Clinical Laboratory Improvement Amendments of 1988 (CLIA)

ORIENTATION

PROGRAM

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
CENTER FOR CLINICAL STANDARDS AND QUALITY (CCSQ)
QUALITY, SAFETY & OVERSIGHT GROUP (QSOG)
DIVISION OF CLINICAL LABORATORY IMPROVEMENT AND QUALITY (DCLIQ)

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OVERVIEW

CMS CLIA POLICY and PROGRAM EXPECTATIONS

The Centers for Medicare & Medicaid Services (CMS) has established the CLIA Orientation Training Program, developed by the Center for Clinical Standards and Quality (CCSQ), Division of Clinical Laboratory Improvement and Quality (DCLIQ), as the official process for orienting a new employee within a State Agency (SA) or Regional Office (RO). To promote consistency, it is **mandatory** that **all** newly hired CLIA SA and RO personnel responsible for any or all parts of the implementation of the CLIA program, successfully complete this orientation training program. This includes staff hired as:

- managerial;
- clerical;
- administrative; and
- surveyors.

This program will provide a foundation to help them successfully perform their CLIA-related duties and also prepare them for basic training conducted by CMS Central Office (CO) and RO. The orientation is conducted and coordinated by both the SA and RO as applicable. The manager of the component in which the individual is hired has the overall responsibility for planning, coordinating, supervising and ensuring completion of the orientation.

This Orientation Manual provides guidance and information on:

- the CLIA program;
- skills needed to perform a survey;
- SA and Federal roles;
- the CLIA Survey process;
- the CLIA data system; and
- resources to clarify or enhance CLIA policies.

As part of the orientation training, the new SA or RO surveyor must participate in surveys under onsite supervision, which should include each laboratory specialty/subspecialty area. The amount of time required to gain proficiency in various areas will differ according to an individual's education, experience and training.

OVERVIEW

CMS CLIA POLICY and PROGRAM EXPECTATIONS

Each new CLIA staff member, surveyor or non-surveyor, is expected to complete all pertinent parts of this manual including the required readings and the assessment activities. The RO/SA must also ensure, through effective supervision, that each of the learning activities results in a maximum gain in knowledge, skills, and abilities.

The RO evaluates the in-service orientation training program in the SA as it relates to continued development of the skills and knowledge of each new surveyor and non-surveyor. This is accomplished by utilizing visits, personal interviews, observing and reviewing surveys and all other pertinent information for non-surveyors.

The SA must send verification (See Addendum) to the RO when each newly hired staff has completed the orientation program. The same form should be completed for all new employees in the RO with a copy forwarded to the CMS CO, DCLIQ.

OBJECTIVES

The CMS CLIA Orientation Training Program is the formal process by which newly employed individuals are introduced to the CLIA survey and certification program and to their job responsibilities.

Objective: The overall objective is to provide information and resources and to develop skills necessary to perform all CLIA-related responsibilities and surveys at an entry level of proficiency.

Specific Objectives: At the conclusion of this training program, the newly hired CLIA laboratory staff should be able to:

- discuss the CLIA program requirements, policies and procedures applicable to his/her duties and explain the roles of the RO/SA;
- independently perform his/her assigned responsibilities at an acceptable level of competence;
- identify deficiencies when they exist, determine the seriousness of survey findings and identify when to discuss them with the RO/SA supervisor, as applicable;
- document all survey findings in a manner that will legally support decisions made;
- identify and utilize resource materials, such as the State Operations Manual, and personnel in the SA or RO to obtain necessary accurate information to perform duties and give appropriate responses; and
- maintain the CLIA data systems.

PROGRAM CONTENT

The orientation program is comprised of six parts and may be customized to address the individual needs of each newly hired employee. The orientation should be conducted over a five to six month period. Recommended time spans are:

Part I -- Medicare, Medicaid & CLIA	2 weeks
Part II -- Roles and Responsibilities	2 to 3 weeks
Part III -- General Survey Principles	3 to 6 weeks
Part IV-- CLIA Survey Process	6 weeks
Part V-- CLIA Data System	4 weeks
Part VI -- Glossary:	1 to 2 weeks

- Abbreviations
- Acronyms
- Definitions

When the orientation program has been completed, each individual will be awarded a certificate of successful completion by the appropriate SA/RO training coordinator. ***Successful completion of the program is a mandatory prerequisite for the Basic Laboratory Training Course.***

Part I <u>Medicare, Medicaid and CLIA Relationships</u>
Background and introduction to the pertinent laws and regulations and how they relate to each other. Identification, organization and content of the CLIA regulations.

Part II <u>State and Federal Roles and Responsibilities</u>
State and Federal roles which include the CMS Regional and Central offices, the Food and Drug Administration, the Centers for Disease Control and Prevention and the Clinical Laboratory Improvement Advisory Committee.

Part III <u>General Survey Principles</u>
General principles for confidentiality, courtesy and conduct, investigative skills, information gathering, compliance determination, documentation skills, and responsibilities as a CLIA laboratory surveyor. (Reminder: Part III experiences should be integrated throughout the five-six month orientation program.)

PROGRAM CONTENT

Part IV CLIA Survey Process
This section emphasizes CLIA survey process tools and the practical application of skills learned in Part III. Under supervision, the surveyor assesses compliance with all CLIA requirements, and writes the Statement of Deficiencies using CMS policies and procedures.

Part V CLIA Data System
This part is an introduction to the various components of the data system, forms, business procedures, billing and certificates.

Part VI Glossary
Abbreviations, Acronyms, Definitions.

Addendum - Staff Evaluation Form

SPECIFIC PERFORMANCE CRITERIA

At the completion of the orientation program, the individual(s) responsible for the implementation of CLIA:

- demonstrates knowledge of the policies and procedures for laboratories in Chapter 6 -"Special Procedures for Laboratories" and Appendix C - "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" of the State Operations Manual (SOM) (CMS PUB 100-7);
- learns and utilizes the terminology and abbreviations related to the CLIA survey and certification processes and is knowledgeable regarding pertinent available resources;
- identifies the statutes from which the State receives authority for the licensure, and certification programs;
- demonstrates effective verbal and written communication skills and techniques with professional, community and lay individuals at all levels;
- becomes familiar with functions of and uses the appropriate CLIA data system applications;
- identifies the differences in State and Federal regulations and how to apply them;
- explains the interface of the organizational structures of the State, Regional office and Federal Government with respect to the survey and certification processes;
- defines the role of a laboratory surveyor with regard to CLIA regulations, policies and procedures;
- efficiently and effectively uses the basic methods of data and information collection and record review during the survey process;

SPECIFIC PERFORMANCE CRITERIA

- under supervision, performs surveys and follows the approved survey and certification procedures and the Outcome Oriented Survey Process (OOSP) outlined in the SOM while effectively assessing a laboratory's compliance with CLIA conditions and standards;

- makes acceptable and legally defensible compliance decisions based on regulatory requirements and professional judgment and coordinates with supervisor and RO as necessary;

- develops accurate, complete and well-organized documentation of observations, findings and factual information obtained from surveys;

- participates in the development of legally defensible deficiency statements using the Principles of Documentation (PoD) and evaluates the plan of correction (PoC) and allegation of compliance (AoC) and other survey related correspondence;

- demonstrates knowledge of available enforcement actions and is able to make appropriate enforcement recommendations to the RO; and

- understands basic quality systems concepts.

PART I

MEDICARE/MEDICAID AND CLIA

MEDICARE/MEDICAID AND CLIA RELATIONSHIPS

Medicare/Medicaid and CLIA '67

The Medicare/Medicaid and CLIA programs have had a distinct relationship since the beginning of the Federal oversight of laboratories.

Regulations published in 1966 under Titles 18 and 19 of the Social Security Act required that laboratories serving as providers in the Medicare program be subject to quality standards established by the Secretary. Title 18 contains the requirements in the Social Security Act for Medicare and Title 19 relates to Medicaid. Medicaid is a State/Federal program that pays for services furnished only by laboratories that meet Medicare conditions of coverage. Because participation in the Medicaid program is governed by Medicare rules, when there is a reference to Medicare, Medicaid is included. The only laboratory requirements in this rule were personnel standards, and they were **only** applicable to free standing facilities, that is, independent laboratories. The Medicare/Medicaid programs were administered by the Social Security Administration (SSA).

The Clinical Laboratories Improvement Act of 1967 (CLIA'67) was passed in 1967. Section 353 of the Public Health Service Act required laboratories that sent specimens via interstate commerce to be subject to regulation by the Federal government. CLIA '67 included requirements for quality control (QC) and proficiency testing (PT). The program was implemented by the Centers for Disease Control (CDC) (currently the Centers for Disease Control and Prevention). During this period of time, the Federal government regulated laboratories under two programs (Medicare /Medicaid for independent laboratories, and CLIA '67 for laboratories conducting interstate testing) through two separate Federal agencies (SSA and CDC).

In 1974 the two programs, Medicare/Medicaid and CLIA'67, adopted each other's standards with both programs having personnel, QC, and PT requirements.

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MEDICARE/MEDICAID AND CLIA RELATIONSHIPS

The Medicare/Medicaid program was later transferred from SSA to the Health Care Financing Administration (HCFA) and CLIA'67 was transferred from CDC to HCFA (HCFA's name was changed to CMS in 2001). Even though the programs were then administered by one Federal agency, there remained two sets of Federal requirements for laboratories.

In 1990, final regulations were published by HCFA for one set of uniform standards for Medicare/Medicaid and CLIA. The two sets of requirements were revised to simplify administration through unification of all laboratory related standards. Outdated and redundant laboratory standards were updated to reflect new technologies.

Medicare/Medicaid and CLIA '88 (CLIA)

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578. CLIA replaced section 353 (e)(2) of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967. The impetus for CLIA was significant problems in cytology "Pap" smear testing that resulted in death as well as a proliferation of testing in unregulated physician office laboratories (POLs).

The final CLIA regulation was published in the Federal Register of February 28, 1992 and became effective September 1, 1992 as 42 CFR Part 493 Laboratory Requirements.

CLIA established uniform quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CLIA applies to all entities, not just those entities billing for Medicare/Medicaid, which conduct tests on human specimens for health purposes (e.g., tests on tissue, blood and urine to detect and treat diseases).

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MEDICARE/MEDICAID AND CLIA RELATIONSHIPS

The CLIA Statute/Law defines a laboratory as any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Any facility that meets this definition must have the appropriate CLIA certificate to perform laboratory tests. The CLIA requirements are based on test complexity.

- CLIA established three categories of tests: waived, moderate complexity, including the subcategory of Provider Performed Microscopy (PPM) Procedures, and high complexity. Waived tests (simple tests with small chance of error or risk of harm, if performed incorrectly) are exempt from the quality standards. Laboratories performing nonwaived (i.e., moderate or high complexity) tests are subject to quality standards and biennial surveys. [See CLIA regulations at 493.5]

- Laboratories performing similar tests must meet the same requirements, whether located in a hospital, doctor's office, or other site. The more complex the test is to perform, the more stringent the requirements. Laboratories are certified at the highest level of testing performed. The FDA is responsible for the categorization of all tests.

State and/or Federal surveyors survey laboratories to determine if they meet applicable CLIA requirements. The CLIA program is entirely user-fee funded by the laboratories it oversees; therefore, CLIA receives no funds from Congress or CMS.

On January 24, 2003, the “Medicare, Medicaid, and CLIA Programs Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications” regulation was published in the Federal register as a Final rule, effective April 24, 2003. This final rule:

- set forth the requirements for certain updated QC provisions and personnel qualifications and introduced basic quality systems concepts into CLIA;

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- consolidated and reorganized the requirements for patient test management, QC, and quality assurance to follow the movement of a patient sample through the laboratory; and
- changed the consensus required for grading PT challenges.

AGENCIES RESPONSIBLE FOR THE CLIA PROGRAM IMPLEMENTATION

CLIA Program responsibilities are a collaborative effort by three agencies: CDC, FDA, and CMS (including the SAs)**.** [See Part II]

LABORATORIES ISSUED A CLIA CERTIFICATE OF WAIVER

Laboratories issued a Certificate of Waiver must only use test systems that are simple laboratory examinations and procedures which employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Waived laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Follow manufacturers' test instructions.

OVERVIEW OF PROVISIONS FOR MODERATE AND HIGH COMPLEXITY (NONWAIVED) TESTS

- Personnel: CLIA sets minimum education, experience and training qualifications and responsibilities for all persons performing or supervising moderate or high complexity (nonwaived) laboratory tests.

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- Quality control and quality assessment: Laboratories must have processes for monitoring their entire operation and test systems to ensure accurate results, resolve identified problems, and routinely communicate applicable information and changes with clients and staff.

- Cytology testing: CLIA sets specific rules (most of which are statutory) for cytology testing including workload limits, personnel standards, quality control procedures and proficiency testing for individuals.

- Proficiency testing: Laboratories that perform nonwaived testing under CLIA must enroll and participate successfully in a CMS- approved PT program(s) for the tests they perform that are listed in Subpart I. PT provides an external evaluation of the accuracy of the laboratory's test results. All other tests must be checked, at a minimum, twice a year. CMS annually approves PT programs under the provisions of Subpart I of the CLIA regulations. Laboratories with a Certificate of Waiver are not required, **under CLIA**, to enroll in proficiency testing. [See also Subpart H]

- Record keeping: Laboratories must maintain records for tests performed throughout all phases of testing and must document their compliance with all applicable CLIA standards.

APPLICATION, REGISTRATION, CERTIFICATES, SURVEYS AND FEES

CLIA was uniquely designed as a user-fee funded program. Fees from the laboratories for certificates and surveys cover the costs to administer the program and are assessed biennially. Fees are assessed, funds are disbursed and CLIA certificates are generated by CMS.

- All entities performing laboratory testing (excluding forensic, research where individual results are not reported, and testing for which

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MEDICARE/MEDICAID AND CLIA RELATIONSHIPS

Substance Abuse and Mental Health Services Administration (SAMHSA) certifies laboratories) must register with CMS by completing the CMS 116 application form, obtain a CLIA certificate, and pay a certificate fee commensurate with the type and volume of testing performed. [See CLIA regulations - Subpart A]

- Laboratories pay a flat fee for a Certificate of Registration, Certificate of Waiver and the Certificate for Provider Performed Microscopy Procedures (PPM).

- Laboratories that perform only waived tests, or certain microscopic tests as part of a patient examination (PPM), are exempt from routine federal surveys but are subject to announced or unannounced inspections under certain circumstances. [493.35(d)(2)(i)-(iv); 493.47(c)(3)]

- Laboratories performing nonwaived testing are surveyed biennially and may choose to be surveyed by: CMS via a SA; a CMS-approved accrediting organization; or be licensed by a CMS-approved State laboratory licensure program (exempt State).

- Laboratories performing nonwaived tests under a Certificate of Compliance are surveyed by the SA. Fees are assessed to cover administrative and survey (inspection) costs and are based on the laboratory's annual volume and types of tests.

- Laboratories performing nonwaived tests that are accredited by a CMS-approved accrediting organization (AO) must apply to CMS for a Certificate of Accreditation, and pay the appropriate certificate fee to CMS including a nominal amount for a validation survey. These laboratories pay their survey fee to the AO.

- Laboratories located in States having a CMS-approved licensure program do not have to register or pay a fee to CMS. The approved States are responsible for the routine surveys and licensure, and the laboratories pay the appropriate administrative fees to their State.

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MEDICARE/MEDICAID AND CLIA RELATIONSHIPS

CMS bills the State for the applicable costs to oversee the State and to cover CLIA related program costs. The only CMS-approved State licensure programs are in New York (except POLs) and Washington.

[See CLIA regulations Subparts B, C, and D regarding specific certificate requirements and Subpart E for approval of AOs and exempt state programs]

MEDICARE/MEDICAID

Medicare law indicates that facilities seeking payment for laboratory services under the Medicare and/or Medicaid programs must meet applicable CLIA requirements and have a valid CLIA certificate. Entities that perform laboratory testing and do not receive Medicare and/or Medicaid reimbursement, must also hold the appropriate valid CLIA certificate and meet the applicable CLIA requirements for the testing they offer.

Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities. Entities wishing to receive Medicare/Medicaid payments must enroll in those programs under the appropriate Medicare provider requirements.

PART I

MEDICARE, MEDICAID AND CLIA

ASSESSMENT

1. The following requirements must be met by CLIA waived laboratories except:
    a. Follow manufacturer's test instructions
    b. Enroll in the CLIA program
    c. Enroll in a CMS-approved PT program
    d. Pay applicable certificate fees biennially

2. Certificate of Compliance laboratories performing nonwaived tests are surveyed by _____.
    a. AO
    b. CMS CO
    c. RO
    d. SA

PART II

ROLES AND RESPONSIBILITIES

STATE ROLES

1864 Agreement

Under CLIA, the SA surveys laboratories under the authority of section 1864 of the Social Security Act in accordance with CMS policies and procedures.

SA Responsibilities

The SA makes determinations of compliance with CLIA requirements based on survey findings. The functions the SA performs are referred to collectively as the certification process. The policies and procedures for these actions are in the SOM Chapters 5 and 6. In the area of laboratories, they include but are not limited to:

1. identifying and enrolling potential laboratory participants;

2. communicating effectively and timely in a verbal and written manner with laboratories, peers, supervisors and ROs according to standard operating procedures (SOPs);

3. managing the CLIA data base using CLIA system applications according to procedure;

4. responding timely to complaints, as per RO direction;

5. attending CO/RO training courses, as directed;

6. developing internal systems and processes to effectively and efficiently perform CLIA related duties and meet the State Agency Performance Review (SAPR) requirements.

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STATE ROLES

7. providing technical assistance to laboratories concerning the regulations to enable laboratories to qualify for participation in the program (meet applicable requirements);

8. scheduling, preparing for, conducting and appropriately following up surveys in which the State agency determines the laboratory's compliance with the CLIA requirements in accordance with the Outcome Oriented Survey Process (OOSP) and within stated timeframes;

9. citing deficiencies according to CLIA PoD as needed using the most appropriate citation;

10. soliciting and reviewing a PoC, recommending certification and recertification, and other follow-up actions;

11. recommending sanctions to the RO if laboratories do not meet the CLIA requirements;

12. conducting validation surveys of accredited laboratories per the SOM protocol;

13. performing periodic PT desk review and corresponding follow ups; and

14. participating in federally directed projects.

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FEDERAL ROLES

CMS, CDC and FDA are the agencies in the Department of Health and Human Services (HHS) which are responsible for CLIA.

CMS CO/DCLIQ

The Secretary of the HHS has designated CMS to administer the Medicare, Medicaid, and CLIA programs. CMS works in conjunction with FDA and CDC.

The Division of Clinical Laboratory Improvement and Quality, within CMS Baltimore CO, administers the CLIA program and is responsible for:

- developing, promulgating, implementing and updating CLIA regulations;
- granting deeming authority (i.e., approval and periodic re-approval) to accreditation organizations and States with licensure programs and monitoring their performance;
- conducting annual approval and re-approval of PT programs and monitoring their performance;
- evaluating, developing, and disseminating CLIA survey and certification policies and procedures, brochures and interpretive guidelines;
- conducting surveyor training in conjunction with the ROs and other experts and developing related materials;
- designing, validating and implementing the CLIA data and billing systems;
- monitoring adherence to the CLIA program requirements with ROs /SAs;

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- facilitating RO consistent application of policies and procedures via regular communication and assistance with problem resolution and enforcement;

- maintaining the CLIA website and internet, other external communication, educational resources, and materials;

- collaborating with CDC, FDA and the CLIAC on all CLIA issues;

- developing and monitoring the CLIA program budget, workload priorities, including strategic planning;

- maintaining CLIA forms development, updates and inventory;

- ongoing collaboration and meetings with accreditation organizations, states with laboratory licensure programs and other private and Federal agencies (Partners in Laboratory Oversight); and

- responding to inquiries from CMS ROs, CMS management, members of Congress, professional organizations and the general public.

CMS CO also coordinates with the CLIA staff and management in the ten ROs, each with a specific geographic jurisdiction. In each RO, the CLIA certification component works with SAs in administering the survey and certification program according to CMS policy. All issues that the ROs cannot resolve are forwarded to CO for possible resolution. The RO also forwards training needs to CO.

Workload and budgeting for the CLIA program (RO, States, CDC and FDA) is administered and monitored by the CO budget team in collaboration with DCLIQ.

CMS RO

The CMS ROs are responsible for ensuring that CLIA laboratories provide

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appropriate quality services and the SAs operate in accordance with the 1864 agreement using CLIA policies and procedures. Their major responsibilities are as follows:

- reviewing survey and certification reports submitted by the SA;
- initiating all adverse actions, imposing alternative sanctions in addition to or in lieu of principal sanctions, canceling or suspending all or part of Medicare payments, as applicable, based on SA/RO recommendations, and issuing of final notices;
- monitoring and surveillance of SA expenditures and approval of State budgets for the provision of cost efficient and effective survey and certification activities;
- assisting CO with training, projects, workgroups and policy development, and problem resolution;
- coordinating with the SA the orientation of all new surveyors and CLIA staff;
- Conducting on-site validation surveys;
- conducting onsite surveys of federally and State-operated laboratories;
- performing transfusion-related fatality surveys and investigations according to CMS policies and procedures;
- coordinating follow up of complaints with SAs and AOs and communicating findings;
- notifying CO of training and policy needs, PT referrals and of highly volatile circumstances;

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- performing State Agency Performance Reviews (SAPR) and Federal Monitoring Surveys (FMS) to ensure SA conformance with CMS policies and procedures;

- providing technical assistance to SAs and laboratories; and

- implementing CMS CLIA policies and procedures in their respective States and ensuring consistent application by the SA.

SAPR and FMS

The SA surveyors' actions are integral to the success of the CLIA Program and directly affect the overall performance outcome of the SA. As SA surveyors perform their daily activities, they should keep in mind that adherence to the guidance documents, particularly the State Operations Manual, including Appendix C, contributes to optimal SA performance and to the success of the CLIA program. The RO evaluates the SA and SA surveyor performance by administering SAPR and FMS assessments. The CLIA SAPR is distinguished from the CLIA FMS by its scope. The SAPR focuses on SA surveys in the aggregate as well as other SA responsibilities such as workload completion, proficiency testing desk review, and CLIA data management. The FMS, which is monitoring and feedback about individual CLIA surveys to ensure the SA is following the OOSP, is used in combination with SAPR to provide a comprehensive overview of SA performance.

SAPR

The CLIA SAPR is an annual evaluation by the RO of each SA's performance of its survey and certification responsibilities under the CLIA Program (refer to Sec 6230 of the SOM) and the 1864 Agreement. The SAPR has been designed not only to measure SA Performance but to promote optimal performance by each SA. Sustained proficiency is recognized and areas of improvement are identified for corrective action by the SA.

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The RO retains its overarching responsibility for program oversight; however, its primary role in the SAPR is to provide education and support for improvement, with flexibility to address the variation in SA sizes and operations.

FMS

The purpose of the FMS system is to:

- monitor each SA surveyor's application of the OOSP;
- determine training needs;
- provide timely feedback for surveyor education; and
- improve survey process performance and consistency.

The CLIA FMS provides an opportunity for the RO and SA to share constructive verbal and written feedback. The feedback is **not** to be used punitively as a personnel evaluation of the SA surveyors.

There are three types of FMS Surveys and the RO has the discretion to select the most appropriate for the circumstances. They are:

1. Observational;
2. Participatory; and
3. Comparative.

The budget call letter prescribes a 1% sample of the survey workload requiring an FMS. The type of FMS utilized is at RO discretion and should be commensurate with SA performance needs. CO solicits and verifies with each RO the actual number of FMSs conducted in each SA as part of each federal fiscal year's activities and whether each SA surveyor received an FMS.

[Reading assignments: SOM, Chapter 6, Sections 6200-6240; OOSP Protocol in Appendix C]

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FEDERAL ROLE

FDA Responsibilities

- Performs and revises test categorization of commercially marketed in vitro diagnostic tests and publishes corresponding guidance and regulations.
- Consults with CDC and CMS on CLIA technical issues.
- Regulates medical devices, blood, biologics, and tissue banks.

CDC Responsibilities

- Provides scientific and technical consultation to CMS and FDA as requested.
- Provides technical assistance in the promulgation of CLIA regulations, interpretive guidelines and CLIA related projects.
- Provides education to laboratories and the general public on good laboratory practices.
- Coordinates CLIAC.
- Leads cytology related projects.
- Conducts CLIA studies and research.
- Assists with the Certificate of Waiver and PPM projects, maintains the data base and issues reports.

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FEDERAL ROLE

CLIAC

The Clinical Laboratory Improvement Advisory Committee provides scientific and technical advice and guidance to the Secretary, HHS; the assistant Secretary for Health; the Director, CDC; the Commissioner, FDA; and the Administrator, CMS, regarding the need for, and the nature of, revisions to the CLIA standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances. CLIAC technical advice or recommendations to HHS are not mandatory to be implemented but are always considered.

PART II

STATE AND FEDERAL ROLES AND RESPONSIBILITIES

ASSESSMENT

1. The functions which the State Agency performs are referred to collectively as the certification process. True or False

2. Federal laboratories are surveyed by State Agencies. True or False

PART III

GENERAL SURVEY PRINCIPLES

CONFIDENTIALITY, COURTESY, AND CONDUCT IN THE LABORATORY

Surveyors have access to confidential information about laboratories, their personnel, clients, medical staff, patients, and State Agency matters**. It is critical that this information is protected by the surveyor at all times.** Confidentiality is a matter of professional conduct and is supported by State and Federal law.

Laboratory professionals, management, office staff, and owners represent a wide range of cultural backgrounds just as our CLIA representatives, and surveyors need to be aware of cultural differences as theyinteract with them. This awareness and sensitivity is especially important during the survey process as many of the site's personnel may be anxious due to the social context of the event. These interactions, in order to be effective, need to reflect:

- an attitude of mutual respect; and
- trust and worth.

They involve the surveyor's personal willingness to:

- communicate;
- be empathetic toward cultures unlike their own;
- avoid racism and ethnocentrism; and
- be realistic and tolerant of differences.

Surveyors must remember that cultural diversity is not only differences in race or ethnicity but may also include such things as:

- age;
- sexual orientation;
- gender;

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CONFIDENTIALITY, COURTESY, AND CONDUCT IN THE LABORATORY

- religion;
- education;
- socio-economic background; and
- geographic origin.

Each cultural group may have different means for expressing and dealing with: formality, verbal expression, nonverbal cues, eye contact, facial expression, dress, touch, personal space, time orientation, use of slang, physical height, hierarchy, movement, etc. The savvy surveyor will be aware of their cultural norms and biases and will work to develop an awareness that allows them to be receptive and truly communicate in all settings with all people they encounter.

Information about a laboratory and its patients **is never** discussed with anyone outside that facility or outside the office. Occasionally personnel in a particular facility will initiate a discussion or questions about other facilities. It is best to reply with a general noncommittal answer, such as "We're not at liberty to discuss other laboratories any more than we are to discuss your laboratory with others." It is never appropriate to review or discuss a facility's finances.

Other standards of conduct include observing the facility's rules such as:

- “No Smoking” areas;
- “No Food or Drink” areas; and
- specialized clothing requirements and restricted areas.

If it is necessary to enter a patient care area while a patient is present, the laboratory supervisor should precede and ensure that patient privacy is respected. Discussions about compliance should not be conducted in the presence of patients or other non-laboratory personnel.

GENERAL SURVEY PRINCIPLES

CONFIDENTIALITY, COURTESY, AND CONDUCT IN THE LABORATORY

The following are some general rules of conduct while inspecting a laboratory and performing CLIA duties.

- Attempt to relieve any survey anxiety.
- Maintain professional demeanor at all times.
- Request records, etc. in advance to minimize interruptions. Request a contact person for your inquiries.
- Do not go unescorted directly into an area where a patient is being examined.
- Be quiet and brief if you must enter a patient area.
- Do not make comments in front of the patients.
- Do not disturb the patients. (But if he/she is obviously aware of your presence, the patient will be more at ease if you just pleasantly make courteous greetings.)
- Do not interrupt critical or precise laboratory activities such as phlebotomy, manual cell counting, STAT testing, and or any other activity where the patient is directly involved.
- Do not criticize the regulations, fees, test systems or manufacturers, policies or employees of the SA or CMS.
- Avoid political and religious discussions.
- Inform the laboratory of the survey activities being performed on an as needed basis.

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- Treat everyone with courtesy and respect at all times regardless of how you are treated.

- Listen carefully to what the staff and management say and employ effective verbal and non-verbal communication skills.

If for any reason a dangerous or threatening situation occurs during an inspection, remove yourself from the situation immediately and if necessary, leave the facility. Contact your supervisor for further guidance.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

INTRODUCTION

This section provides basic guidance to facilitate learning data-collection and investigative skills. Several sources of information are available to surveyors prior to and during the survey that will help them to determine a facility's regulatory compliance. Prior to the survey, the following should be reviewed: test types; specialties and volumes; previous survey report forms; proficiency testing history and reports; statements of deficiencies; plans of correction; complaints; enforcement history; and other information in the laboratory's file.

To compile the most complete information from all sources, surveyors must learn and master certain skills, techniques, and methods to separate relevant from irrelevant information. Many of these skills are learned from experience and training.

Although the final assessment of a laboratory's performance can be somewhat subjective and require surveyors' professional judgment, there are certain methods and techniques which can help the surveyor make a legally defensible decision based on objective information and observations. The OOSP includes several methods to assess performance. This includes observing the staff performing their jobs throughout the entire testing process, interviewing staff, and reviewing records, reports and documents.

The following is an example of use of professional judgment:

> Examination of records indicates that a certain procedure is in place and signed off by the laboratory director, but observation of the staff contradicts this information, i.e., they are not following their own procedure. If this happens, a brief interview with the appropriate personnel may clarify the situation. If the appropriate personnel are not available, the surveyor should investigate the problem more extensively, until it is clarified.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

The quality assessment review in the CLIA survey process relies primarily on interviews and observations of staff and management at all levels, record reviews (e.g. QC, PT, personnel, worksheets, etc.) and patient reports -- and secondarily, on review of official policies, procedures, manuals and the laboratory's own QA plan and measures to determine actual outcomes. These reviews are expanded if problems are identified.

The surveyor must observe the laboratory's entire operation throughout all phases of testing and listen carefully to the staff and management. Make an effort to improve verbal, listening, interviewing and observational skills in order to understand the laboratory's systems and processes that are designed to assure quality. Negative determinations are more acceptable if presented as facts and not accusations or threats. Becoming emotional or confrontational may cause the same reaction in others, which may result in a breakdown in communication.

Practice active listening.

- Be aware of the speaker's reaction, unspoken communication or body language; Respond, if appropriate.
- Pay close attention to what is said and do not half listen while rehearsing a reply or next question;
- Paraphrase what was heard to confirm if the speaker was correctly understood;
- Do not interrupt while others are speaking;
- Respond completely to any questions to the best of your ability; and
- Do not make assumptions; use facts only.

Remember, "IT'S NOT WHAT YOU SAY; IT'S HOW YOU SAY IT."

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

INTERVIEWING

Interviewing staff and management is a useful technique for obtaining information. Interviewing involves both speaking and listening skills. Never use slang, acronyms or vulgarity when conducting an interview; never be too verbose. Language should always be clear, accurate and polite. Remember to be culturally sensitive in your communication style.

Interviewing consists of the following:

- Preparation – Review records to obtain the background information for the situation; identify names, positions and responsibilities of interviewees.

- Opening – Establish rapport; make introductions and explain the purpose of the survey, and briefly summarize the process.

- Questions – Frame questions so as to derive the most accurate and informative answers and in a logical sequence. Do not ask questions that will only give yes or no responses.

- Closure – Indicate clearly that the interview is over and identify what will follow.

- Follow Up – Ensure that all issues and/or questions have been resolved, or commit to follow up if you don't have an answer.

Remember don't talk too much**.** Gather information by utilizing good listening skills.

Leading questions, used discreetly, can be a very effective tool. It is essential to understand the types of questions normally used in an interview. Each type is discussed below with examples.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

- OPEN – This type of question leaves the respondent free to answer fully in his/her own way. Example: “Please explain or demonstrate how wound cultures are set up.”

- CLOSED – This type limits the manner in which the respondent may answer, usually with a yes or no. (These should be avoided except on specific points, because they limit the information obtained, and a series of them makes the respondent feel he is being drilled and the surveyor will be perceived as confrontational.) Example: “Are gloves worn when processing specimens?”

- PRIMARY – Begin an area of questioning. (These primary questions are usually open questions and are rather general.) Example: "Please explain or demonstrate the accessioning system."

- SECONDARY – Follow-up on responses to primary questions or elicit responses on specific points. (This is where closed questions may be appropriate.) Example: "Are Taxo® A discs also used for other strep plates?"

  The following techniques are useful in conjunction with secondary questions:

  - Simple encouragement - Pursue with a nod or a "such as?"

  - Reflective probe - Pick something out of the answer and bring it up for further discussion.

  - Mirror question - Take a response and feed it back. Example: "Let me be sure I have this right..." Rephrase, summarize, restate to confirm and validate.

  - Probe for incomplete response - "What's the next step?" or "Who performs that task?"

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

- NEUTRAL – This type is not shaded or directed by the interviewer and is designed to eliminate bias. These are very beneficial. Example: "What information does the requisition contain?"

- DIRECTED – This is intentionally or unintentionally shaped by the interviewer to affect the outcome. It may be leading or loaded.

- LEADING – Points the way to the desired response.
  Example: "You don't run high complexity tests, do you?"
  - Wrong: "You run high complexity tests, don't you?"
  - Right: "Who performs high complexity testing?"

- LOADED – Uses labels or entrapment.
  Example: "Is the lab administrator dishonest, or just incompetent?"

IMPORTANT NOTE: Use caution with directed leading questions. Avoid using directed loaded questions during the survey.

The following illustrates how the phrasing of a question determines the accuracy and completeness of the answer:

Ineffective interview questions –

Q. Does a secretary/receptionist perform laboratory testing after the qualified testing personnel leaves?

A. No, of course not.

Effective interview questions –

Q. What if you need a test performed and the testing personnel aren't available?

A. We send all laboratory testing out to a reference lab if a result is needed and our testing personnel are not here.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

If more than one surveyor must interview the same person, coordinate with each other and agree upon a time to meet so that teammates are not competing for the interviewee's attention or appear threatening. Listen to each other as well as to laboratory personnel in order to avoid interrupting or presenting a question that has already been asked.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

Individuals have a tendency to modify their behavior in the presence of strangers. The degree to which others modify or guard their behavior will depend in part on the surveyor's conduct. If threatening questions are asked or inquiries phrased in such a way as to put people on their guard, they are likely to refrain from engaging in open conversation. If it appears the staff believes that their confidence will be compromised by information given to management, they may be reluctant to speak freely. Therefore, it is best to play down positions and to conduct the survey in an open and friendly way.

LISTENING

Listening and understanding what is said is vital for accurate and complete data collection. Concentrate on what the person is saying and also on how it is said. Monitor nonverbal communication like facial expressions, hand gestures and other body language, and listen carefully to casual remarks. These often provide clues to what the speaker is really thinking or feeling. Use open nonverbal communication.

Be polite and courteous if the person being interviewed becomes indignant or belabors a point, but consider why there is such sensitivity about that subject. Let the person(s) express themselves fully within reason, since that may reveal at least part of the entire story. Avoid becoming involved in an argument or confrontation. If you do, gently and quickly remove yourself from the situation.

OBSERVATION

Observation of the facility's physical environment, testing systems processes and personnel is another important method of determining compliance. Do not become so involved in taking notes that obvious observations are overlooked. Converse with individuals in terms they can understand. Verify that you are being understood, if you are not sure.

- Pay special attention to comments, conversation, activities, and if the laboratory staff is performing testing according to their written

procedures. Also consider equipment, supplies, safety, environment, workflow and staffing levels.

- Always think: "How does this activity or situation impact on the accuracy, reliability and reporting of test results? Does this relate to the regulations?"

Record all relevant observations promptly and accurately.

RECORD REVIEW

Prior to requesting any information from the laboratory, be aware of all required survey documents. Request the information from the accountable individual -- such as the director, supervisor or testing personnel who was identified as your contact during the entrance conference. The OOSP provides information on record sample size. When announcing the survey, request that the laboratory have standard operation procedures, QC, PT, personnel and QA information available in advance to minimize delays on site and staff time.

DOCUMENTATION

Surveyors should remember to never rely solely on one's memory for information when conducting a survey. All information should be clearly and accurately recorded for later use. Dates, times, places, individuals and purposes should all be identified in writing. To avoid confusion or misplacement of data, every piece of evidence should be organized and identified according to the area or areas it covers. A surveyor will be unable to complete the final survey report and statement of deficiencies (CMS-2567) unless documentation is complete, accurate, and properly organized.

The surveyor should be aware of requirements for legally reliable working notes, since they may be asked to justify in court the reason for their recommendation. It is very important therefore, that a surveyor knows what is considered admissible evidence.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

There are several possible methods the surveyor may use for collecting the information needed to complete the CMS -2567. These may include:

(1) **Written Notes** - These notes probably constitute the most widely used method of documentation. One advantage of written notes is that they can be easily transcribed from working notes to the CMS-2567 without much loss of meaning. The survey report form may be used for personal notes; however, it constitutes pre-decisional material and like any worksheets, is not releasable under the Freedom of Information Act (FOIA), but would be admissible in a court of law. Each surveyor and/or State Agency determines the process or format for completing the Survey Report Form (CMS-1557) and the inclusion or exclusion of personal notes.

After the final survey report is completed, the records are filed for the period of time determined by Federal and State laws. Legal questions can arise, especially concerning involuntary terminations or other adverse actions, and surveyors may have to defend their recommendations for certification in court. If this takes place, surveyors will need the comments on the survey working notes to justify their positions.

(2) **Photographs** - Photographs are an excellent method of obtaining visual documentation, if they are properly organized and documented. The following suggestions will help in the effective use of photographs for documentation purposes:

- If a camera is used that is not self-developing, write a supportive statement describing the picture itself; explain why it was taken and what area of information is covered in the picture. Without this added information, there will be no possibility of identifying the pictures that must be reproduced if the camera did not function correctly or if the film was not processed properly. The most important reason for thorough documentation is to eliminate any guesswork about why the photographs were taken.

- Always advise the laboratory of the intent to photograph an individual or the premises.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

- If a decision is made to photograph a member of the staff, obtain a statement, signed by the individual, giving permission to use the photograph in the survey documentation. The names and faces of those individuals on the photographs must be concealed and names should neither be affixed to the photograph nor appear on the accompanying documentation for privacy reasons.

- Verify if it is permissible to photograph the physical conditions of the premises or the equipment (when there are no patients or employees in the pictures) without written consent.

(3) **Tape/Video Recordings** – Some surveyors have found that taping can be particularly helpful in certain areas of the survey, such as storage areas of reagents, supplies or cytology slides. Although tape/video recordings are accurate and convenient, the following are certain disadvantages to their use.

- Taking notes from the tape/video and then rewriting the notes for the final report simply adds an additional step in the documentation process;

- It is difficult to find specific information quickly on a tape/video unless there is a tape/video recorder with matched numbers to indicate certain areas of information; and

- Filing and storing tapes may be difficult due to bulkiness in comparison to written or electronic notes.

To create an atmosphere of cooperation and communication, the surveyor should always be courteous and straightforward with the staff when choosing to use a tape or video recorder. The surveyor must realize that the facility personnel -- not the tape/video recorder -- are the primary concern. Never attempt to use a recorder without the person's knowledge.

GENERAL SURVEY PRINCIPLES

DATA COLLECTION SKILLS AND INVESTIGATIVE TECHNIQUES

Evaluation of Procedures - Written notes, photographs, and tape/video recordings are the primary methods of recording the information obtained in the survey process. Learn to use each individual method in the most beneficial manner. **Remember, that the objective of each method is to obtain clear and accurate documentation which is legally acceptable.** Adequate documentation will prevent inaccuracies and misunderstandings if the case goes to hearing.

PART III

GENERAL SURVEY PRINCIPLES

ASSESSMENT

1. When photographing a laboratory or staff, you must always advise the laboratory of your intent. True or False

2. The CMS-2567 is releasable under FOIA. True or False

PART IV

CLIA SURVEY PROCESS

TOOLS

CMS has two major tools to be used during the survey process. They are the CLIA regulations 42 CFR Part 493 Laboratory Requirements, and the State Operations Manual (SOM) (CMS PUB. 100-7).

REGULATIONS

Authority: The authority is the CLIA statute section 353 of the PHSA. The CLIA regulations provide the authority to assess compliance in laboratories. Deficiencies are cited in laboratories that do not perform quality testing under the regulations and /or meet CLIA requirements. Some laboratories may actually or potentially jeopardize the life and safety of the individuals they serve.

The CLIA regulations consist of 19 subparts of which six are reserved. The reserved subparts are holding spaces in case an expansion of the CLIA regulation is necessary.

There are four quality systems in the regulation. They are General Laboratory, Preanalytic, Analytic and Postanalytic. These quality systems encompass the total testing process and quality assessment is built into each quality system. The organization of the requirements follows the flow of a specimen through the laboratory.

STATE OPERATIONS MANUAL (CMS PUB. 100-7)

CLIA is mentioned in most of the eight chapters of the SOM; however, there are chapters and an appendix that have specific instructions that relate only to CLIA.

Chapter 5

Complaint Procedures (Sec. 5500-5590)

CLIA SURVEY PROCESS

TOOLS

Chapter 6

"Special Procedures for Laboratories"

This chapter includes all of the policies and procedures necessary for the survey and certification of laboratories.

Appendix C - "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services"

Appendix C is most often referred to as the interpretive guidelines. The first section includes policies, procedures and protocols for conducting surveys.

The second section includes the regulations (excluding subparts E, I, R and T) along with the interpretive guidelines. **These guidelines clarify and/or explain the CLIA requirements for laboratories and surveyors.** The regulation citation and language is listed first in bold print. The guidelines follow the regulation and are not in bold print. The guidelines can be used by laboratories to maintain compliance and by surveyors to help determine compliance.

CAUTION: Only the actual regulations are to be used when assessing compliance and citing deficiencies. Interpretive guidelines have no authority. There is a clear distinction between the CLIA regulations and the interpretive guidelines. Guidelines are not regulatory. However they explain the regulations and give exceptions for some requirements. **Laboratories are always cited against the regulations.**

The Interpretive Guidelines include D-tags. The requirements are coded into a series of alpha numeric data tags that are used to identify specific requirements that reflect the specific problem when citing deficiencies.

CLIA SURVEY PROCESS

TOOLS

RESOURCES

There are additional resources that can also be used to enhance or clarify CLIA policies. Some are available on the various websites.

AVAILABLE VIA THE CMS WEBSITE:

State Operations Manual--
http://www.cms.gov/manuals/downloads/som107c01.pdf

S&C Letters – Policy Memos to States and Regions
http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage These are considered official CMS policy and are subsequently incorporated into Chapter 6 of the SOM.

AVAILABLE VIA THE CLIA WEBSITE:
http://www.cms.gov/clia

CLIA application (CMS-116)

CLIA Brochures

List of approved accreditation organizations

List of approved proficiency testing (PT) providers

RO and SA CLIA contacts

CLIA data and statistics

CLIA fees

CLIA forms

Partners in Laboratory Oversight Document

Principles of Documentation (PoD)

CLIA SURVEY PROCESS

TOOLS

RESOURCES (cont.)

Appendix C –Interpretive guidelines

Enforcement model letters

Certification Boards

Laboratory Registry

CLIA hearings

Laboratory demographics look up

RELATED LINKS OUTSIDE CMS

CLIA Regulations and Chronological list of CLIA regulations
https://wwwn.cdc.gov/clia/Regulatory/Chronology.aspx

Test Categorization
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

*RESOURCES NOT AVAILABLE ON WEBSITES

CLIA Network Newsletter (CNN)

S&C Administrative Info Memos

***Resources not available by website will be distributed by the SA/RO, either electronically or by hardcopy.**

CLIA SURVEY PROCESS

OUTCOME-ORIENTED SURVEY PROCESS

CMS-CLIA uses the outcome-oriented survey process (OOSP) which places emphasis on improving laboratory performance or outcome measurements (i.e., laboratory test results). CMS promotes the use of an educational approach, especially during initial laboratory surveys, to help laboratories understand the regulations and achieve the Quality Systems concepts. The purpose of the survey is to determine whether the laboratory is actually providing accurate and reliable test results and other related services and is operating within the applicable CLIA regulations.

There are a number of pre-survey activities that must be completed to enhance the efficiency and effectiveness of the survey. The survey process is accomplished by using techniques for observation of facilities and protocols, interviews of staff and management and record review.

[Reading Assignment: SOM Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Outcome-Oriented Survey Process, Parts I – IX; Scheduling Surveys, SOM, Chapter 6, Sec. 6102]

CLIA SURVEY PROCESS

TYPES OF SURVEYS

- **Initial** - The first survey conducted after three months of issuance of a registration certificate and before 12 months to assess CLIA compliance of laboratories that perform nonwaived testing.
- **Recertification** – A biennial survey conducted by the SA/RO of a laboratory holding a certificate of compliance.
- **Complaint** – A survey conducted to investigate an allegation of noncompliance with one or more CLIA requirements against a laboratory as authorized by the RO.
  [Read the SOM, Ch. 6, Sec.6224 and Sec. 6136; Review SOM Chapter 5 to determine when an onsite survey is warranted]
- **Validation** - A CLIA survey of a laboratory, issued a certificate of accreditation, or licensed by a State which is CLIA - exempt, to assess compliance with CLIA requirements.
  [Read the SOM Ch. 6, Sec 6150 to 6184, Sec.6226 to 6228]
- **Federal jurisdictional** – A survey conducted by the RO on federally operated laboratories or where the SA lacks jurisdiction or a conflict of interest exists for the SA. An example is the State Public Health Laboratory.
- **Federal Monitoring Survey** (FMS) – A survey conducted by the RO to assess the SA surveyor's performance of the CLIA OOSP. The three types of FMSs are observational, participatory, and comparative.
  [Read the SOM, Chapter 6, Sections 6232 - 6238 for FMS]
- **Follow-up** (post-survey revisit) – A survey conducted to determine the status of corrective action; it can be onsite or offsite (e.g. by telephone) [SOM, Ch. 6, Section 6132]
- **ASCT** – A survey conducted by the American Society for Cytotechnology (ASCT) in a laboratory performing cytology. The ASCT, which is under contract with CMS, performs these specialized surveys which include a retrospective review of previously reported pap testing. The SA or RO may participate in these surveys. These surveys can be the result of a complaint or nomination by SA/RO/CO based on specific criteria.

[Reading Assignments: Facilities with Multiple Sites, SOM CH. 6, Sec. 6036; Appendix C, Sec. IX-B]

CLIA SURVEY PROCESS

DOCUMENTATION OF SURVEY FORMS

For every survey, the appropriate sections of the CMS-116 and CMS-209 forms must be completed by the laboratory. The CMS-1557 and the CMS-2802A, as appropriate, are completed by the surveyor. This information will later be entered into the CLIA data system and will provide updated correct laboratory information. All survey forms and reports must contain sufficient documentation to support the certification recommendation.

The Statement of Deficiencies (CMS-2567) is disclosable to the general public after the laboratory has had an opportunity to respond. Therefore, the surveyor has the responsibility of reviewing completed survey documents which include the completed CMS-2567 and Plans of Correction (PoC).

The CMS "Principles of Documentation" (PoD) **must** be used when developing a Statement of Deficiencies. Deficiencies must be cited using the most appropriate citations that describe the problem in order to facilitate the laboratory's corrections and ensure the CMS-2567 is legally defensible.

[**Refer to the Data Section in Part V of this document for survey forms]**

CLIA SURVEY PROCESS

OVERVIEW OF PRINCIPLES OF DOCUMENTATION

Regardless of the type of documentation chosen for a particular situation, certain principles have been found to be applicable in every instance. Listed immediately below for easy reference are the principles considered in the development and completion of the CMS-2567. Each principle is explained in detail in the document "Principles of Documentation".

Principle #1: Laboratory Compliance and Noncompliance
When a laboratory complies with the requirements applicable to the survey conducted, the CMS-2567 should consist of an explicit statement that the laboratory is in compliance. If a laboratory does not comply with one or more applicable requirements, the CMS-2567 includes corresponding citations of noncompliance.

Principle #2: Using Plain Language
The deficiency citation is written clearly, objectivelyand in a manner that is easily understood. The deficiency citation does not include consultation, advice, comments or direction aimed at the surveyed laboratory.

Principle #3: Components of a Deficiency Citation
A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A. Regulatory Reference:

A Regulatory Reference includes the following components:

1) A survey data tag number;
2) The CFR;
3) The language from that reference which specifies the aspect(s) of the requirements with which the laboratory was noncompliant; and
4) An explicit statement that the requirements were "NOT MET".

B. Deficient Practice Statement

The statement of deficient practice is one component of the evidence. It includes:

1) The specific action(s), error(s), or lack of action (deficient practice);

2) Outcome(s) relative to the deficient practice, when possible;
3) A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases;
4) The identifier of the individuals or situations referenced in the extent of the deficient practice; and
5) The source(s) of the information through which the evidence was obtained.

C. Relevant Facts and Findings

The facts and findings relevant to the deficient practice answer the questions: who, what, where, when, and how. They illustrate the laboratory's noncompliance with the requirements or regulation.
Note: Do not use names; only describe people by positions or job titles.

Principle #4: Relevance of Onsite Correction of Findings
If, during the survey, the laboratory corrects the situation that resulted in the deficiency, a determination of "NOT MET" must be documented on the CMS-2567. The laboratory may indicate its correction in the right-hand column of the CMS-2567.

Principle #5: Interpretive Guidelines
The deficiency citation demonstrates how the laboratory fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for interpreting those requirements.

Principle #6: Citation of State or Local Code Violations
The laboratory's failure to comply with State or local regulations is not documented in the CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action which has been sustained through the hearing process (such as removal of the license to operate), the CMS-2567 should note that the laboratory no longer has a license.

CLIA SURVEY PROCESS

OVERVIEW OF PRINCIPLES OF DOCUMENTATION

Principle #7: Cross-References
The cross-referencing of requirements is an acceptable form of documentation on the CMS-2567 only when it is applicable and provides additional strength to the linked citations.

Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, the linked citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation at the linked site.

Principle #8: Condition Deficiencies
The Condition citation includes deficient practice statements and findings to support the determination of noncompliance with a Condition level requirement. The findings may be incorporated either by cross-references to those requirements which must be corrected to find the Condition to be met or by narrative description of the individual findings.

[Reading Assignment: "Principles of Documentation"]

CLIA SURVEY PROCESS

IDENTIFYING AND CITING DEFICIENCIES

REGULATORY COMPLIANCE DECISION – The evaluation of laboratory compliance with CLIA standards and Conditions.
[Reading Assignment: SOM, Appendix C, Interpretive Guidelines, Section V, OOSP]

STANDARD VS CONDITION LEVEL DEFICIENCIES – CLIA Regulations are Conditions and standards as mandated by the CLIA statute that must be met by laboratories as applicable. The CLIA standards are designed to define component criteria constituting a CLIA Condition. Conditions are usually more serious and comprehensive. Standards address a distinguishable aspect of a Condition.

If noncompliance has been identified, cite the most specific deficiency. 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 using the "Principles of Documentation". Citing the same problem in multiple places confuses the laboratory and dilutes the problem and is therefore unnecessary. Incorrect citations may not be legally defensible.

MANDATORY CITATIONS – Condition-level deficiencies which must be cited regardless of outcome. These are associated with PT performance and enrollment and personnel qualifications and responsibilities.

[Reading Assignment: SOM, Appendix C, Interpretive Guidelines Section VII D; SOM Chapter 6, Section 6120.2.3]

IMMEDIATE JEOPARDY – This is a situation in which immediate corrective action is necessary to prevent harm to patient safety. Three components of immediate jeopardy are seriousness, immediacy, and harm.
[Reading Assignment: SOM, Appendix C, Interpretive Guidelines, Section V]

CLIA SURVEY PROCESS

IDENTIFYING AND CITING DEFICIENCIES

ALLEGATION OF COMPLIANCE (AoC) –required from the laboratory having Condition level deficiencies.
[Reading Assignment: SOM, Chapter 6, Sec. 6134]

PLAN OF CORRECTION (PoC) – required from the laboratory having standard level deficiencies.

[Read Assignment: SOM, Appendix C, Interpretive Guidelines, Section VII]

Noncompliant practices that are not corrected by a laboratory effectively and timely may lead to enforcement actions. **[See next section on Enforcement]**

CLIA SURVEY PROCESS

ENFORCEMENT

Enforcement Selection & Timelines

The purpose of enforcement is to motivate CLIA compliance which sets a standard for laboratory testing to ensure accurate, timely and reliable test results and thereby safeguards public health and safety. Most often, the survey is the beginning of the enforcement process. When a surveyor finds deficiencies, the laboratory is first given an opportunity to correct the problems. If the laboratory is unable or unwilling to correct the deficiencies in a timely manner, enforcement action can be taken against the laboratory. If the problems are repeat deficiencies, more aggressive actions may be taken and the enforcement process accelerated.

The CMS Regional Office has the delegated authority to propose and impose enforcement actions against laboratories. Cases which the surveyors deem to be appropriate for enforcement action must be referred to the Regional Office with a recommended action.

The enforcement actions available in CLIA are divided into alternative and principal sanctions. The choice of sanctions to be proposed is based on the laboratory's history, seriousness and pervasiveness of the problem(s).

Legal Aspects

The CMS-2567 is the legal document which is the basis for any enforcement action. All information on the 2567 must accurately document the deficiencies, be based upon fact and evidence, and be legally defensible. The surveyor may be called upon to testify during the appeals process if a laboratory requests a hearing to contest a finding of noncompliance or proposal of sanction.

[**Reading Assignments: SOM Chapter 6, Sec.6250 – 6299 for the CLIA enforcement process; Sec. 6282 – 6286.6 for enforcement timelines; Sec.6300 – 6316 for the CLIA appeals process; 42 C.F.R. 493.1800 – 493.1850, Enforcement procedures]**

PART IV

CLIA SURVEY PROCESS

ASSESSMENT

1. The laboratory is cited against the Interpretive Guidelines in Appendix C. True or False

2. The purpose of the survey is to determine the laboratory's compliance with the applicable CLIA requirements. True or False

PART V

CLIA DATA SYSTEM

OVERVIEW

The CLIA program is a user-fee funded program which means that each laboratory enrolling in CLIA must pay a certificate fee based on the type of testing performed. The certificate fee schedule can be found on the CLIA website at www.cms.gov/CLIA/ in the "How to Apply for a CLIA Certificate" section. All certificates types are valid for no more than two years.

A Certificate of Waiver (CoW) is issued to a laboratory that performs only tests that are categorized as waived. Waived tests are those tests that have been determined that if performed incorrectly will not pose risk or harm to the patient. The list of waived tests can be found on the CLIA website in the "Categorization of Tests" section. A CoW laboratory is not subject to routine biennial inspections.

A Certificate for Provider Performed Microscopy (PPM) is issued to a laboratory that performs microscopy test procedures and in combination with waived tests. The list of PPM tests are also listed on the CLIA website in the "Categorization of Tests" section. A PPM laboratory is also not subject to routine biennial inspections.

A Registration Certificate is initially issued to a laboratory that requests a Certificate of Compliance or a Certificate of Accreditation. The Registration Certificate for a Certificate of Compliance permits a facility to perform testing until compliance with CLIA requirements is determined through an inspection by the SA or RO.

For a Certificate of Accreditation, the laboratory must provide evidence of accreditation by an approved accreditation program within 11 months after receipt of the Registration Certificate. Upon payment of the appropriate fees (which are based on testing specialties and annual testing volume) a laboratory is issued the Certificate of Accreditation.

CLIA DATA SYSTEM

Support for the Survey and Certification Process

The CLIA data system supports the State agency, CMS RO, and CO in the day-to-day administration of the CLIA program and shares the survey and certification duties with other provider types. CLIA data processing also involves unique functions such as billing laboratories, issuing certificates, linking with Medicare and Medicaid claims processors, monitoring proficiency testing performance, evaluating CLIA equivalency with Exempt States and accreditation organizations, enrolling laboratories located in countries outside the United States, and maintaining current, accurate information for all CLIA certified laboratories.

To accomplish these tasks, CMS uses the Quality Improvement and Evaluation System (QIES) that resides on State servers and supports State-based functionality in the areas of survey and certification, nursing home resident assessments (known as MDS) and assessment data from home health agency patients (known as OASIS). The CLIA data resides in the survey and certification system within QIES called the Automated Survey Processing Environment (ASPEN). [See Exhibit 1, ASPEN Suite: Visual Overview]

ASPEN offers a suite of tools that supports the survey and certification process. They include:

- ASPEN Central Office (ACO) – ACO allows you to enter CLIA certifications for compliance laboratories and validation surveys of accredited laboratories.

- ASPEN Survey Explorer-Quality (ASE-Q) – ASE-Q is a tool used by surveyors in the field to record deficiency findings, generate the CMS-2567, and record specialty and test volume data. The survey shell is created in ACO, exported to ASE-Q, and then the completed survey findings are imported back to ACO for final review and processing.

CLIA DATA SYSTEM

- ASPEN Regional Office (ARO) – ARO allows RO CLIA staff to view pending and completed certifications, approve certifications with conditions out of compliance and authorize a State surveyor to conduct a validation survey via CMS-2802A process.
- ASPEN Complaint/Incident Tracking System (ACTS) – ACTS collects and tracks complaints from the initial reporting through the final findings.
- ASPEN Survey Scheduling and Tracking (AST) – AST is an optional tool to assist you and the RO staff in planning and managing your survey and certification workload.
- ASPEN Web CLIA 116 – ASPEN Web CLIA 116 is a web application that allows for the collection of the CMS-116 application information and related CLIA data including initial applications, demographic updates, terminations, status changes, proficiency testing enrollment and scores, accreditation updates, and issuance of fee coupons, certificates, approving refunds and reconciling laboratory accounts. The users of ASPEN Web CLIA 116 include the: SA, CLIA RO and CO, the accreditation organizations, CLIA exempt States, Proficiency Testing programs, CLIA's accounts reconciliation, billing and certificate issuance contractor, and the Veterans Administration.
- ASPEN Enforcement Manager (AEM) – AEM for CLIA is used by SA and CMS RO staff to capture information related to CLIA enforcement and assists in the issuance of the annual Laboratory Registry.
- Certification and Survey Provider Enhanced Reporting (CASPER) – CASPER is the national reporting system for survey and certification data, and it contains standard and user-designed reports (known as QIES Workbench). To prepare for upcoming surveys and/or monitor proficiency testing performance, the SA uses standard reports to track a laboratory's prior compliance history and any PT failures, to note the size and complexity of the laboratory's testing menu and to check for any past enforcement sanctions or complaint allegations.

CLIA DATA SYSTEM

Contact your State ASPEN Coordinator to obtain access to the ASPEN applications and CASPER reporting. Also, to obtain additional information on these applications, including training manuals, e-learning modules, and procedure guides, log onto www.qtso.com.

You may also contact the QIES Help Desk at 888-477-7876 for immediate assistance.

CLIA Forms and Data Processing

The information a laboratory submits to the SA or RO as part of the CLIA application process is entered into the ASPEN CLIA system. As a State surveyor, the information collected on a survey is entered either through ASE-Q or ACO and then uploaded to the QIES system.

The required CLIA certification forms and corresponding data processes are described below:

- CLIA Application for Certification (FormCMS-116)
  A laboratory initiates enrollment in the CLIA program by completing the CLIA Application Form CMS-116. The application form may be downloaded from the CLIA website at www.cms.gov/CLIA/ in the section called, "How to Apply for a CLIA Certificate." The form contains pertinent CLIA registration information, including laboratory name, address, laboratory director's name, hours of operation and the types and volume of testing performed in the laboratory. The laboratory forwards the completed form to the SA. The application is reviewed for completeness and accuracy, verification of the qualifications of the laboratory director, if appropriate, and screened with the CLIA data base for possible duplicate records. If the review identifies indicators for potential fraud, follow the procedural guidance provided by CLIA CO. When the State agency enters the Form CMS-116 into the ASPEN Web CLIA 116, the CLIA number is system-assigned and the CLIA fee coupon(s) is (are) generated.

CLIA DATA SYSTEM

- The Laboratory Personnel Report (CMS-209)
  The CMS-209 is provided to the laboratory prior to the survey for purposes of updating information, adding new personnel or reporting changes in positions or status. It is part of the documentation that is used during the laboratory's certification survey. The CMS-209 is not entered into ACO, but is either kept with the hard copy certification kit or scanned and attached to the electronic certification kit in ACO.

- The Medicare/Medicaid Certification and Transmittal (CMS-1539)
  The CMS-1539 is used to certify findings to the RO regarding a laboratory's compliance with CLIA requirements. Enter key information into ACO, most notably, the "In Compliance/Not in Compliance with Program Requirements field," the "Surveyor Signature Signoff Date" and the "State Agency Approval Date" on the Transmittal (CMS-1539) tab of the certification kit. After the State finalizes the certification kit and uploads, the ACO will screen the kit for the presence of condition level deficiencies. If conditions are present, the kit is flagged and the CLIA RO is notified via ARO to review and approve the certification (completing the "Regional Office Receipt Date" and "Regional Office Approval Date" on the CMS-1539 form). If there are no deficiencies or only standard level deficiencies, then ACO will not require RO approval and the certification kit is uploaded QIES.

- CLIA Survey Report Form (CMS-1557)
  The CMS-1557 is used to gather information regarding the surveyor's observations during the onsite survey. The surveyor uses the 1557 Specialties tab of the Certification kit to verify or update the specialty and test volume information reported on the CMS-116. The Survey (CMS -1557) tab of the Certification kit is used to record personnel qualifications of the Director and others in the laboratory, based on the complexity level of the testing being performed.

- Statement of Deficiencies and Plan of Correction (Form CMS-2567) and Post Certification Revisit Report (Form CMS-2567B)
  The CMS-2567 is used to document the deficiencies found on the

survey. The surveyor has 10 days after the survey to prepare and send the CMS-2567 to the laboratory. The laboratory has up to 10 days to respond with a PoC or AoC for each deficiency cited. Once the PoC is accepted, the laboratory may be certified to perform testing. The correction of deficiencies is documented using the CMS-2567B form. This information is part of a certification kit that is maintained in ACO.

- Survey Team Composition and Workload Report (CMS-670)
  The CMS-670 is used to report the time each surveyor spends on the different parts of the survey: pre-survey preparation, travel time, onsite, post-survey, administrative and clerical time. This information is part of the certification kit that is maintained in ACO.

- Request for Complaint Investigation or Validation Survey of an Accredited Laboratory (CMS-2802A)
  The RO uses the CMS-2802A to grant approval to the State agency to perform validation surveys in accredited laboratories, and to authorize SA surveyors to investigate complaint allegations in accredited laboratories. The SA may print the CMS-2802A from ACO or ACTS (as appropriate) following RO approval and signoff.

Certification Workflow

The State Agency has the primary responsibility for entry of the CLIA certification and survey findings into ACO. The ASPEN Software (ACO, ASE-Q, and AST-optional) is used during each step of the survey process. These steps include:

- scheduling the survey;
- creating the certification kit;
- assigning the survey team;
- defining the survey shell;
- entering deficiencies;
- reporting testing personnel;
- counting surveyor time;
- approving specialties of testing;
- verifying test volumes;
- verifying plans of correction; and
- reporting certification findings to the RO.

CLIA DATA SYSTEM

Once the SA completes its survey and certification responsibilities, the SA uploads the kit in ACO. At that point, the ACO will screen the laboratory's compliance record and if there are no deficiencies or deficiencies at the standard level only, the record will be successfully uploaded and accepted to QIES. If, however, the laboratory is cited for condition level deficiencies, the record is flagged and remains pending in ASPEN with notification sent to the CLIA RO. The CLIA RO staff is then responsible for final review of flagged certification kits.

Prior to conducting a validation or complaint survey of an accredited laboratory, the State must obtain RO approval via the Request for Complaint Investigation or Validation Survey of an Accredited Laboratory (CMS-2802A). Depending upon whether the SA or RO initiates the selection process, ACO or ARO notifies CLIA staff of the upcoming validation survey and ensures that the RO grants approval before the survey is performed. In addition, the SA must also secure RO approval in cases involving complaint allegations that occur in accredited laboratories. The ACTS generates the CMS-2802A form once the necessary RO approval is obtained.

Using standard reports as a guide, the SA also performs an administrative task that generally occurs outside the routine survey and certification process. This function, most commonly called "PT desk review" involves the monitoring and review of a laboratory's PT performance. The SA can access CASPER Reports 155 (PT Individual Laboratory Profile) and 153 (PT Unsatisfactory/Unsuccessful Report) to assist in PT desk review. According to CLIA policy, the PT monitoring process may result in deficiency citations and/or training and technical assistance for the laboratory and the ACO and CLIA enforcement databases must be updated to reflect any SA actions. PT desk reviews should be performed only on compliance laboratories and should be done routinely every 30-45 days. PT desk reviews are entered into ACO as a Special Survey and not in the Certification kit.

CLIA DATA SYSTEM

CLIA Billing Facts

- Payment Address

  A laboratory should submit its CLIA payments with the fee coupon to:

  CLIA Laboratory Program
  PO Box 530882
  Atlanta, GA 30353-0882

  If a laboratory does not have a copy of its fee coupon, the laboratory should put the CLIA number on the check and send it to the bank. If paying for more than one laboratory, all CLIA numbers must be recorded. A laboratory must NOT photocopy or use another laboratory's fee coupon. This will result in the payment being posted to the wrong CLIA account.

- Lockbox Contractor

  The U.S. Department of the Treasury designates which bank is to function as CLIA's lockbox. The designated bank will collect, process, and deposit CLIA fees daily. The bank electronically transmits this lockbox information to CMS and the fees are applied to the laboratory records in the ASPEN Web CLIA 116.
  Note: The laboratories may also pay CLIA fees online using credit cards or check payments by accessing https://pay.gov/public/home.

- Coupons/billings

  A file containing the CLIA fee coupons is created weekly. The bill issuance contractor downloads the file and mails out the fee coupons. Unless there is an unusually large volume, the mailings are generally completed by the end of the current week. A laboratory will receive one of the following fee coupons:
  1) an initial fee coupon;
  2) the rebill fee coupon (sent 60 days after initial bill); or
  3) the final fee coupon (sent 120 days after initial bill).

  If the final fee coupon is not paid within 60 days of receipt, the laboratory's CLIA certificate will be terminated for nonpayment of fees (termination code = 08).

CLIA DATA SYSTEM

CLIA Certificate inspection fees

The certificate fees are uniform for all laboratories in CLIA regardless of their location. The compliance and validation fees, however, vary by State, as specified in the CLIA regulations.

Certificate Fees – Laboratories that apply for a CLIA certificate must pay a fee for the issuance and renewal of the CLIA certificate based on the nature and scope of tests performed.

Inspection Fees – Laboratories that obtain a Certificate of Compliance (CoC) must pay a compliance fee to cover the cost of an inspection. Laboratories that obtain a Certificate of Accreditation (CoA) must pay a validation fee to cover the cost of a validation inspection.

Certificate of Waiver fee – A laboratory that performs only tests categorized as waived must pay a fixed biennial certificate fee. A certificate renewal fee is sent to the laboratory six months prior to the next scheduled certificate cycle.

Certificate for Provider-Performed Microscopy (PPM) Procedures fee – A laboratory that performs only PPM procedures or only tests specified as PPM and tests categorized as waived must pay a fixed biennial certificate fee. A certificate renewal fee is sent to the laboratory six months prior to the next scheduled certificate cycle.

Certificate of Registration fee – Laboratories applying for a Certificate of Compliance or a Certificate of Accreditation initially receive a fixed Certificate of Registration fee. The Certificate of Registration is valid until such time the laboratories are inspected and determined to be in compliance with the appropriate requirements. Along with the Certificate of Registration fee, laboratories applying for a CoC receive an inspection compliance fee that must be paid prior to the performance of the inspection.

Certificate of Compliance fee – Once a laboratory applying for a CoC is inspected and compliance is determined, the laboratory must pay the appropriate biennial certificate fee which is based on volume and the number of specialties. Twelve months prior to the expiration date of the certificate, a recertification fee is sent to the laboratory.

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Certificate of Accreditation fee – Once a laboratory applying for a CoA shows proof of compliance with the requirements of the approved accreditation organization, the laboratory must pay a biennial certificate fee which is based on volume and number of specialties. Also included is a validation cost. Six months prior to the expiration date of the certificate, the laboratory is sent the validation and certificate fee for its next CLIA cycle.

CLIA DATA SYSTEM

Issuing CLIA Certificates – Key Facts

- Files containing the CLIA certificates are created on Tuesday. CLIA's certificate issuance contractor downloads the file and mails out the fee coupons by the end of the current work week.
- A certificate is issued to a laboratory seeking its initial registration, waived, or PPMP certificate as soon as the requisite fees are fully paid.
- The Certificate of Compliance is issued to the laboratory after the laboratory's inspection is entered into the system and the certificate of compliance fee is paid.
- The Certificate of Accreditation is issued after verification of accreditation by one of the accreditation organizations and subsequently every two years.
- Once all appropriate requirements are met and the requisite fees are paid, the renewal certificates are mailed to the laboratories approximately 30 days in advance of their effective dates.

CLIA Information to Medicare and Medicaid

- Medicare (Common Working File (CWF)) - A weekly file is produced which contains laboratory records that were updated and transmitted to Medicare or added to the ACO from Thursday of the prior week through Wednesday of the current week. The CWF edits incoming claims for laboratory testing (submitted via the Health Insurance Claim form (CMS-1500)) and ensures that testing has occurred in a laboratory holding a current and valid CLIA certificate.

- Medicaid State Agencies (CASPER Report 91) - Each Medicaid State Agency (MSA) is responsible for either downloading CASPER Report 91 on a regular basis or for using the automated download process established by CMS CO. The MSA uses the CLIA information in the file to ensure that laboratories requesting Medicaid reimbursement hold current and valid CLIA certificates.

CLIA DATA SYSTEM

Laboratory Demographics Look-up

The Laboratory Demographics Look-up is available on the CMS CLIA website. This is a data base of all active laboratories currently contained in the CLIA data system. This resource allows you to perform a search by CLIA number, laboratory name, city, State, zip code, application type and/or exempt status. When the search is performed, the look-up program will return demographic information on the laboratory, including CLIA number, laboratory name, address, telephone number, where the laboratory testing is performed, the type of CLIA certificate, and the date the certificate expires.

CLIA DATA SYSTEM

Exhibit

Exhibit 1 – ASPEN Suite – Visual Overview

Exhibit 1 is a display of the ASPEN Suite of tools. There are 5 doors representing the 5 software packages in ASPEN, including ACO, ACTS, AEM, AST and AWEB. Arrows from 4 of the 5 doors (all but the ASPEN Web CLIA 116 door) point to a cylinder in the middle of the picture, representing the flow of data from the individual tools to the State servers. One arrow points from the State server to a larger cylinder on the right representing the QIES national database. Data from the state servers must be uploaded to the national database. Another arrow points from the 5th door (the ASPEN Web CLIA 116 door) directly to the national database. In the upper left hand corner of the picture is a surveyor working with ASE-Q on a laptop. Another arrow points from the laptop to the Sybase database, showing that ASE-Q data is stand-alone data that must be imported to ACO or ACTS before it can be uploaded to the state server.

CLIA DATA SYSTEM

Exhibit 1

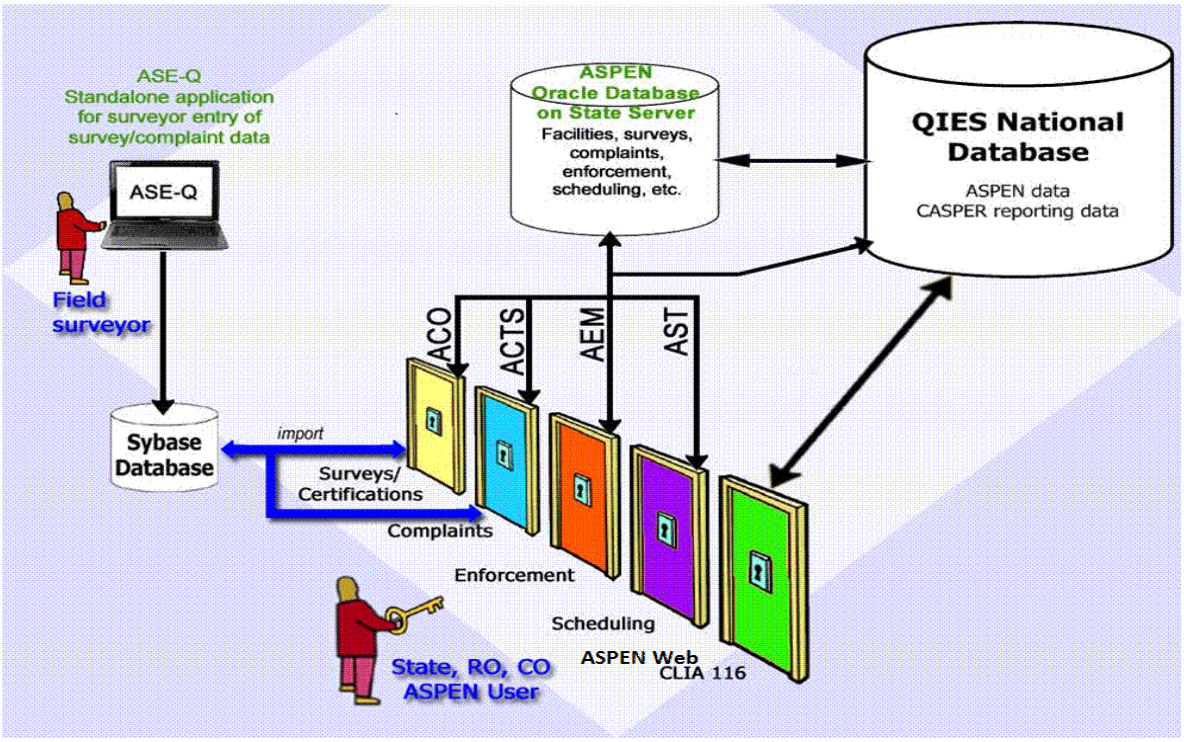

Figure 1: Surveyor Uploads to ASPEN from which information can be retrieved from 5 doors (ACO for Survey information, ACT for Complaints, AEM for Enforcement, AST for Scheduling and ASPEN Web CLIA 116).

CLIA DATA SYSTEM

ACRONYMS AND DEFINITIONS

ACO **ASPEN Central Office**
This software allows you to enter CLIA certifications for compliance laboratories and validation surveys of accredited laboratories.

ACTS **ASPEN Complaint/Incident Tracking System**
This software collects and track complaints from the initial reporting through the final findings.

AEM **ASPEN Enforcement Manager**
This software is used by CMS RO staff to capture information related to CLIA enforcement and to assist in the issuance of the annual Laboratory Registry.

ARO **ASPEN Regional Office**
This software allows RO CLIA staff to view pending and completed certifications, to approve certifications with conditions out of compliance, i.e., flagged kits, and to authorize a State surveyor to conduct a validation survey via CMS-2802A process.

ASE-Q **ASPEN Survey Explorer-Quality (ASE-Q)**
This software is a tool used by surveyors in the field to record deficiency findings, to generate the CMS-2567, and to record specialty and test volume data. A 'survey shell' is created in ACO, exported to ASE-Q, and then the completed survey findings are imported back to ACO for final review and processing.

ASPEN **Automated Survey Processing Environment**
This is the suite of tools that currently consists of ACO, ACTS, AEM, ARO, ASE-Q, AST and CLIA 116.

CLIA DATA SYSTEM

ACRONYMS AND DEFINITIONS

ASPEN Web CLIA 116

This software includes the collection of initial applications, demographic updates, terminations, specialty and test volume revisions, certificate status changes and accreditation updates. The users of ASPEN CLIA include: the SA, RO, CMS CO, the accreditation organizations, CLIA exempt States, Veterans Administration, PT programs and, CLIA's accounts reconciliation, billing and certificate issuance contractor.

AST **ASPEN Survey Scheduling and Tracking**
This optional tool assists you and the RO staff in planning and managing your survey and certification workload.

CASPER **Certification and Survey Provider Enhanced Reporting** This is the national reporting system for QIES information, including survey and certification data, and contains standard and user-designed reports (known as QIES Workbench).

CMPTS **Civil Money Penalty Tracking System**
This software tracks the imposition and collection of civil monetary penalties. CLIA enters information in this system by using the CMP tabs in the AEM.

Lockbox The bank (designated by the Department of the Treasury) which collects, processes, and deposits CLIA fees daily.

MDS **Minimum Data Set**
This includes the clinical information collected on residents of nursing homes and the data is used for care planning and quality improvement.

CLIA DATA SYSTEM

ACRONYMS AND DEFINITIONS

OASIS **Outcome Assessment Information Set**
This is clinical information collected on patients of home health agencies and the data is used for care planning and quality improvement.

QIES **Quality Improvement and Evaluation System**
QIES encompasses all the aspects of data collection and reporting on Medicare, Medicaid, and CLIA providers including survey and certification and assessment data. CASPER, ASPEN, and the MDS and OASIS assessment data are components of QIES.

QW **QIES Workbench**
This provides for ad-hoc QIES data access. Enables a user to select and extract any subset of QIES data into a custom report format or into a custom file format. QW allows a user the ability to select any condition or combination of conditions.

WebEx This is an Internet-based software application that allows for interactive training and demonstrations and is used to educate CMS CO, RO and SA staff on QIES applications.

PART V

CLIA DATA SYSTEM

ASSESSMENT

1. The surveyor uses the 1557 Specialties tab of the Certification kit to verify or update the specialty and test volume information reported on the CMS-116. True or False

2. ACO is the software in the ASPEN System that allows you to enter CLIA certifications for compliance laboratories and validation surveys of accredited laboratories. True or False

PART VI

GLOSSARY

The glossary on the following pages includes a partial listing of abbreviations, acronyms, and definitions relating to the survey and certification process. There will be many more which you will hear, or read, during the period of your orientation course. You will no doubt want to add them to this section for continuing reference.

A2LA - American Association for Laboratory Accreditation

AAB - American Association of Bioanalysts

AABB - AABB

AACC - American Association for Clinical Chemistry

AAFP - American Academy of Family Physicians

AHRQ - Agency for Healthcare Research and Quality

ALJ - Administrative Law Judge

AMA - American Medical Association

AO - Accreditation Organization

AOA - American Osteopathic Association

AoC - Allegation of Compliance

APHL - Association of Public Health Laboratories

ARC - American Red Cross

ASC - Ambulatory Surgical Centers

ASC - American Society for Cytology

GLOSSARY

ABBREVIATIONS AND ACRONYMS

ASCLS	-	American Society for Clinical Laboratory Science
ASCP	-	American Society for Clinical Pathology
ASCT	-	American Society for Cytotechnology
ASHI	-	American Society for Histocompatibility and Immunogenetics
ASM	-	American Society of Microbiology
CAP	-	College of American Pathologists
CCSQ	-	Center for Clinical Standards & Quality
CDC	-	Centers for Disease Control and Prevention
CFR	-	Code of Federal Regulations
CLIA	-	Clinical Laboratory Improvement Amendments of 1988
CLIAC	-	Clinical Laboratory Improvement Advisory Committee
CLS	-	Clinical Laboratory Scientist
CLSI	-	Clinical and Laboratory Standards Institute
CLT	-	Clinical Laboratory Technician
CO	-	Central Office
COLA	-	COLA
CT	-	Cytotechnologist

GLOSSARY

ABBREVIATIONS AND ACRONYMS

DAB	-	Departmental Appeals Board (formally Grants Appeals Board)
DHHS	-	Department of Health and Human Services
DCLIQ	-	Division of Clinical Laboratory Improvement and Quality
DO	-	Doctor of Osteopathy
DSC	-	Division of Survey & Certification (RO)
EHR	-	Electronic Health Record
ES	-	Exempt State
FDA	-	Food and Drug Administration
FMS	-	Federal Monitoring Survey
FOIA	-	Freedom of Information Act
FR	-	Federal Register
FTC	-	Federal Trade Commission
GAO	-	Government Accountability Office
GYN	-	Gynecology
HHA	-	Home Health Agency
HIPAA	-	Health Insurance Portability and Accountability Act

GLOSSARY

ABBREVIATIONS AND ACRONYMS

HRSA - Healthcare Research Services Administration

IQCP - Individualized Quality Control Plan

LBA - Live Blood Cell Analysis

LPN - Licensed Practical Nurse

MA - Medical Audit/Medical Assistant

M.D. - Doctor of Medicine (Medical Director)

MLT - Medical Laboratory Technician

MPA - Master of Public Administration

MPH - Master of Public Health

MT - Medical Technologist

NFPA - National Fire Protection Association

NHA - Nursing Home Administrator

NIH - National Institute of Health

NIST - National Institute of Standards and Technology

NP - Nurse Practitioner

NTIS - National Technical Information Services

OBRA - Omnibus Budget Reconciliation Act

OCR - Office of Civil Rights

GLOSSARY

ABBREVIATIONS AND ACRONYMS

OGC	-	Office of General Counsel
OIG	-	Office of the Inspector General
OSHA	-	Occupational Safety and Health Administration
OOSP	-	Outcome–oriented survey process
PA	-	Physician's Assistant, Pathology Assistant
Part A	-	Provider Reimbursement – Medicare
Part B	-	Supplier and Physician Reimbursement – Medicare
Path.	-	Pathology
Pharm. D.	-	Doctor of Pharmacy
PHS	-	Public Health Service
P.L.	-	Public Law
PoC	-	Plan of Correction
PoD	-	Principles of Documentation
POL	-	Physician Office Laboratory
PPM	-	Provider-Performed Microscopy Procedures
PT	-	Proficiency Testing/Prothrombin Time
Pub.	-	Publication

GLOSSARY

ABBREVIATIONS AND ACRONYMS

QC	-	Quality Control
QA	-	Quality Assessment
QSOG	-	Quality, Safety & Oversight Group
RHC	-	Rural Health Clinic
RN	-	Registered Nurse
RO	-	Regional Office
RT	-	Respiratory Therapist
SA	-	State Agency
SAPR	-	State Agency Performance Review
SNF	-	Skilled Nursing Facility
SOM	-	State Operations Manual (Pub.100-7)
SOP	-	Standard Operating Procedures
Std.	-	Standard
Title VI	-	Civil Rights Act
Title XVIII	-	Social Security Act - Medicare Program
Title XIX	-	Social Security Act - Medicaid Program
TJC	-	The Joint Commission
VA	-	Department of Veterans Affairs

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DEFINITIONS

Administrative Law Judge (ALJ) - One of a group of specifically designated individuals from the Office of Hearings and Appeals, Social Security Administration, responsible for conducting evidentiary hearings under the Medicare and Medicaid administrative appeals processes**.**

Agreement (1864) - Under section 1864 of the Social Security Act (the Act), CMS contracts with the States to perform various survey and certification functions. Under this agreement (1864), States consent to perform survey and certification functions, while the Secretary consents to pay the States for reasonable costs related to the performance of these functions.

Allegation of Compliance - Documentation submitted by a laboratory indicating that condition-level deficiencies are being or have been resolved.

Appeal Process (CLIA) - The Public Health Service Act (PHSA) mandates that every laboratory is subject to CLIA requirements. Section 1641 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) requires that laboratories participating in the Medicare program comply with CLIA requirements. This consolidated set of Federal requirements allows one set of procedures for all appeal actions by laboratories. These procedures are set forth in the regulations at 42 CFR Part 493.1844 and provides for reconsideration following an initial determination by the RO. The following actions are initial determinations and therefore subject to appeal:

- Suspension, limitation, or revocation of the laboratory's CLIA certificate because of noncompliance with CLIA requirements;
- Denial of a CLIA certificate;
- Imposition of intermediate sanctions under 42 CFR Part 493.1806 through 493.1807 (but not the determination as to which intermediate sanction(s) to impose); and
- Denial or the cancellation of the laboratory's approval to receive Medicare payment for its services.

A laboratory dissatisfied with an initial determination may request an administrative hearing before an ALJ. If the laboratory is dissatisfied with

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DEFINITIONS

the ALJ decision, the laboratory may request appeals council review of the ALJ decision. A laboratory dissatisfied with a decision that upholds the imposition of a civil money penalty or the suspension, limitation, or revocation of a CLIA certificate may, file with the U.S. Court of Appeals**.**

Beneficiary - An individual entitled to receive Medicare services.

Complaint Survey - An onsite survey conducted by Federal RO or SA surveyors to investigate an allegation against a laboratory of noncompliance with one or more CLIA requirements.

Deemed Status - The status of a laboratory that participates in the CLIA program by virtue of its accreditation by an approved accreditation organization, whose standards have been determined by HHS to be at least equivalent to the CLIA requirements. A laboratory deemed to meet the CLIA requirements is not routinely surveyed for CLIA purposes.

Deficiency - Noncompliance with one or more applicable CLIA program requirements.

Denial - Non approval of a laboratory's initial request for CLIA certification based on noncompliance with CLIA program requirements**.**

Due Process - Those rights of appeal afforded laboratories that are the subjects of adverse action taken by the State or DHHS. See Reconsideration, ALJ, Appeals Council Review, Appeal Process, and Departmental Appeals Board.

Freedom of Information Act (FOIA) - Establishes the right of the public to have access to numerous types of Federal information.

Plan of Correction (PoC) - A plan of action(s) submitted by a laboratory designed to correct deficiencies cited by the SA within a period of time acceptable to the authority that determines compliance with CLIA requirements.

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DEFINITIONS

Procedure Manuals - A written manual containing the analytical methods used by the laboratory, readily available and followed by laboratory personnel. These may consist of notebooks, manufacturer instrument manuals, package inserts, computer data, card files, etc. Specific contents of a procedure manual are listed in the CLIA regulations under Analytical Systems.

Proficiency Testing (PT) - An external form of quality control which involves sending a specimen to a clinical laboratory for analysis. The specimen, although labeled as a PT sample, contains constituents in amounts unknown to the laboratory. The laboratory performs testing on the PT samples and sends its test results to the PT program for evaluation. The PT program determines whether the results fall within a prescribed range of acceptable criteria. PT is also an acronym for prothrombin time.

Reconsideration - The initial action in the administrative review process for any laboratory dissatisfied with a denial or non-renewal of its CLIA Certification. The facility must submit a request for reconsideration within 60 days following the determination.

Regional Office (RO) - One of the ten Federal offices under HHS which audits the SA certification actions and provides technical and administrative assistance to SAs, the public and laboratories. Each RO has a CLIA representative.

Regulations - Requirements or standards established by State, Federal or local agencies pursuant to law and having the effect of law.

State Operations Manual (SOM) - Policy and procedural manual for survey and certification programs.

Statutory Requirements - Requirements passed by Congress and signed into Federal law; also refers to requirements established by State laws.

Transfusion Related Fatality - Fatalities related to the administration of blood or blood components which must be reported to the Public Health

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DEFINITIONS

Service/Food and Drug Administration (FDA). FDA evaluates these reports and may initiate an investigation to determine whether remedial action is necessary or has been taken. FDA also refers some of these investigations to CMS for the RO/SA to follow-up under CLIA.

ADDENDUM

STAFF EVALUATION FORM
(Newly Hired CLIA Staff)

Name_____

Date Employed_____

Job Title _____

A. PROGRAM CONTENT

	Satisfactory	**Needs Improvement**
Part I		
Part II		
Part III		
Part IV		
Part V		
Part VI		

B. OVERALL RATING OF PERFORMANCE

Satisfactory_____	**Needs Improvement**_____

C. SUGGESTION TO IMPROVE PERFORMANCE

Evaluator_____ **Date**_____