Laboratory Accreditation

Organization Survey Activity Guide

What's New for Laboratory Accreditation Survey Process 2025

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

Preparing for Surveyor Arrival

Overview

The surveyors

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

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:

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 moa numimed for 6.6 (i) 2it5ial 0.5 (r 6.6 (esu9 (be) 10.5 (r)-)-6

Pr (sm)2 (r)-pPrberort Llr6 Co[P)2 (r)-4.9)11.6(t)-5.99)18.6(r)-O6(of)-C6()-1.2 (:)JJ0 Tc Tf71.95 0 Td()TjEMC /LBody x

IQCP:

IQCP documentation for all applicable test systems

- o Risk Assessment
- o Quality Control Plan
- o 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

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	1 st day	
Opening Conference	15-30 minutes	1 st day, as early as possible	
Orientation to Organization	30-45 minutes	1 st day, as early as possible	
Regulatory Review	30-45 minutes	1 st day; must occur before or just after Surveyor Planning Session	
Proficiency Testing Validation/Performance Improvement Data Review	90-180 minutes	1 st 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	

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:

- o Accessing the Joint Commission's website at www.jointcommission.org
- o 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 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

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 impro ag7 0 Td[a2.6n)10.5 (t)-6.6 (e y)-1.9 (ou)2.6 (or)-6 (e y &MCIyo)1.6 (i30TJ05n08

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

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

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

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

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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.

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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