Office Based Pathology Services: Preparing for Your Survey

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The Joint Commission’s Vision
All people experience the safest, highest quality, best-value health care across all settings.

The Joint Commission’s Mission
To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.
Objectives

- Review the differences between the CLIA regulations and state inspection versus The Joint Commission standards and survey process
- Explain our Tracer Methodology approach
- Describe the survey process
- Discuss some of the most challenging standards related to pathology labs
- Identify resources available to assist with preparing for your first survey and continuous compliance
Why the Joint Commission?

- Largest and oldest organization dedicated to survey process and risk evaluation for over 19,000 health care organizations
- Professional surveyor cadre
- Tracer methodology and system evaluation
- Lab Advantage combined services option (PT, CE, and accreditation)
- Organizational alignment for operational synergy
- Cost is based on volume
- Annual procedure review can be done by signing one cover sheet
The Joint Commission

- Standards and EPs
- Employed Surveyor Cadre
- Priority Focus Process
- Intracycle Monitoring
- National Patient Safety Goals
The Joint Commission Standards

- In compliance with CLIA regulations – deemed status
- Developed with input from professional laboratory organizations
- Emphasizes the results a laboratory should achieve instead of the specific method of compliance
- Addresses processes that follow laboratory specimens from collection to result reporting
The Joint Commission Standards

Focuses on the provision of high quality, safe laboratory services that contribute to and support the overall health care delivery system

CAMLAB chapters
- Environment of Care
- Emergency Management
- Leadership
Employed Surveyor Cadre

- Effective evaluators
  - Process is thorough, fair, and objective
  - Process is inclusive of mandatory (regulatory) and collaborative (inspirational) modes
  - Process is guided by surveyor onsite experiences and data review
  - Process looks at systems and integration, not a list of tasks
- All have clinical laboratory management experience
- A full time surveyor will evaluate approximately 50 – 60 laboratories nationwide a year
- Anatomical pathologist surveyors are available upon request
- Surveyors receive continual training and performance monitoring
Priority Focus Process

- Data driven tool that provides surveyors with pre-survey information that has been developed using a standardized methodology.
- Helps surveyors evaluate health care organizations’ performance more consistently.
- Helps to focus the surveyors’ assessment on quality and safety issues specific to an individual laboratory.
- Sources used includes The Joint Commission, the laboratory and other public sources.
- PFP reports are posted to your extranet site quarterly and as changes warrant:
  - The top four-to-five priority focus areas
  - The clinical/service groups.
Intracycle Monitoring

- Periodic Performance Review
- Located on your Joint Commission extranet site
- Can be accessed before your initial survey
- Can be performed by a surveyor onsite, by SIG over the phone, or internally
- Opportunity to ask questions and develop plans of action in a non-punitive manner
- In 2012 we will be piloting a revised intracycle monitoring program
  - It will be called Focused Review
  - It will help the organization better concentrate on patient risk points
NPSG.01.01.01

Use at least two patient identifiers when providing laboratory services.

EP 1 Use at least two patient identifiers when administering blood or blood components; when collecting blood samples and other specimens for clinical testing; and when providing other treatments or procedures. The patient’s room number or physical location is not used as an identifier.

EP 2 Label containers used for blood and other specimens in the presence of the patient.
NPSG.02.03.01

Report critical results of tests and diagnostic procedures on a timely basis.

- **EP 1** Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:
  - The definition of critical results of tests and diagnostic procedures
  - By whom and to whom critical results of tests and diagnostic procedures are reported
  - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures

- **EP 2** Implement the procedures for managing the critical results of tests and diagnostic procedures.

- **EP 3** Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.
Comply with either the current Centers or Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

EP 1 Implement a program that follows categories IA, IB, and IC of either the current CDC or WHO hand hygiene guidelines.

EP 2 Set goals for improving compliance with hand hygiene guidelines.

EP 3 Improve compliance with hand hygiene guidelines based on established goals.
Tracer Methodology

- Uses actual patients as the framework for assessing standards compliance
- Individual tracers follow the experience of care through the entire health care process in the organization
- System tracers evaluate the integration of related processes
  - Coordination and communication among disciplines and departments
  - In-depth discussion and education regarding the use of data in performance improvement
Tracer Methodology

Documents reviewed during tracers
- Order
- Instrument maintenance records, quality control
- Policies and procedures
- Employee competency
- Process improvement
- Patient medical records

Staff interviews and direct observations

Reference document
http://www.jointcommission.org/tracer_methodology_101/
Preparation Tips

**e-Application**

- Required upon initial application for survey and verify information annually
- Included information: ownership, demographics, types and volumes of services provided
- Drives the anticipated number of survey days, number and type of surveyors, survey agenda activities, pricing, and short notice notification
- Inaccurate or incomplete information may necessitate an additional survey and cause the organization to incur additional survey charges
- Description for calculating non-waived volumes at http://www.jointcommission.org/Guidelines_for_CountingTests_for_CLIA/
Preparation Tips

Know who your resources are at The Joint Commission:

- **Account Executive:**
  - 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
  - On initial surveys, will be assigned after the e-App has been submitted

- **Standards and Interpretation Group:**
  - Responsible for clarification of standards
  - Phone at 630-792-5900 Option 6, 8:30 a.m. - 5:00 p.m. CT
  - Online question form at [http://www.jointcommission.org/standards_information/online_question_form.aspx](http://www.jointcommission.org/standards_information/online_question_form.aspx)
  - FAQs online at [http://www.jointcommission.org/standards_information/jcfaq.aspx](http://www.jointcommission.org/standards_information/jcfaq.aspx)
Preparation Tips

Know which standards apply to your laboratory
- E-dition allows you to sort by program and specialty
- Found on your extranet
- Makes the standards more manageable
- Print or email
- Contact your account executive for assistance
Preparation Tips

- **Required Written Documentation (RWD) section of the CAMLAB**
  - List of elements of performance that require written documentation
  - It is meant to be a guide in preparing for the survey
  - Written documentation includes policy, procedure, plan, CLIA certificate, license, evidence of testing, documentation of reviews by supervisors and directors, data, lists, performance improvement reports, specimen identification and labels, MSDS, and meeting minutes
  - The primary emphasis will be on how your laboratory carries out the functions described in the *CAMLAB*. The documentation review will be used along with interviews and visits to the patient care setting
Preparation Tips

Perform a Tracer

- Focus on issues of particular concern for laboratories and process interfaces with clinical staff.
- Consider your laboratory’s past testing activity as a starting point
- Select the medical record of a patient who received multiple laboratory tests, including tests performed at point of care sites
- Instead of one person conducting the tracer, consider walking through one as a group
- Don’t forget to consider the beginning and end of a process, not just the outcome
Preparation Tips

Documentation list for your survey

- The 24 month reference in the following items is not applicable to initial surveys, except for proficiency testing data.

- For initial surveys, a minimum of 4 months of data must be available for review.
Preparation Tips

As a laboratory, you should have the following information and documents available for the surveyor to review during the Surveyor Planning Session:

- Name of key contact person who can assist in planning tracer selections
- CLIA Certificates, Specialties and Subspecialties, State Licenses, and personnel license or certification if required by the state or organization policy
- An organizational chart and map of the facility
- Ability to retrieve testing records for patients who have had laboratory tests or other services for the past 24 months (4 months if an initial survey)
- Performance improvement Data for the past 24 months (4 months if an initial survey)
- Proficiency data by CLIA number for the past 24 months
Preparation Tips

As a laboratory, you should have the following information and documents available for the surveyor to review during the Surveyor Planning Session:

- Results of periodic laboratory environment inspections from the safety committee or safety officer
- Manifests for the disposal of hazardous waste for the past 24 months (4 months if an initial survey)
- A list of specialties and subspecialties performed by the lab
- A list of tests performed (test menu) and instruments used including all ancillary and point of care sites
- Measures of Success (MOS) identified in the Plan of Action from the Periodic Performance Review

**Note:** Surveyors may need to see additional documents throughout the survey to further explore or validate observations or discussions with staff.

- Employee personnel files will be reviewed. These files should include employee education records, competency documentation, and annual evaluations.
Preparation Tips

- Resources and Tools available
  - CAMLAB
  - *Perspectives* monthly publication
  - Joint Commission Center for Transforming Healthcare
  - Joint Commission extranet site
    - Leading Practice Library
    - E-dition web-based manual
  - Joint Commission webpage
    - CLSI crosswalk
    - Standards’ Frequently Asked Questions
    - Tracer Methodology 101 article
    - Sign up for E-Alerts
    - Lab Focus
    - Free audio conferences
On-Site Survey Activities

- Surveyor photo, bio and survey agenda are posted to your extranet site at 07:30 local time
- Check your Notification of Schedule Events on your mobile device
- Depending on the complexity of the organization a survey may last more than one day and could involve a team of surveyors
- Once the surveyor arrives, the organization’s extranet must be checked for confirmation of the survey and identification of the surveyor
- Preliminary Planning Session
- Opening Conference
- Orientation to the Organization
On-Site Survey Activities

- A daily briefing occurs every morning of a multiday survey, with the exception of the first day
- Competency assessment
- Personnel education/qualification verification
- Regulatory review
- Proficiency testing validation/performance improvement data review
- Individual tracers
- Physical environment
- Survey report preparation
- CEO exit briefing and organization exit conference
A preliminary report is available on the extranet until midnight of the day the survey has been completed.

The accreditation decision is not made until all of your organization’s post-survey activities are completed.

The final summary of survey findings report will be posted on your extranet site.

- It will include which findings require an Evidence of Standards Compliance (ESC) submission within 45 days (direct impact standards) and/or 60 days (indirect impact standards).

Upon approval of your organization’s last submitted ESC, your accreditation decision is posted to your extranet site and to Quality Check (www.qualitycheck.org)
From Survey Report to Accreditation Decision

How accreditation decisions are made

- Criticality model
- The more immediate the risk the shorter the period of time given to address noncompliance
- All partially compliant and insufficiently compliant EPs must be addressed

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Standards Clarification

- Organizations have the opportunity to submit a clarifying ESC if they believe that their organization was in compliance with a standard at the time of the survey.
- The clarification must be submitted within 10 business days following the posting of the organization’s report to the extranet.
- When submitting clarifying ESCs after a survey event, it is important to follow the directions in the submission tool. You need to address the EP as well as the actual surveyor observation.
- The submission of a clarification does not negate the requirement for submission of a corrective ESC within 45 or 60 days if the RFI continues, nor does it provide an organization with additional time to submit its ESC.
Corrective ESC

An acceptable corrective ESC report must detail the following:

- Action(s) that the organization took to bring itself into compliance with a standard
- The title of the person(s) responsible for implementing the corrective actions or approving a revised policy, procedure, or process
- Compliance at the EP level and include a Measure of Success (MOS) if applicable

There may be times when an ESC will also be conducted on site by a surveyor

- Provides the opportunity to evaluate the organization’s success in correcting issues
- Allows the surveyor to provide coaching and guidance to the organization supporting its efforts to achieve and maintain compliance
Measure of Success (MOS)

- A numerical or quantifiable measure, usually related to an audit to determine if action was effective and sustained
- Due four months after notification of an acceptable ESC
- Not required for all ESCs
Challenging Standards

**DC.02.01.01 EP1** Written laboratory procedures for each test meet the following requirements:

- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers’ instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory’s current practice.
- They are readily available to staff performing the testing.

*See CAMLAB for additional Notes.*
Challenging Standards

- **DC.02.03.01 EP 2** The laboratory report includes the name and address of the laboratory performing the test.
- **EC.02.02.01 EP 9** The laboratory implements processes to minimize risks associated with the selection, handling, storage, transport, use, and disposing hazardous gases and vapors.
- **EC.02.04.03 EP 7** The laboratory performs preventative maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.
- **EC.02.04.03 EP 10** The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers’ guidelines. The temperature is documented.
The laboratory identifies potential emergencies and the direct and indirect effects that these emergencies may have on the need for its services or its ability to provide those services. (See also IC.01.06.01, EP 4)

Note 1: Some organizations refer to this process as a hazard vulnerability analysis (HVA).

Note 2: The potential of an emergency situation stemming from a surge in infectious patients is addressed in the "Infection Prevention and Control" (IC) chapter.
Challenging Standards

HR 01.01.01 EP 1 An individual qualified to provide technical consultation or supervision and general supervision is on duty or is available whenever testing requires consultation or supervision.

HR.01.02.03 EP 1 The qualifications of the laboratory director of record meet the requirements set forth in federal and state law and regulation.

HR.01.02.05 EP 3 The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.
Challenging Standards

**IC.01.03.01 EP 2** The laboratory identifies its infection risks based upon the laboratory services it provides.

**IC.02.01.01 EP 2** The laboratory uses standard precautions, including the use of personal protective equipment, to reduce the risk of infection.

**IC.02.01.01 EP 6** The laboratory minimizes the risk of infection when storing and disposing of infectious waste.
Challenging Standards

LD.04.01.01 EP 2 The laboratory provides laboratory services in accordance with licensure requirements, laws, and rules and regulations.

LD.04.01.01 EP 4 Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.
Challenging Standards

- **NPSG.02.03.01 EP 3** Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.

- **QSA.13.03.01 EP 3** The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage.
Challenging Standards

QSA.13.06.01 EP 3 Each time of use for patient testing, the laboratory performs quality controls for each type of histologic stain used. The quality control results are documented.

*Note: Documentation may be contained in a dictated report or on a separate log.*
From Accreditation to Continuous Compliance

- Concentrate on incorporating the frameworks and concepts of standards and EPs into day-to-day work rather than viewing the concepts as rules that must be followed.

- Read *Perspectives* each month to identify new/updated standards, scoring, standards interpretation.

- Sign up for E-Alerts.

- Complete your intracycle monitoring.

- Contact SIG to submit standard questions.

- Enter your information into Lab Central.
Standards Interpretation Group

Phone:
630-792-5900 Option 6

Online:
http://www.jointcommission.org/Standards/OnlineQuestionForm/

FAQs:
http://www.jointcommission.org/Standards/FAQs
Leading Practice Library

- Open to all of our accredited organizations

- Database to formally identify and share leading practices (including case studies, white papers, tools, policies, etc.) which reflect excellent compliance with Joint Commission standards and National Patient Safety Goals.

- Sort by program
Center for Transforming Healthcare

- Formed in 2009 to find solutions to pressing health care issues identified by CEOs
- Uses DMAIC principles to analyze and identify root causes which vary by institution
  - One size does not fit all for persistent issues!
- Projects include:
  - Hand hygiene
  - Hand off communications
  - Wrong Site surgery
  - Surgical Site infections (with ACS)
  - Safety Culture
- Solutions database available from Joint Commission to enter your own data and perform your own project to improve care
Lab Central

New customer portal that improves the accreditation process:

- Allows organizations to organize files in one place to make surveys more efficient
- Surveyors can review data before the survey to get better snapshot of organization
- Data available for ICM discussion with SIG
- Provides a place for private document management

Current projection is summer implementation for initial voluntary use
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### Quick Links:

- LAB INFORMATION
- PERSONNEL
- DOCUMENT REPOSITORY
- TEST SYSTEMS
- PROFICIENCY TESTING

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Achieve the Gold Seal

Electronic Standards Manual

The Joint Commission
### Personnel:

The Personnel section of LAB Central is where you can review information we have on staff personnel within your laboratory. The information you see here can be updated in the LAB Central database by contacting your Account Executive. You can upload and store documents related to personnel through this section.

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Resources on the Web

Centers for Medicare & Medicaid Services (CMS)
- COPs: [www.cms.hhs.gov/CFCsAndCOPs/](http://www.cms.hhs.gov/CFCsAndCOPs/)

Centers for Disease Control and Prevention (CDC)
- [www.phppo.cdc.gov/clia](http://www.phppo.cdc.gov/clia)

Food and Drug Administration CLIA Database Search

CLSI-Joint Commission Crosswalk

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Contact Us

General information:
- Your account executive (see your organization’s secure Extranet site for specifics)

Information on becoming accredited
- Contact Eileen Stawczyk or Jennifer Rhamy
- Phone: 630-792-5248 or 630-792-5754
- Email: jrhamy@jointcommission.org

Standards questions
- Phone: 630-792-5900, Option 6
- Online:
  http://www.jointcommission.org/Standards/OnlineQuestionForm/
Review

✓ Reviewed the differences between the CLIA regulation and a state inspection versus The Joint Commission standards and survey process
✓ Explained our tracer methodology
✓ Described the survey process
✓ Discussed some of the most challenging standards related to pathology lab
✓ Identified resources for you to use for your initial survey and continuing compliance