CLIA AND CAP: THE BENEFITS OF UNDERSTANDING REGULATORY TO ADVANCE YOUR LAB CAREER

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LEARNING OBJECTIVES

- Compare and contrast the regulatory oversight of CLIA and CAP
- List benefits of knowing regulatory requirements
- Describe how knowledge of regulatory requirements can advance the career of a Medical Laboratory Professional

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)

- ORIGINALLY PASSED IN 1967 TO PROVIDE QUALITY STANDARDS AND OVERSIGHT OF CLINICAL LABORATORIES ENGAGED IN INTERSTATE COMMERCE
- IN 1987, A SERIES OF NEWSPAPER ARTICLES ALERTED THE PUBLIC TO QUESTIONABLE CLINICAL LABORATORY TESTING PRACTICES, INCLUDING PROBLEMS IN PHYSICIAN OFFICE LABORATORIES AND ERRORS IN CYTOLOGY TESTING
- CONGRESSIONAL HEARINGS WERE HELD IN 1988 TO INVESTIGATE THE QUALITY OF CLINICAL LABORATORY TESTING RESULTING IN THE AMENDMENT OF THE PUBLIC HEALTH SERVICES ACT (PUBLIC LAW 100-578)

Clinical
Laboratory
Improvements
Amendments

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)

- THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) WAS PASSED FOR CERTIFICATION AND OVERSIGHT OF CLINICAL LABORATORY TESTING NATIONWIDE, REGARDLESS OF WHERE THE TESTING IS PERFORMED. THIS CHANGE EXPANDED THE SCOPE OF LABORATORIES SUBJECT TO REGULATION TO BETTER ENSURE ACCESS TO QUALITY TESTING IN ALL US SETTINGS

- ANY LABORATORY OR FACILITY THAT PERFORMS DIAGNOSTIC TESTING FOR HUMAN BEINGS NEEDS TO BE CERTIFIED BY CLIA AND MUST COMPLY WITH THE REGULATIONS
  - EXCEPTION: LABS LICENSED BY A STATE AND CMS-APPROVED ARE CLIA-EXEMPT

- THE CLIA REGULATIONS SET QUALITY STANDARDS TO ENSURE THE ACCURACY, RELIABILITY, AND TIMELINESS OF CLINICAL LABORATORY TESTING

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) CONTINUED

- TO MEET THE INTENT OF THE CLIA LAW, THE FOLLOWING GUIDING PRINCIPLES INFORMED THE DEVELOPMENT OF THE FINAL CODE OF FEDERAL REGULATIONS (CFR) **ISSUED IN 1992** AND APPLY TO ANY SUBSEQUENT REGULATORY CHANGES
  - ENSURE QUALITY REGARDLESS OF WHERE CLINICAL LABORATORY TESTING IS PERFORMED OR WHO IS TESTED
  - PRESERVE ACCESS TO CLINICAL LABORATORY TESTING IN ALL SETTINGS AND FOR ALL PEOPLE NATIONWIDE
  - ENCOURAGE THE DEVELOPMENT AND USE OF NEW TECHNOLOGY AS BROADLY AS POSSIBLE
  - SET AND APPLY MINIMAL STANDARDS BASED ON TEST COMPLEXITY
  - ESTABLISH COST-EFFECTIVE REQUIREMENTS THAT ARE ACHIEVABLE IN ALL SETTINGS THAT PERFORM TESTING
- HTTPS://WWW.CDC.GOV/CLIA/INDEX.HTML
- CODE OF FEDERAL REGULATIONS: PART 493 – LABORATORY REQUIREMENTS
  - HTTPS://WWW.ECFR.GOV/CURRENT/TITLE-42/CHAPTER-IV/SUBCHAPTER-G/PART-493

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) REGULATE ALL LABORATORY TESTING (EXCEPT RESEARCH) PERFORMED ON HUMANS IN THE US THROUGH CLIA.

- CMS IS THE ENFORCER OF THE RULES
- CLIA IS THE LIST OF RULES

CLIA CERTIFICATE TYPES

(waived & moderate complexity)

Certificate of Accreditation: Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.

CLIA ACCREDITED ORGANIZATION: CAP

- THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP) IS A PATHOLOGIST-DIRECTED ORGANIZATION THAT FOSTERS AND ADVOCATES BEST PRACTICES IN PATHOLOGY AND LABORATORY MEDICINE

- IN 1994, CAP WAS GRANTED DEEMED STATUS BY CMS AND IS RECOGNIZED AS HAVING THE TOUGHEST AND MOST EXACTING STANDARDS IN THE CLINICAL LABORATORY

- https://www.cap.org/about-the-cap/historical-timeline

CLIA ACCREDITED ORGANIZATION: COLA

- COMMISSION ON OFFICE LABORATORY ACCREDITATION (COLA) IS A PHYSICIAN-DIRECTED ORGANIZATION WHOSE PURPOSE IS TO PROMOTE HEALTH AND SAFETY THROUGH ACCREDITATION AND EDUCATIONAL PROGRAMS. IN 1993, COLA WAS GRANTED DEEMED STATUS BY CMS TO PROVIDE LABORATORY ACCREDITATION.
  - HTTPS://WWW.COLA.ORG/

WHAT DOES CAP HAVE THAT CLIA DOESN'T?

- ✓ DISCIPLINE-SPECIFIC CHECKLISTS WITH ANNUAL UPDATES
- ✓ PEER INSPECTIONS (BY CAP PARTICIPANTS)
- ✓ CAP REQUIREMENTS COMMONLY EXCEED THE STANDARDS, BOLSTERING PATIENT CARE AND SAFETY
- ✓ THE CAP RETAINS DEEMED STATUS WITH THE JOINT COMMISSION AND MANY US STATE AGENCIES
- ✓ PROFICIENCY TESTING PROGRAM

WHAT ELSE DOES CAP HAVE THAT CLIA DOESN'T?

- ✓ SPECIFICS REGARDING MOLECULAR TESTING
- ✓ COMPREHENSIVE MOLECULAR PATHOLOGY CHECKLIS

- CLIA HAS TWO MENTIONS OF MOLECULAR

(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

SPECIMEN COLLECTION, HANDLING, AND REPORTING

Specimen collection, handling, and results reporting are critical. Specific instructions for the proper collection and handling of specimens must be made available to laboratory personnel and to anyone collecting patient test materials that are sent to the laboratory.

Inspector Instructions:

DISCOVER	• Follow a patient/client specimen beginning with test ordering through patient identification, phlebotomy/collection, labeling, transport, receipt and processing, delivery to test area, analysis, result review, and reporting. Determine if practice matches related policies and procedures.

SPECIMEN COLLECTION INSTRUCTIONS

Inspector Instructions:

READ	• Sampling of specimen collection policies and procedures • Specimen handling policies and procedures for referral of testing
OBSERVE	• Specimen collection manuals (available)

Inspector Instructions:

READ	• Representative sample of procedures for completeness, laboratory director approval, and review. Current practice must match contents of policies and procedures.
ASK	• How do you access procedures? • What procedure has most recently been implemented or modified? • How do you ensure all copies of procedures are up to date? • How are changes in procedures documented and communicated to staff? • How are discontinued policies and procedures removed from general access? • Show me how you access procedures when your network is down
DISCOVER	• Identify a newly-implemented procedure in the prior two years and follow the steps through authoring, laboratory director approval, and staff training

WHAT DOES CAP HAVE THAT CLIA DOESN'T: INSPECTION HINTS

CLIA VS CAP

§493.1256 Standard: Control procedures

(e) For reagent, media, and supply checks, the laboratory must do the following:

(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in § 493.1261(a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

(4) Before, or concurrent with the initial use -

(i) Check each batch of media for sterility if sterility is required for testing;

(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

(g) The laboratory must document all control procedures performed.

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

COM.30350 Reagent Storage and Handling **Phase II**

All reagents (eg, chemicals, stains, media) are stored and handled as defined by the laboratory and following the manufacturer's instructions.

NOTE: Reagents must be stored and handled in a manner that will prevent environmentally-induced alterations that could affect reagent stability and test performance. Prepared reagents must be properly stored, mixed, when appropriate, and discarded when stability parameters are exceeded.

If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily. Refer to the Temperature-Dependent Instruments, Equipment, and Environment section of the checklist for requirements for monitoring and recording temperature.

If the laboratory identifies a problem with a reagent that was used for patient testing (eg, expired vial or reagent subjected to unacceptable storage conditions, etc.), the laboratory must evaluate the potential impact on patient test results and retain records of the evaluation and actions taken.

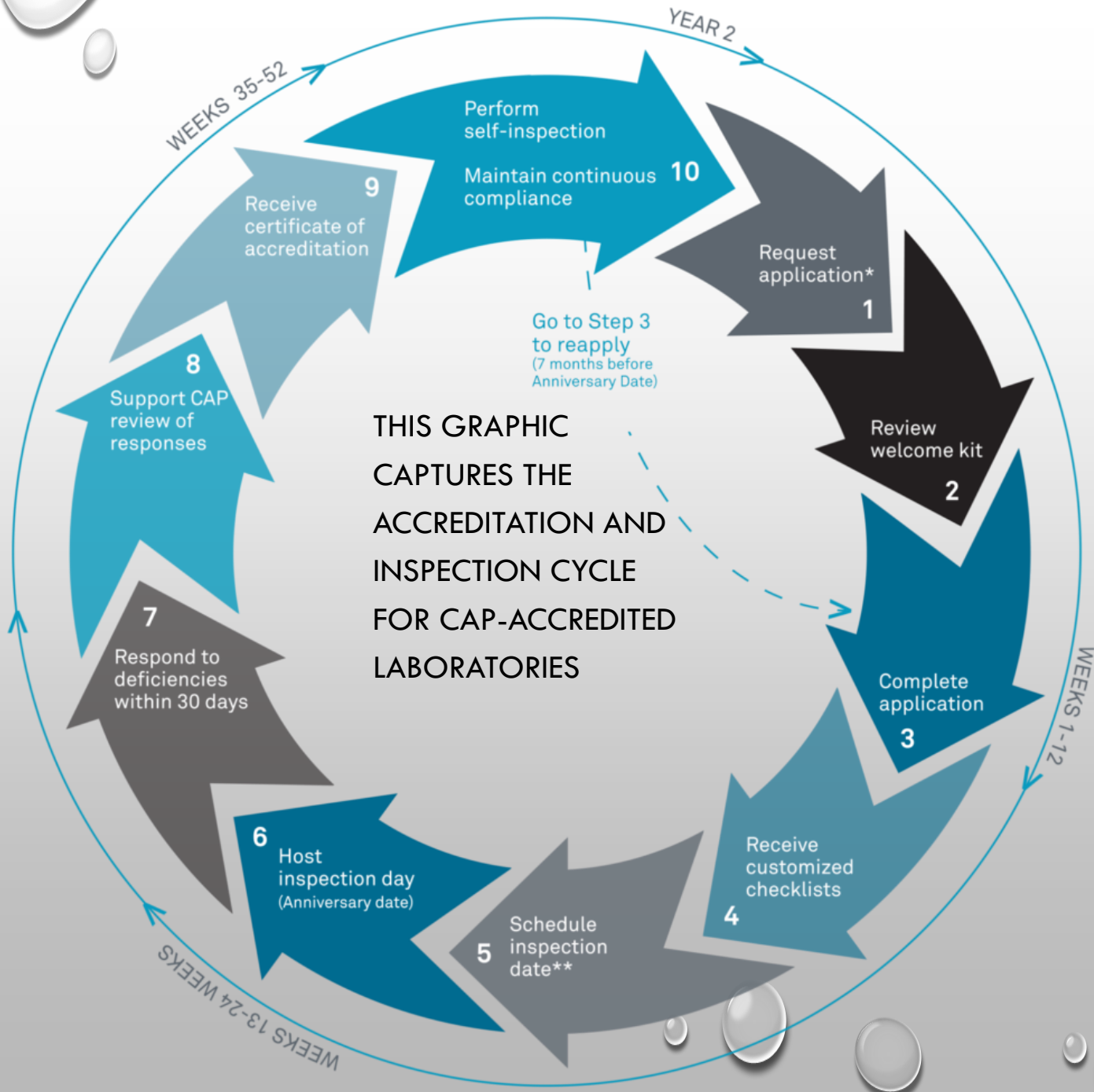
Evidence of Compliance:

✓ Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring

REFERENCES

1) Gonzales Y, Kampa IS. The effect of various storage environments on reagent strips. *Lab Med.* 1997;28:135-137
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1252(b)]
3) Clinical and Laboratory Standards Institute (CLSI). *One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (aPTT) Test; Approved Guideline—Second Edition.* CLSI document H47-A2 (ISBN 1-56238-672-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2008.

CAP: All Common Checklist



THIS GRAPHIC CAPTURES THE ACCREDITATION AND INSPECTION CYCLE FOR CAP-ACCREDITED LABORATORIES

WHY IS IT IMPORTANT TO BE FAMILIAR WITH REGULATORY REQUIREMENTS?

Test complexity designations
Testing personnel requirements
Proficiency testing requirements

- WAIVED
- MODERATE COMPLEXITY
- HIGH COMPLEXITY

Labs must be compliant with these regulations!

MORE REASONS TO BE FAMILIAR WITH REGULATORY REQUIREMENTS?

- Test Validation
- Test Verification
- Instrument Maintenance
- Quality Control Measures

- CLIA DICTATES THE REQUIREMENTS FOR EACH OF THESE COMPONENTS OF DIAGNOSTIC LABORATORY TESTING

- Code of Federal Regulations:
  - Public Health Title 42
  - Chapter IV CMS and HHS
  - Subchapter G Standards and Certifications
  - Part 493—Laboratory Requirements

VERFICATION VS VALIDATION
§ 493.1253 Standard

- VERIFICATION
  - UNMODIFIED, FDA-APPROVED TEST SYSTEMS
  - PERFORMS AS CLAIMED
    - ACCURACY
    - PRECISION
    - REPORTABLE RANGE
    - VERIFY MANUFACTURER'S REFERENCE INTERVALS

- VALIDATION
  - MODIFIED FDA-APPROVED OR LABORATORY DEVELOPED TESTS (LDT)
  - ALL VERIFICATION TESTING PLUS:
    - ANALYTICAL SENSITIVITY
    - ANALYTICAL SPECIFICITY
    - LIMIT OF DETECTION
    - STABILITY
    - CARRYOVER (AS APPLICABLE)
    - LINEAR RANGE
    - ANY MISCELLANEOUS PARAMETER CONSIDERED IMPORTANT TO THE TEST

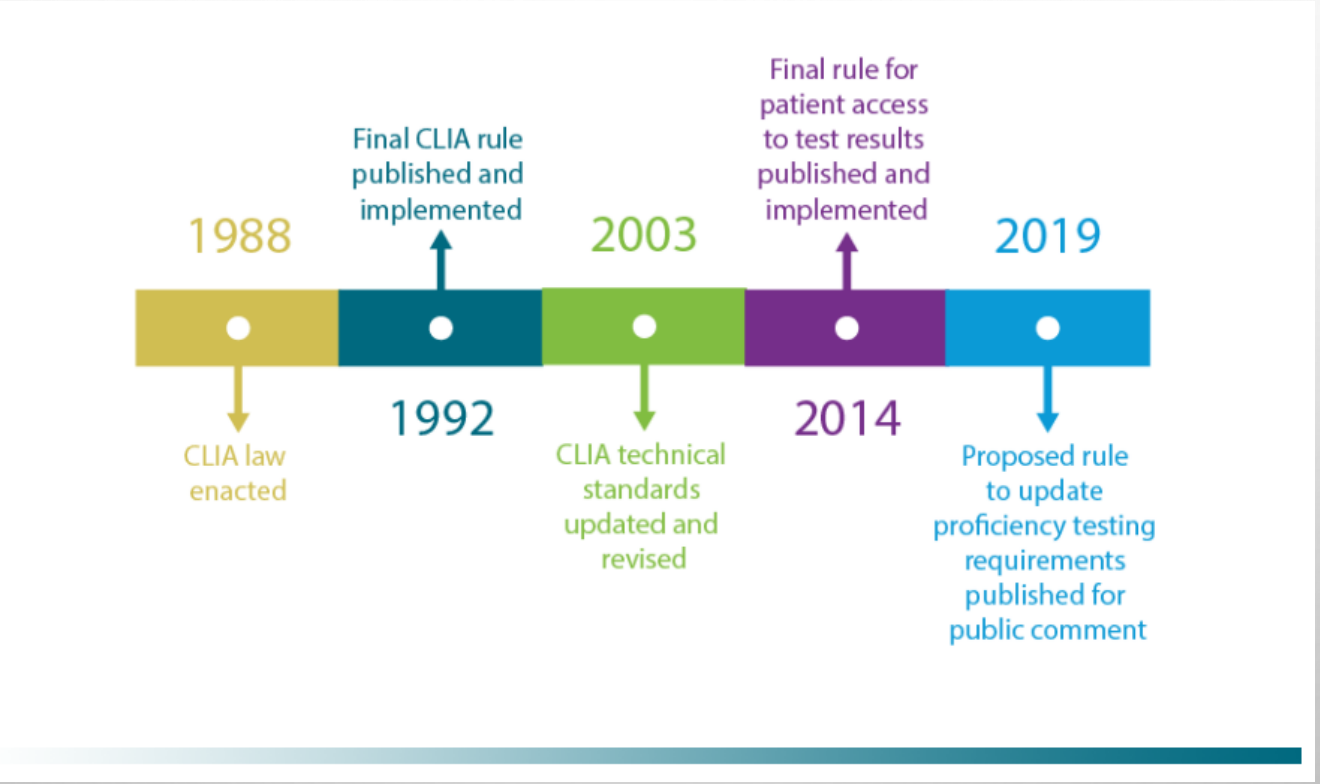
CODE OF FEDERAL REGULATION (CFR) HIGHLIGHTS

- Personnel Qualifications—High Complexity
  - **§ 493.1443 Standard: Laboratory Director Qualifications**
  - **§ 493.1449 Standard: Technical Supervisor Qualifications**
  - **§ 493.1461 Standard: General Supervisor Qualifications**
  - **§ 493.1489 Standard: Testing Personnel Qualifications**

Different Education Requirements!

- Grandfather Clauses *"on or before February 28, 1992"*

MAJOR CLIA REGULATORY MILESTONES



THE CODE OF FEDERAL REGULATION (CFR) HIGHLIGHTS

Proficiency Testing—Evaluates the laboratory system

- **§493.801 Condition: Enrollment and testing of samples.**

  Each laboratory must enroll in a proficiency testing (PT) program that is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.

Competency Testing—Evaluates the laboratory personnel

- **§ 493.1425 Standard; Testing personnel responsibilities for Moderate Complexity**
- **§ 493.1495 Standard; Testing personnel responsibilities for High Complexity**

- **§ 493.1423 Standard; Testing personnel qualifications for Moderate Complexity**
- **§ 493.1489 Standard; Testing personnel qualifications for High Complexity**

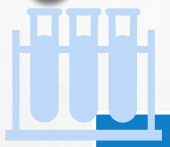
CODE OF FEDERAL REGULATION HIGHLIGHTS

- Quality System for Nonwaived Testing—To implement and monitor a quality system for the entire laboratory
  - **§ 493.1200 Introduction**
    - **Requires written policies and procedures for a quality system**
    - **Evaluates the total testing process (preanalytic, analytic, and postanalytic)**
    - **Ensures continuous improvement**

CODE OF FEDERAL REGULATION HIGHLIGHTS (CONT'D)

- Analytic Systems—*"the heart of the clinical laboratory"*
  - **§ 493.1250 Introduction**
    - **§ 493.1251 Written policies/procedures for each test**
    - **§ 493.1253 Verification vs Validation**
    - **§ 493.1254 Instrument maintenance and function checks**
    - **§ 493.1255 Calibration and verification procedures**
    - **§ 493.1256 Control procedures**
    - **§ 493.1281 Comparison of test results (aka Method Comparison)**
    - **§ 493.1282 Corrective actions**
    - **§ 493.1283 Test records**
    - **§ 493.1289 Analytic systems quality assessment**

SOME BENEFITS OF KNOWING REGULATORY REQUIREMENTS



Variety in job responsibilities

- Internal inspector
- Author policies & procedures
- Manage staff competency
- Manage proficiency testing
- Verifications
- Validations

External inspection opportunities

- Learn from other lab's mistakes
- Identify, replicate, and implement other lab's achievements

Reimbursement

- MolDX® Program (Administered by Palmetto GBA)
- New changes started 4-17-22
- The Protecting Access to Medicare Act of 2014 (PAMA)

BENEFITS OF KNOWING REGULATORY REQUIREMENTS

Career advancement

- Internal opportunities
- External opportunities

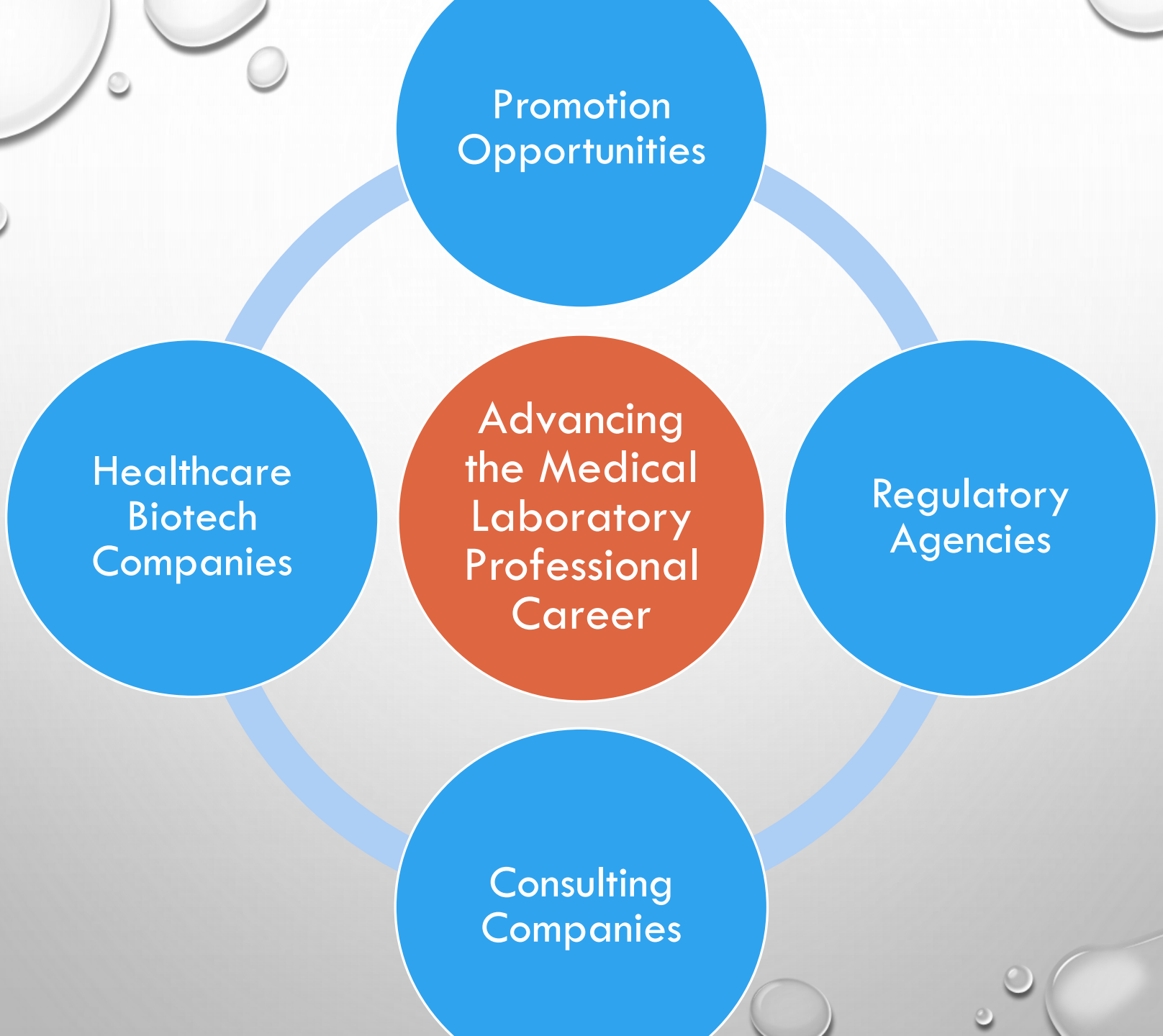
Educational opportunities

- New laboratory staff
- MLT/MLS programs
- Conferences

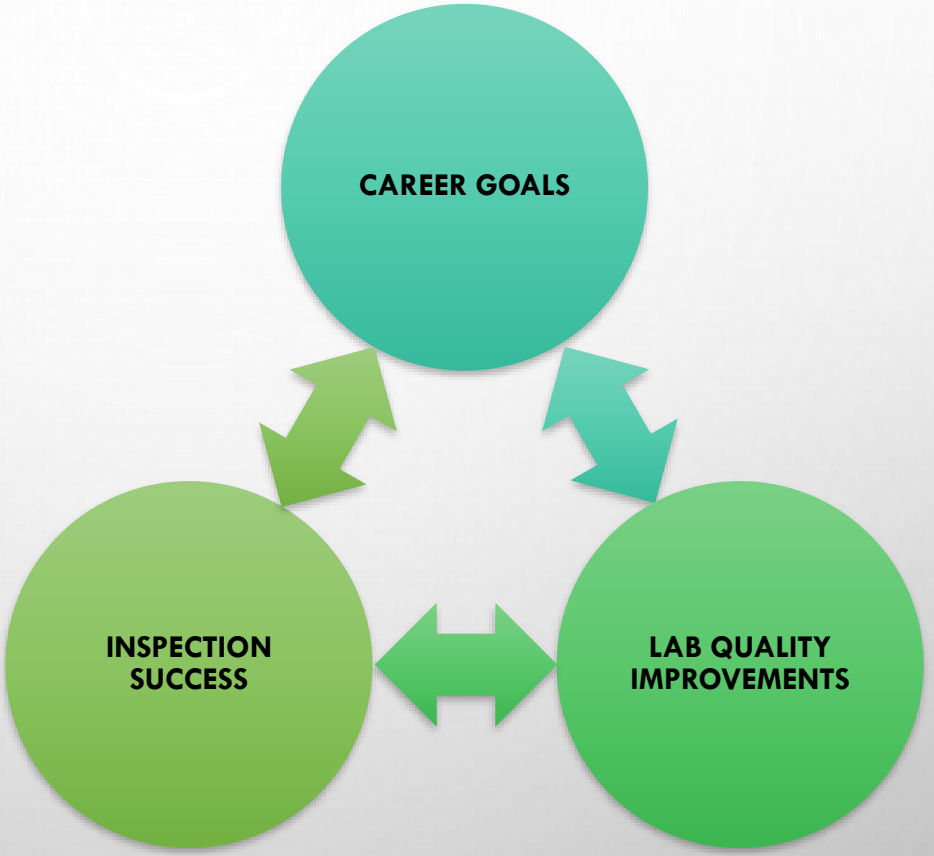
Quality Management System

- § 493.1200
- Monitor all phases of the total testing process
- Ensure continuous improvement of lab performance and services

"If you see something, say something."


Promotion Opportunities
Healthcare Biotech Companies
Advancing the Medical Laboratory Professional Career
Regulatory Agencies
Consulting Companies

MORE BENEFITS OF KNOWING REGULATORY REQUIREMENTS



#thehiddenprofession

Thank You

REFERENCES

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