WISCONSIN DEPARTMENT of HEALTH SERVICES

Clinical Laboratory Improvement Amendments (CLIA) Laboratory Provider Forum

State of Wisconsin
CLIA Team

November 29, 2023

Laboratory Survey Preparation and Process Part I

Welcome

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Objectives

Provide information so laboratories are well prepared and ready for a CLIA survey

- Updating the CMS-116 CLIA Application and CMS-209 Laboratory Personnel Report
- Overview of Survey Readiness and Organization of Documents and Records for Review
- Review of Personnel Responsibilities and Qualifications

Disclaimer: The information presented in this CLIA Provider Forum is for educational purposes only. Refer to Standards and Certification: Laboratory Requirements (42 CFR 493) for official CLIA Regulations.

To Ask a Question

- Click the Q&A button
- Type your question in the Q&A box and Submit
- Please DO NOT submit questions using the Chat Button

CLIA Program Oversight and Administration

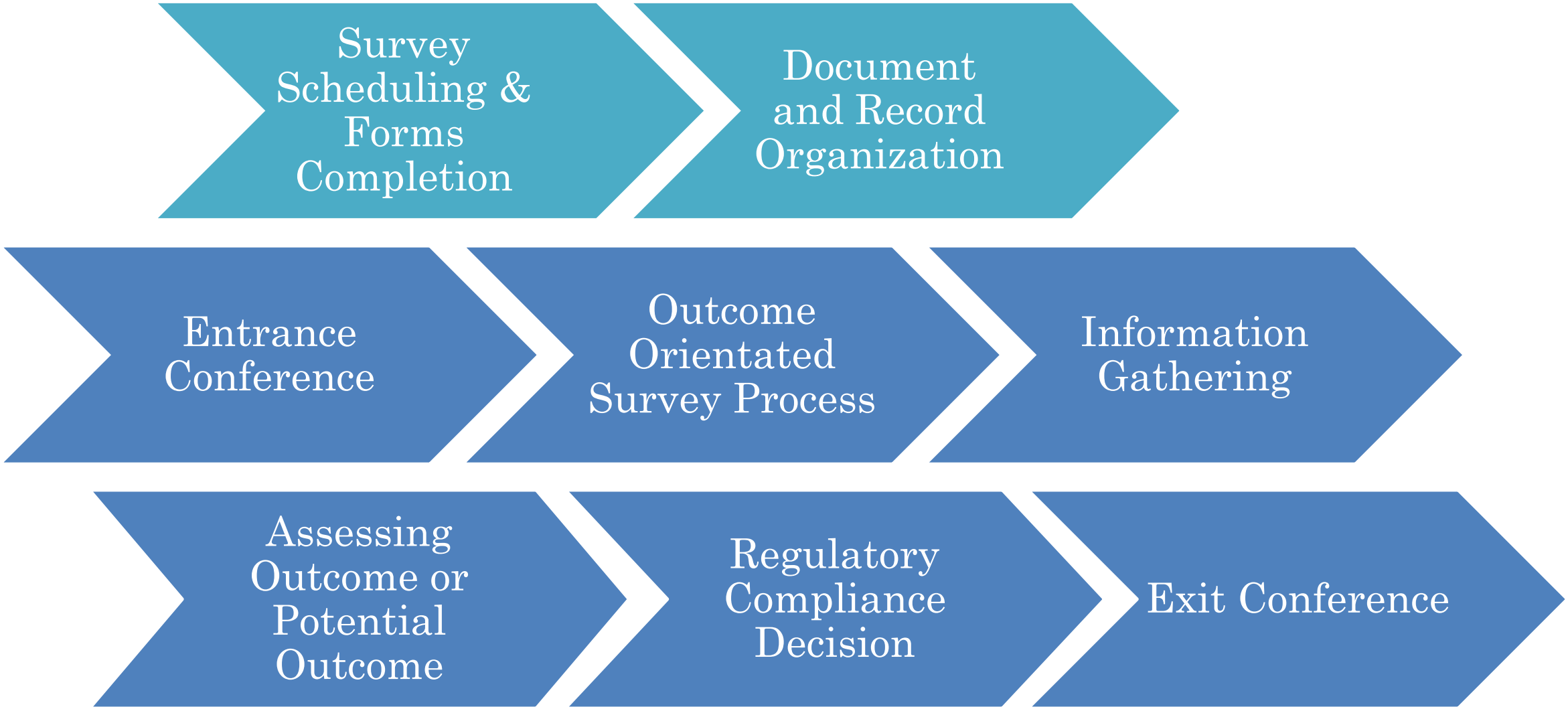
- The Centers for Medicare & Medicaid Services
- The Food and Drug Administration
- The Centers for Disease Control and Prevention

CDC, Lab Training, Introduction to CLIA

Types of CLIA Certificates

CDC, Lab Training, Introduction to CLIA

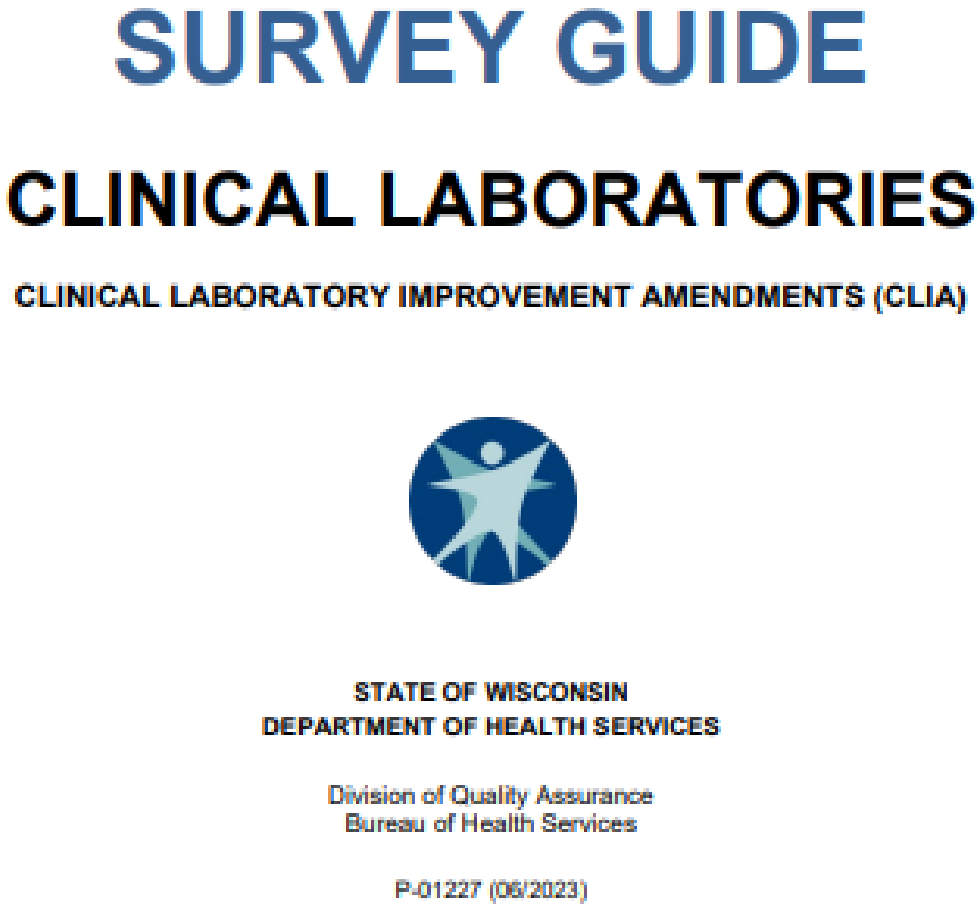
CLIA Survey Preparation and Process Summary



Survey Guide for Clinical Laboratories

- CLIA Survey Guide (P-01227)

https://www.dhs.wisconsin.gov/publications/p01227.pdf


SURVEY GUIDE

CLINICAL LABORATORIES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

STATE OF WISCONSIN
DEPARTMENT OF HEALTH SERVICES

Division of Quality Assurance
Bureau of Health Services

P-01227 (06/2023)

Survey Preparation and Readiness
Scheduling and Form Completion

Tracy Moraine, Laboratory Certification Officer

Survey Types and Scheduling

- Routine Recertification Surveys
  - 2-week notice
  - Occur every other year
- Initial Survey
  - Occur 3 to 12 months after entry into federal CLIA database
- Validation Surveys
  - Must be completed within 90 days of accreditation survey
- Complaints
  - Unannounced

Official Survey Announcement

- Announcement Letter
  - Includes date and time of survey and a list of items to have ready
- CMS-116 CLIA Application
- CMS-209 Laboratory Personnel Report

Please submit all forms prior to the survey.

CMS-116 CLIA Application

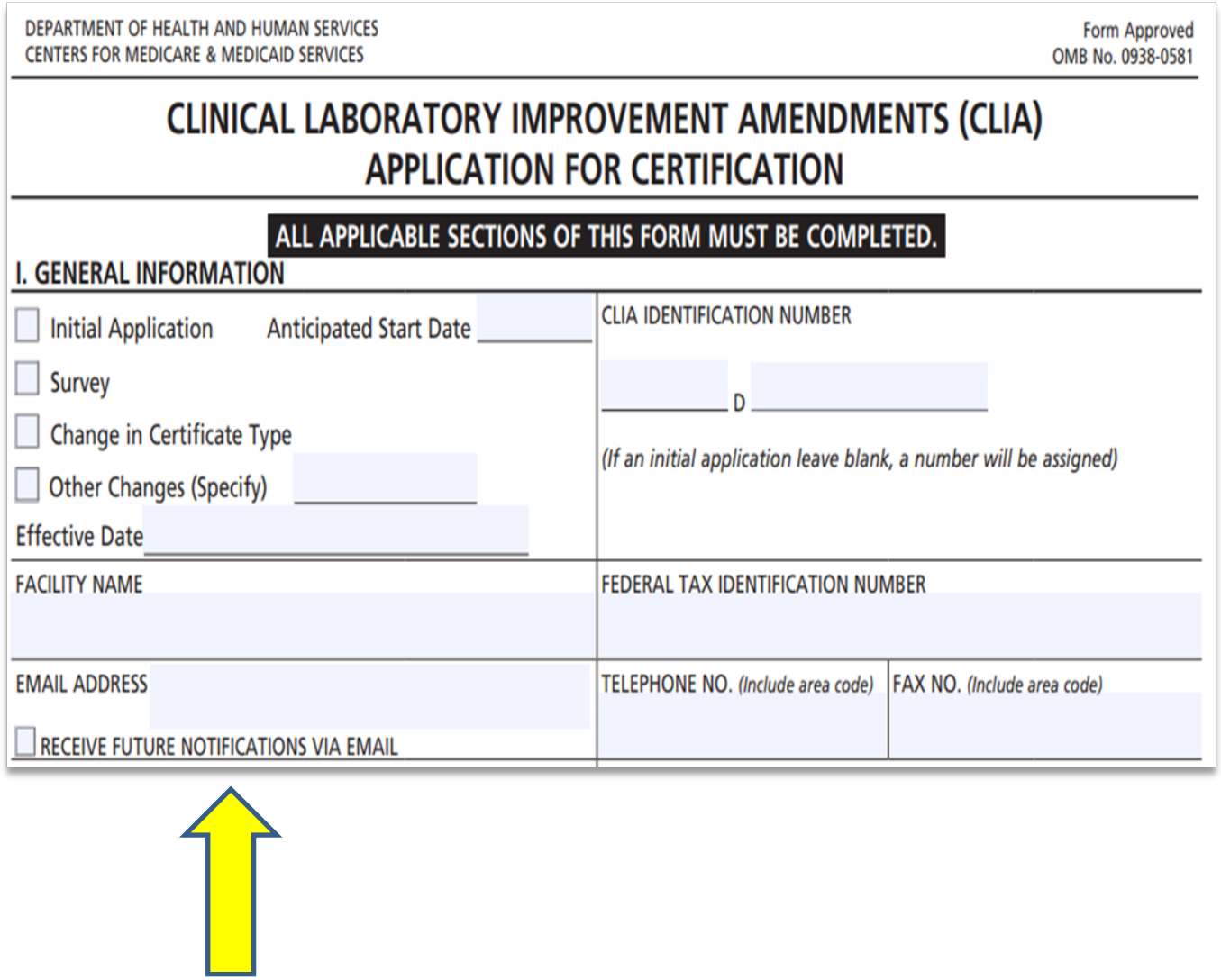
Pre-filled CMS-116 CLIA Application

- Review information, make changes as needed—including test volumes
- Laboratory Director (LD) must sign
  - "Wet" signature or traceable electronic signature is required

Remember to Update: notifications via email, FAX NO. or enter N/A, test volumes, and the foreign ownership question.

Electronic Certificate Availability

- CMS will email a link to your CLIA certificate when available
- Also available via the CMS / CLIA website through the 'Laboratory Demographics Lookup' S&C QCOR (cms.gov)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

Test List

- Can submit a separate Test List file with your CLIA 116 Application
- Test List file should include columns for Analyte Name, Instrument or Kit Name and Manufacturer

It may be helpful for the laboratory to include a column to indicate Proficiency Testing Provider/Survey or Twice a Year Accuracy Checks along with a column for Test Complexity.

Testing Complexity Personnel Requirements

Moderate Complexity	High Complexity
Laboratory Director	Laboratory Director
Clinical Consultant	Clinical Consultant
Technical Consultant*	
	Technical Supervisor*
	General Supervisor/ Cytology Supervisor
Testing Personnel	Testing Personnel
* If performing Moderate and High Complexity Testing, need a TC and TS.	

Many Laboratory Director duties may be delegated to qualified laboratory personnel, but delegation must be in writing. Delegation must recur when there is a new Lab Director. The Laboratory Director is responsible for ensuring that all requirements are met, including delegated duties.

CMS-209 Laboratory Personnel Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0151

LABORATORY PERSONNEL REPORT (CLIA)

(For moderate and high complexity testing)

1. LABORATORY NAME		2. CLIA IDENTIFICATION NUMBER
Your Lab		52D9999999
3. LABORATORY ADDRESS *(NUMBER AND STREET)*	**CITY**	**STATE** / **ZIP CODE**
123 Main Street	Your Town	WI / 99999

4. Instructions:

a. List below all technical personnel, by name, who are employed by the laboratory. Check (4) the appropriate column for each position held. For TC and TS **follow instructions on reverse.** For laboratories performing moderate complexity testing, list the positions of D, CC, TC and TP. For laboratories performing high complexity testing, list the positions of D, CC, TS, GS and TP. For cytology, list D, CC, TS, CT/GS and CT.

b. Indicate highest level of testing for which personnel are qualified: Use (M) for moderate and (H) for high complexity.

Positions:
D - Director
CC - Clinical Consultant
TC - Technical Consultant
TS - Technical Supervisor
GS - General Supervisor
TP - Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

5. TELEPHONE *(INCLUDE AREA CODE)*
(999) 999-9999

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)
QUALIFIES ACCORDING TO SUBPART M

DATE OF SURVEY _____

EMPLOYEE NAMES			a. POSITION HELD							b.
LAST NAME	FIRST NAME	MI	D	CC	TC	TS	GS	TP	CT/GS	CT	M OR H
Doctor, Ima			✓	✓							H
Smart, Vera					7						H
					8	8					H
Best, Wanda							✓	✓			H
Break, Anita								✓			H
Light, Ray O.								✓			M

Technical Consultant / Technical Supervisor Identifiers

- Page two of the CMS-209 Form

5. For 4(a) TC/TS:
   When listing those individuals holding technical consultant/technical supervisor (TC/TS) positions, use the following grid to indicate the specialty(ies)/subspecialty(ies) in which they presently function. Record the number corresponding to the specialty/subspecialty in the appropriate column (TC/TS). When an individual functions as a TC/TS in more than one specialty/subspecialty, use a separate line for each specialty/subspecialty.
   GRID:
   1. Bacteriology [42 CFR 493.1449(c)]
   2. Mycobacteriology [42 CFR 493.1449(d)]
   3. Mycology [42 CFR 493.1449(e)]
   4. Parasitology [42 CFR 493.1449(f)]
   5. Virology [42 CFR 493.1449(g)]
   6. Diagnostic Immunology [42 CFR 493.1449(h)]
   7. Chemistry [42 CFR 493.1449(i)]
   8. Hematology [42 CFR 493.1449(j)]
   9. Immunohematology [42 CFR 493.1449(q)]
   10. Clinical Cytogenetics [42 CFR 493.1449(p)]
   11. Histocompatibility [42 CFR 493.1449(o)]
   12. Radiobioassay
   13. Histopathology [42 CFR 493.1449(l)]
   14. Oral Pathology [42 CFR 493.1449(m)]
   15. Cytology [42 CFR 493.1449(k)]
   16. Dermatopathology [42 CFR 493.1449(l)(2)]
   17. Ophthalmic Pathology [42 CFR 493.1449(l)(3)]

CMS-209 Laboratory Personnel Report

☐ Check (✔) here if additional space is needed to list all technical personnel. Copy this page and attach continuation sheet(s) to the original form.

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

6. SIGNATURE OF LABORATORY DIRECTOR

7. PRINTED NAME OF LABORATORY DIRECTOR

8. DATE

FORM CMS-209 (01/2021) IF CONTINUATION SHEET PAGE ___ OF ___

Save the CMS-209 Form for each survey and update each survey cycle.

Survey Preparation and Readiness
Organization of Documents & Records

Documents and Records to have Ready and Accessible

- Laboratory Policies and Procedures
- Personnel Records
- Quality Records
- Performance Verification Records for all modified, revised or newly introduced test systems
- Quality Management Policies and Procedures
- Proficiency Testing Records
- Test Records for all tests currently performed
- List of Duties and Responsibilities assigned to each person involved in the testing process

Laboratory Policies and Procedures

- A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.
- The current laboratory director must approve, sign and date all new and revised policies and procedures prior to use. Include the initiation date - laboratory specific.
- Policies and procedures may be printed and/or electronic and must be available to all staff.
- Include discontinued policies/procedures with the discontinuation date noted. Retain for 2 years from discontinuation.

Test Procedure Requirements

- Patient preparation & specimen handling, including specimen acceptability, rejection and storage
- Microscopic exams
- Step-by-step instructions (calculations and interpretation)
- Storage and preparation of reagents and other materials
- Calibration, calibration verification procedures
- Quality Control: type, identity, number, frequency, criteria for acceptable control results

Test Procedure Requirements (cont.)

- Corrective actions to take when controls or calibrations are not acceptable
- Limitations, including interfering substances
- Reference intervals (normal values)
- Panic or alert values
- References
- System for entering results in the patient record
- Steps to take if test system is inoperable

Laboratory Policies and Procedures

Laboratories must have policies and procedures that address the following:

- Confidentiality of Patient Information
- Specimen Identification & Integrity
- Complaint Investigation
- Communications
- Personnel Competency Assessment
- Proficiency Testing Evaluation
- Quality Assessment

Have printed documents organized in folders or binders and ready for review.

For labs with electronic/on-line document systems, granting the surveyor temporary access simplifies procedure review.

Personnel Records — Qualifications Training and Competency Assessment

Personnel Qualifications—Acceptable Documentation

- Diploma with degree stated
- Transcript with degree stated
- Primary Source Verification
- International Equivalency Evaluation for foreign degree

ASCP board certification is not recognized as a form of degree verification.

Personnel Records — Training

- Training Records
  - New staff member training records
  - New test system, kit, or analyte training records for all testing personnel
- Training should ensure the individual has:
  - Skills to properly collect, handle, process, transport and store specimens;
  - Skills to perform each test method following standard procedures including knowledge of reagent stability and storage, and maintenance, calibration, and quality control requirements;
  - Ability to problem solve and take appropriate corrective actions;
  - Understanding of factors that influence test results and the ability to assess and verify the validity of patient test results prior to reporting.

Personnel Records — Competency Assessment Requirements

Competency Assessment Records

- Semi-annual competency for testing personnel the first year
- Annual competency for all testing personnel after first year
- Competency assessment is required for technical consultant (TC), clinical consultant (CC), technical supervisor (TS) and general supervisor (GS) roles along with laboratory director delegated duties
- Retain records for at least 2 years

Quality Records

- Quality control, including any quality assurance program data and individualized quality control plans (IQCPs)
- Instrument maintenance records and function checks
- Any corrective action for instrument or quality control issues
- Routine calibrations
- Calibration verification

Performance Verification Records

For all modified, revised or newly introduced test systems

- FDA-cleared or approved tests
  - Verification studies must include Precision, Accuracy, Reference Range for target population, and Reportable Range
- Laboratory modified FDA-cleared tests or Laboratory Developed Tests (LDTs)
  - Must establish and verify performance specification for: Precision, Accuracy, Reference Range for target population, and Reportable Range, Sensitivity, Specificity, Calibration, Quality Control, Function Checks and Maintenance

Any new test method or new analyzer must have performance verification records reviewed and signed by the laboratory director, or designee prior to reporting patient results.

Quality Management Procedures and Records

- Quality records should include preanalytic, analytic and postanalytic measures, along with general laboratory and facility measures
- Written policies and procedures that monitor, assess and correct problems
  - Review effectiveness of corrective actions and document discussion with appropriate staff
  - Examples: specimen labeling errors, rejected samples, redraws, QC issues, turnaround times, corrected reports

Proficiency Testing Records

- Proficiency Testing Instructions
- Instrument Testing Records
- Attestation Statements
- Proficiency Testing Survey Results
- Documentation of Survey Result Review and Corrective Action as needed

Test Records

- Patient Logs, if in use
- Printed results used for manual result entry or review
- Patient reports, including preliminary and corrected reports, critical value report documentation
- Results from a reference laboratory

Electronic reports must be readily accessible.

List of Duties and Assigned Responsibilities

For Each Person Involved in the Testing Process

- Delegation for Technical Consultant, Technical Supervisor, General Supervisor and Clinical Consultant must be in writing
- Testing Personnel Individual Duties
  - Identify which procedures each individual is authorized to perform, is supervision required, and whether they can report test results without review

Personnel Responsibilities and Qualifications

Joann Amend, Laboratory Certification Officer

Testing Complexity Personnel Requirements

Moderate Complexity	High Complexity
Laboratory Director	Laboratory Director
Clinical Consultant	Clinical Consultant
Technical Consultant*	
	Technical Supervisor*
	General Supervisor/ Cytology Supervisor
Testing Personnel	Testing Personnel
* If performing Moderate and High Complexity Testing, need a TC and TS.	

Many Laboratory Director duties may be delegated to qualified laboratory personnel, but delegation must be in writing. Delegation must recur when there is a new Lab Director. The Laboratory Director is responsible for ensuring that all requirements are met, including delegated duties.

Laboratory Director (LD) Responsibilities

for Moderate* & High** Complexity Testing

*See § 493.1407 for Details

**See § 493.1445 for Details

The LD is responsible for the overall operation and administration of the laboratory including:

Quality Lab Services	Space, Environment & Employee Safety	Adequate Staffing of Appropriate Lab Personnel	Written Responsibilities & Duties for All Lab Personnel	High Complexity General Supervisor Supervision of Testing Personnel
Test Method Selection & Performance Verification	Quality Control & Quality Assessment Programs	Proficiency Testing	Acceptability Levels for Analytical Performance	Remedial Action for Unacceptable Analytical Performance
Training & Competency of Testing Personnel	Policies & Procedures for All Phases of Testing	Availability of Approved Test Procedure Manuals+	Test Reports & Interpretation	Lab Client Consultation

+LD must approve and sign off on all new and revised test procedures

Laboratory Director (LD) Responsibilities (cont.)
for Moderate* & High** Complexity Testing

*See § 493.1407 for Details
**See § 493.1445 for Details

- If qualified, the LD may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of these roles.
- If the LD delegates their own responsibilities, they must ensure that these duties are properly performed.
- The LD must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
- The LD may direct no more than five non-waived testing laboratories.

Laboratory Director Qualifications

for Moderate Complexity Testing*

*See § 493.1405 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO	Yes	• Board certified in anatomic pathology (AP) and/or clinical pathology (CP) OR • Equivalent qualifications for board certification in AP and/or CP
MD/DO/DPM	Yes	• One year directing/supervising non-waived laboratory testing OR • 20 CME in lab practice commensurate with director responsibilities OR • Equivalent 20 CMEs for lab practice obtained during medical residency
Doctoral in chemical, physical, biological or clinical lab science	N/A	• Board certified by American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology OR • One year directing/supervising non-waived laboratory testing
Masters in chemical, physical, biological or clinical lab science	N/A	• One year laboratory training/experience in non-waived testing AND one year of supervisory laboratory experience in non-waived testing
Bachelors in chemical, physical, biological science or clinical lab science	N/A	• Two years of laboratory training/experience in non-waived testing AND two years of supervisory laboratory experience in non-waived testing

Laboratory Director Qualifications
for High Complexity Testing**

**See § 493.1443 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO	Yes	• Board certified in anatomic pathology (AP) and/or clinical pathology (CP) OR • Equivalent qualifications for board certification in AP and/or CP
MD/DO/DPM	Yes	• Two years directing/supervising high complexity testing OR • One year of laboratory training during medical residency
Doctoral in chemical, physical, biological or clinical lab science	N/A	• Board certified by an HHS approved board OR • Previously qualified high complexity testing LD serving prior to 2/24/2003

Clinical Consultant (CC) Responsibilities

for Moderate* and High** Complexity Testing

*See § 493.1419 for Details
**See § 493.1457 for Details

- The CC provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.
- The CC must:
  - Be available to provide clinical consultation to the laboratory's clients;
  - Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
  - Ensure that reports of test results include pertinent information required for specific patient interpretation; and
  - Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

Clinical Consultant Qualifications
for Moderate* and High** Complexity Testing

*See § 493.1417 for Details
**See § 493.1455 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience	
MD/DO/DPM	Yes	• None	
Doctoral in chemical, physical, biological or clinical lab science	N/A	MOD	• Board certified by American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology
		HIGH	• Board certified by an HHS approved board OR • Previously qualified high complexity testing LD serving prior to 2/24/2003

Technical Consultant (TC)* & Technical Supervisor (TS)** Responsibilities

for Moderate* and High** Complexity Testing

*See § 493.1413 for Details

**See § 493.1451 for Details

- The TC/TS is responsible for the technical and scientific oversight of the laboratory including the following:
  - Test Methodology Selection
  - Test Procedure Verification and Test Performance Characteristics
  - HHS Approved Proficiency Testing Program Enrollment and Participation
  - Laboratory Quality Control Program
  - Technical Problem Resolution and Corrective Action
  - Ensuring that Test Results are Reported Promptly, Accurately, and Proficiently
  - Appropriate Training of Testing Personnel
  - Competency Evaluations of Testing Personnel
  - For Cytology, see additional TS responsibilities**
- TC/TS is not required to always be onsite when testing is performed but must always be accessible to the laboratory to provide on-site, telephone or electronic consultation

Technical Consultant Qualifications

for Moderate Complexity Testing*

*See § 493.1411 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO	Yes	• Board certified in anatomic pathology (AP) and/or clinical pathology (CP) OR • Equivalent qualifications for board certification in AP and/or CP
MD/DO/DPM	Yes	• One year of laboratory training/experience in non-waived testing, in the designated specialty or subspecialty of service
Doctoral or Masters in chemical, physical, biological or clinical lab science	N/A	• One year of laboratory training/experience in non-waived testing, in the designated specialty or subspecialty of service
Bachelors in chemical, physical, biological science or clinical lab science	N/A	• Two years of laboratory training/experience in non-waived testing, in the designated specialty or subspecialty of service

Technical Supervisor Qualifications

for High Complexity Testing**

**See § 493.1449 for Details

Specialties: Diagnostic Immunology, Chemistry, Hematology
Subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO	Yes	• Board certified in clinical pathology (CP) OR • Equivalent qualifications for board certification in CP
MD/DO/DPM/Doctoral	Yes except Doctoral	• One year of laboratory training/experience in high complexity testing in specialty of service AND 6 months in subspecialty of service
Masters in chemical, physical, biological or clinical lab science	N/A	• Two years of laboratory training/experience in high complexity testing in specialty of service AND 6 months in subspecialty of service
Bachelors in chemical, physical, biological science or clinical lab science	N/A	• Four years of laboratory training/experience in high complexity testing in specialty of service AND 6 months experience in subspecialty of service

Technical Supervisor Qualifications (cont.)

for High Complexity Testing**

**See § 493.1449 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
Specialty: Immunohematology		
MD/DO	Yes	• Board certified in clinical pathology (CP) OR • Equivalent qualifications for board certification in CP
MD/DO/DPM	Yes	• One year of laboratory training/experience in high complexity testing for the specialty of immunohematology
Subspecialty: Histocompatibility		
MD/DO/DPM/Doctoral in biology or clinical lab science	Yes except Doctoral	• Four years of laboratory training/experience in histocompatibility OR • Two years of laboratory training/experience in immunology AND two years of laboratory training/experience in histocompatibility
Specialty: Cytogenetics		
MD/DO/DPM/Doctoral in biological, including biochemistry or clinical lab science	Yes except Doctoral	• Four years training/experience in genetics, two of which are in clinical cytogenetics

Technical Supervisor Qualifications (cont.)

for High Complexity Testing**

**See § 493.1449 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
Subspecialties: Histopathology, Cytology, Oral Pathology		
MD/DO	Yes	• Board certified in anatomic pathology (AP) or subspecialty applicable boards OR • Equivalent qualifications for board certification in AP or subspecialty applicable boards
Tests in Dermatopathology		
MD/DO	Yes	• Board certified in anatomic pathology (AP), dermatopathology or dermatology OR • Equivalent qualifications for board certification in AP, dermatopathology or dermatology
Tests in Ophthalmic Pathology		
MD/DO	Yes	• Board certified in anatomic pathology (AP) OR equivalent qualifications for board certification in AP • Board certification in ophthalmic pathology AND one year of formal post-residency fellowship training in ophthalmic pathology

General Supervisor (GS) Responsibilities

for High** Complexity Testing Only

**See § 493.1463 for Details

- The GS is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.
- The GS must:
  - Be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems;
  - Provide day-to-day supervision of high complexity test performance by a testing personnel;
  - Monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

General Supervisor

for High** Complexity Testing Only

**See § 493.1461 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
• Qualify as a high complexity testing Lab Director and/or Technical Supervisor		
MD/DO/DPM	Yes	• One year of laboratory training/experience in high complexity testing
Doctoral, Masters, or Bachelors in chemical, physical, biological or clinical lab science	N/A	• One year of laboratory training/experience in high complexity testing
Qualify as Testing Personnel with an Associate in laboratory science or equivalent education and training	N/A	• Two years of laboratory training/experience in high complexity testing

Testing Personnel (TP) Responsibilities

for Moderate* and High** Complexity Testing

*See § 493.1423 for Details

**See § 493.1495 for Details

- The TP are responsible for specimen processing, test performance, and for reporting test results and must do the following:
  - Follow the laboratory's procedures;
  - Maintain proficiency testing records;
  - Adhere to the QC policies and document all QC activities, calibrations and maintenance performed;
  - Follow the laboratory's corrective action procedure whenever test systems are not operating acceptably;
  - Identifying problems that may adversely affect test performance or reporting of test results and correct the problems or notify the technical consultant, clinical consultant or director;
  - Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.
- For high complexity testing, an individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

Testing Personnel

for Moderate Complexity Testing*

*See § 493.1423 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO/DPM	Yes	• None
Doctoral, Masters, Bachelors or Associate's in chemical, physical, biological or clinical lab science	N/A	• None
High School Graduate or equivalent	N/A	• Documented training appropriate for the testing performed prior to analyzing patient specimens • Completed military medical laboratory procedures course of at least 50 weeks and held the military enlisted occupational specialty of Medical Laboratory Specialist

Testing Personnel
for High Complexity Testing**

**See § 493.1489 for Details

Degree	Licensed in WI	Board Certification and Laboratory Training & Experience
MD/DO/DPM	Yes	• None
Doctoral, Masters or Bachelors in chemical, physical, biological or clinical lab science	N/A	• None
Associate in a laboratory science or medical laboratory technology or equivalent education and training	N/A	• Equivalent education of at least 60 hours meeting courses as outlined in the regulation** AND completion of a clinical laboratory training program OR at least 3 months documented laboratory training in each specialty that the individual performs high complexity testing

CLIA Resources

Anita Iwanski, Laboratory Certification Officer

CLIA Survey Resources

- CLIA Regulations, CMS Survey Guide, CLIA Brochures & FDA CLIA Database
  - Standards and Certification: Laboratory Requirements (42 CFR 493)
  - Survey Procedures and Interpretive Guidelines for Laboratories
    - Also know as the State Operations Manual (SOM), Appendix C
  - CLIA Brochures
  - FDA CLIA Database—Test Complexity Look-up

CLIA Survey Resources (cont.)

- DHS Survey Guide for Clinical Laboratories
- Association of Public Health Laboratories (APHL) CLIA Resources
  - APHL Guide for CLIA Internal Audits Related to High Complexity Testing (CLIA Audit Checklist)
  - APHL Laboratory Internal Audit Plan

Search "CLIA" in the APHL Search for other useful resources.

CLIA Resources

- Department of Health Services (DHS) CLIA Webpage
  - The "Memos, Publications, & Resources" tab has links to many of the CLIA Survey Resources and additional federal resources.

Just type "CLIA" in the DHS Search box to get to the CLIA pages.

CLIA Educational Resources

- CDC Division of Laboratory Systems (DLS)

CLIA Educational Resources (cont.)

- CDC OneLab™

OneLab™
A Unified Response to Training Needs

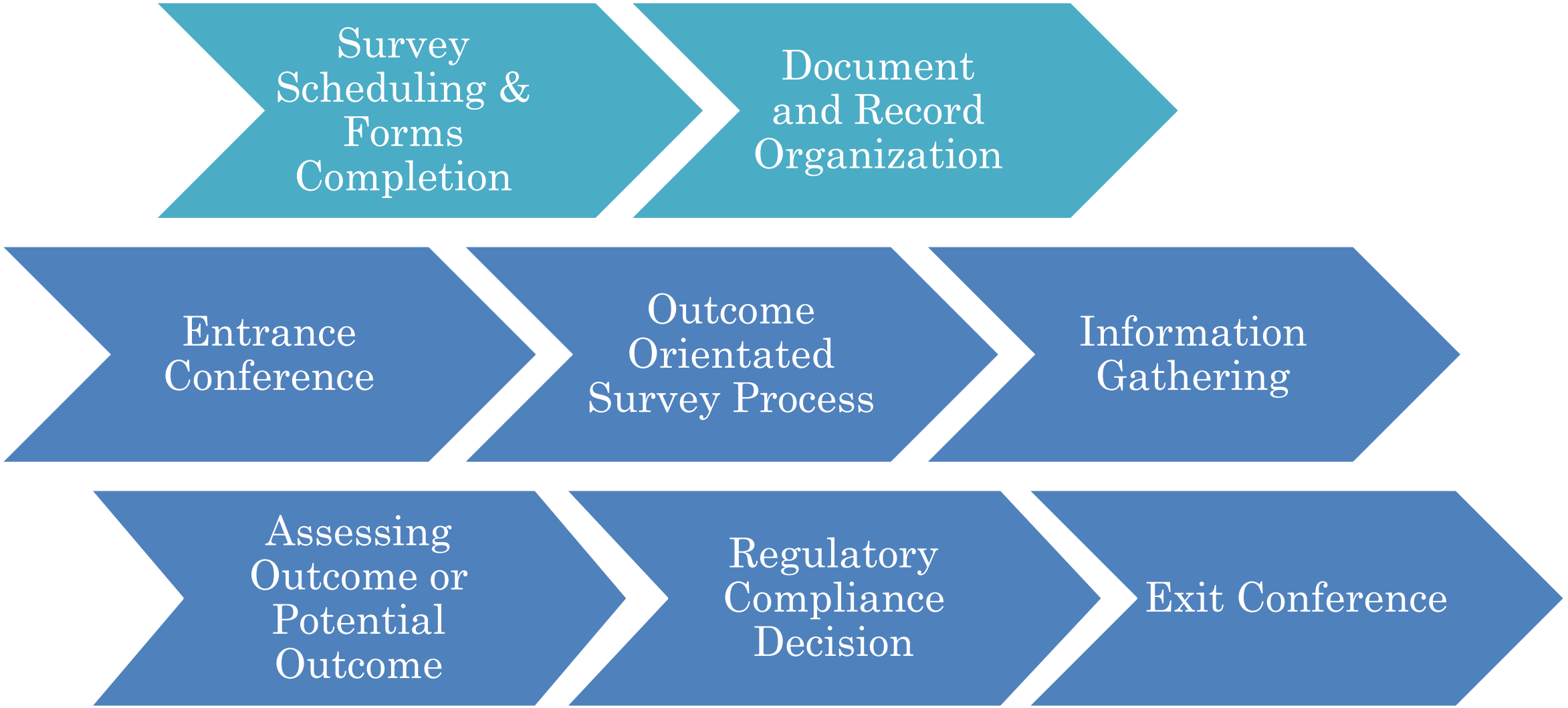
CLIA Updates and Correspondence

- DHS GovD CLIA Message
  - Sign up to receive email notices about DQA and CMS CLIA memos, DQA Quarterly Information Updates, and health care policy-related information.
  - Join our email list *Look for the sign-up on the DHS CLIA Webpage.*
- DHS CLIA Mailbox
  - Email for all of your CLIA questions and correspondence.
  - DHSDQACLIA@WI.GOV

Questions and Answers

Angela Mack, LCCS Section Manager

CLIA Survey Preparation and Process Summary



Future Forums

January 24, 2024

- ***Laboratory Survey Preparation and Process Part II***

- Competency Assessment
- New Test Performance Verification
- CMS-2567 Statement of Deficiencies (SOD), Response Requirements & Frequently Cited Deficiencies
- Immediate Jeopardy, PT Referral & CLIA Regulation Updates

February 21, 2024

- ***Certificate of Waiver (CoW) and Provider Performed Microscopy (PPM)***

- CLIA Application Updates, Fees & Certificates
- PPM Overview, Personnel Competency Assessment, and Resources
- CoW CLIA Requirements, Best Practices & Resources

Thank You!