APPENDIX C

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR LABORATORIES AND LABORATORY SERVICES

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR LABORATORIES AND LABORATORY SERVICES

POLICY FOR CONDUCTING SURVEYS

The Outcome-Oriented Survey Process

Interpretive Guidelines for Laboratories and Laboratory Services

POLICY FOR CONDUCTING SURVEYS

Survey protocols and interpretive guidelines are established pursuant to pertinent sections of the Social Security Act, the Public Health Service Act, the Clinical Laboratory Improvement Amendments (CLIA) of 1988, and the CLIA regulations at 42 CFR Part 493 to provide guidance to personnel conducting surveys of laboratories. The protocols and guidelines clarify and/or explain the Federal requirements for laboratories and are required for use by all surveyors assessing laboratory performance based on these Federal requirements. The same survey protocols are used by the regional office (RO) and/or State Agency (SA) surveyors.

The following protocols represent an outcome-oriented method to be used to conduct the survey. The focus of the survey is to assess how the laboratory monitors its operations and ensures the quality of its testing. The intended use of these protocols is to promote consistency in the approach to the survey process, and to ensure that a laboratory's operations are reviewed in a practical, efficient, and effective manner so that at the completion of the survey there is sufficient information to make compliance determinations. While the purpose of the protocols and guidelines is to provide direction in preparing for the survey; in conducting the onsite survey; and for analyzing, evaluating, and documenting survey findings; the surveyor's professional judgement is the most critical element in the survey process.

CMS' objective is not only to determine the laboratory's regulatory compliance but also to assist regulated laboratories in improving patient care by emphasizing those aspects of the regulatory provisions that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process especially on initial laboratory inspection to help laboratories understand and achieve the quality system concepts. It is the surveyor's objective, using professional judgement, to determine, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel, and review of the laboratory's relevant documented records, whether it is producing quality test results (i.e., accurate, reliable, and timely). The primary objective of the survey process is to determine whether or not the laboratory meets the CLIA requirements. The surveyor meets this objective by employing an outcome-oriented survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

Surveyors must make every effort to minimize the impact of the survey on laboratory operations patient care activities, and to accommodate staffing schedules and departmental workloads as much as possible. In facilities providing direct patient care, e.g., physician offices, clinics, residential care facilities, and hospitals, surveyors must avoid interrupting or interfering with patient care. Surveyors must respect patient privacy and confidentially at all times in all survey settings.

Provider-Performed Microscopy (PPM) procedures are moderate complexity tests subject to routine biannual surveys except when the laboratory holds a certificate for PPM procedures.

When performing a survey on a facility that conducts PPM procedures, the appropriate requirements at 42 CFR Part 493, Subparts C, H, J, K, M, and Q apply. (Refer to Section IX for information concerning conducting surveys of laboratories holding a certificate for PPM Procedures.)

For information concerning conducting surveys of waived testing, refer to Section IX.

THE OUTCOME-ORIENTED SURVEY PROCESS

The principal focus of the outcome-oriented survey is the effect (outcome) of the laboratory's practices on patient test results and/or patient care. The outcome-oriented survey process is intended to direct the surveyor to those requirements that will most effectively and efficiently assess the laboratory's ability to provide accurate, reliable, and timely test results.

In the outcome-oriented survey process, the surveyor reviews and assesses the overall functioning of the laboratory and evaluates the laboratory's ability to perform quality testing; that is, the surveyor evaluates the laboratory's quality system. The quality system requirements in the Introduction to Subpart K and the General Laboratory, Preanalytic, Analytic, and Postanalytic Quality Assessment requirements are appropriate guides for the surveyor to organize the review.

In the outcome-oriented survey process, emphasis is placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to produce quality results. The surveyor reviews the cross-section of information to verify that the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices, and identifying and resolving problems effectively.

If the findings from the review of the laboratory's ongoing mechanisms for ensuring quality test results are sufficient to make the determination of compliance and if the evaluation does not warrant a more in-depth review, the surveyor concludes the survey and asks if the laboratory has any questions about CLIA requirements.

Note: Although Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, includes guidelines and instructions for each regulatory requirement and encompasses all types of laboratory facilities, use only those portions applicable to the laboratory operations and complexity of testing performed.

I. IDENTIFYING SOURCES OF INFORMATION

A. Scheduling Surveys.--For efficiency when scheduling, attempt to cluster surveys geographically. Schedule the recertification survey at least 6 months prior, but no earlier than 12 months prior to the expiration of the laboratory's current certificate. In order to permit observation of actual testing during the initial survey, schedule the initial survey at least 3 months after the laboratory opens. Any new laboratories, and if at all possible, complaint and validation surveys in the geographic area should be worked into the survey schedule. Extenuating circumstances require RO review.

Establish a date and time for the survey once the schedule has been completed. If a laboratory operates more than one shift or location, schedule survey hours to include a representative cross-section of shifts or locations, as necessary.

To enhance survey effectiveness and efficiency, except in the case of complaints, consider mailing the following forms to the laboratories before the scheduled survey date. Request the laboratory complete the forms and either return them to the SA or hold them for review during the onsite survey.

- Disclosure of Ownership and Personnel and Control Interest statement. Collect on initial survey and with change of ownership. (Refer to the State Operations Manual (SOM) Chapter 2, §2005.) Consult the annual laboratory registry or CLIA/Online Survey Certification and Reporting (OSCAR) database to assist with determining whether the owner has had a laboratory certificate revoked within the last 2 years;

- Laboratory Personnel Report (CLIA), Form CMS-209 (required) with directions for completing or updating information, adding new personnel or changes in positions or status; and

o Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form CMS-116 (required) with signature of current owner/operator/director; (Refer to Section IX Additional Information for counting test volumes).

Request the following information be accessible and retrievable at the time of survey:

o Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary);

o Reference laboratories' client services manual, if applicable;

o Records of tests referred to other laboratories;

o Personnel records, including:

- Diplomas, certificates, degrees;
- Training, and experience;
- Continuing education;
- Competency assessment;
- Duties/responsibilities; and
- Personnel changes.

o Quality control records, including:

- Remedial action information;
- Calibration and calibration verification records;
- Statistical limits; and
- Instrument maintenance and function checks records.

o Proficiency testing (PT) reports, including:

- Test runs with PT results;
- Direct printouts; and
- Remedial actions for unsatisfactory results.

o Quality system assessment plan and documentation;

For each of the systems:

- policies and procedures to monitor, assess, and correct identified problems;
- documentation of ongoing assessment activities, including
  -- review of the effectiveness of corrective actions taken
  -- revision of policies and procedures prevent recurrence of problems; and
  -- discussion of assessment reviews with staff.

o Safety information; and

o Patient testing records:

- Requisition (patient charts may be used);
- Work records (direct printouts); and
- Patient test reports (patient charts may be used).

B. Announced and/or Unannounced Surveys.--Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced surveys. Complaint or revisit surveys must be conducted on an unannounced basis. (Refer to the SOM, Chapter 6, §6106 for policy regarding announced and/or unannounced surveys. For announced surveys, allow up to four-weeks notice.) When applicable, the laboratory may be notified by telephone or mail. Notification <u>may</u> include the actual date and time of the survey. For either an initial CLIA or

recertification CLIA survey, an unannounced survey may be performed after one appointment is cancelled by the laboratory. The laboratory must be informed of this when originally notified about the survey. Request that the laboratory notify the RO or SA, as appropriate, if its laboratory operations are not conducted during usual hours of operation or only on specific days and times. Surveys are to be conducted during the laboratory's routine hours of operation. Confirm the laboratory's certificate type and advise the laboratory to notify the SA of any changes that would necessitate a different certificate. If the laboratory has applied for a certificate of accreditation, ask the laboratory to provide documentation (e.g., written verification from the accreditation organization) of its accreditation status.

C. Pre-Survey Preparation--Prior to each survey, review the laboratory's file, including the CLIA-database information. To determine the size of the survey team and the expected time required for the survey, consider the number of sites under the certificate, the scope and volume of testing, and the test complexity.

1. Personnel--Include the completed or updated Form CMS-209 in each survey package. Use this information during the onsite survey to evaluate positions currently held by employees in accordance with the requirements. Focus on new personnel since the last survey.

2. Services Offered--Review the CLIA application, the list of tests and specialties/subspecialties, and any correspondence from the laboratory to determine the complexity of tests performed. Ascertain whether the laboratory has changed complexity of testing, specialties/subspecialties, added/deleted tests or services, since the last survey.

3. PT--Review PT records to ensure that the laboratory is enrolled and participating in an approved program for each PT regulated analyte, specialty, and subspecialty for which testing is performed. Note any unacceptable, unsatisfactory, or unsuccessful scores and any analyte, specialty, and/or subspecialty that are not evaluated by the proficiency testing program provider. Use this information to target particular tests for review during the survey.

4. File Review--Evaluate the laboratory's ability to maintain compliance between surveys by reviewing its file for:

o Previous survey results and plans of correction, noting patterns, number, nature of deficiencies, and dates of correction;

o Enforcement action(s) taken or in progress, e.g., limitations of the certificate or voluntary withdrawal of a specialty, subspecialty, or analyte/test due to unsuccessful proficiency testing or loss of qualified personnel; and

o Complaint allegations noting frequency, significance, severity and, if substantiated, the resolution.

II. ENTRANCE INTERVIEW

The entrance interview sets the tone for the entire survey. Be prepared, positive, courteous, and make requests, not demands. Upon arrival, present the appropriate identification, introduce other team members, inform the facility's administrator, director, or supervisor of the purpose of the survey, the time schedule, and explain the survey process. Identify a contact person and establish a communication level based on the degree of technical knowledge of the contact person.

If the laboratory consists of multiple testing sites, verify all information concerning testing performed at each site. If one or more sites do not meet the multiple site exceptions in the regulations (42 CFR §§493.35(b), 493.43(b) and 493.55(b)), explain the reason and have the owner/operator/director complete Form CMS-116 for each applicable site. (Refer to Section IX for information concerning conducting surveys of multiple testing sites under one certificate.)

Inform the laboratory that the survey will include a tour of the facility, record review, observation, and interviews with personnel involved in the pre-analytic, analytic, and post-analytic phases of the testing process. Establish personnel availability and discuss approximate time frames for survey completion. Determine whether the deficiencies, when identified, are to be discussed with testing personnel, and explain that an exit conference may be held to discuss survey findings. Refer to the SOM, Chapter 6, §§6124 and 6126 for additional information regarding the exit conference.

Request that the laboratory collect any documents, records, or information that may be needed to complete the survey, and solicit and answer any questions the laboratory may have concerning the survey process.

III. INFORMATION GATHERING

The technique for information gathering includes observation, interviews, and record review and these are usually performed concurrently. The information gathering process is critical in the determination of quality laboratory testing. Gather sufficient information to evaluate the laboratory's operations without being overly intrusive or gathering excessive information. As each laboratory is unique in the services offered, the order of gathering information may be different for each survey. The timing for observing testing and the availability of staff for interview may determine the sequence of the survey.

Consider the laboratory's compliance history (deficient practices and Plans of Correction). Verify the correction and continued compliance with all previously cited deficiencies. Pay particular attention to deficiencies that the laboratory has failed to correct. Refer to enforcement requirements the 42 CFR Part 493, Subpart R, if needed.

A. Organizing the Survey.--Consider the following variables when making determinations for organizing the survey and the areas to be reviewed:

- o Purpose of the Survey:
  - Initial or recertification (Refer to SOM Chapter 6, §§6112-6114 regarding CLIA recertification using the Alternative Quality Assessment Survey (AQAS)):
  - Complaint;
  - Follow-up; and/or
  - Validation.
- o Pre-survey Information:
  - Problematic PT;
  - Previous survey deficiencies;
  - Complaints; and/or
  - Enforcement actions.
- o Size and Organization of the Laboratory:
  - Type of instruments/test procedures;
  - Type of information system(s);
  - Number of supervisors and testing personnel;
  - Number of testing sites;
  - Scheduling of testing (e.g., Stat, daily, weekly shifts);
  - Number of specialties/subspecialties;
  - Test volume;
  - Record availability; and/or
  - Type of patients/clients served.

B. Observation of Facilities and Processes.--Observe the laboratory's physical layout. These observations should include specimen collection and processing, "prep" and clean-up areas, testing and reporting areas, and storage areas. Whenever possible, observe specimen processing and test performance, noting information which would precipitate

revisiting an area, interviewing personnel, or requesting records for review. Observe and verify that reagents, kits, and equipment correlate with test menu, clients served and results reported. Also observe whether staffing appears adequate for test volume. Schedule the survey date/time to observe personnel performing specimen processing, testing, and reporting of results in each specialty/subspecialty of service. If it is not possible to observe testing, ask for a verbal walk-through of the procedure. Do not distract staff when observing operations and personnel activities.

Focus observations on:

- o Specimen integrity;
- o Quality control performance;
- o Skills and knowledge of personnel regarding:
  - Performance of testing;
  - Evaluation of test results;
  - Identification and resolution of problems; and
- o Interactions of personnel regarding:
  - Availability of supervisor to staff; and
  - Communication among personnel.

At all times respect patient privacy and do not interfere with patient care and confidentiality.

C. Interviews.--Interview staff to confirm observations and obtain additional information, as necessary. Obtain information to identify personnel interviewed, such as name or code. Ask open-ended questions, e.g., probes from the guidelines, and if necessary, repeat or restate the response given by the staff to confirm what was said.

During the interview of personnel, evaluate their knowledge and skills for performing tests, identifying problems and the methods for corrective and remedial actions. Interviews should include as many staff members as necessary to form a judgement as to the ability of staff to perform their duties. Handle all staff or individual allegations of problems as complaints. Determine, as best as possible, the validity of the allegations prior to leaving the laboratory. Do not cite deficient practices or complaints based on allegations without verification. Conduct a follow-up investigation, if appropriate, of serious allegations or complaints that cannot be substantiated during the present survey, e.g., falsified test results or referral of PT specimens to another laboratory for testing.

D. Record Review.--Gather relevant information that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory including records encompassing the time period since the last certification survey. Determine all new tests, new test methods, and new equipment added since the prior survey and review documentation relevant to as many of these factors as possible when reviewing laboratory records. The amount of records selected and reviewed is not intended to be statistically valid, but rather a representative cross-section of various records. Avoid predictable patterns of gathering information (e.g., same tests or time periods). Do not allow the laboratory to select the records for review. Consider the types of clients and/or facilities that the laboratory serves, e.g., nursing homes, pediatric, dialysis units, public health clinics, cancer clinics, and routine physicals. Choose a variety of patient records across the laboratory's spectrum of clients. When test information must be gathered from medical records, be considerate when handling these records, as they contain confidential information. If possible, review medical records in the presence of office or laboratory personnel and with consideration to confidentiality.

Subpart K delineates the laboratory's responsibility for performing its own internal reviews. This is an excellent starting point for an outcome-oriented survey. Review a cross-section of information selected from records of quality system assessment activities within each of the four systems. Review a cross-section of information simultaneously assessing the laboratory's

ability to provide quality test results as well as its ability to identify and correct problems. Refer to the quality system assessment portions of the regulations as a guide for organizing your selection and review of information to assess the laboratory's overall compliance. Investigate further any problems identified but not addressed by the laboratory's quality system assessment. If the laboratory is failing to monitor (or effectively monitor) its own system and correct its problems, you can direct the laboratory to the requirements and the relevant sections for its particular setting.

Make copies of any records needed to support deficient practices.

Assure that reviews of PT (Subpart H), Facility Administration (Subpart J), Quality System (Subpart K) and Personnel (Subpart M) include the following:

1. PT.--Verify the laboratory is appropriately enrolled and participates in a CMS approved PT program(s) for each specialty, subspecialty, analyte, and/or test for the entire period of time the laboratory has been performing testing for each regulated test (not just shortly before the survey).

If the laboratory has unacceptable analyte/test results or unsatisfactory performance in specialties or subspecialties since the last survey, review the specific record, corrective action, and any other data such as education and training of staff associated with PT remediation. Include both patient test results and QC records which were assayed in the same run as the failed PT in the review. In addition:

- o Verify that the laboratory has reported results under the appropriate methodology/instrumentation used for test performance, e.g., automated vs. manual hematology;

- o Verify that the laboratory did not engage in inter-laboratory communications and/or refer its PT samples for testing prior to reporting results to the PT provider;

- o Verify that PT samples were handled, prepared, processed, examined, tested, and reported, to the extent practical, in the same manner as patient samples; and

- o For tests where there is no PT available and/or those tests performed by the laboratory that are not included in subpart I, determine that the laboratory verifies the accuracy of each test at least twice a year.

2. Facility Administration.--Review records for the appropriate retention times and assure the laboratory adheres to appropriate safety, arrangement, space, ventilation, and contamination procedures. If the facility provides transfusion services, verify that the arrangement is current, the blood products are stored appropriately, and transfusion reactions are investigated and reported to the appropriate authorities in a timely manner.

3. Quality System .--General Laboratory, Preanalytic, Analytic, and Postanalytic System Quality Assessment--Using the patient test requisitions, test records, test results, and test reports or, as applicable, patient charts, review all phases of the laboratory testing processes, including instructions for specimen storage. If possible, when reviewing individual patient test results, correlate test requisition(s) or medical record information with final report(s). Refer to Postanalytic Systems Quality Assessment for guidance in reviewing and correlating patient test results. After determining the patient population serviced by the laboratory, e.g., geriatrics, public health clinics, dialysis units, health fairs, and hospitals, review the following:

- o A cross-section of patient test results encompassing all specialties and subspecialties of testing performed in the laboratory in sufficient numbers to determine if results vary significantly from expected population norms;

- o Worksheets or instrument printouts, looking for outliers, trends, etc., when tests are performed in batches;

- Several worksheets, instrument printouts, or medical records over time for tests performed at random;

- Test results that are disproportionately abnormal or normal; and

- The correlation of initial test results and/or test result of various analytes of a patient over time.

Review QC practices and evaluate whether the laboratory is following its own QC protocols or those procedures specified by the manufacturer. Review QC results, including outliers, shifts, trends, and corrective actions taken, when necessary.

Refer to the establishment and verification of performance specifications at 42 CFR Part 493.1253 for guidance in reviewing the laboratory's policies and criteria for adding a new method, test system or analyte to its test menu.

Correlate reported patient test data with QC data and/or quality systems assessment records to ensure proper performance and documentation of controls. Review original test data (instrument printouts or computer files). Verify that patient results have not been reported when QC data was unacceptable according to the laboratory's protocol.

Consider the following in relation to the laboratory's patient population:

- New methodologies and equipment;
- QC and calibration materials used;
- Source and availability of QC limits;
- Evaluation and monitoring of QC data; and
- Corrective action for QC failures.

4. Personnel.--The scope of the review of personnel records (qualifications, training, and competency) will be related to the type of survey, type and complexity of testing performed, and the observations and findings of the survey. For initial CLIA certification surveys, evaluate the qualifications and experience of the laboratory director and each technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, and cytotechnologist. Evaluate the qualifications and experience of a cross-section of testing personnel.

For CLIA recertification surveys, it is not necessary to review personnel records of individuals previously evaluated unless there have been changes in the individual's position and/or the laboratory's test menu since the last survey. Focus on any new laboratory director, technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, cytotechnologist, and testing personnel. Refer to Subpart M for additional information concerning personnel training, experiences, competency, and qualifications.

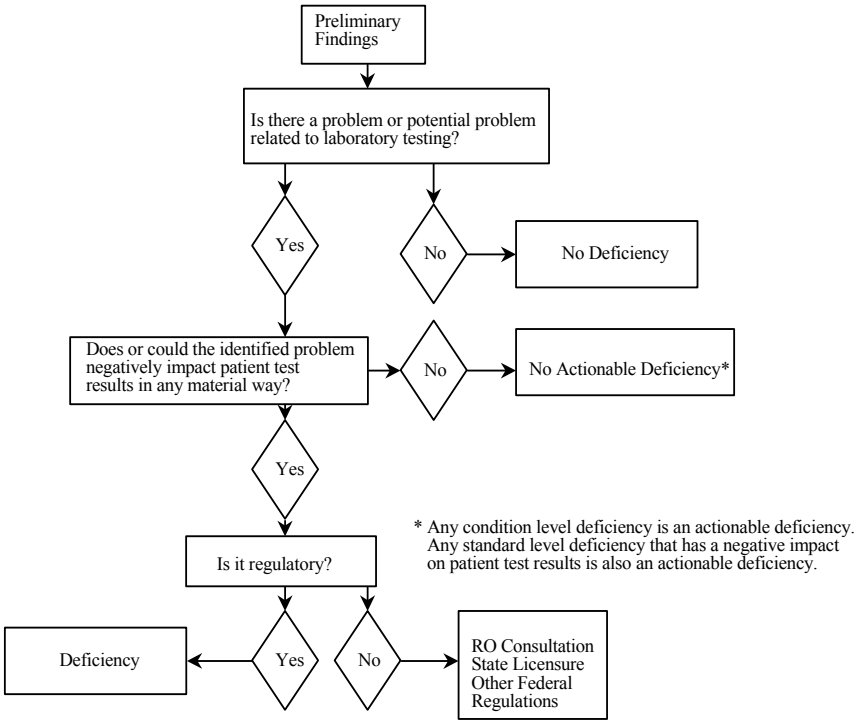
IV. ASSESSING OUTCOME OR POTENTIAL OUTCOME

If the information gathered indicates that the laboratory has established, implemented, and maintained appropriate ongoing mechanisms for ensuring quality test results by monitoring, evaluating, and resolving any problems in its practices, and your findings do not warrant a more in-depth review, conclude the survey. However, if you cannot make an assessment of the laboratory's performance based on the cross-section of information you collected, it may be necessary to expand the cross-section (e.g., number of sites, observations, or number of records). If your findings reveal potential problem areas with any test procedures, ensure the review is sufficient in breadth and depth to substantiate whether a negative or potentially negative outcome exists. If a problem or potential problem related to patient test results is found, determine the nature and seriousness of the problem.

The survey process allows the freedom to increase or decrease the number and types of records reviewed, the personnel interviewed, and the observations made as individual needs are identified.

Analyze your findings for the degree of severity, pervasiveness, survey history, frequency of occurrence, and impact on delivery of services, i.e., accuracy, reliability, and timeliness of test results. One occurrence of a deficiency directly related to a potential adverse impact on patient testing may be cited. On the other hand, some preliminary findings may have so slight an impact on outcome that they do not warrant a citation.

Refer to the following chart in assessing outcome. Refer to the next section for guidance in determining regulatory compliance.

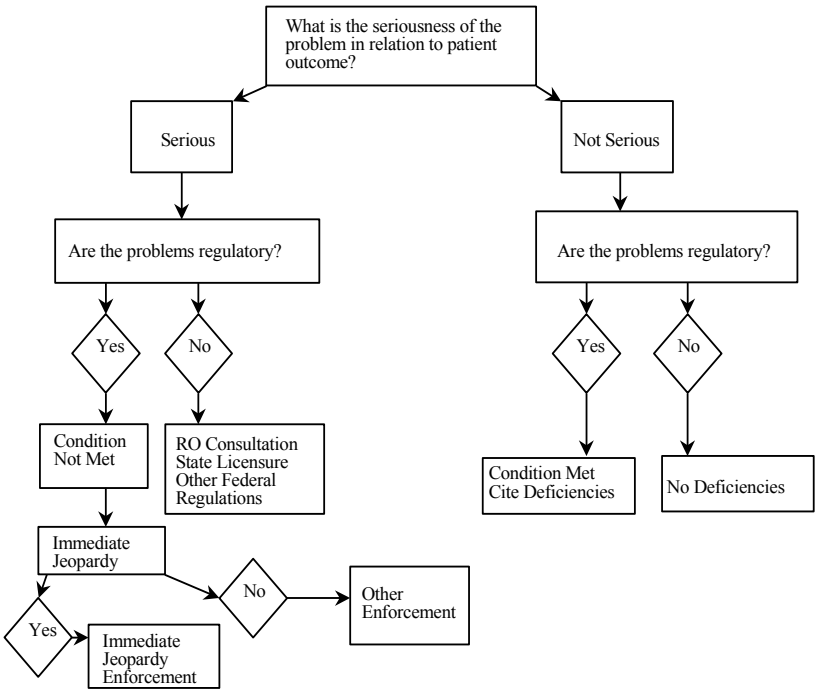


V. REGULATORY COMPLIANCE DECISION

After all necessary information has been collected and the outcome or potential outcome has been evaluated to determine if a preliminary finding constitutes a deficiency, determine if it is a condition level deficiency. Review the findings and decide if additional information and/or documentation are necessary to substantiate a deficient practice.

The number of deficiencies does not necessarily relate to whether or not a condition is found out of compliance, but rather its impact or potential impact on the quality of laboratory services and the results reported. Consider a condition out of compliance for one or more deficiencies if, in your judgment, the deficiency (ies) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care.

o Determining Immediate Jeopardy.--Immediate jeopardy is defined in 42 CFR §493.2 as "a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health." (See 42 CFR, section 493.1812 providing the enforcement actions to be taken when deficiencies pose immediate jeopardy.) Refer to the following chart for guidance in determining regulatory compliance.



- What is the seriousness of the problem in relation to patient outcome?

  - Does the problem result in inaccurate test results?
  - Does the problem result in a high probability of inaccurate test results?
  - Is the situation one in which immediate corrective action is necessary because the laboratory's noncompliance has already caused or is likely to cause serious injury, harm, or death to individuals served by the laboratory or to the health or safety of the general public?

- What are the regulatory considerations?

  - Are regulatory deficiencies identified?
  - Do the deficiencies pose an immediate jeopardy to patient health and welfare?
  - Do the deficiencies warrant removal of a certificate?
  - Is there an option for other enforcement remedies?

VI. EXIT CONFERENCE

The purpose of the exit conference is to review your findings with the laboratory and is not meant to be all-inclusive. It is the continuation of the educational survey process and the beginning of due process. The exit conference is the first opportunity for the laboratory to present additional information in response to the findings. Acknowledge staff cooperation and operational support, as appropriate, before addressing the non-compliant issues.

If immediate jeopardy or condition-level deficiencies are identified, inform the laboratory of the seriousness of the problem(s)/finding(s) and indicate that they are not final and are subject to review. Consider the following when conducting an exit conference:

- Conduct the exit conference with the facility's administrator, director, consultant, or supervisor, and/or other invited staff;

- Describe the requirements that are not in compliance and the findings that substantiate these deficiencies;

- Provide the laboratory an opportunity to discuss and provide additional information regarding deficiencies. It is the laboratory's responsibility to determine the corrective action(s) necessary to remedy the problem(s);

- Provide instructions and the time frame necessary for submitting a plan of correction as referenced in SOM Chapter 6, §6130;

- Refer to SOM Chapter 6, §6126 for additional information on the exit conference including the presence of counsel, taping of the exit conference, and situations that would justify refusal to conduct or continue an exit conference. If a tape is made of the exit conference, get a copy before you leave;

- Inform the facility of your intended recommendation to the RO to certify, recertify, or deny certification of the laboratory; and

- At the exit interview, inform the laboratory (director/administrator/supervisor) of changes in test volumes which may result in fee changes.

VII. DEVELOPMENT OF THE STATEMENT OF DEFICIENCIES

Choose the most appropriate regulatory citation when documenting a deficiency. If deficient practices are a result of failure of the laboratory to properly perform quality assessment, cite the deficiency using the quality assessment requirements. If deficient practices are more basic, such as a failure of the laboratory to perform or perform correctly certain tasks or requirements, then cite the deficiency in the specific area of the regulation such as personnel, general laboratory systems, preanalytic systems, analytic systems or postanalytic systems. Supporting

information for documenting deficiencies should be complete, clear, and concise. Write deficiency statements in terms that allow a reasonably knowledgeable person to understand the aspects of the requirements that are not met. Avoid writing the same deficiency in several places. Write your statement of evidence following the format described in the Principles of Documentation.

For some cited deficiencies, The Automated Survey Processing Environment (ASPEN) system may request that you list the appropriate specialty or subspecialty identifier code(s) for each D-tag. Use the list provided on Form CMS-1557 that identifies the code number for each specialty and subspecialty (e.g., the code number for the specialty of hematology is 400). This is applicable to standard and condition-level deficiencies.

A. Standard-Level Deficiencies.--If noncompliance has been identified, cite the most specific standard available. For instance, if the deficient practice(s) is related to control procedures:

o Cite the appropriate D-tag in the specialty/subspecialty standards under 42 CFR §§493.1261 through 1278, which are Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility if such standard is available; OR

o Use the appropriate D-tag under 42 CFR §§493.1251 through 493.1256 and 42 CFR §§493.1281 through 493.1289, if an appropriate D-tag is NOT available in the specialty/subspecialty standards.

EXAMPLE: A laboratory performs fluid cell counts using a hemocytometer. The laboratory failed to perform manual fluid cell counts in duplicate. Use D5543.

EXAMPLE: A rheumatologist performs rheumatoid factor (RF) titers. The rheumatologist failed to include control materials for the RF titer. Use D5451.

B. Condition-Level Deficiencies.--When the deficient practice is of such a serious nature that correction is necessary for the laboratory's testing to continue, cite the most appropriate condition and document the finding using the format in the Principles of Documentation. As stated in the Principles of Documentation, the laboratory must correct those standard-level deficiencies that are used to support the condition-level noncompliance before the condition can be considered back in compliance.

Options within Subpart K:

- Specialty and Subspecialty conditions--Use these conditions when deficiencies are in a specialty or subspecialty in one or all phases of testing. D5002-D5038
- General Laboratory Systems--Use this condition when deficiencies are related only to general laboratory systems and are pervasive throughout the laboratory. D5200
- Preanalytic--Use when deficiencies are related only to the pre-analytic phase of testing and are pervasive throughout the laboratory. D5300
- Analytic--Use when deficiencies are related only the analytic phase of testing and are pervasive throughout the laboratory. D5400
- Postanalytic--Use when deficiencies are related only to the postanalytic phase of testing and are pervasive throughout the laboratory. D5800

C. Choosing the Appropriate Condition.--Review the regulatory language at each of the conditions, noting the requirements that must be met for the condition to be in compliance. For example: The condition of Bacteriology (42 CFR Part 493.1201) states the laboratory must meet the requirements at 42 CFR Part 493.1230 through 493.1256, 493.1261 and 493.1281 through 493.1299 (General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems). Serious problems in one or more of these areas can cause the condition of Bacteriology to be out of compliance.

In comparison, the condition statement for Preanalytic Systems states the laboratory must meet the requirements at 42 CFR Part 493.1241, 493.1242 and 493.1249 for each specialty or subspecialty of testing. Serious preanalytic deficiencies that are pervasive throughout the laboratory (not related to specific specialties or subspecialties) could cause the condition of Preanalytic Systems to be out of compliance. Caution: An enforcement action based on non-

compliance with the condition of General Laboratory Systems, Preanalytic Systems, Analytic Systems or Postanalytic Systems would be a revocation or a suspension of the certificate and could not be a limitation of the CLIA certificate for one or more specialties.

Standard level deficiencies written in one subpart cannot be the basis for a condition in another subpart. Deficiencies in Proficiency Testing or Personnel would not be the basis for the condition of Bacteriology to be out of compliance. It is not uncommon for a surveyor to identify issues that crossover between subparts of the laboratory or the regulations, but deficiencies must be cited at the appropriate area of the regulations. For example, failures in proficiency testing may be caused by an error in specimen identification, test system malfunction, or lack of training for staff. Avoid citing more than one deficiency for the same issue, unless each deficiency focuses on a different aspect of the issue (instrument malfunction vs. staff training).

EXAMPLE:

A laboratory has deficiencies in Bacteriology under D-tags at Preanalytic Systems (D5300), Quality Control Procedures (42 CFR Part 493.1256) and the Bacteriology specialty location (42 CFR Part 493.1261). The surveyor may write the condition of Bacteriology out of compliance (D5002) based on the deficiencies cited at the three areas. If the laboratory offers testing in other specialties or subspecialties and does not make correction of the Bacteriology deficiencies, the certificate could be limited for the subspecialty of Bacteriology.

EXAMPLE:

A laboratory has deficiencies in General Laboratory Systems (D5200) that are pervasive throughout all specialties and subspecialties of testing. The surveyor would cite the condition of General Laboratory Systems out of compliance. To be in compliance with this condition, the laboratory must correct all deficiencies used to support this compliance decision. Any enforcement action would be related to the certificate and not a limitation of one or more specialties.

EXAMPLE:

A laboratory has deficiencies in Bacteriology under D-tags in the control procedures (42 CFR Part 493.1256) and at the Bacteriology specialty location (D5002), both of which are in the Analytic Systems condition and Routine Chemistry deficiencies under D-tags in control procedures (42 CFR Part 493.1256).

- The surveyor may write the condition of Bacteriology out of compliance (D5002) based on the deficiencies cited in the Bacteriology specialty area (42 CFR Part 493.1261) and the D-tags in Control Procedures area (42 CFR Part 493.1256).

- The surveyor may also write the condition of Routine Chemistry out of compliance (D5016) based on the Routine Chemistry deficiencies cited in the control procedures area (42 CFR Part 493.1256). Even though the D-tags used to determine condition-level noncompliance in Routine Chemistry are cited in the Control Procedures area, the appropriate condition to mark out of compliance is the applicable subspecialty of Routine Chemistry (D5016).

- If the laboratory performs only the subspecialties of Bacteriology and Routine Chemistry and if the deficient practices are pervasive, the surveyor may write the condition of Analytic Systems out of compliance (D5400).

In the preceding example, if the two subspecialty conditions are considered out of compliance, the laboratory can choose to correct one subspecialty without the other and the SA can recommend an adverse action to remove the subspecialty that has not been corrected. If the surveyor had cited the condition of analytic systems out of compliance, and the laboratory had only corrected one of the specialty areas, an adverse action would to be taken against the entire certificate (laboratory) and not just the subspecialty. Use the conditions of General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems only when the

deficiencies are pervasive throughout the laboratory and correction must be made for the entire laboratory to continue testing in any specialty.

VII. SURVEY REPORT DOCUMENTATION AND DATA ENTRY

Following each survey, as applicable, complete the following additional documentation. This information remains in the official file, either at the SA or RO. Also include Forms CMS-209, appropriate ownership information (completed by the laboratory) and the Alternative Quality Assessment Survey (AQAS) form (completed by the laboratory, if applicable) in the official file.

As applicable, complete the following:

Form CMS-1557, Survey Report Form (CLIA);

Form CMS-462A/B, CLIA Adverse Action Extract;

Form CMS-2567, Statement of Deficiencies and Plan of Correction;

Form CMS-2567B, Post Certification Revisit Report;

Form CMS-1539, Certification and Transmittal;

Form CMS-670, Survey Team Composition and Workload Report;

Form CMS-282, Blood Bank Inspection Checklist and Report; and

Form CMS-562, Medicare/Medicaid/CLIA Complaint Form.

Following the survey, enter into the CLIA/OSCAR/ODIE data system(s) any revisions, additions, or deletions to the application (Form CMS-116) information. Refer to the CLIA Systems Users Guide for specific information and instruction. Enter into the ODIE data system the Certification Kit, which consists of:

Form CMS-1539, Certification and Transmittal;

Form CMS-1557, Survey Report Form (CLIA) - pages 1 and 2;

Form CMS-2567, Statement of Deficiencies and Plan of Correction; and

Form CMS-670, Survey Team Composition and Workload Report.

Enter into the CLIA/OSCAR data system, when applicable:

Form CMS-462A/B, CLIA Adverse Action Extract; and

Form CMS-562, Medicare/Medicaid/CLIA Complaint Form.

The CMS Form 668B has been developed to assess the survey process from the viewpoint of the laboratory. Leave this form with all laboratories that receive either an onsite survey or the AQAS. The laboratory will complete this form.

IX. ADDITIONAL INFORMATION

A. COUNTING TESTS

Total annual volume for waived tests, if any, should be recorded on the CLIA application (Form CMS-116) in the waived testing section. The total annual volume for nonwaived tests, including PPM procedures, should be reported on the form in the Nonwaived Testing section by specialty and subspecialty. Only tests that are ordered and reported should be included in

the laboratory's test volume(s). Calculations (e.g., A/G ratio, MCH, MCHC, HCT, and T7), QC tests, and PT assays should not be counted.

o For chemistry tests, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).

o For complete blood counts, each measured individual analyte that is ordered and reported is counted separately. Differentials count as one test.

o For urinalysis, microscopic and macroscopic examinations each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

o For microbiology, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.

o For allergy testing, each allergen is counted as one test.

o For gynecologic and nongynecologic cytology, each slide (not case) is counted as one test.

o For immunohematology each ABO, Rh, antibody screen, cross match, or antibody identification is counted as one test.

o For histocompatibility, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.

o For histopathology, each block (not slide) is counted as one test. Autopsy services are
not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains, including immunohistochemistry, performed on slides to the total number of specimen blocks prepared by the laboratory.

o For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient (i.e., a bone marrow and a venous blood specimen received on one patient are counted as two tests).

B. CONDUCTING SURVEYS OF MULTIPLE TESTING SITES UNDER ONE CERTIFICATE

1. As specified in 42 CFR Part 493, all not-for-profit or State or local government laboratories engaged in limited public health testing and certified under a single certificate must meet all applicable requirements of 42 CFR Part 493. Each location is subject to a survey, although not every location may be included in the cross-section of information gathered during the current certification survey period. If there is a central or primary location, include it in the initial CLIA certification survey. Select a representative portion of the remaining locations for onsite survey.

Select sites for the survey based on:

- Types of testing performed;

o Types of clients and/or facilities served, e.g., pediatric, geriatric, residential/emergency care, or health assessment screens;

o Location(s) participating in PT; and

o Problems or complaints identified either at the central or primary location, or other testing sites.

2. In a hospital, laboratory testing sites under one certificate should be inspected using the criteria listed above.

3. Temporary testing sites, including mobile units, should be inspected using the criteria listed in A above. Refer to the SOM Chapter 6, §6034 to assist with determining what constitutes a mobile unit. Every effort should be made to schedule the survey to coincide with testing at temporary locations.

Many Home Health Agencies (HHAs) may have fallen under the exception contained in the CLIA regulations for not-for-profit or government entities involved in limited public health testing. HHAs may also fall under the CLIA certification exception for laboratories with temporary testing locations. Refer to Transmittal Number 98-1 (Program Memorandum, State Survey Agencies) to assist with determining (on a case-by-case basis) whether or not a Medicare HHA actually qualifies to have multiple testing sites under a single CLIA certificate.

A laboratory having multiple sites under one certificate is required to enroll in only one PT program(s) for each specialty/subspecialty/analyte tested under that certificate even though the same analyte may be tested at multiple locations using different test systems, methodologies, or personnel.
Assure that PT records indicate the location at which the tests were performed, and that all other locations have been compared with the system selected for PT, as specified in 42 CFR 493.1281(a).

A condition may be considered out of compliance for deficiencies found at <u>one</u> or more locations.

C. CONDUCTING SURVEYS OF WAIVED TESTS

In <u>any</u> laboratory holding a CLIA certificate, waived tests <u>are not</u> subject to routine survey. A survey of waived tests may be conducted <u>only</u> when authorized by the RO to:

o Collect information on waived tests;

o Determine if a laboratory is testing outside their certificate;

o Investigate an alleged complaint; and/or

o Determine if the performance of such tests poses a situation of immediate jeopardy.

D. CONDUCTING SURVEYS OF CERTIFICATE FOR PPM PROCEDURES

If a laboratory holds a <u>Certificate for PPM procedures</u>, do not conduct a certification or recertification survey of these facilities. However, a survey may be conducted as specified in 42 CFR Part 493, Subpart Q (i.e., randomly to determine whether the laboratory is performing tests in addition to those listed as PPM procedures or waived tests, to collect information regarding the appropriateness of tests specified as PPM, to determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to the public, and to evaluate a complaint from the public). When performing a survey of PPM procedures, the appropriate requirements in 42 CFR Part 493 Subparts H, J, K, M and Q apply.