

DATE: August 8, 2002

Ref: S&C-02-38

FROM: Director
Survey and Certification Group
Center for Medicaid and State Operations

SUBJECT: Final Guidance Package for Clinical Laboratory Improvement Amendments of 1988 Federal Monitoring Survey Process (CLIA-FMS)

TO: State Survey Agency Directors

The purpose of this note is to provide your organization a courtesy copy of our most current version of the CLIA-FMS package. The attachment parallels what was previously presented during the Spring of 2002. The intent of the package is to also identify the fulfillment of the State agency (SA) training needs to improve the survey process and provide the RO and Central Office documentation of SA oversight to ensure appropriate follow-up occurs.

The protocol has been disseminated to each of our CLIA Regional Offices (RO) as part of achieving consistent use of the FMS process by the CLIA RO Laboratory Consultants for the CLIA State Agency surveyors. All CLIA RO Consultants are expected to use this package as a basic foundation in order to achieve consistent application of the CLIA-FMS process. The guidance package will become effective during July 2002. The CLIA-FMS will ultimately become an essential piece of the comprehensive State Agency Performance Review for CLIA currently under development.

If you have any questions about the information contained in this package, please call me at (410) 786-3407 or email me at www.jyost@cms.hhs.gov.

Steven A. Pelovitz

**Clinical Laboratory Improvement Amendments of 1988 (CLIA) -
Federal Monitoring Surveys (FMS)
National Guidance Package**

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**Clinical Laboratory Improvement Amendments of 1988 (CLIA) -
Federal Monitoring Surveys (FMS)
National Guidance Package**

A. Introduction.

The purpose of this package is to provide standardized guidance that creates consistency among Regional Office (RO) surveyors in selecting, conducting, documenting and providing feedback about CLIA-FMS surveys. This guidance can be enhanced by the RO as necessary; however, certain elements will be required for all CLIA-FMS. The guidance package will be used to assess State Agency (SA) surveyor performance during Observational, Participatory, and Comparative surveys for the selected laboratory. The role of the RO surveyor is to obtain enough information to provide an objective assessment about the SA surveyor's adherence with required performance factors as part of determining compliance with CLIA requirements surveyed.

B. Goal and Intent of the CLIA-FMS

The primary goal of the CLIA-FMS is to monitor each SA surveyor's use and performance of the CLIA Outcome-oriented Survey Process (OSP) to determine training needs, to provide timely feedback for surveyor education and to improve survey process performance. Verbal and written feedback from the RO surveyor is to be provided in an objective and constructive manner. A key to providing objective and constructive feedback is identifying surveyor's strengths as well as areas for improvement as part of providing feedback.

RO surveyors perform CLIA-FMS surveys for the following purposes:

- Monitoring and improving SA surveyor performance: interpreting regulatory requirements, applying survey policies and procedures, using the Principles of Documentation, assessing compliance with the CLIA requirements, and conducting the CLIA OSP for laboratories;
- Identifying training and/or technical assistance needs of a surveyor such as assessing the surveyor's ability to identify issues pertinent to test results and patient outcome;
- Identifying and resolving any problems that may arise for a surveyor, and/or a laboratory; and
- Providing documented feedback to the SA, RO and Central Office (CO).

C. Overview of the CLIA-FMS Guidance Package

- Skill Sets (Exhibit A). Exhibit A contains information about four sets of key survey skills that are to be exhibited in efficient and effective surveys. All of the skill sets (Organization, Communication, Information

Gathering, and Investigation) are interrelated. This can also serve as a reference document for the State Agencies and State surveyors.

- CLIA-FMS Review Criteria (Exhibit B). This is a summary of the activities of the OSP, other State Operations Manual (SOM) policies and procedures; and various responsibilities necessary for performing survey activities effectively.
- Examples of Comments (Exhibit C). This exhibit includes comments that may be used as part of the written feedback to the SA supervisor and the SA surveyor regarding the RO surveyor's assessment and findings. The examples within Exhibit C are **hypothetical** illustrations of surveyor performance.

D. CLIA-FMS Survey Types

A description of the 3 types of CLIA-FMS is as follows:

1. The Observational CLIA-FMS is a survey in which the RO surveyor accompanies the SA surveyor and interacts as necessary during the survey process. The interaction is also intended to provide guidance at the appropriate times during the survey process. The RO surveyor and SA surveyor communicate about findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.

The RO surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA regulations, policies, and the OSP. It is important that the RO surveyor communicates and interacts in a neutral non-judgmental manner, providing objective and constructive feedback about the SA surveyor's strengths and weaknesses. The SA surveyor prepares the Form CMS/HCFA-2567 after discussing the deficiencies with the RO surveyor.

2. The Participatory CLIA-FMS is a survey in which the RO surveyor observes the SA surveyor 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 OSP, regulations, and policies. The Participatory FMS also affords an opportunity for the RO surveyor to demonstrate a different survey approach when deemed necessary. The goal is to jointly identify deficiencies by the RO and the SA surveyor. Both the SA and RO surveyor collaborate on a final compliance determination when there are different conclusions.
3. The Comparative CLIA-FMS is a survey in which the RO surveyor surveys the laboratory after the SA surveyor, preferably within 30 days but no later than 60 days and afterwards compares the deficiency citations to those of the SA surveyor, those of the SA surveyor. 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 the separate surveys. If an issue arises, then the RO surveyor must contact the SA surveyor for clarification.

E. Considerations for Selecting and Planning the CLIA-FMS

Generally, when an adverse action has been initiated against a laboratory, the laboratory it is not scheduled for a CLIA-FMS. However, the Comparative CLIA-FMS may be conducted as the revisit survey. RO surveyors should have an idea of the amount of data system consultation that the SA will need prior to the selecting the type of CLIA-FMS to be used. Complaint surveys are always acceptable as FMS for Observational or Participatory, but should be performed no later than 60 days of the State survey.

F. Conducting the CLIA-FMS

1. Select the SA surveyor and laboratory facility.
2. Determine the type of CLIA-FMS (Observational, Participatory, or Comparative) that is to be performed.
3. Schedule the survey.
4. Use the CLIA-FMS Review Criteria (Exhibit B), as applicable, for the survey.
5. Provide verbal feedback to the surveyor at the conclusion of the survey.
6. Provide written feedback to the surveyor and SA supervisor (immediate, annual, and CO).

G. Feedback to the SA Surveyor and the SA Supervisor.

The primary objective of the feedback on the CLIA-FMS process is to identify and document individual surveyor skill, training and/or technical assistance needs and pertinent strengths, in order to facilitate ongoing performance improvement. Therefore, the RO surveyor **must** provide verbal feedback to the SA surveyor at the conclusion of every Observational/Participatory CLIA-FMS.

1. Verbal Feedback. The RO surveyor provides the SA surveyor with objective and constructive verbal feedback based on the CLIA-FMS Review Criteria (Exhibit B) and Skill Sets (Exhibit B). The feedback should include remarks on strengths and areas for improvement noted in the comment section of the CLIA-FMS Review Criteria; i.e., effective use of OSP and Principles of Documentation (POD). Following a Comparative survey, the RO should contact the SA surveyor regarding specifics noted in the CLIA-Review Criteria.
2. Written Feedback. No later than 45 days after the survey, the RO surveyor sends written feedback to the CLIA SA supervisor and a courtesy copy to the surveyor. The written feedback includes the RO's assessment based on the

CLIA FMS Review Criteria (Exhibit B) and the skill sets (Exhibit A), any recommendations to the SA and reflects the verbal feedback given to the surveyor following the survey. See Exhibit C for examples of comments about hypothetical findings and recommendations. For Observational and Participatory surveys, the letter **must** include specific comments regarding the surveyor's training needs and specific recommendations where appropriate in relationship to the minimum Skill Sets, FMS Review Criteria, Principles of Documentation, and the CLIA OSP. For Comparative surveys, the letter must include specificity about only those review criteria that can be assessed without the SA surveyor present, as well as the results of the comparison of deficiency citations.

G. Annual Report to SA

The RO sends the SA Supervisor (an a courtesy copy to CO) an annual summary report of the CLIA-FMS Reviews and any other findings related to the intent of CLIA-FMS as found in section B of this package. The report must incorporate a summary assessment of each SA surveyor's utilization of the CLIA OSP, POD and skill sets and ability to determine CLIA compliance, with an assessment of the surveyor's knowledge of and adherence to, pertinent CLIA policies and procedures. The report also requests a report deadline for SA response that indicates the specific activities and timeframes for addressing each surveyor's skill, technical assistance, and/or training needs.

H. Feedback to CO.

CO requests to be notified whenever training needs are identified, or policy and/or procedure clarifications are needed. Other significant findings or issues should also be brought to the attention of CO so that training modifications, training refreshers, and policy clarifications can be made and distributed. Compilation of each RO's reports will provide an overview of proficiency in performance of the OSP, POD, and skill sets and identify local and/or pervasive training needs.

EXHIBIT A Skill Sets

The Regional Office's (RO) role is to obtain sufficient information to make an appropriate determination regarding the surveyors' adherence to CLIA policies and procedures.

An additional aid for the RO to determine skill and training needs for the SA surveyor(s) are the 4 skill sets which can be used as a guide for improvement, not only for the RO, but also for the SA and surveyors. The RO may identify other applicable skills during their FMS reviews and should apply good judgement in their recommendations to the SA in these supplemental areas for improvement on education and/or training. The skill sets include organization, communication, information gathering, and investigation and are summarized below. Each of the 4 types of basic skill sets are interrelated and are part of performing the various CLIA survey functions/activities effectively. All 4 skills need not be separately observed; rather a single situation may demonstrate one or more skills simultaneously.

Organization Skill:

This skill is necessary to coherently and consistently adhere to the CLIA OSP. Surveyors that organize their survey activities exhibit professionalism, confidence, and credibility. Every aspect of a survey provides an opportunity to collect information consistent with the purpose of the survey and to conduct the survey systematically. Although there is a broad base of sensory input and other distractions, it crucial that the surveyor(s) remain focused during the survey process, and also observe relevant information and adapt as needed.

Although organization lends itself to certain variables from person to person, the SA surveyor should make efficient use of costly survey time by demonstrating an ability to function in an orderly and structured fashion. For example, the surveyor's ability to put together his/her survey notes and survey information would facilitate his/her decision on the laboratory's compliance with a particular requirement.

The following considerations are important in the RO's assessing the surveyor(s)' ability to demonstrate organization and providing objective and constructive RO feedback regarding this skill:

- There is a survey plan that has been well thought out, relevant information is available, and the survey approach has been developed prior to conducting the survey;
- The plan is followed, but adjustable, as needed;
- The plan is realistic and promotes efficient time management.
- Determination of compliance is accurate and timely.

Communication Skills:

This skill is necessary to express oneself effectively, verbally and in writing, and is required for the successful exchange of ideas and information. Basic keys to effective communication are

active listening, using appropriate body language and diplomatically handling difficult people and/or situations.

Being professional and courteous adds to the surveyor's credibility. Communicating positive feedback on the laboratory's commendable practices also adds to the surveyor's credibility and serves as a foundation of success on which the laboratory can build. The surveyor(s) should demonstrate the ability to communicate effectively to all appropriate parties throughout the entire OSP.

- Pre-survey Preparation: The RO surveyor can determine whether or not the pre-survey preparation was effective even though the RO surveyor does not directly observe these activities. The RO surveyor can inquire and discuss the SA's pre-survey activities at the outset of the FMS.
- Entrance Interview: The relationship between the surveyor(s) and the laboratory facility is validated during the entrance interview/conference. Confident, clear, complete and concise communication is crucial to establish and maintain a professional reviewer's role. The surveyor(s) provides the laboratory the plan and approach for the survey at this time.
- Information Gathering: While information gathering includes techniques for observation, interviews, and record review, effective interviews are conducted to obtain facts or specific and pertinent information. Communicate and clarify findings with the personnel directly involved in the issues being investigated. All interview questions should be clear, concise, open-ended, and non-threatening. Surveyor's notes and information gathering should be sufficient to formulate the statement of deficiencies.
- Outcome Assessment: The surveyor(s) should use common sense, professional judgment, and relevance (a.k.a. CPR) and the decision should be based on the flow chart(s) in the OSP. Each member of the survey team should agree with the assessment of the findings. If problems are found or not enough information is completed to make a determination of outcome, the SA should expand the investigation accordingly.
- Exit Conference: This allows the surveyor and laboratory facility to discuss the survey findings and intended recommendations to certify, re-certify, etc. The exit conference provides the entity an opportunity to provide additional information. Instructions are provided regarding timeframes and contact persons to ensure that a complete and acceptable Plan of Correction (PoC) is submitted.
- Development of the Statement of Deficiencies: The surveyor promptly chooses the most appropriate regulatory citation and writes the citation in an accurate, complete, clear, and concise manner following the Principles of Documentation. The citations should facilitate the laboratory's ability to provide a credible PoC. The surveyor should provide timely feedback to laboratory regarding its PoC, as appropriate.

Information Gathering Skill:

This skill enables the surveyors to identify the information needed to determine the scope, pervasiveness, and seriousness of problems that may have an impact on the laboratory's compliance. It also enables the surveyors to ascertain the laboratory's approach to ensuring quality testing. Every moment of a survey provides an opportunity to collect information. A cross section of information is gathered, reviewed and verified in an orderly and logical manner. To maximize the use for costly on-site time, the surveyor limits his/her inquiry to issues that are pertinent and within the scope of the CLIA requirements.

The preliminary findings are made from the information obtained by *observation*, *interviews*, *facts*, *events*, or *documentation* reviews. These preliminary findings help the surveyor to focus on what types of relevant information will be needed to confirm or negate the surveyor's assumptions. The surveyor will now be able to identify the sources of information and the method to be used to gather the information.

Sources of information may be observation of techniques or equipment, records (QC, PT, QA, calibration, etc.), interviews, etc. Effective interviews are conducted in a clear concise manner to obtain facts or specific and relevant information, not impressions, conclusions, judgements, etc. Surveyors should utilize a non-combative interview technique versus an interview that is aggressive and/or threatening (i.e. interrogation). Information gathered must completely and accurately support the hypothesis made regarding laboratory compliance.

Investigative Skills:

The investigative skills are techniques surveyors use to gather, preserve, or create various forms of information, in a manner that results in valid conclusions. The surveyor should make a systematic inquiry or examination into the laboratory's practices conditions and environment to either support or deny compliance determinations. The surveyors should remain focused on relevant monitors and information. The surveyor must carefully record the information obtained. It is critical that the surveyors be able to support the final compliance decision based on the CLIA OSP.

Surveyors must have the knowledge of the regulations and how to apply them in order to relate deficient practice(s) to their findings to determine if the findings have identified a "true symptom" of a failed system. The surveyors are able to make decisions by evaluating findings in the context of public health responsibilities and recommend appropriate actions when patient health is at risk regarding laboratory test outcomes.

The surveyor should demonstrate the following Investigative Skills:

- Ability to develop a hypothesis from initial information obtained by observation, fact, or event.
- Ability to determine the forms of relevant information needed to resolve (confirm or negate) the hypothesis or issues effectively, efficiently, and conclusively.
- Ability to identify symptom of a system failure when examining the various elements – who, what, when, where, how, and why –which often become apparent in the course of the survey.

- Information gathering that is relevant to the problem, including verification of findings with key personnel.
- Good judgement in determining sources of information, gathering and preserving information, and identifying information that supports the deficiency.
- Ability to assess pervasiveness, scope, and severity of the problem.
- Ability to avoid bias and distractions to find the source of the problem, if possible.

Investigative Skills are critical throughout the entire OSP particularly the following activities/functions:

- Pre-survey Preparation: Systematic review of the previous survey findings, proficiency testing information, complaints, and conversation in the course of scheduling, communications between surveyors, or information clues prior to the survey may effect the investigation direction. The RO surveyor does not directly observe these activities/functions. However, through direct communication prior to and during the survey, the RO is able to determine that the pre-survey preparation was effective. Once on site, the RO can also communicate with the facility to determine that the pre-survey preparation was effective.
- Entrance Interview: The surveyor should begin gathering information and be aware of hints that may draw him/her to areas that need further investigation.
- Information Gathering: During this activity/function via interviews, laboratory tours, observation, and record reviews, the surveyor may come upon many clues, that need further investigation to prove or disprove a hypothesis drawn. (Examples: On PT review, there are Coulter printouts while the lab has a Sysmex. QC values are out of control; however, the values don't appear so on the Levy-Jennings charts that the laboratory has chosen to use.) Gather the clues and see if they follow a pattern. Expand the information gathering as the situation warrants.
- Exit Conference: During this activity, the surveyor should carefully confirm the findings to assure the laboratory's is aware of the deficient practices. A systematic approach to the exit conference will ensure that the surveyor has not misunderstood or misinterpreted information, which can be clarified at this time.

CLIA-FMS REVIEW CRITERIA (Exhibit B)

State Agency Surveyor Identification Code:	Type of Laboratory Facility:
Date of Survey RO _____ SA _____	Type of CLIA Survey: Initial/Re-certification/Complaint(s)/ Add Specialty or Subspecialty
Type of CLIA-FMS: Observational, Participatory or Comparative	Check Yes if the activity was met. Check No if the activity was not met. Check NA if the activity was not applicable to this survey.

Yes	No	NA	<u>SURVEY FUNCTION OR ACTIVITY</u>	Comments (Note areas that need improvement and areas of pertinent strength.)
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			<p>I. PRE-SURVEY PREPARATION</p> <ul style="list-style-type: none"> • Schedules announced or unannounced surveys. • Uses a scheduling protocol (e.g. geographic areas and timing). • Sends forms to laboratory prior to survey <i>or brings the forms as part of the onsite survey.</i> • Reviews database information systematically (e.g. OSCAR/ODIE reports/summaries and fee status). <ul style="list-style-type: none"> - Previous history/compliance, complaints, proficiency testing (PT) data, specialty/subspecialty services offered and test volumes. • Determines number of testing sites under certificate. 	
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			<p>II. ENTRANCE INTERVIEW</p> <ul style="list-style-type: none"> • Ensures proper identification and introductions. • Interacts professionally with facility staff. • Explains purpose, time schedule, and survey process. • Discusses OSCAR/ODIE information. <ul style="list-style-type: none"> - Understands counting tests and verifies test volumes. - Informs laboratory that volume changes may result in fee changes, and has laboratory director/designee sign or initial such an acknowledgement. • Verifies whether test methodologies have been deleted or added. • Verifies personnel qualifications (e.g. new personnel and responsibilities). 	
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Yes	No	NA	<p align="center">CLIA-FMS REVIEW CRITERIA (Exhibit B)</p> <p align="center"><u>SURVEY FUNCTION OR ACTIVITY</u></p>	<p align="center">Comments</p> <p align="center">(Note areas that need improvement and areas of pertinent strength.)</p>
			<p>III. INFORMATION GATHERING</p> <ul style="list-style-type: none"> • Evaluates the laboratory's operations. <ul style="list-style-type: none"> - Size and organization of the laboratory • Evaluates facility's space and environmental conditions, and workflow. <ul style="list-style-type: none"> - Observes and verifies that reagents, kits, and equipment correlate with test menu, clients served, and test volume. • Evaluates Quality Assurance (QA) plan and activities. • Evaluates PT enrollment, performance, and corrective actions. • Evaluates Quality Control (QC) protocols and performance (including outliers, shift, trends, and corrective actions). • Evaluates calibration, reagents, maintenance and function checks, and validation (if applicable). • Interviews staff to confirm observations and obtains necessary information. Handles allegations from staff appropriately. <ul style="list-style-type: none"> - Verifies that position responsibilities are met. • Investigates forwarded information thoroughly if related to an allegation of noncompliance and if this is a complaint survey. • Determines if the complaint is substantiated (if this is a complaint survey). • Handles difficult situations and people well. • Reviews adequate and representative cross-section of information, including records encompassing the time period since the previous survey. • Evaluates Patient Test Management (PTM). • Evaluates patient test results (particularly from periods of PT and QC failures). <ul style="list-style-type: none"> - Considers specimen collection and handling, test records, reports and referrals, and turn- around- times. - Considers same patient with different days and different tests for clinical correlation. • Demonstrates sensitivity to confidentiality of laboratory records and operations. 	

Yes	No	NA	<p align="center">CLIA-FMS REVIEW CRITERIA (Exhibit B)</p> <p align="center"><u>SURVEY FUNCTION OR ACTIVITY</u></p>	<p align="center">Comments</p> <p align="center">(Note areas that need improvement and areas of pertinent strength.)</p>
			<p>IV. ASSESSING OUTCOME OR POTENTIAL OUTCOME</p> <ul style="list-style-type: none"> • Knows when to conclude the survey or continue more in-depth review. • Considers all factors in decision-making. • Identifies and determines the source of problems selected. • Assess accurately, proficiently, and efficiently whether the identified problem “does or could negatively impact patient test results”. • *Uses the <u>(assessing outcome) flow chart</u> available from Appendix C, of the SOM, Transmittal No. 7 (March 1999) on page C-11. 	
			<p>V. REGULATORY COMPLIANCE DECISION</p> <ul style="list-style-type: none"> • Determines whether problems identified are regulatory, and then condition or standard level. • Recognizes Immediate Jeopardy. • *Applies the <u>(regulatory compliance decision) flow chart</u> available from Appendix C, of the SOM, Transmittal No. 7 (March 1999) on page C-12. 	
			<p>VI. EXIT CONFERENCE</p> <ul style="list-style-type: none"> • Conducts the Exit Conference with appropriate personnel. • Describes CLIA requirements not in compliance and the findings that substantiate these deficiencies. <ul style="list-style-type: none"> - Solicits information to determine if technical assistance is necessary to correct the problem. • Provides laboratory personnel an opportunity to discuss and/or provide any additional information regarding the preliminary problems noted. • Understands it is the laboratory’s responsibility to determine the corrective action(s) necessary to remedy the problem(s). • Provides the laboratory instructions, name of contact person, and time frame necessary for submitting a plan of correction. • Informs the facility of intended recommendations to certify, re-certify, or deny certification of the laboratory. 	

*The reference to the flow charts is to save space. However, each RO ensures that the SA surveyor has prior knowledge of these visual aids (released March 1999) before being assessed.

Yes	No	NA	CLIA-FMS REVIEW CRITERIA (Exhibit B) <u>SURVEY FUNCTION OR ACTIVITY</u>	Comments (Note areas needing improvement and areas of pertinent strength.)
			VII. DEVELOPMENT OF THE STATEMENT OF DEFICIENCIES <ul style="list-style-type: none"> • Chooses the most appropriate regulatory citation(s) to document a deficiency. • Writes supporting information for documenting deficiencies completely, clearly, and concisely. • Writes the deficiency statement in terms which allow a person to understand the aspects of the requirements which are not met. • Writes statements of evidence following the format described in the Principles of Documentation. • Understands when State Licensure tags can be included on the Form CMS/HCFA-2567. 	
			VIII. SURVEY REPORT DOCUMENTATION AND DATA ENTRY <ul style="list-style-type: none"> • Contacts (immediately) supervisor and/or RO in situations of Immediate Jeopardy or serious problems, as necessary. Makes recommendation to RO when enforcement actions are necessary. • Completes applicable survey forms accurately. • Enters certification kit correctly and efficiently and timely into OSCAR/ODIE, etc. Makes necessary corrections to OSCAR/ODIE, etc. 	

CLIA-FMS REVIEW CRITERIA (Exhibit B, continued)

IX. Summary of Skill Sets Assessment – Outcome-oriented Survey Process (OSP)		Pre-Survey	Entrance Conference	<i>Information Gathering</i>	Exit Conference	Form HCFA-2567
Outcome Assessment						
Organization						
Communication						
<i>Information Gathering</i>						
Investigation						

X. Additional Comments:

XI. RO Consultant _____

EXHIBIT C **Examples**

Clinical Laboratory Improvement Amendments of 1988 (CLIA) – **Federal Monitoring Surveys (FMS)**

Exhibit C provides the Regional Office (RO) examples of comments that can be used when preparing written feedback to the State Agency (SA) surveyor regarding the FMS survey findings. The purpose of the feedback is to facilitate survey performance improvement and to notify the SA about training and/or technical assistance needs (for surveyors). The examples are not intended to serve as model language, but are illustrations of possible approaches or situations. The RO can customize its feedback according to each state's specific needs, progress, and environment. However, the feedback to the surveyor must address and include an assessment of the following:

- Use of the Outcome-oriented Survey Process (OSP). Survey activities/functions including but not limited to; Pre-survey Preparation, Entrance Interview, Information Gathering, Assessing Outcome or Potential Outcome, Regulatory Compliance Decision Making, and Exit Conference.
- Development of a Statement of Deficiencies using the Principles of Documentation (PoD);
- Skill Sets (Exhibit A).

The narrative for the findings, either positive feedback or recommendations for improvement must be:

- Specific;
- Objective;
- Constructive; and
- Written in a manner that addresses the knowledge base and skill level as demonstrated by the SA.

Each RO's objective and concisely written assessment is an important factor to appropriately and fairly handle the SA surveyor's identify in conjunction with addressing his/her need(s). Also, the written assessment is needed as part of documenting the FMS findings. This method of operation supports effective communication between the RO, SA, and Central Office (CO) and it provides a record of national and local training/technical assistance needs (of surveyors) and how those needs are met.

EXHIBIT C, continued

Example 1 MORE EFFECTIVE:

(Surveyor XYZ) overlooked the ____ (sub) specialty. This area might have been quickly identified or discovered as part of the Pre-survey preparation, Entrance Interview, or during onsite observations.

RO Surveyor Recommendation: Review the protocol in the Outcome-oriented Survey Process (OSP) for information gathering before, during, and/or after the onsite survey. Ensure that the surveyor knows how to obtain and use the information from OSCAR/ODIE Report(s) ____ that includes application (Form CMS/HCFA-116) information, previously certified (sub) specialties; particularly for Pre-survey preparation. Ensure that onsite observations are part of determining facility compliance.

CO NOTE: We assume there would be communication between the RO and SA at the time of the survey. This is meant to be an example of poor Pre-survey preparation & poor time management. It might also demonstrate that the surveyor didn't plan and organize his/her time and data in conjunction with preparing for or during the survey.

Example 2 MORE EFFECTIVE:

The Blood Bank and Histocompatibility areas were not surveyed thoroughly. Therefore, problems went undetected/unsurveyed for ____ period of time. The surveyor is less familiar with the regulations & the technical aspects of Blood Bank and Histocompatibility areas.

RO Surveyor Recommendation: Provide technical assistance and regulatory training in these areas. Include training of the related sections of the survey process in order to survey such area(s) of the laboratory more effectively. If possible, have the surveyor go on survey with another surveyor who is more experienced in these areas to learn key points about surveying these (sub) specialties.

Example 1 LESS EFFECTIVE: (Surveyor XYZ) overlooked the ____ (sub) specialty.

Example 2 LESS EFFECTIVE:

(Surveyor XYZ) did not survey the Blood Bank as thoroughly as other areas and missed two problems.

EXHIBIT C, continued

Example 3 MORE EFFECTIVE:

(Surveyor XYZ) identified, during the course of the survey, that half of the patient test (Phenytoin) results from the Epilepsy Clinic had results of “none detected”. The surveyor also noted quality control (QC) results running on the high side for most days of testing patient specimens. By identifying inconsistent findings (outcomes), the surveyor demonstrated an ability to relate surveyor knowledge, laboratory experience and understanding of the regulations to outcome assessment during the survey. In helping the laboratory focus on outcomes, the surveyor then explained the necessity of correlating patient and QC results as part of their Quality Assurance (QA) program.

RO Recommendation: The surveyor used all the skills, tools, and procedures associated with the Outcome-oriented Survey Process (OSP) effectively. This recommendation is here only to reinforce the importance of utilizing the laboratory’s QA plan to monitor test results in relationship to certain patient information with other laboratory data as one means to gather and/or confirm information investigated. The laboratory is responsible for monitoring test results as part of its QA program.

Example 4 MORE EFFECTIVE:

(Surveyor XYZ) demonstrates extensive experience in surveying and is well accomplished at identifying problems. However, there was an inability to associate the problem identified with potential outcome. For example, numerous problems were noted in Quality Control (QC) results that were out of the acceptable range without any identification or corrective action.

The surveyor did not review any patient test results for any of the days indicating out of range QC results, in order to assess the potential for reporting of erroneous patient results. In addition, the surveyor did not recognize the relationship of the QC problems to the need for laboratory staff training. The surveyor failed to make the relationship of the lack of knowledge of

Example 3 LESS EFFECTIVE:

In helping the laboratory focus on outcome, (Surveyor XYZ) explained the necessity of performing certain functions in relationship to patient test results.

Example 4 LESS EFFECTIVE:

(Surveyor XYZ) didn’t incorporate assessing outcome as a part of the survey process.

EXHIBIT C, continued

Example 4, continued, MORE EFFECTIVE:

laboratory staff on handling out of range QC results with the lack of direction or supervision by the director or the technical supervisor.

RO Recommendation: Need to provide enhanced training and examples regarding outcome assessment and impact on potential patient (test) outcomes in upcoming participatory surveys. Need to reinforce Principles of Outcome Assessment from the OSP to the surveyor via repeat Basic Training and in practice by permitting the surveyor to accompany others in the State/RO who are skilled in assessing impact on outcome.

Example 5 MORE EFFECTIVE:

(Surveyor XYZ) demonstrated proficient knowledge and understanding of the regulations to be able to identify deficiencies and to be able to develop a Statement of Deficiencies (SOD) that is clear, concise, and follows the Principles of Documentation (POD). The citations selected are the best to legally defend the problems that were identified.

Example 6 MORE EFFECTIVE:

(Surveyor XYZ) can improve the survey quality by incorporating Quality Assurance (QA) into the entire review of the laboratory while progressing through the survey, rather than treating QA as separate topic. For example, when reviewing Quality Control (QC), ask about the laboratory's corrective actions and the effectiveness of its corrective actions in preventing recurrences of problems/errors. Application of basic Quality Systems concepts will also facilitate the surveyor's ability to view the entire operation from a QA perspective.

Example 5 LESS EFFECTIVE:

The Statement of Deficiencies is well written.

Example 6 LESS EFFECTIVE:

(Surveyor XYZ) treats QA as a separate topic and should try to integrate it more.