



Waived Testing: Tips for Resolving the Top Noncompliance Standards

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Objectives



- Identify the top noncompliance waived standards by program
- Implement tips that should keep your organization in compliance with the waived standards
- Create mock tracers to help you monitor compliance
- Identify the available Joint Commission resources

Waived Testing

- Simple laboratory examinations and procedures which:
 - Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible
 - Pose no reasonable risk of harm to the patient if the test is performed incorrectly

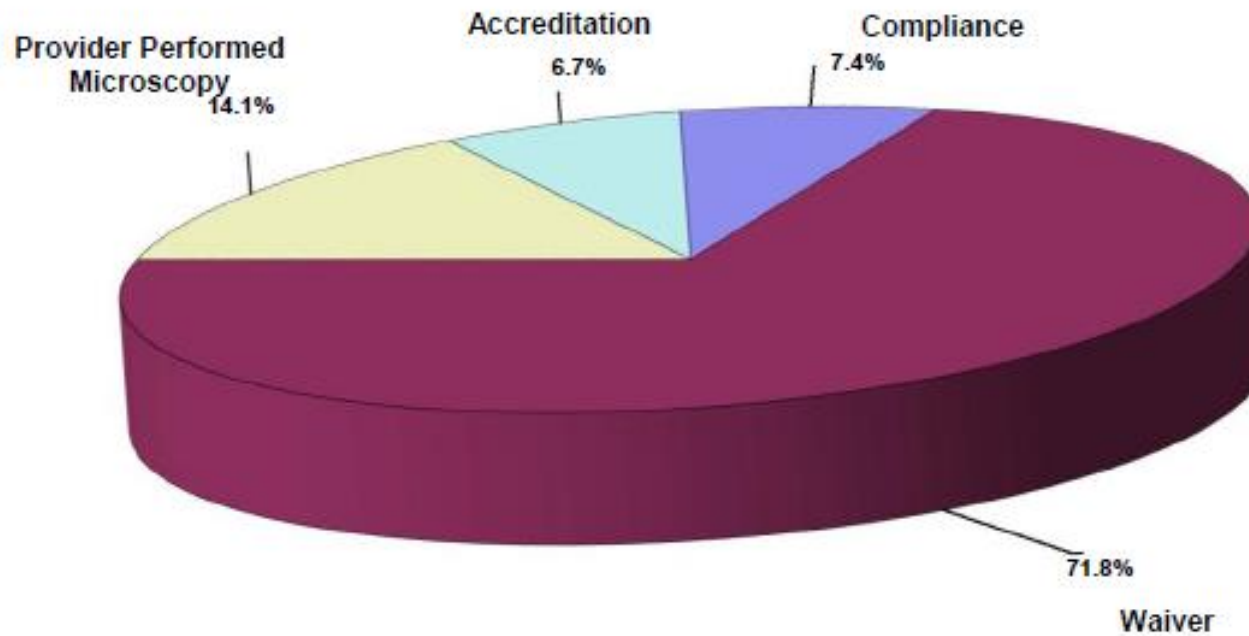


Waived Testing

- No federally defined qualifications
- Anyone can be the Laboratory Director
 - The Joint Commission recommends that the individual at least meet the minimum qualifications defined in CLIA for moderate complexity testing personnel
- Anyone can perform testing



CLIA Labs by Certificate Type (Non-Exempt Only)



Source: CMS CLIA database Jan 2016

CMS Certificate of Waiver Project

- Started with CO and OH and 200 CoWs & PPM certificates
 - >50% had quality/certification problems
 - OH: 10% testing beyond their means
 - CO: 7% testing beyond their means
- April 2002: CMS initiates visits at 2.5% of all CoW labs (460 labs)
 - 32% failed to have current manufacturer instructions
 - 32% did not perform quality control as required
 - 16% failed to follow current manufacturer instructions
- CMS will continue to perform education visits at 2% of CoWs

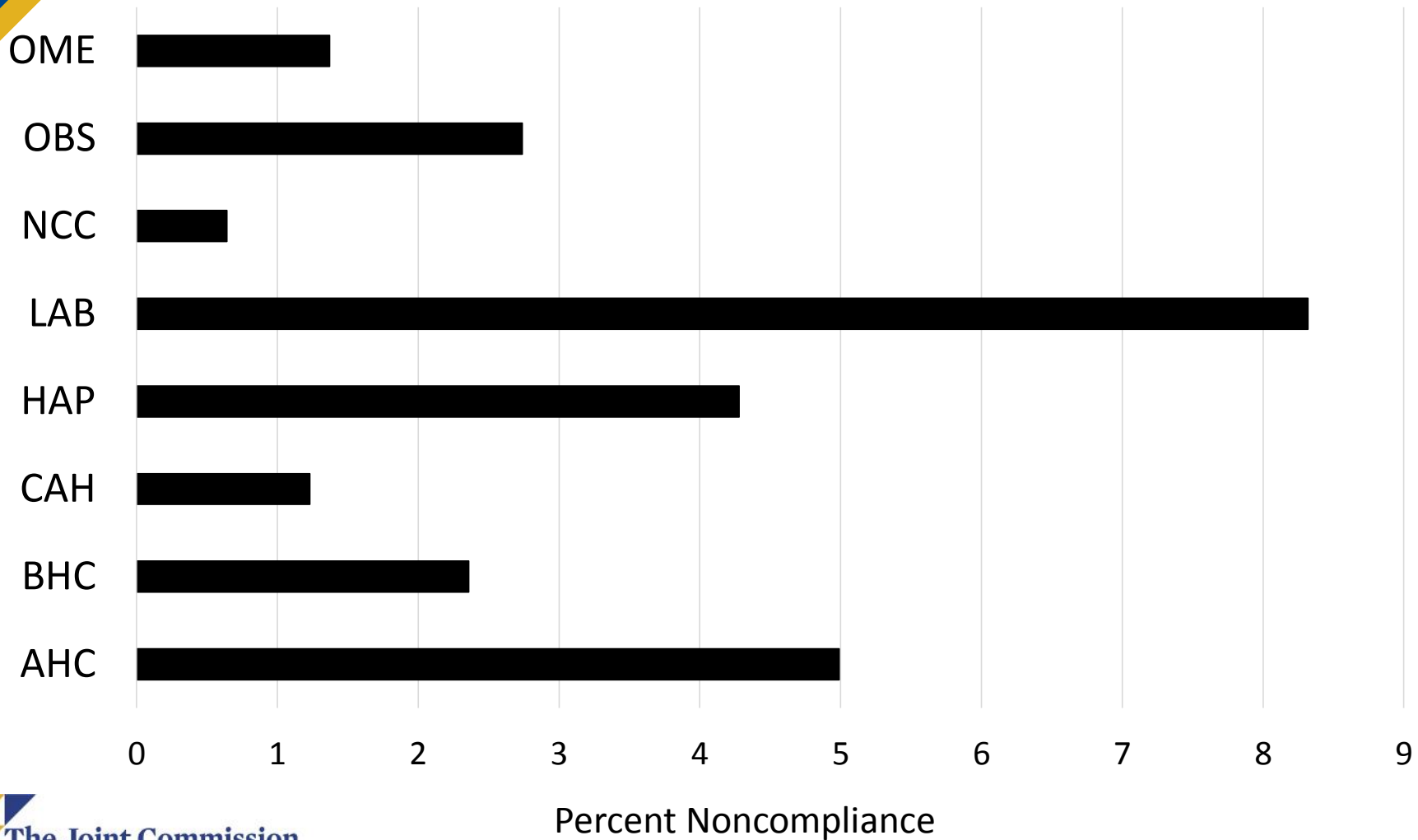
The Joint Commission Waived Testing Standards

- Waived Testing is included in all accreditation programs
- 5 standards
 - WT.01.01.01 Policies/Procedures
 - WT.02.01.01 Staffing
 - WT.03.01.01 Competency
 - WT.04.01.01 Quality Control
 - WT.05.01.01 Records



WT.01.01.01

Policies/Procedures



WT.01.01.01

Policies/Procedures

- EP 1 Diagnostic versus screening
- EP 2 Policies/procedures requirements**
- EP 3 Package inserts as policies/procedures
- EP 4 Approval of policies/procedures
- EP 5 Policies/procedures available to testing staff
- EP 6 Policies/procedures are followed**
- EP 7 Confirmatory testing
- EP 8 Clinical use of results
- OME: EP 9 For deemed status, must maintain compliance with CLIA '88

WT.01.01.01

EP 2 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:

- Clinical usage and limitations of the test methodology
- Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
- Specimen type, collection, and identification, and required labeling
- Specimen preservation, if applicable
- Instrument maintenance and function checks, such as calibration
- Storage conditions for test components
- Reagent use, including not using a reagent after its expiration date
- Quality control (including frequency and type) and corrective action when quality control is unacceptable
- Test performance
- Result reporting, including not reporting individual patient results unless quality control is acceptable
- Equipment performance evaluation



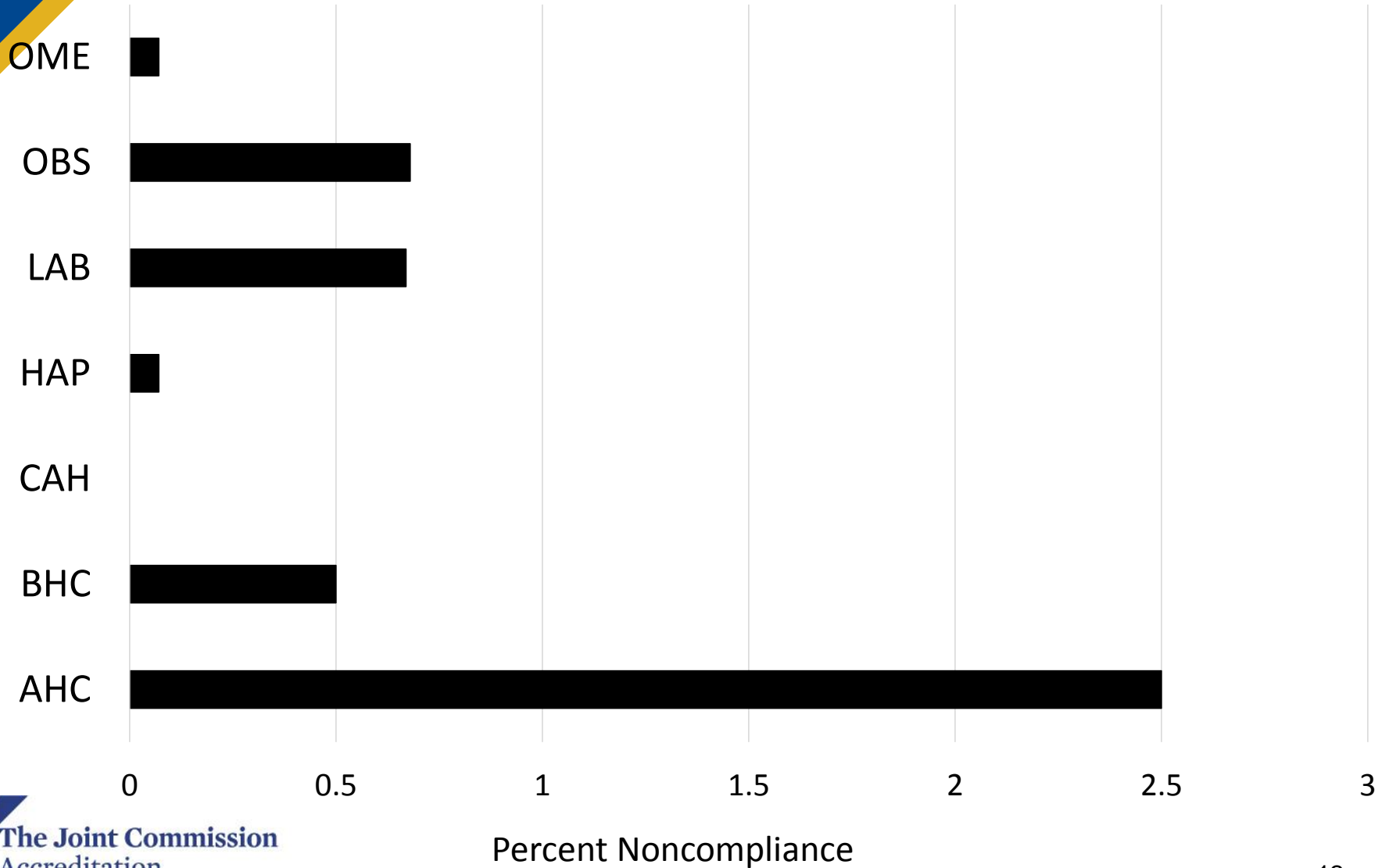
EP 6 Written policies, procedures, and manufacturers' instructions for waived testing are followed.

WT.01.01.01 Tips



- ✓ Create a procedure template or checklist that includes all the key components in EP 2
- ✓ Set a reminder schedule for updating and reviewing waived testing procedures
- ✓ Incorporate manufacturer instructions/package inserts recommendations, intended use, limitations, and precautions into your policies and procedures
- ✓ Manufacturer instructions/package inserts should be reviewed for changes with every new shipment
- ✓ Perform random direct observations outside of annual competency assessments; include discussions about confirmatory testing
- ✓ Ensure policies/procedures address when confirmatory testing is required; monitor results of confirmatory testing
- ✓ Can do a study to validate ending confirmation testing requirements

WT.02.01.01 Staffing



WT.02.01.01 Staffing

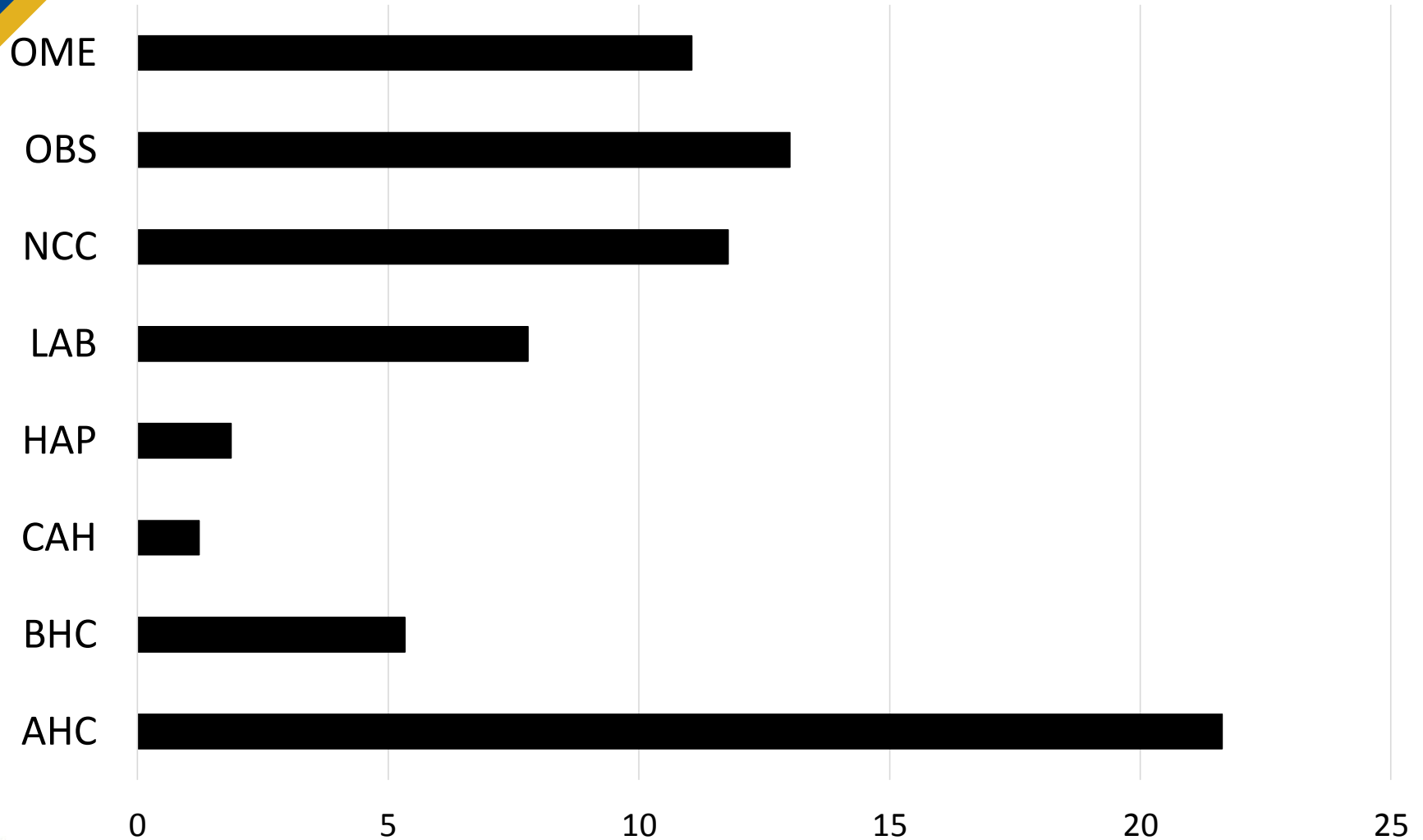
- EP 1 Identify, in writing, the staff who can perform testing
- EP 2 Identify, in writing, the staff responsible for supervising waived testing

WT.02.01.01 Tips

- ✓ Define operators by including it in a job description or by keeping an Operator List
- ✓ Define supervisory oversight by including it in a job description or by keeping a list by name
- ✓ Inactivate access for terminated employees
- ✓ If using an operator and/or a supervisory oversight list, schedule a review of the lists on a regular basis
- ✓ If using job descriptions, review them on a regular basis



WT.03.01.01 Competency



WT.03.01.01 Competency

- EP 1 Orientation, training and competency assessment is provided
- EP 2 Orientation is documented
- EP 3 Training is documented
- EP 4 Instrument operation and maintenance training is documented
- EP 5 Methods to assess competency**
- EP 6 Competency assessment is documented and assessed at defined intervals**

WT.03.01.01



EP 5 Competency for waived testing is assessed using at least two of the following methods per person per test:

- Performance of a test on a blind specimen
- Periodic observation of routine work by the supervisor or qualified designee
- Monitoring of each user's quality control performance
- Use of a written test specific to the test assessed

EP 6 Competence for waived testing is assessed according to organization policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented.

WT.03.01.01 Tips

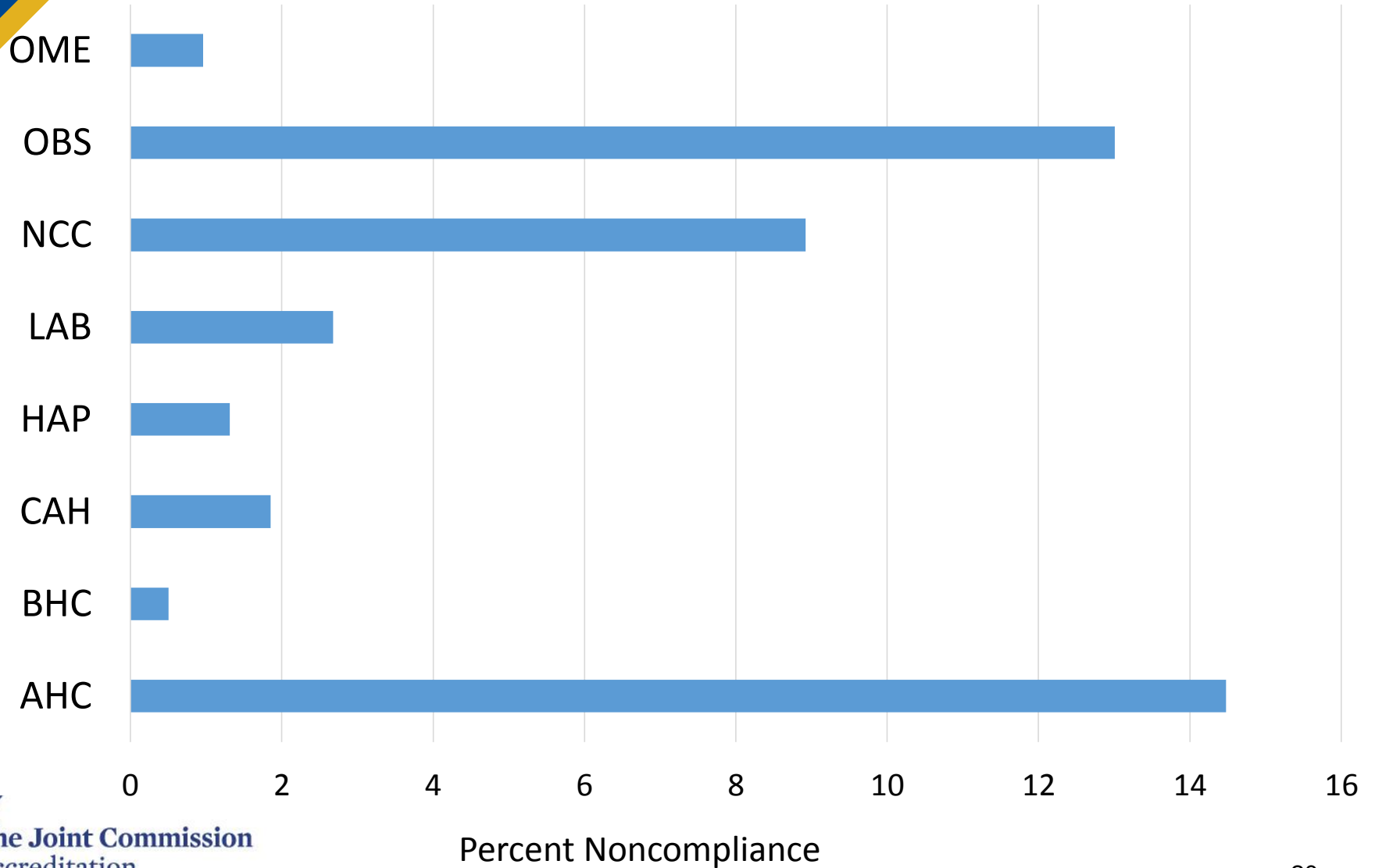
top tips...

- ✓ Use routine quality surveillance activities to meet some of the assessment methods
- ✓ Use credentialing and privileging process for non-instrumented waived tests
- ✓ Use annual skill fairs for POCT personnel
- ✓ Make this automated and electronic (quizzes)
- ✓ Have two years of records available during survey
- ✓ Leading Practice Library has examples of forms
- ✓ Policy should include what to do if an employee fails the competency assessment
- ✓ Scheduling competency assessment activities on department calendars
- ✓ Annual means 12 months +/- 30 days
- ✓ Standardize orientation and training
- ✓ Use instrument lockout functions if available

Competency Requirements

Joint Commission Requirement	Nonwaived Testing including PPMP	Waived Testing
Methods	Use 6 methods per Test System <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Problem solving skills 5. Direct observation of instrument checks 6. Monitoring result reporting 	Use 2 of 4 methods per Test <ol style="list-style-type: none"> 1. Blind testing 2. Direct observation of routine testing 3. Monitoring of QC performance by each user 4. Written test
Initial Orientation and Training and Annual Assessment	<p>Yes</p> <p>Plus Semi-annual in the first year</p>	<p>Yes</p>
Signatures	Both the director/supervisor AND the employee must sign that the individual has received training and is competent prior to performing testing independently	No signature required but the director/designee assesses competency

WT.04.01.01 Quality Control



WT.04.01.01 Quality Control

- EP 1 Approval of a written quality control plan
- EP 2 Documented quality control rationale**
- EP 3 Non-instrument based quality control checks**
- EP 4 Instrument based quality control checks**
- EP 5 Instrument based quality control requires two levels of controls when commercially available**
- OME: EP 6 Instrument based quality control checks

WT.04.01.01

EP 2 The documented quality control rationale for waived testing is based on the following:

- How the test is used
- Reagent stability
- Manufacturers' recommendations
- The organization's experience with the test
- Currently accepted guidelines



EP 3 For non–instrument-based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined by the organization's policies.

Note: If these elements are not defined by the manufacturer, the organization defines the frequency and number of levels for quality control.

WT.04.01.01

- **EP 4** For instrument-based waived testing, quality control checks are performed on each instrument used for patient testing per manufacturers' instructions.
- **EP 5** For instrument-based waived testing, quality control checks require two levels of control, if commercially available.

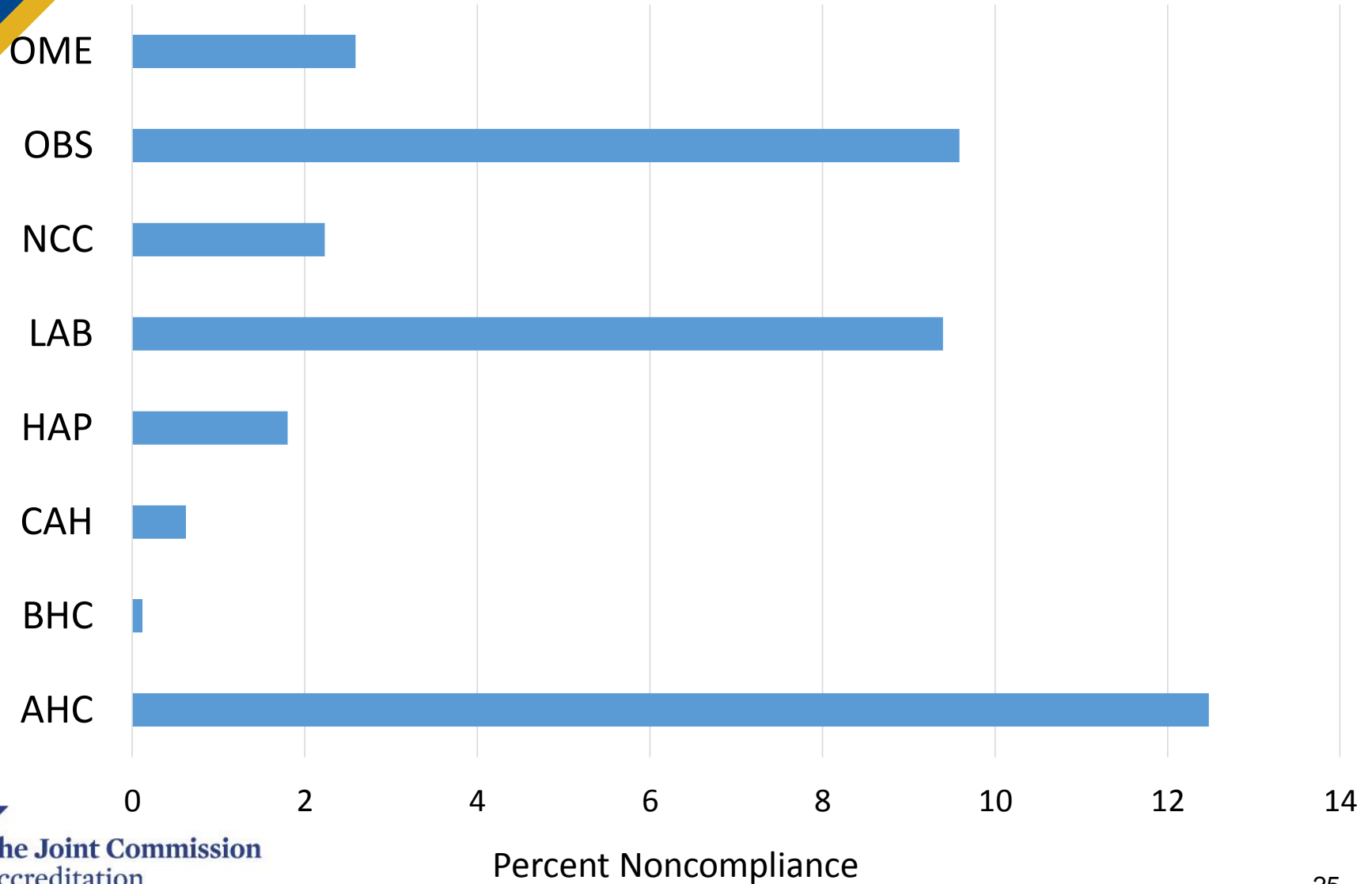


WT.04.01.01 Tips

- ✓ Ensure quality control policies for non-instrument and instrument based testing meets the manufacturer's recommendations
- ✓ Make quality control results a mandatory response field
- ✓ Review manufacturer's instructions with every new shipment
- ✓ Address compliance failures by performing a detailed root cause analysis and implementing fixes
- ✓ For non-interfaced tests, perform mock tracers to ensure quality control is being documented
- ✓ Assign and rotate performance of quality control
- ✓ Perform mock tracers to check for two levels of quality control



WT.05.01.01 Records



WT.05.01.01 Records

- **EP 1 Internal and external quality controls are documented**
- EP 2 Test results are in the patient record
- **EP 3 Reference intervals accompany quantitative test results**
- **EP 4 Test results can be associated with quality control results**
- EP 5 All records are retained for at least two years

WT.05.01.01

EP 1 Quality control results, including internal and external controls for waived testing are documented.

EP 3 Quantitative test results reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served.

EP 4 Individual test results for waived testing are associated with quality control results and instrument records.



WT.05.01.01 Tips



tips!

- ✓ Train staff on the difference and purpose of internal and external quality control
- ✓ Use a log that includes Quality Control results (internal and external) and lot numbers
- ✓ Make Quality Control (internal and external) and lot numbers a mandatory entry
- ✓ Review results for reference ranges – if not with the results does the staff know where to find them?
- ✓ Review reference ranges for the specific test methodology used and patient population served
- ✓ If possible seek test systems that electronically track the elements of an audit trail, e.g. patient identifier, test date, test lot number, results, QC lot numbers, QC results, testing personnel identifier

The Key to Continuous Compliance is...

performing you own Mock Tracers!



The Purpose of Mock Tracers

- Evaluate the effectiveness of policies and procedures
- Engage staff in looking for opportunities to improve processes
- To be certain compliance issues have been addressed
- **Benefit: Heightens the awareness of the regulatory requirements**



Tracer Methodology

■ Evaluates the following

- Compliance with standards and National Patient Safety Goals (NPSGs)
- Consistent adherence to policy and consistent implementation of procedures
- Communication within and between departments/programs/services
- Staff competency for assignments and workload capacity
- Personnel requirements and qualifications
- The physical environment as it relates to the safety of patients, visitors, and staff



Tracer Methodology

- Patients are the framework
- Follows the experience of care
- **Begins with a test result**
- Includes preanalytics and postanalytics
- Involves multiple staff, the patient, and even family
- All specialties and subspecialties for a 2 year period
 - 13 – 24 months
 - 6 – 12 months
 - Within the last 6 months



Starting Points for Waived Testing

Common starting points for tracers

- Patients who cross settings
- Critical results
- Low volume tests/locations
- Tests requiring confirmatory testing
- New tests
- Tests that use instruments
- Direct observations
- Proficiency Testing results



Documents Reviewed

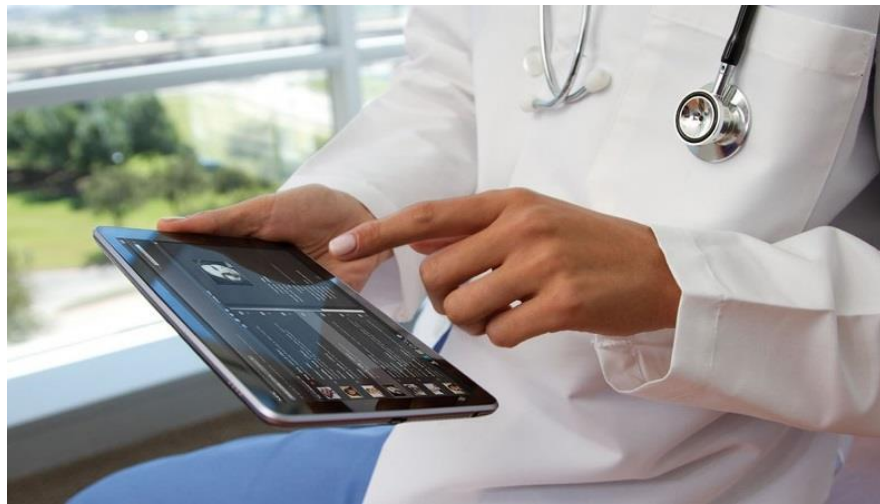
Examples of documents reviewed

- Instrument maintenance records, quality control, proficiency testing
- Testing logs
- Policies and procedures
- Employee competency, training, education, and qualifications
- Process improvement
- Patient medical records
- Waste disposal records
- Manufacturer instructions



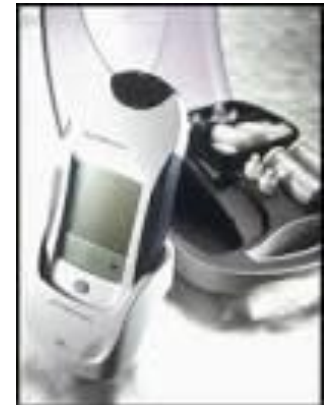
Patient Medical Record

- ▶ Order for the test
- ▶ **Reference Ranges**
- ▶ **Name and address of the performing laboratory**
- ▶ Documentation for critical results
- ▶ Results for all testing performed
- ▶ Results of confirmatory testing if required



Waived Testing

- Is the test really waived?
- Testing location**
- Reference Ranges**
- Is the result in the medical record?**
- Quality Control (internal and external) and tied to patient results
- Lot numbers
- NPSGs
- Centrifuges/Pipettes
- Policy and Procedures
- Maintenance records**
- Temperatures**



Employee File

- **Documentation of education/qualifications**
- State license if required
- Orientation
- Training
- **Waived annual (+/- 30 days) competency using two out of 4 methods of assessment**
- Nontechnical competency once every two year or more frequent if required by policy
- Performance evaluation
- Flu vaccine



Final Advice

- Start small
 - Documentation review only (small scale tracer)
- Make it a requirement
 - Report results out to the Quality Department
 - Add the performance of tracers to all job responsibilities
- The first one is usually the most difficult and takes the most time to complete



Small Scale Tracer



QC, Maintenance, Storage
Conditions, Lot Numbers,
Additional Equipment,
Environment, Proficiency Testing

Identify the Testing
Personnel, Sample
Processor and
Specimen Collector

Identify the instrument/test

Start with the patient result

Orders, Results,
Reference Ranges,
Testing Location,
Critical Results
Communication

Pull the
patient
medical
record

Education, Qualifications,
Licensure (if applicable),
Orientation, Training,
Competency, Evaluation,
Flu vaccine

Resources for Tracers

- ▶ Observe surveyors during surveys and intracycle monitoring events
- ▶ Survey Activity Guide (SAG)
- ▶ Lab Tracer Methodology Toolkit
- ▶ Joint Commission Resources (items for purchase) www.jcrinc.com
 - Tracers with Accreditation Manager Plus (AMP)
 - Publications:
 - *Tracer Methodology*
 - *More Tracers*



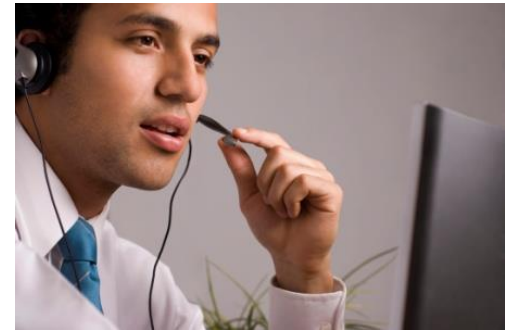
Who are you going to call?

Account Executives

- Primary contact between The Joint Commission and the organization
- Responsible for coordinating the survey planning and handles policies, procedures, accreditation issues or services and inquiries throughout the accreditation cycle


Standards Interpretation Group


- Laboratorians
- Same resource that the surveyors use
- Responsible for interpretation of standards
- Phone at 630-792-5900 Option 6, 8:30 a.m. - 5:00 p.m. CT
- Online question form at <https://web.jointcommission.org/sigsubmission/sigsubmissionform.aspx>
- FAQs online at http://www.jointcommission.org/standards_information/jcfaq.aspx



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- [Use of Restraint and Seclusion for Organizations Using Joint Commission Accreditation for Deemed Status](#)
- [Management of Hazardous Waste in Health Care Facilities](#)
- [Environment of Care](#) (EC.04.01.01, EC.04.01.03, EC.04.01.05)
- [Sample Collection](#)
- [Suicide Risk](#) (NPSG.15.01.01)
- [Safe Medication Storage MM.03.01.01](#)
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CDC Resources



<http://wwwn.cdc.gov/clia/Resources/WaivedTests/>

- MMWRR R&R Good Laboratory Practices for Waived Testing Sites
- To Test or Not to Test? Booklet
- Ready? Set? Test! Poster
- Ready? Set? Test! Booklet
- Ready? Set? Test! Online course

Questions



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