Laboratory Accreditation

Organization
Survey Activity Guide

2025

Issue Date: June 23, 2025

What's New for Laboratory Accreditation Survey Process 2025

New or revised content for 2025 is identified by underlined text within the noted activities.

Changes effective: July 1, 2025

New! Infection Prevention and Control Assessment Tool for Laboratory Programs

Laboratory Accreditation (LAB)
Organization Survey Activity Guide (SAG)

Contents

How to Use this Guide

The Joint Commission's Survey Activity Guide is available on your organization's extranet site.

This guide contains:
- Information to help you prepare for survey
- An abstract of each survey activity that includes logistical needs, session objectives, an overview of the session, and suggested participants
- Sessions are listed in the general order that they are conducted.

A template agenda and a list of survey activities that occur during an onsite visit are posted to your organization's *Joint Commission Connect* extranet site in proximity to the time your application is received and reviewed. When the template agenda and survey activity list is available, please download and review the activities and think about the people you might like to have involved. The activity list includes a column in which you can record participant names or positions next to each of the sessions. Identifying key participants (and their phone numbers) for each session, including back-ups, is important. Consider including possible meeting locations and surveyor work space in your planning documents. Reference the sessions in this Survey Activity Guide and learn more about what you can expect to occur during the activity.

The template agenda and activity list include suggested duration and scheduling guidelines for each of the activities. On the first day of survey, there will be an opportunity for you to collaborate with the surveyor in preparing an agenda for the visit that is considerate of your day-to-day operations.

Please recognize that this Survey Activity Guide is created for small and large organizations. Some organizations will have one surveyor while others will have multiple surveyors. If you have any questions about the number of surveyors who will arrive at your site, please contact your Account Executive. If you are unsure of your Account Executive's name or phone number, call the Joint Commission switchboard operator at 630-792-3007 for assistance.

Preparing for Surveyor Arrival

Overview
The surveyors arrive unannounced or with short notice for most surveys. Please consult the program accreditation manual, "The Accreditation Process chapter", "Unannounced Surveys" section, for more information about exceptions to the unannounced survey process. Changes to these exceptions may occur at any time and are published in the Joint Commission newsletter *Perspectives*.

***All CMS deemed surveys or surveys conducted for CMS recognition are unannounced.**

Comments received from staff in accredited organizations indicate that a planned approach for the surveyor's arrival allows them to feel calmer and more synchronized with the survey. Whether the surveyor arrival is announced or unannounced, the first hour of the surveyor's day is devoted to planning for your survey activities. This planning requires review of specific documents provided by your organization which can be found on the Document Lists for each accreditation program in the pages that follow. If these documents are not available when the surveyors arrive, they immediately begin to evaluate the care, treatment, or services provided to one of your patients/residents/individuals served through an individual tracer.

Preparing for Survey
Prepare a plan for staff to follow when surveyors arrive. The plan should include:

- Greeting surveyors: Identify the staff usually at the main entrance of your organization. Tell them about The Joint Commission and educate them about what to do upon the arrival of surveyors. Explain the importance of verifying any surveyor's identity by viewing their Joint Commission identification badge. This badge is a picture ID.
- Who to notify upon their arrival: Identify leaders and staff who must be notified when surveyors arrive. Create a list of names, phone numbers, or cell phone numbers. Also, include the individual who will be the surveyor's "contact person" during the survey. Identify alternate individuals in the event that leaders and staff are unavailable.
- A location for surveyors: Ask surveyors to wait in the lobby until an organization contact person is available. Surveyors will need a location that they will call their "base" throughout the survey. This location should have a desk or table, electrical outlet, phone access**, and internet access**.
- Validation of survey: Identify who will be responsible for the validation of the survey and the identity of surveyors. Identify the steps to be taken for this process. (See Surveyor Arrival for these steps.)

- Readiness Guide and Laboratory Program Document List: The Guide is created for you to use as a planning tool and can be included with your survey plan. Your organization should be prepared to have documents available for surveyors as soon as your organization validates their identity. **If this information is not immediately available for surveyors at the Surveyor Preliminary Planning Session, they will begin the survey with an individual tracer.**
- Identifying who will provide the Safety Briefing for the surveyors
    - The purpose of the Safety Briefing is for your organization to inform surveyors about any current safety or security concerns and how Joint Commission staff should respond if your safety plans are implemented while they are on site.
    - **The briefing is informal, five minutes or less**, and should take place once the surveyors are settled in the "base" location reserved for their use throughout the survey.
    - Situations that should be covered include fire, smoke or other emergencies; workplace violence events (including active shooter scenarios); any contemporary issues the surveyors may experience during the time they are with you (for example, seasonal weather-related events, anticipated or current civil unrest, or labor action)
- Identifying who will serve as escorts for the surveyor(s).
- Identifying who will assist the surveyor(s) with review of electronic records of care, if applicable to your organization; surveyors may ask to print some components of the record to facilitate tracer activity and subsequent record review.
- Identifying your organization's expectations for the on-site survey and who will share these with the surveyor.

Note: When a situation is identified that could be a threat to health and safety, surveyors contact the Joint Commission administrative team. The Joint Commission either sends a different surveyor to investigate the issue or the surveyor on site will be assigned to conduct the investigation. Investigations include interviews, observation of care, treatment and service delivery and document review. Your cooperation is an important part of this process. Surveyors collaborate with the Joint Commission administrative team and outcomes will be communicated to your organization when a determination is reached.

Readiness Guide

Actions to take when surveyor arrives	Responsible Staff	Comments:
Greet surveyor(s)		
Verify identity		Look at picture ID to ensure they are from the Joint Commission
Ask them to wait		Location:
Validate authenticity of survey		Contact: _____ (this individual has a user ID and password to access the organization's Joint Commission extranet site) Phone number:_____

Note: Please download the entire Laboratory Survey Activity Guide for additional information on how to prepare for survey

The Laboratory program Document List and Survey Activity List appear on the pages that follow. These lists are intended for use with the Laboratory Accreditation Survey Activity Guide.

Survey Planning and Readiness Notes:

Please review the Survey Activity List to assist you in preparing for your survey. The list includes the potential survey activities that can occur on an accreditation survey, including the suggested duration, and suggested timing for these activities. This information will allow your organization to begin identifying participants that need to be involved in the survey. The activity list includes a column for your organization to use for recording participant names, possible meeting locations, times that could conflict with participant availability, or any other notes.

Please work with your surveyor(s) to confirm the best day and time for specific survey activities to take place.

Contact your Account Executive with any questions related to this information

Laboratory Accreditation Document List

As a Laboratory, you will need the following information and documents available for the surveyor to review during the Surveyor Planning Session which occurs on the first day of survey:

> *Note: The 24-month reference in the following items is not applicable to initial surveys, except for proficiency data. For initial surveys, a minimum of 4 months of data must be available for review.*

Please note that this is not intended to be a comprehensive list of documentation that may be requested during the survey. Surveyors may need to see additional documents throughout the survey to further explore or validate observations or discussions with staff.

Organization Information:
- Name of key contact person who can assist surveyors in planning tracer selections
- An organizational chart and map of the facility

Regulatory Review:
- CLIA Certificates, Specialties and Subspecialties, State Licenses
- A list of specialties and subspecialties performed by the laboratory, a list of tests performed (e.g., the test menu) and major instruments used by the laboratory service, including all other ancillary and point-of-care sites performing laboratory tests
- Form CMS-209 to be completed by the laboratory onsite (please refer to the CMS website to obtain the form)

Proficiency Testing:
- Proficiency data by CLIA number for the past 24 months (required for initial and resurveys) including all investigations, worksheets, and attestations, the last 6 events.
- A list of tests that do not use proficiency testing for accuracy and precision for verification
- Results of alternative performance verifications

Process Improvement, Infection Control and EOC:
- Performance Improvement Data for the past 24 months
- Results of periodic laboratory environment inspections from the safety committee or safety officer and manifests for disposal of hazardous waste
- Emergency Operations Plan, and evaluations of exercises and responses to actual emergencies
- Errors/accidents/nonconformances/complaints
- Internal and external audits/assessments, PI monitors
- Most recent culture of safety and quality evaluation data

Credentials, HR File Review and Competency Assessments:
- Laboratory Director(s) credential file and contract
- Personnel licenses or certification if required by the state or the policy of the organization
- List of all testing personnel qualifications, hire date, training & competency records for the past 24 months
- Proof of highest level of education for testing personnel

IQCP:

- IQCP documentation for all applicable test systems
    - Risk Assessment
    - Quality Control Plan
    - Quality Assessment
- Implementation date
- Documentation of review of Quality Control Plan
- In cases where IQCP was discontinued, risk assessment documentation for the past 24 months

General Laboratory Documentation:

- Ability to retrieve testing records for patients who have had laboratory tests or other services for the past 24 months
- Correlations and Calibration Verifications for the past two years for all test systems
- A list of new instruments and new tests that have been implemented in the past two years and their validation studies
- Temperature charts
- QC records including EQC and attempts at IQCP
    - Include daily quality control with dates and times performed as well as peer data
- List of critical equipment/supplies and maintenance records
- Policies, processes, and procedures
- The normal patient prothrombin time mean for your current lot of thromboplastin reagent
- The international sensitivity index (ISI) value specific to the lot of thromboplastin reagent in use.

Miscellaneous:

State of California Surveys: Using the **Surveyor Checklist to Unique Requirements of California Department of Public Health**, laboratories should review and ensure compliance to specific state regulations that apply to their facility (the form is available on the organizations secure Joint Commission *Connect* extranet site under the Survey Process tab, Laboratory Tools)

Laboratory Accreditation Survey Activity List

Activity Name	Suggested Duration of Activity	Suggested Scheduling of Activity	Key Organization Participants (Refer to Survey Activity Guide for more info.)
Surveyor Arrival and Preliminary Planning, includes the Safety Briefing	15-30 minutes	1st day	
Opening Conference	15-30 minutes	1st day, as early as possible	
Orientation to Organization	30-45 minutes	1st day, as early as possible	
Regulatory Review	30-45 minutes	1st day; must occur before or just after Surveyor Planning Session	
Proficiency Testing Validation/Performance Improvement Data Review	90-180 minutes	1st day, must occur immediately after Regulatory Review	
Lunch	30 minutes	At a time negotiated with the organization	
Tracer Activity	60-120 minutes	Tracer activity occurs throughout the survey; the amount of tracer activity varies by organization	
Environment of Care and Emergency Management	45-90 minutes	Organization and surveyor determine if these topics will be covered during tracer activity, in a scheduled meeting, or a combination of the two	
Issue Resolution	30 minutes	As needed; end of each day except last; can be scheduled at other times as necessary	
Team Meeting/ Surveyor Planning	30 minutes	Mid-day and/or end of each day except last when more than one surveyor on site	
Daily Briefing	15-30 minutes	Start of each survey day except the first day; can be scheduled at other times as necessary	
Human Resources and Competence Assessment	60-120 minutes	After completion of most tracer activity; some topics may be explored, and some record review may occur during Tracer Activity; additional record review takes place at scheduled time	
Report Preparation	60-120 minutes	Last day of survey	
CEO Exit Briefing	15 minutes	Last day of survey	
Organization Exit Conference	30 minutes	Last day, final activity of survey	

NOTE: Regulatory review may be extended for laboratories performing IQCP to provide adequate time for document review

Surveyor Arrival and Preliminary Planning

Organization Participants
Suggested participants include organization staff and leaders, the staff responsible for coordinating The Joint Commission survey, individual or individuals that will provide the Safety Briefing to surveyors, if different than the accreditation contact or survey coordinator, and others as needed and identified by surveyors.

Logistical Needs
Identify a location where surveyors can wait for organization staff to greet them and a location where surveyors can consider as their "base" throughout the survey. This area should have a desk or table, telephone, **internet access,** and access to an electrical outlet, if possible. Provide the surveyors with the name and phone number of a key contact person who will assist them in coordinating survey activities and tracer selection.

Overview
Surveyors arrive at approximately 7:45-7:50 a.m. unless business hours, as provided in the application, indicate that your organization opens later. Surveyors will check in at the front desk, identifying themselves as Joint Commission surveyors.

Surveyor Arrival Activities
- Implement your Readiness Guide as discussed in the Preparing for Surveyor Arrival section
- Notify key organization members as identified in the pre-survey planning session of the surveyor's arrival
- Validate that the survey is legitimate by accessing your Joint Commission extranet site. A staff member in your organization with a login and password to your Joint Commission extranet website will follow through with this by:
    - Accessing the Joint Commission's website at www.jointcommission.org
    - Click on "the Joint Commission Connect" logo
    - Enter a login and password
    - If you cannot access the extranet site to validate the survey or identify the surveyors, call your Account Executive
- Your organization's extranet site contains the following information:
    - Confirmation of scheduled Joint Commission event authorizing the surveyor's presence for the unannounced survey
    - Surveyor name(s), picture, and biographical sketch
    - Survey agenda.
- If you have not already downloaded a copy of your survey agenda, do so at this time.
- Begin gathering and presenting documents as identified in the Laboratory Accreditation Document List found earlier in this guide. Surveyors will start reviewing this information immediately.

Preliminary Planning Activities

Objectives
Surveyors will:

- Learn about any current organization safety or security concerns and how they should respond if organization safety plans are implemented.
- Review and confirm the survey agenda
- Plan for tracer activity
- Review documents to become acquainted with your organization

Overview
After surveyors have arrived and their identification has been verified, surveyors immediately begin planning for tracer activity by reviewing the documents you provide them. They begin discussing the focus of the survey with the other surveyors (when applicable). If documents are not available for surveyors to review during this session, they will proceed to areas where care, treatment, or services are provided and begin individual tracer activity.

The organization is requested to provide surveyors with a Safety Briefing (informal, no more than five minutes) sometime during this activity. The purpose of this briefing is to inform the surveyors of any current organization safety or security concerns and how Joint Commission staff should respond if your safety plans are implemented while they are on site. Situations to cover include:

- Fire, smoke, or other emergencies
- Workplace violence events (including active shooter scenarios)
- Any contemporary issues the surveyor may experience during the time they are with you (for example, seasonal weather-related events, anticipated or current civil unrest, or labor action)

Opening Conference

Organization Participants
Suggested participants include members of the governing body and senior leadership (representing all laboratory programs/services), laboratory director on the CLIA certificate, and laboratory manager/supervisor. Attendees should be able to address leadership's responsibilities for planning, resource allocation, management, oversight, performance improvement, and support in carrying out your organization's mission and strategic objectives. Other attendees may include at least one member of the governing body or organization trustee and leaders of the medical staff, when applicable.

Logistical Needs
The duration of this session is approximately 15-30 minutes. Immediately following this session is the Orientation to the Organization activity. If possible, designate a room or space that will hold all participants and will allow for an interactive discussion. Inform surveyors at this time of any agenda considerations that may impact the activities for the day.

Objectives
Surveyors will:
- Describe the structure of the survey
- Answer questions your organization has about the survey
- Review your organization's expectations for the survey

Overview
Surveyors introduce themselves and describe each component of the survey agenda. It is important for you to discuss and review your organization's expectations for the on-site survey with the surveyor(s). Questions about the on-site visit, schedule of activities, availability of documents or people and any other related topics should be raised at this time. Surveyors will also take time to introduce your organization to the revised Clarification procedures and new SAFER™ reporting process if your organization is not yet familiar with these features of accreditation.

Orientation to the Organization

Organization Participants
Suggested participants include the same participants as the Opening Conference. Suggested participants include members of the governing body and senior leadership. Attendees should be able to address leadership's responsibilities for planning, resource allocation, management, oversight, performance improvement, and support in carrying out your organization's mission and strategic objectives. Other attendees may include at least one member of the governing body or organization trustee and leaders of the medical staff, when applicable.

Logistical Needs
The suggested duration of this session is approximately 30-45 minutes. **Do not prepare a formal presentation**. This session is an interactive discussion, and it is usually combined with the Opening Conference.

Objective
Surveyors will learn about your organization through an interactive dialogue to help focus subsequent survey activities.

Overview
During this session surveyors become acquainted with your organization. They begin to learn how your organization is governed and operated, discuss leaders' planning priorities, and explore your organization's performance improvement process.

Governance and operations-related topics for discussion include:

- Laboratory's role in the organization's mission, vision, goals, and strategic initiatives
- Organization structure
- Operational management structure
- Leadership Safety Culture
- Laboratory information management system, especially the format and maintenance of laboratory results in patient clinical records
- Contracted services and performance monitoring, including telepathology services
- National Patient Safety Goals
- Community involvement
- Laboratory role in emergency management planning
- Laboratory patient population
- Organization activities related to risk awareness, detection and response as it relates to cyber emergencies
- Test utilization and process for addition/deletion of tests and quality management system in place (e.g., IQCP)

Discussion topics include your:

- Leaders' ideas of your organization's potential risk areas
- Leaders approach to completing the Focused Standards Assessment (FSA) Tool and methods used to address areas needing improvement (resurveys only)
- Management and leadership's oversight and other responsibilities

Senior Leadership Role in Improving Performance discussion topics may include:

- How leaders set expectations, plan, assess, and measure initiatives to improve the quality of services
- Routine performance monitoring and identifying and prioritizing improvement projects
- Use of data in strategic and project-level decision-making and planning
- Improvement methodology and improvement tools being used
- Organization approach to safety, including selection of Proactive Risk Assessment topics, resulting improvements, and Board/Governance involvement in safety issues
- Provision of laboratory personnel and resources including time, information systems, data management, and staff training

  Note: Surveyors will request examples of performance improvement initiatives including evidence that performance was achieved and sustained.

Proficiency Testing Validation/Performance Improvement Data Review

Organization Participants
Laboratory director(s) on all CLIA certificates held by the organization, the laboratory administrative director and/or manager and other staff or laboratory staff as designated by the organization

Logistical Needs
The suggested duration of this session is approximately 90-180 minutes. A room is needed to accommodate organization and Joint Commission surveyor participants.

Objective
The surveyor will verify that the laboratory is enrolled and participates in a CMS-approved proficiency testing program for each regulated analyte and will review proficiency testing performance for regulated and non-regulated analytes (if applicable), including documentation of remedial action for each result exceeding acceptable limits.

Overview
During this session the surveyor will review and discuss the following documents with laboratory representatives:

- All proficiency testing results for the last two years (previous six testing events)
- All records of test handling, preparation, processing, examination, and results reporting, and signed attestation statements provided by the proficiency feedback reports
- Documentation of review of each proficiency report and documentation of review of problems or potential problems with remedial actions, as indicated
- Performance improvement data
- Record retention policies and procedures

Regulatory Review - LAB

Organization Participants
Laboratory leadership

Logistical Needs
The suggested duration of this session is approximately 30 minutes. A room is needed to accommodate organization and Joint Commission surveyor participation.

Objective
The surveyor will verify that licensing and services provided by the laboratory comply with law and regulation.

Overview
During this session the surveyor will:

- Verify CLIA certificates:
  - Director
  - Specialties/subspecialties
  - Type corresponds to level of testing
- Verify license requirements of lab, director and staff
- Verify proficiency testing provider and enrollment period
- Determine test volumes per CMS guidelines for specialties
- Review of IQCP documentation, if applicable

Individual Tracer Activity

Organization Participants
Suggested participants include staff and management involved in the individual's care, treatment, and services.

Logistical Needs
The suggested duration of individual tracer activity varies but typically is 60-120 minutes. Care is taken by surveyors to assure confidentiality and privacy and they will seek the help and guidance of staff in this effort. Surveyors may use multiple individual served/patient records of care, treatment or services during an individual tracer. The purpose of using the record is to guide the review, following the care, treatment, or services provided by the organization to the individual served/patient.

A surveyor may arrive in a setting/unit/program/service and need to wait for staff to become available. If this happens, the surveyor may use this time to evaluate environment of care issues or observe the care, treatment, or services being rendered.

If there are multiple surveyors conducting the survey, they will make every effort to avoid visiting areas at the same time and will try to minimize multiple visits to the same location. However, an individual tracer does follow where the individual served/patient received services.

Objective
The surveyor will evaluate your organization's compliance with standards as they relate to the care and services provided to individuals served/patients.

Overview
Most survey activity occurs during individual tracers. The term "individual tracer" denotes the survey method used to evaluate your organization's compliance with standards related to the care, treatment, and services provided to an individual served/patient. Most of this survey activity occurs at the point where care, treatment, or services are provided.

Initially, the selection of individual tracer candidates is based on your organization's clinical services as reported in your e-application. Surveyors will select enough individuals served/patients to trace allowing for review of all laboratory specialties and subspecialties. As the survey progresses, the surveyors may select patients/individuals served with more complex situations and whose care crosses programs and different laboratory specialties. Additional tracers may be selected based on several other indicators such as: Review of proficiency testing and quality control data, most frequent diagnoses treated by the organization, selected locations within the hospital, and a range of service dates.

To evaluate consistency of practice for the previous two years, surveyors will be selecting at least one individual served/patient clinical record for review from the following periods of time preceding the current date of survey:

- 13 to 24 months
- 6-12 months
- Within the last 6 months

The individual tracer begins in the setting/laboratory specialty/service/location where the individual served/patient and his/her record of care are located. The surveyor starts the tracer by reviewing a record of care with the staff or person responsible for the individual's care, treatment, or services. The surveyor then begins the tracer by:

- Following the course of laboratory testing from preanalytical through post analytical phases of testing.
- Assessing the interrelationships between disciplines, departments, programs, services, or units (where applicable), and the important functions in the care, treatment or services provided by the laboratory and the leadership.

During the individual tracer, the surveyor observes the following (includes but is not limited to):

- Care, treatment or services being provided to individuals served/patients by clinicians, including physicians
- Infection control issues (e.g., techniques for hand hygiene, appropriate personal protective equipment (PPE) ~~sterilization of~~ equipment cleaning and disinfection/sterilization, ~~disinfection, laboratory, and housekeeping~~environmental cleaning and disinfection)
- The environment as it relates to the safety of patients/individuals served and staff
- Quality control, IQCP documentation (as applicable), maintenance and testing performance

During the individual tracer, the surveyor interviews staff about:

- Processes as they relate to the standards
- Intradepartmental and interdepartmental communication for the coordination of care, treatment or services. (e.g., hand offs)
- The use of data
- Individual served/patient flow through the organization
- National Patient Safety Goals
- Orientation, education, and competency of staff
- The information management systems they use for care, treatment and services (paper, fully electronic or a combination of the two) and about any procedures they must take to protect the confidentiality and integrity of the health information they collect
    - Back up procedures they've been instructed to use if the primary system is unavailable
    - If internet-connected health information, equipment, or devices are used in care, treatment, or service, staff may be asked to describe their access procedures (passwords, authentication, etc.), confidentiality measures, and instructions on down-time procedures
    - How they approach risk awareness, detection and/or response as it relates to potential cyber emergencies
- Other issues

During the individual tracer, the surveyor may speak with available physicians and licensed practitioners about:

- Organization processes that support or may be a barrier to individual served/patient care, treatment and services
- Communications and coordination with other physicians and licensed practitioners (hospitalists, consulting physicians, primary care practitioners)

- Awareness of roles and responsibilities related to the Environment of Care, including prevention of, and response to incidents and reporting of events that occurred

During the individual tracer, the surveyor may interview individuals served/patients and their families about:

- Coordination and timeliness of services provided
- Education, including discharge instructions
- Response time when call bell is initiated or alarms ring, as warranted by care, treatment or services
- Perception of care, treatment or services
- Staff observance of hand-washing and verifying their identity
- Understanding of instructions (e.g., diet or movement restrictions, discharge, and provider follow-up), as applicable
- Other issues

Using individual tracers for continuous evaluation

Many organizations find tracer activity helpful in the continuous evaluation of their services. If you choose to conduct mock tracers, in addition to clinical services, consider the following criteria in selecting patients/individuals served.

- Top ten DRGs for the organization
- Inconsistent or trending proficiency test performance
- Emergency release, transfusion reaction, and blood transfusions
- List of critical values from randomly selected dates
- Positive blood cultures from randomly selected dates
- Microbiology special requests
- Patients/individuals served who move between programs/services that have experienced laboratory services, for example:
    - Patients being discharged from the hospital to home with scheduled follow-up in ambulatory care
    - Patients discharged from the hospital to home with planned home care
    - Patients discharged from the hospital to a nursing care center or residence
    - Patients referred to another specialty provider within the same organization

Laboratory Tracer Activity

- Patient sample testing in laboratory sections (i.e., hematology, chemistry, microbiology, blood bank)
- Policy and procedures that guide testing performance of patient samples
- Maintenance of laboratory equipment
- Preanalytical, analytical and post analytical procedures

Blood Bank Tracers

- Transfusion reaction reports
- Quality control results for day (month) of testing
- Maintenance of equipment for day (month) of testing
- Lot number in use for day (month) of testing
- Acquisition/disposition records (for products infused)
- BPD incidents and/or reports

- Permanent patient record system and system for recording alloantibodies/transfusion reactions
- Follow blood product to a patient
- Cell salvage, blood warmers
- Therapeutic apheresis procedures (phlebotomy or plasma apheresis)
- Blood utilization statistics and reports

Bacteriology, Mycology and AFB Tracers

- Validation of new tests, or equipment, or process
- Media receipt and quality control (if applicable)
- Manual biochemical quality control
- Automated biochemical quality control (ID per lot)
- Sensitivity quality control (manual and automated)
- Maintenance
- Lot numbers in use at time of tracers
- Review infection control policy; interview overseeing i~~I~~nfection c~~C~~ontrol processes at the laboratory ~~coordinator~~
- TAT or AFB smears
- Review antibiogram
- Confirmatory testing (if applicable ex. Strep screen)

Chemistry Tracers (include quantitative Immunology if applicable)

- Quality control for day (month) of testing
- Maintenance for month of testing
- Calibration prior to day of testing
- Calibration verification (if applicable) last two years
- Lot numbers in use at time of testing
- Correlation (if applicable) last two years
- Review of validation of new tests or equipment implemented in last two years

Coagulation Tracers

- Quality control for day (month) of testing
- Maintenance for month of testing
- Calibration (if applicable) prior to day of testing
- Calibration Fibrinogen every six months (if applicable)
- Lot numbers in use at time of testing
- Correlation (if applicable) last two years
- Review data for last new lot of PT reagents; check NV and ISI with instrument(s) setting
- Review of validation of new tests, or equipment, or process

Hematology Tracers

- Quality control for day (month) of testing including open and closed modes
- Maintenance for month of testing
- Calibration prior to day of testing
- Calibration verification (if applicable) last two years
- Lot numbers in use at time of testing
- Correlation (if applicable) last two years
- Review of validation of new tests, or equipment, or process
- Review of manually entered results

Molecular Tracers

- Review the validation studies for next generation sequencing bioinformatics pipelines
- Review clinical validity and clinical utility

Serology, Virology, Urinalysis, Waived tests (in Lab)
- Quality control and review of manually entered data (UA MICRO)
- Maintenance, if applicable
- Identifiers on tubes and slides
- Centrifuge settings
- Audit trail of kit lot numbers

Tissue Tracers
- Inventory system for tracking tissue/cellular products
- Annual FDA verification of supplier
- Temperatures for room, refrigerator and freezers
- Emergency backup, functional alarms for refrigerators and freezers
- Chart record of the implant/cellular product
- Look back policy

Waived Test (outside lab) Tracers
- Observe finger stick if possible
- Documentation of external and internal controls
- Reference ranges (age specific) on patient medical record
- Reagents (lot numbers and expiration dates)

Anatomical Pathology Tracers

Cytology
- If GYN by Sure Path or Thin Prep, see certification of screeners and pathologist(s) include proficiency
- Maintenance
- Quality control documentation for cytology stain by qualified cytotech or pathologist
- Screening time sheets for each screener
- Workload records for every employee, including pathologists performing initial screening for both GYN and non-GYN and outside workload records if applicable
- Every six months review of each screener
- Review order and report of each tracer patient
- Statistics for 10% review, five year look back for abnormal PAP
- Review of validation of new tests or equipment or process
- Review of random sample of negative GYN slides

Histology

- Review the Histopathology Quality Management Plan
- Review ASR immunochemical tests for analytical and clinical performance

Surgical Pathology
- Order and report of each tracer patient
- Blocks and slides of each tracer patient
- Quality control documentation for ALL histological stains by qualified pathologist
- Exposure reports (formalin and xylene)
- Maintenance (including cryostat)

- Review frozen vs. final correlations, correct name/address of performing lab on report
- Findings for all AP (if any)
- QA results for review of surgical pathology readings
- Transport times and staff training
- Mohs micrographic surgery policy and procedures

Necropsy (Autopsy)

- Review provisional and final reports of all autopsies in last two years
- Visit morgue (if applicable) refrigerator temperatures, PPE, spill kit, personnel decontamination area

IVF Laboratory Tracers

- CLIA certificate for all specialties performed
- Director credentials
- Laboratory Supervisor and staff qualifications
- Building tour (if freestanding) EOC
- Safety, fire, infection control, and emergency preparedness policies, alarm systems for storage of embryo, etc.
- Alarm systems of embryo, etc.; back up plans
- Cultural diversity, language
- Consents, including disposition policies
- Transfer of reproductive products to other facilities (FDA registration required TS standards)
- Technical standards for compliance in the clinical laboratory testing

Human Resources and Competence Assessment

Organization Participants
Suggested participants include staff responsible for the human resources processes; orientation and education of staff; assessing staff competency. There should be someone with authority to access information contained in personnel and training files.

Logistical Needs
The suggested duration for this session is 60-120 minutes. Personnel file contents (including, job descriptions, education, certification/licensure if required, performance evaluations), competencies, and training records for staff selected by the surveyor. Inform the surveyor at the Opening Conference if extra time is required to retrieve this information.

Objectives
The surveyor will:
- Learn how your laboratory meets the CLIA-required competency assessment for testing personnel
- Learn about your laboratory's orientation, education, and training processes as they relate to technical and non-technical staff, encountered during individual tracers
- Identify specific staff members (based on tracer activity) whose training records and personnel files they want to review to verify laboratory personnel and competency assessment processes

Overview
The surveyor discusses the following topics:
- Internal processes for determining compliance with policies and procedures, applicable law and regulation, and Joint Commission standards
- Methods used to determine staffing adequacy, frequency of measurement, and what has been done with the results
- Performance improvement initiatives related to competency assessment for staff
- Orientation of staff to your organization, job responsibilities, and/or clinical responsibilities
- Experience, education, and abilities assessment
- Ongoing education and training
- Competency assessment, maintenance, and improvement
- Competency assessment process for contracted staff, as applicable
- Other topics and issues discovered during the tracer activity

Environment of Care and Emergency Management

Organization Participants
Suggested participants include individuals familiar with the management of the laboratory equipment, instruments, utility systems relating to laboratory resources, and emergency management of the laboratory environment. This may include the safety management coordinator, security management coordinator, facility manager, building utility systems manager, information technology (IT) representative, and the person responsible for emergency management.

Logistical Needs
Surveyors will spend approximately 30-60 minutes evaluating these topics during the survey. In cooperation with your organization, the surveyor will determine if these topics will be covered during tracer activity, in a scheduled meeting, or a combination of the two.

Objective
Assess the laboratory's degree of compliance with relevant standards and identify vulnerabilities and strengths in the laboratory's Environment of Care (EC) and Emergency Management (EM) processes.

Evaluate the laboratory's preparedness for emergencies and disasters that may occur in the laboratory or community that could affect the laboratory's ability to provide services.

Overview

Environment of Care

The surveyor observes and evaluates your organization's performance in managing the laboratory environment through:

- A tour in the main area where most laboratory services are provided
- Review of environmental considerations for other laboratory testing sites, including point-of-care testing, during visits to those areas
- Exploring functions such as laboratory safety, infection control, security, safety equipment, space and configuration, storage of chemicals, management of information, and leadership
- Interviews with staff about safety and infection control practices, equipment use, use of hazardous materials and waste disposal, and security of information

Emergency Management

I. **For Laboratories that are independent organizations** (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by

The Joint Commission, the surveyor evaluates that the required written EM documentation (listed below) has been updated and reviewed at least every two (2) years as follows:

- Hazard vulnerability analysis
- Emergency operation plan and policies and procedures
- Communications plan

II. **For Laboratories that are independent organizations**, the laboratory staff should be prepared to discuss the following.

Part 1: "Actual" emergencies or disaster incidents

The laboratory describes what "actual" events impacted them and how they utilized their risk assessment, emergency operations plan, policies, and procedures to prepare for these events.

Be prepared to discuss:

- Actual emergencies or disaster incidents that have occurred in the past 12-36 months in which the emergency operations plan was activated
- What services the laboratory was able to provide during the event(s) (if applicable)
- Were these event(s) previously identified and risk prioritized as part of the laboratory's risk assessment (hazard vulnerability analysis)?
- What communication methods were used to notify staff, patient, and others about the event(s)?
- If the laboratory remained open during these events, were there any staffing issues or additional staffing needed to support the delivery of services (if applicable)
- If the laboratory remained open, how did the laboratory manage, obtain, and resupply critical resources during the event(s)?

Part 2: Emergency exercises

As part of planning and preparedness, the laboratory describes what emergency exercises they recently conducted as they should be based on past experiences, known risks/hazards, recent changes to their emergency operations plan, policies, or procedures. These exercises should be comprehensive enough to gain a realistic understanding of the laboratory's readiness for a real emergency or disaster incident.

Be prepared to discuss:

- Describe the one (1) required annual exercise the laboratory conducted to test its emergency operations plan and response procedures.
- The objective or intent of the emergency management exercise that the laboratory selected. Note: The annual exercise may be either an operations-based (full-scale or functional) or a discussion-based (such as a mock drill, tabletop, seminar, or workshop)

Part 3: Education and training

The laboratory describes what education and training they provided to their staff in the past 12–36 months.

Be prepared to discuss:

- Initial and ongoing education and training that was provided to staff

- How the laboratory validates staff knowledge of emergency response procedures

Part 4: Evaluation, After-action and improvement plans, and review

The laboratory describes the evaluation process, lessons learned, and actions taken to improve the program.

Be prepared to discuss:

- As a result of recent events and/or exercises, were any gaps identified in the emergency operations plan or policies or procedures?
- What lessons were learned? What was identified as opportunities for improvement based on recent events and/or exercises? How were they incorporated into revised plans, policies, and procedures?

III. **For laboratories located inside a Joint Commission–accredited hospital or critical access hospital** and are integrated into the hospital's emergency management program, emergency operations plans and policies and procedures.

Note: For laboratories located inside a Joint Commission–accredited hospital or critical access hospital, the surveyor verifies that the laboratory has a copy or access to the hospital's emergency operations plans and policies and procedures.

Be prepared to discuss:

- How laboratory staff accesses and utilizes the hospital's emergency management plans and policies and procedures
- How laboratory staff participate in the hospital's the emergency management program, emergency operations plan, policies and procedures, communication plan, education, training, emergency exercises
- What roles and responsibilities laboratory staff would have during an emergency or disaster incident, how they communicate with the hospital and other external agencies, and how they will continue to provide services and obtain resources needed during an emergency to remain operational
- What education and training laboratory staff have received, such as sheltering in place or evacuating
- What emergency management exercises/drills (not fire drills) have the laboratory staff participated in the past 12–36 months?

Infection Prevention and Control Program Assessment Tool for the Laboratory Program

Required Documents:

- Assessment of infection risks
- Infection prevention and control policies and procedures
- Protocols for high-consequence infectious diseases or special pathogens

Infection Prevention and Control Program Leader
Standard/EP: IC.04.01.01 EP 1

- ✓ The laboratory's infection prevention and control program is under the direction of a designated and qualified professional who has training in infection control.

Note: Examples of education and training may include in-person or online courses or training from recognized entities (state public health, CDC), professional associations and societies (for example, ADA, AAMI, AORN, APIC, SHEA, IDSA, etc.), or colleges and universities.

Policies and Procedures
Standard/EP: IC.04.01.01 EP 3

- ✓ The laboratory has written policies and procedures to guide its activities and methods for preventing and controlling the transmission of infections and communicable diseases. The policies and procedures are in accordance with applicable law and regulation, nationally recognized evidence-based guidelines, and standards of practice, including the use of standard precautions.

Relevant topics in federal, state, and local law and regulations include but are not limited to:

1. Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard 29 CFR 1910.1030 and Personal Protective Equipment Standard 29 CFR 1910.132
2. Health care worker immunization requirements
3. Reporting of communicable diseases and outbreaks
4. Handling, storage, transportation, and disposal of infectious waste Standard Precautions include the following:
1. Hand hygiene
2. Environmental cleaning and disinfection
3. Sharps safety
4. Appropriate use of personal protective equipment
5. Minimizing potential exposures or use respiratory hygiene and cough etiquette
6. Cleaning and disinfection of reusable medical equipment

Annual Risk Assessment
Standard/EP: IC.06.01.01 EPs 1, 2

- ✓ The laboratory has a written assessment of its identified risks for infection, contamination, and exposure that pose a risk to patients and staff based on the following:
    - Blood and infectious materials handled by the laboratory staff
    - Workflows or practices for sample acquisition, handling, transport, and preparation
    - Relevant infection control issues identified by the local, state, or federal public health authorities that could impact the laboratory
    - Laboratory staff contact with patients, if applicable

Note 1: Risks may include organisms with a propensity for transmission within health care facilities (for example, norovirus, respiratory syncytial virus [RSV], influenza, COVID-19) and airborne pathogens (for example, tuberculosis [TB]).
Note 2: Organizations may use risk assessment recommendations from established authorities, for example Biological Risk Assessment: General Considerations for Laboratories (cdc.gov)

Implementation of Activities for the Surveillance, Prevention, and Control
Standard/EP: IC.06.01.01 EP 3

- ✓ Staff adhere to **Hand hygiene** practices:
    - Use an alcohol-based hand rub or wash with soap and water for the following clinical indications:
        a. Immediately before touching a patient
        b. Before performing an aseptic task (e.g., placing an indwelling device) or handling invasive medical devices
        c. Before moving from work on a soiled body site to a clean body site on the same patient
        d. After touching a patient or the patient's immediate environment
        e. After contact with blood, body fluids or contaminated surfaces
        f. Immediately after glove removal
    - Perform hand hygiene with soap and water when hands are visibly soiled.
- ✓ Staff adhere to **sharps safety practices**: Sharps are disposed in accordance with applicable state and local laws and regulations and organization policies.

Environmental cleaning and disinfection

- ✓ Laboratory uses EPA-registered disinfectants, including disposable wipes, in accordance with manufacturers' instructions (for example, dilution, storage, shelf-life, contact time, and method of application).

Personal protective equipment (PPE)

Proper selection and use of PPE is based on the nature of hazard and potential for exposure to blood, body fluids and/or infectious material:

- ✓ Staff wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious materials, mucous membranes, non-intact skin, potentially contaminated skin, or contaminated equipment could occur.
- ✓ Staff wear a gown that is appropriate to the task to protect skin and prevent soiling of clothing during procedures and activities that could cause contact with blood, body fluids, secretions, or excretions.
- ✓ Staff use protective eyewear and a mask, or a face shield, to protect the mucous membranes of the eyes, nose and mouth during procedures and activities that could generate splashes or sprays of blood, body fluids, secretions, and excretions. Masks, goggles, face shields, and combinations of each are used according to the need anticipated by the task performed.
- ✓ Staff remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area or work area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area or work area and closing the door.
- ✓ Staff remove and discard disposable gloves upon completion of a task or when soiled during the process of care.
- ✓ **Minimizing potential exposures**
- ✓ The laboratory prompts patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the organization.

Cleaning and disinfection

- ✓ The laboratory cleans and disinfects reusable medical devices and equipment (for example, point-of-care devices) in accordance with manufacturers' instructions.
- ✓ Staff can verbalize who is responsible for cleaning and disinfection of reusable devices and equipment.
- ✓ Staff maintain separation between clean and soiled equipment to prevent cross contamination.
- ✓ Single-use equipment is discarded after use.

Reporting Communicable Diseases and Outbreaks
Standard/EP: IC.06.01.01 EP 4

- ✓ Discuss with the program leader the process for reporting of communicable diseases and outbreaks in accordance with state and local public health authorities' requirements.

Occupational Health
Standard/EP: IC.06.01.01 EP 5

- ✓ The laboratory implements policies and procedures to minimize the risk of communicable disease exposure and acquisition among its staff, in accordance with law and regulation. The policies and procedures address the following:
  - o Screening and medical evaluations for infectious diseases
  - o Immunizations
  - o Staff education and training
  - o Management of staff with potentially infectious exposures or communicable illnesses
- ✓ ***For laboratories where respirators are required for staff safety or required by the employer:*** The laboratory has a respiratory protection program that details required worksite-specific procedures and elements for required respirator use, including fit testing for staff at risk.
- ✓ Following an exposure incident, post-exposure evaluation and follow-up, including prophylaxis as appropriate, is available to the exposed staff and performed by or under the supervision of a practitioner.

Note: An exposure incident refers to a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an individual's duties.

- ✓ Laboratory policies and procedures are followed for management of staff with potentially infectious exposures or communicable illnesses (for example, regarding contact with patients).

Preparedness for High-Consequence Infectious Diseases or Special Pathogens
Standard/EP: IC.07.01.01 EPs 1,2

While there is not a standardized definition for high-consequence infection, infectious diseases or special pathogens, expert consensus defines these as novel or reemerging infectious agents that are easily transmitted from person-to-person, have limited or no medical countermeasures (such as an effective vaccine or prophylaxis), have a high mortality, require prompt identification and implementation of infection control activities (for example, isolation, special personal protective equipment), and require rapid notification to public health authorities and special action. Examples of high-consequence infectious diseases or special pathogens include MERS, novel influenzas, mpox clade 1, Ebola or other viral hemorrhagic fever diseases. This list may change, however, to reflect current regional or global outbreaks or to include future emerging agents.

- ✓ The laboratory develops and implements protocols for high-consequence infectious diseases or special pathogens. The protocols address the following:
  - o Procedures for specimen or samples collection, labeling, preparation, handling, packaging, and transport
  - o Required personal protective equipment and proper donning and doffing techniques

- Infection control procedures to support safe specimen collection and management while the patient is in isolation using the hierarchy of controls (for example, the use of dedicated point of care devices for routine laboratory testing)
- Procedures for waste management, secure specimen containment and disposal, and cleaning and disinfecting spaces, surfaces, and equipment
- Procedures for informing public health authorities and key staff

✓ The laboratory develops and implements education and training and assesses competencies for the staff who will implement protocols for high-consequence infectious diseases or special pathogens.

Note: Training, education, and competency assessment occur as required by laboratory policy or in accordance with law and regulation.

Issue Resolution

Note: This activity takes place as needed at the surveyor's discretion.

Organization Participants
None, unless otherwise requested by the survey team

Logistical Needs
For surveys lasting more than one day, 30 minutes is scheduled toward the end of each day except the last for surveyors to conduct either Special Issue Resolution or engage in Surveyor Planning or Team Meeting activity. The surveyor will inform your organization's contact person what activity they will be conducting.

Surveyors will inform your organization's contact person of what documentation, if any, is needed for the issue resolution activity if being conducted and any staff who they would like to speak with or locations they want to visit.

Overview
Surveyors explore issues that surfaced during the survey that could not be resolved at the time they were identified (staff unavailable for interview, visit to another location required, additional file review required, etc.). Depending on the circumstances, this may include:

- The review of policies and procedures
- The review of additional patient/resident/individual served records to validate findings
- Discussions with staff, if necessary
- Review of personnel and credentials files
- Review of data, such as performance improvement results
- Other issues requiring more discussion

Surveyor Planning / Team Meeting

Note: This activity takes place as needed at the surveyor's discretion.

Organization Participants
None

Logistical Needs
For surveys lasting more than one day, 30 minutes is scheduled toward the end of each day except the last for surveyors to conduct either Special Issue Resolution or engage in Surveyor Planning or Team Meeting activity. The surveyor will inform your organization's contact person of the activity they will be conducting. The suggested duration for this session is 30 minutes.

Overview
Surveyors use this session to debrief on the day's findings and observations and plan for upcoming survey activities.

Before leaving the organization, surveyors will return organization documents to the survey coordinator / liaison. If surveyors have not returned documentation, your organization is encouraged to ask surveyors for the documents prior to their leaving.

Daily Briefing

Organization Participants
Suggested participants include representative(s) from governance, CEO/Administrator or Executive Director, individual coordinating the Joint Commission survey, and other staff at the discretion of organization leaders

Logistical Needs
The suggested duration for this session is approximately 15 to 30 minutes and occurs every morning of a multi-day survey, except for the first day. Surveyors may ask to hold a daily briefing before concluding activity on the first day, depending on circumstances. If a surveyor cannot participate in this session because they are surveying at a remote location, you may be asked for assistance with setting up a conference call to include all surveyors and appropriate staff.

Objective
The surveyor will summarize the events of the previous day and communicate observations according to standards areas that may or may not lead to findings.

Overview
The surveyors briefly summarize the survey activities completed the previous day. During this session the surveyors make general comments regarding significant issues from the previous day, note potential non-compliance, and emphasize performance patterns or trends of concern that could lead to findings of non-compliance. The surveyors will allow you the opportunity to provide information that they may have missed or that they requested during the previous survey day. You may also present surveyors with information related to corrective actions being implemented for any issues of non-compliance. Surveyors will still record the observations and findings but will include a statement that corrective actions were implemented by the organization during the on-site survey.

Your organization should seek clarification from the surveyors about anything that you do not understand. Note that the surveyors may decide to address your concerns during a Special Issue Resolution Session, later in the day. It is important for you to seek clarification if you do not understand anything that the surveyors discuss.

Surveyor Report Preparation

Organization Participants
None

Logistical Needs
The suggested duration of this session is approximately 60-120 minutes. Surveyors need a room that includes a conference table, power outlets, telephone, and internet access.

Overview
Surveyors use this session to compile, analyze, and organize the data collected during the survey into a report reflecting your organization's compliance with the standards. Surveyors will provide you with the opportunity to present additional information at the beginning of this session if there are any outstanding surveyor requests or further evidence to present from the last day of survey activity. Surveyors may also ask organization representatives for additional information during this session.

CEO Exit Briefing

Organization Participants
Suggested participants include the Chief Executive Officer (CEO) or Administrator, if available

Logistical Needs
The suggested duration of this session is approximately 10 to 15 minutes.

Objectives
Surveyors will:
- Review the survey findings as represented in the Summary of Survey Findings Report
- Discuss any concerns about the report with the CEO/Administrator
- Determine if the CEO/Administrator wishes to have an Organization Exit Conference or if the CEO/Administrator prefers to deliver the report privately to your organization

Overview
Surveyors will review the Summary of Survey Findings Report (organized by chapter) with the most senior leader. Surveyors will discuss any patterns or trends in performance. Surveyors will also discuss with the most senior leader if they would like the Summary of Survey Findings Report copied and distributed to staff attending the Organization Exit Conference.

Organization Exit Conference

Organization Participants
Suggested participants include the CEO/Administrator (or designee), senior leaders and staff as identified by the CEO/Administrator or designee.

Logistical Needs
The suggested duration of this session is approximately 30 minutes and takes place immediately following the Exit Briefing.

Objectives
Surveyors will:
- Verbally review the Summary of Survey Findings Report, if desired by the CEO
- Review identified standards compliance issues

Overview
Surveyors will verify with participants that all documents have been returned to the organization. You are encouraged to question the surveyor about the location of documents if you are unsure.

Surveyors will review the Summary of Survey Findings Report with participants. Discussion will include the SAFER™ matrix, Requirements for Improvement, and any patterns or trends in performance. Surveyors will provide information about the revised Clarification process. If follow-up is required in the form of an Evidence of Standard Compliance (ESC) the surveyors explain the ESC submission process.

Note: Surveyors will direct you to information on your extranet site that explains “What Happens after Your Survey.”

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