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Common Laboratory Quality and Regulatory Requirements and Sharing Regulatory Responsibilities

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What we will cover

- Introduction
- CLIA Overview
- Requirements
  - Laboratory Basics
  - Time sensitive requirements
  - The “Q” word
  - Personnel Responsibilities
  - Interpretive Changes Over Time
- The “Open Book” Test
- Top Five Reasons Why We Still Get It Wrong

Introduction

CLIA Overview

Regulatory History

- CLIA (1966,1988)
  - To ensure quality laboratory testing is performed throughout the United States, the Centers for Medicare & Medicaid Services (CMS) established the Clinical Laboratory Improvement Amendments which were enacted in 1992.
  - U.S. laboratories can elect to meet the CLIA regulations by following the requirements of one of the laboratory accrediting organizations under a CLIA Certificate of Accreditation. These organizations' requirements are equal to or more stringent than CLIA.
- ISO
  - International Standards
    - ISO 9000:1987, 9001:2008: Quality management systems standards.
    - ISO 17025:2005: Technical standards for testing and calibration laboratories.
    - ISO 15189:2012: Specifically for medical testing laboratories.

CLIA Deemed Status Organizations

LIST OF APPROVED ACCREDITATION ORGANIZATIONS UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

- American Association of Blood Banks (AABB), 8101 Glenbrook Road, Bethesda, Maryland 20814-2749, (301) 907-6977, www.aabb.org
- American Association for Laboratory Accreditation (A2LA), 5202 Presidents Court, Suite 220, Frederick, Maryland 21703, (301) 644-3248, Fax (240) 454-9449, www.a2la.org
- Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP) (formerly known as the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)) 506 North Clark, Suite 301 Chicago, Illinois 60654 (312) 920-7383 American Society for American Osteopathic Association, 142 East Ontario Street, Chicago, Illinois 60611, (312) 202-8070, www.osteopathic.org
- American Society for Histocompatibility and Immunogenetics (ASHI), 15000 Commerce Parkway, Suite C, Mt. Laurel, New Jersey 08054, (856) 638-0428, www.ashi-hla.org
- COLA, 9881 Broken Land Parkway, Suite 200, Columbia, Maryland 21046-1195, (410) 381-6581, www.cola.org
- College of American Pathologists (CAP), 325 Waukegan Road Northfield, Illinois 60093-2750, (800) 323-4040, www.cap.org
- Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181, (630) 792-5000, www.jointcommission.org

Requirements

CLIA

- General Information
  - Test Classifications, Certificates
  - Accreditation
- Proficiency Testing
- Quality Systems for Non-waived Testing
  - Pre-analytic, Analytic, Post-analytic
- Personnel Requirements
  - Lab Director, Technical Consultant, Technical Supervisor, General Supervisor, Testing Personnel
- Inspections
- Enforcement Procedures
- Consultations
  - The Clinical laboratory Improvement Advisory Committee

Proficiency Testing

- Required for non-waived testing
- Includes regulated analytes
- Enrollment in Proficiency Testing programs
  - Alternative PT
- Includes criteria for successful participation by lab specialty or sub-specialty
- Provision for not sharing samples or results between laboratories
  - Can be problematic in large health systems
- Addresses PT failures and responsibilities

Quality Systems

- Technical requirements fall into this category
- Pre-analytic
  - Orders, specimen collection
- Analytic
  - Analysis, quality control, instrument specifications and maintenance, linearity etc.
- Post-analytic
  - Resulting, reports

Personnel Requirements

- Defines requirements and Responsibilities for:
  - Laboratory Director
  - Technical Consultant
  - Technical Supervisor
  - General Supervisor
  - Testing Personnel

- One person may meet requirements for more than one of these positions
- **Recommendation:** Define which category is applicable for each member of the laboratory technical staff, even if that person is not currently serving in that role.

Enforcement Procedures

- Deficiencies
  - Immediate Jeopardy
  - Condition Level
  - Requirements for timely correction of deficiencies
  - Plan of Correction
- Sanctions
  - Limitation of Medicare payments
  - Suspension of Medicare payments
  - Civil Monetary Penalties
  - Suspension, limitations
  - Suspension, limitation or revocation of the CLIA certificate
  - Cancellation of Medicare approval
- Appeals Procedure

The “Open Book” Test

Did you ever have an “Open Book” Test?

- The bi-annual inspection required under the CLIA regulations is like an Open Book test. The regulations list the requirements, if not all the details around the requirements.
  - Only minor modifications made since inception (1992)
  - All agencies with CLIA Deemed Status must follow the requirements
  - So, there should be no reason to fail??

- BUT:
  - Much of the lab industry has changed since 1992
    - Equipment
    - New Technologies
    - Staffing Levels
  - Interpretation of the CLIA requirements has changed over time
    - Personnel education and experience documentation
    - Competency requirements

Five Top Reasons We Still Get It Wrong

Number 5

- Lack of Institutional Support
  - Inability to hire the most qualified personnel
  - Insufficient personnel to complete all the tasks required
  - Inability to purchase reference resources (CLSI documents etc.)
  - Lack of capital to replace aging equipment

  - Can this be fixed??

Number 4

- Lack of Involvement by the Laboratory Medical Director
  - Does not spend sufficient time on Lab Director duties
  - Inexperienced or not informed on the requirements of the position
  - Poor communication skills

  - Can this be fixed??

Number 3

- "Our (fill in the blank) is out on a medical leave (or recently retired)"
  - Medical issues with an aging workforce are a fact of life
  - The staff with the most experience and knowledge are also the folks most vulnerable- knee replacements, hip replacements, and more serious medical issues
  - Retirement is a fact of life
  - Can this be fixed?

Number 2

- Excuses
  - “We don’t have time.”
  - “Patient results come first”
  - “If we could just hire more people….”
  - “ We had a bad inspector”
  - “We have been using the same answers to inspectors for years and now those are not good enough”

  - Can this be fixed??

Number 1

- No Overall Plan For Success
  - Plan should include:
    - A master schedule of events for the year (proficiency testing, instrument comparisons, method validations, competency assessments)
    - Standardized processes, procedures and forms for how to implement items on the calendar
    - Clearly defined Roles and Responsibilities
    - Regular (monthly) schedule review
  - Can this be fixed?- Absolutely!!

Sharing Responsibilities

Example: Large Health System

- Multiple Hospitals in the same system can share resources to help everyone
  - Procedures (must be modified to be site specific). This can be especially helpful as the system standardizes equipment.
  - Forms example: Competency Assessment
  - Provide a resource for discussing and addressing new /revised regulatory requirements
  - Standardize and automate data collection for Quality Indicators
  - Provide resources for “mock” inspections

Example: Small Community Hospital

- Scale the Regulatory Readiness Program for the size of the operation
- Share responsibilities among the staff according to their CLIA job category
  - Competency Assessments: Technical Consultants, CLIA Lab Director
  - Proficiency Testing- all technical personnel
  - Instrument Maintenance- all technical personnel
  - Review and approval of new policies/procedures- CLIA Laboratory
  - Review of existing policies and procedures: delegated by the CLIA Lab Director
  - Quality Control review: designated by the CLIA Laboratory Director

Question

What is your experience/advice?

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