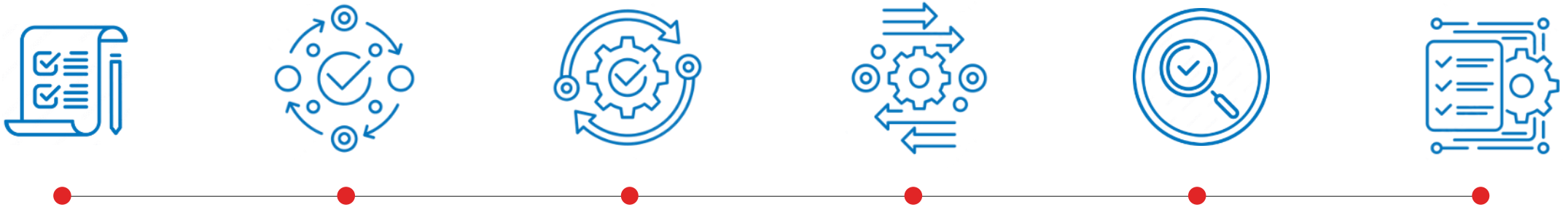
MYINSPECTION™
MAKE COMPLIANCE EASY

Laboratory Compliance
Make It Easy!

September 19, 2023

Today' Conversation

Regulation Overview
Inspectors/Surveyors Focus



- Licensure
- Testing Categorization Training
- Documentation
- Instrumentation
- Environmental Monitoring
- Proficiency Testing

What it Takes!

- **Technical Consultant** - If needed, work with an expert
- **CLIA Regulations** - Comply and keep up to date
- **Staff Training** - Key to success
- **Accreditation Agency** - Helpful with on-going education and support
- **Documentation** - Systematic electronic organized records making it simple to edit store and retrieve

Poll #1

What are your lab’s top 3 challenges with compliance?

a. Time

b. Manpower

c. Training

d. Interpretation of requirements

e. Staff turnover

Regulation Overview

- **FDA 510(k) Clearance** - Medical Device Manufacturer requirement prior to product release
- **FDA CFR (Code of Federal Regulations)** Governing regulations for all laboratory testing approvals
- **CLIA 88** - Regulation requirements for all laboratories licensed to perform testing
- **Accreditation Choices** - CAP, COLA, TJC, State if applicable

Licensure Certificates

Certificates

- **Waiver** - Allows lab to perform any test categorized by the FDA as waived complexity
- **Provider Performed Microscopy** (PPM)
- **Registration** - Allows moderate and high complexity testing until inspection/survey is performed and lab, is compliant with CLIA regulations
- **Compliance** - Allows lab to perform moderate and/ or high complexity testing post a satisfactory survey
- **Accreditation** - Issued by a CMS approved accreditation agency

Testing Categorization & Training Requirements

- **FDA Categories** - Waived or non-waived. Non-waived can include moderate and high complexity testing
- **FDA 510(k) Clearances** are issued to medical device/consumable manufacturers prior to release
- **Waived Tests** - Simple testing procedures with insignificant risk of erroneous results
- **Non-Waived Tests** - Moderate complexity/high complexity tests - based on specific criteria that includes expertise qualified to evaluate data output
- **Provider** - Performed Microscopy (PPM) is limited testing and is not subject to regular compliance inspections/surveys

Documentation Requirements

Policy/Procedure Must Be:

- Aligned with compliance requirements
- Reviewed, approved and documented by laboratory director - includes revisions
- Documented, utilized by trained staff and retained
- Accessible to staff at all times
- Reviewed biennially or more frequently if required by accreditation agency
- Retained (if retired) for a minimum of 2 years or longer based on accreditation agency requirements

Instrumentation

Instrument Validation is a Requirement and Must Include:

- Laboratory Director review, approve, sign and date all processes/procedures, package inserts, operator's manuals before use as a test method
- The most up to date documentation should replace any previous versions
- Documentation must be retained on-site for the life of the instrument plus 2 years (or longer if required by accreditation agency or state)

Laboratory Staff Training Requirements

- Testing personnel must be trained for each test/method/instrument
- Training must be documented for each staff member prior to performing testing
- Training requirements apply for changes to testing procedures and protocols
- Testing personnel should be evaluated at 6 months, 12 months and annually thereafter
- Each lab will retain qualification documentation for review by inspectors/surveyors

Poll #2

What percentage of your time is spent preparing your lab for inspection/survey?

a. <10%

b. 10-25%

c. >25%

Environmental Monitoring

All Refrigerator and Freezer Devices must be National Institute of Standards and Technology (NIST) Certified

NIST Certified Thermometers

- Come with certificate of calibration with a date for recalibration
- Calibration expiration- thermometers must be recalibrated or replaced

All Environmental Parameters must be Measured Daily Including:

- Temperature of ambient air
- Refrigerators & freezers
- Incubators
- Instruments if appropriate
- Room humidity

Testing ranges

- All test methods and instruments have operating ranges for temperature/humidity as documented in operator's manuals or package inserts
- Laboratories should utilize all manufacturer established operating ranges
- All readings must be within the established range
- Out of range results must be documented with corrective action until reading returns to required range

Proficiency Testing Requirements

- Registration for proficiency testing for all regulated analytes
- Proficiency testing for non-regulated analytes at least 2 times/year, this can be an internal study. Example: split sample testing
- **Testing Personnel** - Lab must rotate staff for proficiency testing. All testing personnel must participate in proficiency testing
- Testing is performed the same way as patients
- Corrective actions must be completed for all unsatisfactory, unscored, lack of participants and any satisfactory performance less than 100%

Note: Proficiency testing sharing - CMS will invoke sanctions for labs that share results, send proficiency testing to other labs for evaluation and compare results with other comparable laboratories

Wrap Up

Train your team!

Implement a user friendly, electronic documentation system

Do the daily environmental checks and document

Keep all records up to date

Pass proficiency testing- follow the rules and create accurate records