPR does not treat the Performance Result for each Criterion as a score or grade.

Next, the percentage in the Performance Result is compared to the percentage of the **"Performance Threshold"** listed for the Criterion. The Performance Threshold is another element of the SAPR designed for consistency in RO review. The Performance Threshold serves as a demarcation point; if the performance result is lower than the Performance Threshold, it is a signal for the RO reviewer to request the SA to submit a written corrective action plan for improvement. **Please note: The Performance Threshold percentage should not be considered as an expected level of performance.** When a SA's Performance Result is higher than the Performance Threshold, a written Corrective Action Plan is not requested; however, the SA is expected to continue to strive for improvement, because the goal is optimal performance. For example, if the SA's Performance Result is 91 percent and the Performance Threshold is 85 percent, the SA is expected to continue ongoing improvement efforts, even though a written Corrective Action Plan has not been requested. Further, when a SA's Performance Result is 100 percent, the efforts should not cease—they should be directed at sustained proficiency.

> We note here that the ROs have the option to request a Corrective Action Plan regardless of the Performance Result, if, in their judgment, it is needed to effect improvement. This prerogative is consistent with the RO's role in monitoring and facilitating SA performance of all survey and certification responsibilities. The overarching responsibility for program oversight is not superseded or limited by the structure of the SAPR.

The "**Corrective Action Plan**" need not be lengthy or complex, however it should reflect in-depth assessment by the SA and be suited to the extent of improvement needed. For example, if the SA is not reviewing PoCs, it will require a more extensive plan than if the SA has a review system set-up, but the review does not include participation by all the surveyors. The Corrective Action Plan must be written and indicate the following:

1) The action that will be taken.
2) How it will be instituted and how it will be monitored and evaluated to verify that the action was successful and complete.
3) The person responsible for completion of the corrective action.
4) The approximate timeframe or date of completion of the corrective action.

When designing corrective action plans, states should be mindful of the need to demonstrate success through positive outcomes.

Lastly, is the **"Reference,"** which indicates the authorities or sources (e.g., SOM citation) for the SA responsibilities. This assures the SAs that the subject matter of the review is indeed required. The Reference may also double as an informational feature for those who were otherwise unaware of a policy change or requirement.

Summary Report

The RO will summarize the results of the SAPR in a written report to the SA, noting areas of sustained proficiency as well as areas needing improvement. A copy of each report will be maintained in the CMS Central Office (CO) as documentation of the SA performance reviews. The data will be analyzed; initiatives aimed at professional development or performance improvement may be developed accordingly.

Sample Sizes

In several Criteria, the Method of Evaluation calls for selection of a sample. For consistency, we have prescribed the sample size. Usually it is rather small, however it may be increased if a fuller picture is needed. The size of the sample is not intended to be statistically valid. It is merely a snapshot of a specific area of performance for concluding whether improvement is needed. It is not intended to be an exact assessment or an in-depth assessment of the extent of improvement needed. The in-depth assessment is reserved for the SA, who knows its operations best, and can use that data to prepare an effective corrective action plan.

A Word About "Systems"

For SAPR review purposes, the term “system” is interchangeable with the terms “mechanism,” "process" or others that relate to the way a state organizes, completes and tracks the work for consistency with its CLIA survey and certification responsibilities. The "system" could be any mechanism that is effective and retrievable—from an automated system to a spiral tablet.

Feedback

CO welcomes SA and RO feedback or suggestions about any aspect of the SAPR, including the Worksheets. CO is also interested in ideas about automating the review.

CLIA State Agency Performance Review

FY 2004

REVIEW CRITERIA

Criterion # 1:	Personnel Qualifications
Criterion # 2:	Ongoing Training Activities
Criterion # 3:	Financial Management
Criterion # 4:	Data Management
Criterion # 5:	Completion of Workload Targets
Criterion # 6:	Survey Time Frames
Criterion # 7:	Survey Selection and Scheduling
Criterion # 8:	Proficiency Testing Desk Review
Criterion # 9:	Outcome-Oriented Survey Process
Criterion # 10:	Principles of Documentation
Criterion # 11:	Acceptable Plan of Correction
Criterion # 12:	Enforcement
Criterion # 13:	Complaints

Performance Review Criterion # 1: Personnel Qualifications

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

Performance Indicators:

1. Health Professional Qualifications as set forth in the SOM at 4009B.
2. Education, Training, and Experience as set forth in the SOM at 4009C.
3. Completion of SA orientation program based on a CMS-developed orientation program, as in SOM 4009-C.
4. Completion of a CMS-developed Basic Surveyor Training Course within the first 12 months of employment (4009-C);

   OR

   If a Basic Surveyor Training Course is not available within the first 12 months of employment: the individual has completed sufficient orientation for RO evaluation, and the SA ensures that the individual attends the next available Basic Surveyor Training Course.

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

Method of Evaluation:

1. Review SA mechanism/system/process for monitoring training.
2. Review surveyor personnel information (system, personnel files, etc.) to verify that the performance indicators are satisfied for each surveyor. If Performance Indicator #3 or #4 is not applicable to a newly hired individual, it should not be counted when computing the performance results.

Performance Measurement:

Performance Threshold: 100%

Corrective Action Plan Required if performance results are less than 100%.

Reference:

SOM: 4003.2; 4009 A-E; 4018; 6410

CMS Program Memorandum – September 24, 1992; CMS Program Memorandum – December 3, 1992

Budget Call Letter

1864 Agreement: Article IV; Parts A - Organization, B – Personnel; Article V - C; Evaluation

Performance Review Criterion # 2: Ongoing Training Activities

The SA has implemented a plan of ongoing training activities aimed at continuously improving the performance of its survey and certification activities.

Performance Indicators:

1. For all surveyors (full-time, part-time, contract), the SA utilizes feedback or information from the following sources to improve survey skill level:
    a. RO comments after SA orientation
    b. Federal Monitoring Survey
    c. RO review of any CMS-2567s
    d. SA internal review of Deficiency Statements for consistency with Principles of Documentation.
    e. SA internal review of Plans of Correction for consistency with Criteria for Acceptability

2. The SA has on-going activities focused on:
    a. Reducing inconsistencies in interpretation of the regulations
    b. Ensuring surveyor adherence to the SOM
    c. Improving individual surveyor skills, as needed.
    d. Measuring progress in improving surveyor skills (data from SoD review, PoC review, others).

3. [OPTIONAL—ONLY REVIEW PI #3 in FY 2004 if SA has had performance indicator #2 in effect for a year or more] The SA evaluates the effectiveness of the training for each surveyor and modifies as necessary the modes and content based on the evaluation results.

4. All SA surveyors (full-time, part-time, contract) attend CMS mandatory training.

5. The SA provides opportunities for enhancing professional expertise through various modes such as in-service education; state and/or CMS RO conferences; classroom training; seminars and workshops; and survey skill development through observing or accompanying federal or other state surveyors.

6. For all non-surveyors in the CLIA program, the SA has an ongoing training program aimed at improving the quality of each individual's contribution to the SA's overall performance.
    a. Non-surveyor staff have access to the Data Entry Users Guide and are trained on CMS policies and system programming updates.
    b. The training program identifies each non-surveyor's training needs and includes direct input from the non-surveyor staff.

Performance Review Criterion # 2: (continued)

Method of Evaluation:

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 training activities and should apply the performance indicators in a manner that is reasonable for the particular SA administrative and operational set-up.

1. Select a sample of surveyors and non-surveyors. In a state with 1-10 staff, select all staff for review. In states with greater than 10, select 10. If sample size is insufficient to make a determination, expand the sample as needed.

2. Review SA's process for review and training activities.
    a. Review for attendance at CMS mandatory training.
    b. Ask the SA to demonstrate how they utilize the feedback and information from the sources listed in performance indicator #1.
    c. Ask the SA to show how they focus on items listed in performance indicator #2.
    d. Does the SA evaluate the effectiveness of the training program? [Review only if Performance Indicator #3 is applicable.]

3. Interview staff (surveyor, non-surveyor) to determine the following:
    a. Does the SA consider suggestions/input from staff for training needs?
    b. Is there discussion on SA/RO feedback on survey findings with staff?
    c. Are actions taken to improve the Statements of Deficiencies written by each surveyor and does the SA evaluate the effectiveness of those actions?

Performance Measurement:
Performance Threshold: 90 percent
Corrective Action Plan Required if performance results are less than 90 percent or if the SA has not implemented a training plan.

Reference:
SOM: 4003.2; 4009; Sections C & D; 6410
1864 Agreement: Article IV, Section B - Personnel; Article V – Evaluation, Section C-8, 13

Performance Review Criterion #3: Financial Management

The SA has effective financial management and ensures that CLIA survey and certification financial responsibilities are carried out in accordance with CMS policies.

Performance Indicators:

1. The SA completes the budget reports–HCFA 102, HCFA-105, HCFA-1465A and HCFA-1466--in accordance with:
    a) the instructions in the State Operations Manual (form completion); and
    b) the Budget Call Letter /related instructions (content).
2. The SA submits the required quarterly expenditure reports timely*.
3. The equipment purchases listed on the HCFA-1466 are used for the CLIA Program as reported.
4. The SA staff positions (professional and clerical) listed on the HCFA-1465A are occupied as reported.

* Consider "timely" as up to 45 days after the end of each quarter (SOM 4740)

Note: Hard copy budget forms are no longer utilized—electronic system is in effect.

Method of Evaluation:

1. Review budget report submissions, HCFA-102, HCFA-105, HCFA-1465A, HCFA-1466, and verify that they were completed in accordance with the SOM instructions and Budget Call letter—electronic submission required.
2. Verify that the quarterly expenditure reports were submitted timely.
3. Verify that the equipment purchased for the CLIA program is being used consistent with HCFA-1466.
4. Verify that CLIA SA staff positions listed on the HCFA-1465A are occupied as reported.

Performance Measurement:

Performance Threshold: 85 percent.

Corrective Action Plan Required if the performance results are less than 85 percent.

Reference:

1864 Agreement: Article V-Evaluation: C-9, 10; Article IX-Cost of Administration, Section M
SOM: 4500; 4600; 6400: Special Procedures for Laboratories; Budget & Administration
Annual CLIA Budget Call Letters

Performance Review Criterion # 4: Data Management

The SA has mechanisms in place to ensure that the OSCAR data is accurate and current.

Performance Indicators:

1. Data entry policies and procedures are current, available, and in use by all staff who enter data into the system.
2. SA assists the RO/CO on OSCAR/ODIE projects as requested.
3. The SA has a mechanism for identifying and resolving data entry problems.
4. The following types of data are entered accurately:
    a) CMS-116
    b) CMS-2567, CMS-670, CMS-1557
    c) Certificate changes
    d) Updates/changes for name, address, telephone number, laboratory director, specialty, total volume, voluntary & involuntary closures, and reactivations.
5. The following types of data are entered within specified timeframes: [See NOTE in Method of Evaluation]
    a) Complaints within 45 days of date of survey
    b) CMS-116: reasonable time
    c) Updates/changes for name, address, telephone number, laboratory director, specialty, total volume, voluntary & involuntary closures, , and reactivations: reasonable time
    d) CMS-2567, CMS-670, CMS-1557: reasonable timeframes

Method of Evaluation:

1. Select a sample of 15 CLIA numbers for which data was entered during the fiscal year under review. If the sample doesn't include at least 2 (each) initial surveys, recertification surveys, complaints, certificate changes or updates, substitute other CLIA numbers so that the sample includes this combination, when feasible (**exclude validation surveys and AQAS for FY2004).** Expand the sample for further examination of specific fields or types of information, if warranted by the particular circumstances in a state (e.g., check the accuracy of telephone numbers if there were statewide changes in area codes, or focus further on complaints if there is a history of complaints not being entered into the system)

NOTE: The review of performance indicators #5b, c and d is informational only and can serve as a baseline for the state. When calculating the performance results for this Criterion, only factor in the review results for #4a, b, c, d and #5a; do not factor in the results for PI # 5b, c, and d.

Since the SOM currently does not prescribe timeframes for most CLIA data entry actions, the timeframes listed below can be considered as "reasonable" and can serve as benchmarks for the states until a formal policy is issued by CMS.

CMS-116 -- up to 15 days after receipt by the SA
CMS-2567, CMS-670, CMS-1557 -- up to 45 days after the date of survey
Certificate changes and updates -- up to 45 days after receipt by SA

Performance Review Criterion # 4 (continued)

In instances where a significant number of data entries are well beyond the "reasonable" timeframes, and, in the judgement of the RO, improvement efforts are unlikely without formal notification, the RO may request a corrective action plan.

1. Does the SA use the ODIE Pending Field; AQAS Sent date?
2. Does the SA have a monitor in place to track AQAS, AQAS verification surveys?

NOTE: Disregard AQAS for FY 2004. No AQAS is performed.

3. If data-entry problems were identified through RO monitoring, did the SA take action to correct the situation?
4. Review personnel files/interview data entry personnel regarding the data entry policies and procedures in use.
5. Are personnel proficient in retrieving user-defined as well as standard OSCAR/ODIE reports?

Performance Measurement:
Performance Threshold: 95 percent
Corrective Action Plan Required
if performance indicator #1 is not met,
if performance indicator #3 is not met, or
if the performance results are less than 95 percent

NOTE: FY 2004—Form 209 and CHOWs were removed from the review due to difficulties in obtaining data for SAPR purposes.

Reference:
SOM Sections 4149; 6136; CLIA Program Memoranda*;* OSCAR Data Entry Users Guide

Performance Review Criterion # 5: Completion of Workload Targets

The SA completes workload targets as specified in budget call letter (form HCFA-105) or RO-approved amended HCFA-105.

Performance Indicators:

1. Meets the number of initial surveys.
2. Meets the number of recertification surveys.
3. Meets the number of AQAS surveys (10 percent number of surveys/budget call letter)*.
4. Meets the number of AQAS Verification Surveys (10 percent number of surveys/budget call letter).
5. Meets the number of validation surveys/one simultaneous, when feasible.
6. Meets the number Certificate of Waiver (COW) Survey Project (2 percent of total number of COW labs)
7. Meets the minimum productivity level of 120 surveys (112 initial/8 follow-up) per surveyor per year.

NOTE: No AQAS performed in FY 2004 AQAS. Exclude AQAS and AQAS verification from the review.

Method of Evaluation:

Note: The Budget Call Letter is an estimate because of daily fluctuations in the laboratory universe, facility locations, and certificate types. When an SA can demonstrate the accuracy of their completed workload, even though the numbers differ from those in the Budget Call Letter, consider the performance indicator as met.

* In some states, the number of laboratories that qualify for AQAS may be fewer than 10 percent. In those states, if the state performed AQAS on all that qualified, count the performance indicator as met.

1. Review Budget Call Letter or HCFA-105 for target values.
2. Tally the total number of completed surveys from the SA's monthly workload reports.
3. Review the CMS-670 forms **or other reliable information** to verify that each surveyor performed the minimum number per FTE.

Performance Measurement

Performance Threshold: 95 percent
Corrective Action Plan required if the performance results are less than 95 percent.

References:

SOM: 4010; 4011; 6100; 6112 – 6114; 6420, 6422, Budget Call Letter
1864 Agreement, Article V-section C

Performance Review Criterion # 6: Survey Time Frames

The SA has implemented a tracking system to ensure that the survey time frames are met.

Performance Indicators:

1. Initial Surveys: Conducted no earlier than 3 months (90 days) of data entry date of the CMS-116 (or if State Law has different requirements). [June 18, 1996 CO Memorandum]
2. Recertification Surveys: Conducted no later than 6 months (180 days) prior to the expiration date of the current certificate.
3. AQAS surveys: Conducted no later than 6-months (180 days) prior to the expiration date of the current certificate.
4. AQAS Verification Surveys: Conducted no later than 60 days after the AQAS survey in the SA.
5. Validation surveys: Conducted no later than 90 days after the accreditation inspection date.

NOTE: No AQAS performed in FY 2004. Exclude AQAS and AQAS verification from the review.

Method of Evaluation:

1. Select a sample to review for each category as follows:
   a) Initials: 10 or 10 percent of the total number of initial surveys, whichever is higher.
   b) Recertification Surveys: 10 or 10 percent of the total number of recertification surveys, whichever is higher.
   c) AQAS surveys: If the AQAS total is less than 10 surveys, review all surveys. If 10 or more, review 10.
   d) AQAS Verification Surveys: Review all surveys.
   e) Validation Surveys: If the validation total is less than 10, review all. If 10 or more, review 10.
2. Review SA's tracking method/system/mechanism for ensuring survey time frames are met.
3. Use OSCAR or other information to determine number of labs not surveyed prior to certificate expiration date.
4. Use OSCAR or other information to ascertain average time intervals between survey dates.

NOTE: Exclude Method of Evaluation 1(c) and (d) from FY 2004 review.

Performance Measurement

Performance Threshold: 85 percent
Corrective Action Plan Required if the SA does not have a tracking mechanism or if the performance results are less than 85 percent.

Reference:
1864 Agreement, Article V, Section C; AQAS Protocol; Validation Survey Protocol

Performance Review Criterion # 7: Survey Selection and Scheduling

The SA selects and schedules surveys according to Federal policy and instructions.

Performance Indicators:

1. Selections for AQAS Surveys as made in accordance with SOM 6112.
2. Selections for onsite follow-up visits are made in accordance with the SOM (usually condition-level deficiencies -- SOM 6132 and Budget Call Letter).
3. Selections for mail/telephone follow-ups are made in accordance with the SOM (usually standard-level deficiencies -- SOM 6132 and Budget Call Letter).
4. When scheduling, surveys are clustered for geographical proximity (SOM 6102).
5. COW surveys are incorporated into the routine scheduling (and geographical clustering, when possible) of the entire survey workload (Budget Call letter).
6. Improvement action is taken in response to FMS feedback, if any, about survey selection or scheduling efficiency, e.g. laboratory is requested to complete forms and have certain records available upon surveyor's arrival.

NOTE: No AQAS performed in FY2004. Exclude AQAS from the review.

Method of Evaluation:

1. Interview staff to determine how the SA schedules surveys.
2. Pull a sample of AQAS surveys. If AQAS total is less than 10, review all. If 10 or more, review 10.
    a. Run OSCAR Report 155, 96. Do labs selected meet criteria?
    b. Compare CMS-670 to verify AQAS survey was actually performed.
3. Pull a sample of 10 follow-up visits from OSCAR and/or enforcement log.
    a. Determine if onsite follow-ups were completed for condition-level deficiencies, (excluding conditions out for PT enrollment)
    b. Determine if mail follow-ups were completed for standard-level deficiencies and resolved within 12 months.
4. Select a sample of 10 trips that involved travel to 2 or more laboratories, and determine if the visits were clustered for geographical proximity. If not proximate, verify that clustering was precluded by the scheduling priorities of SOM 6102, and count the performance indicator as met. Verify that COW surveys are incorporated into the scheduling, and geographical clustering when possible.
5. Review FMS feedback regarding survey selection and scheduling efficiency. In announced surveys was the laboratory requested to complete forms and have records available for surveyor? What action was taken in response to any feedback noting area for improvement?

NOTE: Exclude Method of Evaluation #2 from FY 2004 review.

Performance Measurement:
Performance Threshold: 85 percent
Corrective Action Plan Required if the performance results are less than 85 percent.

Reference:
1864 Agreement, Article V, section C; Article 11, Sections A1; B, E, C1
SOM: 6100 – 6106; 6112; Appendix C, C-4; Budget Call Letter

Performance Review Criterion # 8: Proficiency Testing Desk Review

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

Performance Indicators:

1. The SA has implemented a mechanism to track PT failures.
2. First Unsuccessful Participation: The SA is able to:
    a. Identify
    b. Prepare timely notification of PT failures to the laboratory
    c. Prepare CMS-2567
    d. Notify the laboratory to get training/technical assistance, as appropriate
    e. Track each case to completion/resolution
3. Second Unsuccessful Participation: The SA is able to:
    a. Identify
    b. Prepare timely notification of PT failures to the laboratory
    c. Prepare CMS-2567
    d. Apply PT failure sanctions, when appropriate
    e. Track each case to completion/resolution

Method of Evaluation:

1. Review the SA tracking mechanism.
2. Select 15 PT Desk Reviews.
    a. Include a cross-section of first and second unsuccessful participation in the review
    b. Review correspondence and CMS-2567s
    c. Have the PT failures been resolved?
    d. Has the SA initiated sanctions action when required?

Performance Measurement:

Performance Threshold: 85 percent

Corrective Action Plan Required if the SA has not implemented a mechanism to track PT failures or the performance results are less than 85 percent.

Reference:

1864 Agreement Article II, Section E
SOM 6054 - 6058
Budget Call Letter

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

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

Performance Indicators:

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

Method of Evaluation:

1. Select a sample of observational and participatory FMS surveys. If 1-10 were performed, review all. If more than 10 were performed, review 10. In states with more than one surveyor, ensure that all surveyors are represented in the sample, whenever possible. Review the correspondence containing the feedback about the surveys in the sample along with the FMS review checklists.
    a. Do the FMS surveys demonstrate use of OSP by the SA surveyors?
    b. Do the FMS surveys and CMS-2567 review indicate surveyors' proficiency in assessing outcome?
2. Review the SA's mechanism for communicating SOM directives, changes to surveyors.
    a. Select a couple of major program directives or SOM issuances and interview survey staff to determine whether they received them and are familiar with them.
3. Interview surveyor and/or supervisor to ascertain whether and how the SA utilizes the FMS feedback to identify areas for improvement in conducting outcome-oriented surveys.

Performance Review Criterion # 9 (continued)

Performance Measurement:
Performance Threshold: 95 percent
Corrective Action Plan Required if any of the following apply:

the average of the performance results for performance indicators #1– #5 is less than 95 percent

the performance result for performance indicator # 1 is less than 100 percent

the performance result for performance indicator # 2 is less than 100 percent

References:
SOM Section 4018: Regulatory Role of Surveyor & Consultation
1864 Agreement

Article V-Evaluation; Section C

Article II – Functions To Be Performed by the State; Sections A-1; C; E

SOM Appendix C: Survey Procedures & Interpretive Guidelines for Laboratories & Laboratory Services,
SOM 6100 - 6108

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

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

Performance Indicators:

1. The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the PoD on an on-going basis. In States with fewer than 100 SoD annually, 10% or 10, whichever is higher, are reviewed. In states with 100 or more SoD annually, at least 50 are reviewed.
2. The SA SoD review process includes participation by all surveyors, as an opportunity for skill improvement.
3. Specific area(s) of improvement identified in RO feedback (FMS and other RO reviews of SoD), if any, are incorporated by the SA into their SoD review process.
4. The SA compares results periodically (e.g., quarterly, semi-annually) to track progress of surveyor improvement or to document sustained proficiency in SoD.
5. The SA SoD review identifies the areas of improvement for each surveyor, as needed.
6. The SA SoD review process quantifies* and documents the state-wide results annually so that the state can compare results across federal fiscal years.

   *** For standardization, all states should derive their results by dividing 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.**

Method of Evaluation:

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

1. Ask the SA for an overview of their review system and/or other review activities they may use, and documentation of their review findings during the past year. Seek sufficient information about the review system to determine whether the performance indicators are met.
2. Has the SA correctly identified the areas of improvements needed for each surveyor's Statements of Deficiencies? [Indicate in comments if needs are not correctly identified].
3. For the record, obtain a copy of the annual state-wide results of the SoD review, as documented by the SA.

Performance Measurement:
Performance Threshold: = 100 percent
Correction Action Plan Required if the performance results are less the 100 percent.

Reference:
SOM: 6130; Appendix C
Laboratory Principles of Documentation

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

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

Performance Indicators:

1. * The SA reviews the PoCs for consistency with former SOM 6130 for FY 2004 --"The plan must be specific and timeframes realistic, stating exactly how the deficiency will be corrected or how it was corrected." [In FY2005, use the Criteria for Acceptability.] In States with fewer than 100 PoC annually, 10% or 10, whichever is higher, are reviewed. In States with 100 or more PoC annually, at least 50 are reviewed.
2. The SA PoC review process includes participation by all surveyors, as an opportunity for skill improvement.
3. Specific area(s) of improvement identified in RO feedback (FMS and other RO review of PoC), if any, are incorporated by the SA into its PoC review process.
4. The SA compares results periodically (e.g. quarterly, semi-annually) to track progress of surveyor improvement or to document sustained proficiency in PoC acceptance.
5. The SA PoC review identifies the areas of improvement for each surveyor, as needed.
6. The SA PoC review process quantifies** and documents the state-wide results annually so that the State can compare results across federal fiscal years.

**** For standardization, all states should derive their results by dividing the total number of D-tags that meet the Criteria for Acceptability by the total number of D-tags cited on the CMS-2567's reviewed.**

Method of Evaluation:

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

1. Ask the SA for an overview of their review system and/or other review activities it may use, and documentation of its review findings during the past year. Seek sufficient information about the review system to determine whether the performance indicators are met.
    a. Does the SA provide guidance to SA surveyors on what is an acceptable PoC?
    b. Are the surveyors skilled in instructing the laboratories how to complete an acceptable PoC?
    c. Does the review process utilize the FMS feedback about surveyor's instructions to laboratory at the exit conference?
2. Has the SA correctly identified the areas of improvements needed for each surveyor for acceptable PoCs? [Indicate in comments if needs are not correctly identified].
3. For the record, obtain a copy of the annual state-wide results of the PoC review, as documented by the SA.

Performance Measurement:

Performance Threshold: 100 percent

Corrective Action Plan Required *if the performance result is less than 100 percent.*

References: SOM 6130 for FY2004; SOM Appendix C; [PoC Criteria for Acceptability for FY2005]

Performance Review Criterion # 12: Enforcement

SA has a process to ensure consistent application of policies and procedures for determining non-compliance and recommending appropriate sanctions to the RO.

Performance Indicators:

1. The SA surveyors adhere to the SOM instructions when taking enforcement actions.
2. The SA has a mechanism in place for tracking enforcement actions and for meeting time-frames and modifications are made to it in response to FMS feedback, when warranted.
3. SA surveyors are able to correctly identify immediate jeopardy.
4. SA surveyors are able to correctly identify non-immediate jeopardy.
5. Action is taken when FMS feedback indicates improvement is needed in a surveyor's ability to differentiate between immediate jeopardy and non-immediate jeopardy.
6. SA surveyors correctly identify that certain enforcement actions require RO referral, such as the following:
    a. Improper referral of proficiency testing
    b. Failure to submit PoC
    c. Failure to correct all deficiencies within 12 months (unaccredited laboratories)
    d. Failure to provide requested information
7. The SA correctly requests credible allegations of compliance for condition-level enforcements.
8. In surveys of accredited laboratories (validation surveys or complaint investigations), the SA correctly requests plans of correction for condition-level deficiencies only. NOTE: This indicator is informational only; if this task is delegated to the SA, comment, but exclude from Performance Measurement.
9. The SA sends enforcement letters for unsuccessful participation in proficiency testing.

Method of Evaluation:

1. Ask the SA for an overview of the mechanism for tracking enforcement actions and meeting time frames.
2. Select all or 10, whichever is fewer, enforcement actions on 90-day track and determine whether the performance indicators are met.
    a. Has the SA surveyor correctly identified jeopardy situations?
    b. Has the SA followed SOM notification procedures?
    c. Did the SA conduct a revisit to assess compliance and was it appropriate for the severity of the condition-level deficiencies?
3. Select all or 10, whichever is fewer, enforcement actions forwarded to the RO for processing (23-day track) and determine whether the performance indicators are met.
    a. Did the SA follow SOM notification and process procedures?
    b. Has the SA correctly identified jeopardy situation?
    c. Review enforcement related actions/correspondence.
4. For those enforcement actions reviewed, did the deficiencies, as written, support the sanction/enforcement recommendations? [If not, indicate in comments for Criterion on PoD]

Performance Review Criterion # 12 (continued)

5. Based on FMS information, did the SA surveyors identify jeopardy situations consistent with the survey findings?
6. Review the CLIA monthly workload report. Is the SA reporting PT failure sanctions (technical assistance/training)?

Performance Measurement:
Performance Threshold: 90 percent
Corrective Action Plan Required if any of the following apply:
if the performance results are less than 90 percent
if performance indicator # 1 is not met
if performance indicator # 2 is not met

References:
1864 Agreement Article V, Section C
SOM 6250 – 6316

Performance Review Criterion # 13: Complaints

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

Performance Indicators:

1. The SA has a mechanism to track complaints from receipt to resolution.
2. The SA surveyors adhere to the SOM instructions for complaints.
3. The SA acknowledges and notifies complainant.
4. The SA triages/evaluates complaints for proper disposition.
    a. SA conducts investigations for the following only when authorized by the RO: COW, PPMP, COA, Facilities testing w/out a certificate
    b. Forwards all COA complaints received in the SA to the RO for disposition.
    c. Forwards to another agency (OIG, FDA, OSHA, another SA as required by law, etc), as necessary.
5. Complaints are scheduled in accordance with established procedures/priorities.
6. Complaint investigations are:
    a. Conducted in accordance with established time-frames from CMS-2802A form.
    b. Unannounced.
7. The SA takes appropriate post-investigation actions.
8. There is resolution and closeout of each complaint.

Method of Evaluation:

1. Review the SA mechanism for logging in and tracking complaints.
2. Interview staff to determine how complaints are handled. Verify their understanding that ALL COA complaints must be forwarded to the RO for disposition. Also verify that all staff are aware of the need to closely coordinate with the RO when SA is delegated the complaint for action, especially when problems have attracted media attention.
3. Review some complaints. If the total number of complaints is 1 – 10, review all. It the total number is more than 10, review 10. Follow their paths through the SA tracking system and determine if the applicable performance indicators are met. Verify that each complaint investigation was entered into the data system as substantiated or unsubstantiated.
4. Review CMS-2802A to verify RO authorization.

Performance Measurement:

Performance Threshold: 90 percent

Corrective Action Plan Required *if either of the following apply:*

performance indicator #1 is not met

if the performance results were less than 90 percent

References:

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

SOM: 6136 – 6138; 6174 – 6184