



Laboratory Accreditation Guide Information and Resources

The laboratory is a key contributor not only in providing test results and a diagnosis but also in improving patient care. As a performance improvement organization with almost 40 years of experience with laboratories, we're here to help you with the accreditation process. We encourage you to use the many resources that are available to your laboratory. As you're pursuing accreditation, whether it's your initial survey or a resurvey, we've provided some handy information to help you navigate your way.

How to begin? To receive an initial application for lab accreditation, or for general information about lab accreditation, contact us at qualitylabs@jointcommission.org.

Who's your "go to" person at The Joint Commission? Your account executive! They can assist you with questions about your application, survey date or schedule, and can answer specific questions related to your accreditation. Call 630-792-3007 to learn which account executive will assist you through the process.

What is the eligibility criteria for lab accreditation?

Any laboratory may apply for Joint Commission accreditation if all the following requirements are met:

- The laboratory is in the United States or its territories or, if outside the United States, is operated by the US government or under a charter of the US Congress. If required by law, the laboratory has a facility license or registration to conduct its scope of services. The laboratory must have a non-waived CLIA certificate.
- The laboratory can demonstrate that it continually assesses and improves the quality of its care, treatment, and/or services. This process includes a review by clinicians or qualified designee as defined by CLIA, including those knowledgeable in the type of services provided by the laboratory.
- The laboratory identifies the services it provides, indicating services it provides directly, under contract, or through some other arrangement.
- The laboratory provides services that can be evaluated by The Joint Commission's standards.

Survey activity guide

Once you request an accreditation application for your laboratory, you will gain access through a secure log-in to the Joint Commission extranet site, "Joint Commission Connect®." There you will find a Survey Activity Guide, which provides great detail about the survey agenda and provides preparation for the on-site review. You'll have access to document checklists, sample agendas and other useful guides and information.

What type of accreditation decisions are awarded?

The final accreditation decision, which will be valid for approximately two years, is based on a laboratory's compliance with Joint Commission standards. Decisions are awarded in one of the below categories:

- Limited, Temporary Accreditation (valid only for six months)
- Accredited
- Accreditation with Follow-up Survey
- Preliminary Denial of Accreditation
- Denial of Accreditation

Have a standards question?

The Standards Interpretation Group (SIG) is available to answer specific questions about standards and how they are interpreted. This is a no-cost service accessed through the Joint Commission website. Use the online form at https://www.jointcommission.org/standards_information/jcfaq.aspx. For the laboratory program, the designated Associate Directors have extensive laboratory experience. To provide consistency of interpretation, these are the same experts our surveyors use.

The standards manual

The Joint Commission's *Comprehensive Accreditation Manual for Laboratories and Point of Care Testing (CAMLAB)* is the place to begin when preparing for accreditation. The *CAMLAB* contains functional standards that are organized around the flow of services provided in a laboratory. The rationales and elements of performance will show you how to understand what the standards mean, how you can show compliance, and how your performance affects your accreditation decision. The standard is the goal. The elements of performance are the requirements that must be in place to meet the goal.

The accreditation process begins...

The accreditation process begins when you submit your application. It is best to submit your application when you are confident your laboratory can demonstrate compliance with the accreditation requirements and applicable elements of performance by the time of your on-site survey date. For initial surveys, you may request a ready date for survey within your application. Keep in mind that we will want to see 4 months working experience with the standards on your initial survey. Thirty days before the start of the initial survey a letter will be uploaded to your Joint Commission Connect extranet notifying you of your scheduled initial survey event and the assigned surveyor(s).

After The Joint Commission accepts a laboratory's accreditation application and receives the deposit fee, both parties begin preparing for the on-site survey. A good way to begin is to review the accreditation requirements and conduct mock tracers to see where improvements are needed, and then take measures to put new policies or processes in place as needed.

The Joint Commission schedules an employed laboratory surveyor, or team of employed laboratory surveyors to match a laboratory's needs and specialties. A laboratory can select the option of having an employed pathologist surveyor accompany the laboratory surveyor. The length of the survey depends on the complexity and size of the laboratory. The on-site survey uses tracer methodology, which follows a sample of patients through their experiences with the laboratory, to evaluate individual components of service. The survey follows actual patient records through the facility and includes interviews with key personnel, observation of the laboratory's administrative activity, assessment of the physical facilities and equipment, review of documentation, and observation of interactions with other departments and senior leadership.

Early survey option for lab accreditation

Some laboratories requesting a traditional survey may not be quite ready for full evaluation and may prefer the early survey option. The early survey option allows a lab new to Joint Commission accreditation to enter the accreditation process in two stages. This makes it possible to set up the business operations on a foundation of compliance with administrative and organizational standards. The early survey option is different than a normal, full survey in that it consists of two on-site visits.

First survey

The first survey can be conducted and announced as early as two months before the lab begins operations, provided it meets the following criteria:

- it is licensed or has a provisional license;
- the building in which services will be provided is identified, constructed, and equipped to support such services;
- it has identified its chief executive officer or administrator, and a qualified laboratory director; and
- it has identified the date it will begin operations, if applicable.

The Joint Commission requires written evidence of these criteria within 30 days before conducting the first survey. The first survey is a limited survey, addressing physical environment policies and procedures, plans, and related structural considerations for providing services. Following this initial survey, assuming that the laboratory can demonstrate compliance with the abbreviated set of standards, the organization receives preliminary accreditation.

Second survey

The second survey under the early survey policy is an announced, initial full accreditation survey. The Joint Commission conducts this survey within six months after the first survey. If at six months the organization is not ready for the second survey, the organization's Preliminary Accreditation decision will change to Unaccredited.

Based on survey results, the organization's accreditation decision then changes to one of the following:

- Accredited
- Denial of Accreditation

The effective date of the accreditation decision is the day after the second survey if the organization does not receive any Requirements for Improvements (RFIs). If the organization receives at least one RFI and therefore must submit an acceptable ESC report that resolves all RFIs, the effective date for accreditation is the date of the acceptable ESC submission. The organization's accreditation cycle begins the day after the second survey was conducted, unless The Joint Commission reached a decision to deny accreditation.

Award certificate

If a laboratory is in compliance with all standards at the time of the on-site survey, the accreditation decision is rendered at the same time that the laboratory's Summary of Survey Findings Report is available. The accreditation decision will be effective the day after the last day of the survey. If the laboratory is not fully compliant with one or more standards at the time of survey, the laboratory is required to complete and submit an Evidence of Standards Compliance (ESC) report.

In that case, the effective date is set retroactively as the date on which the last acceptable ESC that resolves all requirements for improvement is submitted. The ESC can be submitted directly via the laboratory's secure extranet site Joint Commission Connect.

Laboratory Multiorganization Survey Option

The Joint Commission offers a multi-laboratory system the option of using a modified survey process if it owns or leases at least two laboratories. This option has the following three components:

1. A corporate orientation held at the beginning of the year
2. Full surveys of participating organizations with a dedicated survey team leader. The team leader is dedicated to the organization for two years.
3. A corporate summation after the last organization in the system is surveyed

The orientation session provides an opportunity for corporate staff to orient the surveyor or survey team to the structure and practices of the system. The corporate summation provides an overall analysis of the system's strengths and weaknesses. It also provides education related to accreditation survey findings across the system. The survey team leaders compile the information necessary to support the corporate summation. The organization has the option of choosing only an orientation, only a summation, or both an orientation and summation.

Through the laboratory corporate survey option, The Joint Commission accredits the individual laboratories that are part of the multi-organization system, not the system itself. Therefore, each laboratory within a system receives its own accreditation decision and Accreditation Survey Findings Report. The findings and decision for one laboratory within a system have no bearing on those of another laboratory within the system.

Concurrent Survey Option

The Joint Commission offers a concurrent survey option for laboratories or systems with multiple Joint Commission accredited laboratories. This option provides a structure across the entire system and has the following components:

1. Unannounced surveys of participating laboratories occur at the same time
2. Each participating laboratory must demonstrate compliance with all Joint Commission requirements independent of any other laboratories within the system
3. Each laboratory health care organization will receive a separate survey report and accreditation decision

The years in between surveys -- intracycle monitoring (ICM) process

The intracycle monitoring process helps accredited laboratories maintain peak performance throughout the two-year cycle of accreditation. Facilitating this process is the ICM Profile – a comprehensive extranet workplace – that provides resources and tools to help identify risk points of standards compliance.

The ICM contains:

- Focused Standards Assessment (FSA), which is an electronic self-assessment tool used to identify and correct performance areas not in compliance with the standards before the next on-site survey. At approximately 12 months after a biennial survey, an accredited laboratory is required to perform an FSA and submit any findings along with corrective actions to ensure continuous compliance.
- For an additional fee, the laboratory can choose to have a laboratory surveyor come onsite and perform the assessment.

Questions about the ICM process?

Contact your organization's dedicated account executive at 630.792.3007.

Resurvey information

In the year between on-site surveys, The Joint Commission requires ongoing self-assessment and continuous improvement activities. As the accreditation process does not end when the on-site survey is completed, neither does the need for updates and changes to policies and procedures. Below are updates to specific procedures for the accreditation process. Accredited laboratories undergoing future surveys are encouraged to read this section to prepare for future changes, as well as continually study and improve their systems and operations as continuous compliance with the Joint Commission standards contributes directly to quality patient care.

Unannounced surveys

Since January 2006, laboratories that have already completed their initial survey are surveyed on an unannounced basis unless the laboratory's total annual testing volume is less than 25,000 or is a freestanding IVF laboratory. Laboratories undergoing an unannounced survey should be aware of the following:

- Joint Commission surveys are unannounced and occur 18 to 24 months after the previous full survey.
- On the morning of a laboratory's unannounced survey, the following information will be posted by 7:30 a.m. (local time) to your Joint Commission extranet site, Joint Commission Connect:
 - o Letter of introduction from The Joint Commission
 - o Survey agenda
 - o Biography and picture of surveyor(s) assigned
- The laboratory will not receive any communication from the surveyor prior to the survey.

- Accredited laboratories will be able to identify up to 10 days each year in which an unannounced survey should be avoided. Consult the included calendar within the e-application for a list of holidays when The Joint Commission does not survey. Make sure to include any regional events or other holidays in which it may be difficult to conduct a survey. The Joint Commission will make every effort to accommodate the laboratory regarding avoiding these 10 days. However, The Joint Commission reserves the right to conduct a survey during an “avoid period”.
- The organization is required to fulfill an Accreditation Participation Requirement (APR), which requires organizations seeking accreditation to continuously inform the public about their organization’s ability to report any complaints or concerns about safety to The Joint Commission.

For laboratories whose total annual testing volume is less than 25,000 or are a free standing IVF laboratory, you qualify for short notice of your next biennial survey event. Seven business days before the start of the survey a letter will be uploaded to your Joint Commission Connect extranet notifying you of your scheduled survey event. The designated primary lab contact will also receive a phone call.

Fees and annual billing

For all Joint Commission accreditation programs, a subscription billing package approach involves annual billing at a base rate and the assessment of add-on fees to cover all survey-related direct costs in those years in which on-site surveys are conducted. This annual fee structure aligns with the reality that Joint Commission accreditation-related services are now provided on a continuous basis. For additional information, contact the Pricing Unit at (630) 792-5115.

Resources available for your laboratory

There are many complimentary resources available to help your organization before, during and after the survey process. Please view them often as they are there for your benefit and are frequently updated.

The Joint Commission website www.jointcommission.org provides current Joint Commission news, standards information, helpful tips for publicizing your accreditation status, a listing of liability insurers that recognize Joint Commission accreditation and much more.

Laboratory Tracer Methodology Toolkit provides starting points, tips, questions and a form to use to create your own mock tracers and track your performance. It is available upon request through qualitylabs@jointcommission.org

Leading Practice Library

The Leading Practice Library is a collection of real-life solutions that have been successfully implemented by organizations. Solutions address such areas as competency assessment documentation, instrument methodology change protocol and policies for communicating critical test results. It is located on Joint Commission Connect under “Resources and Tools.”

Standards BoosterPaks™

These searchable documents provide detailed information about a particular standard or National Patient Safety Goal area, including evidence, rationale, references and frequently asked questions. Topics include High-Level Disinfection (HLD) and Sterilization and more. These are located on Joint Commission Connect under “Resources and Tools.”

Targeted Solutions Tool (TST)™ and the Joint Commission Center for Transforming Healthcare

The TST is an online tool that can help accurately measure your organization’s performance in relation to complex quality and safety problems, identify barriers to high quality performance, and direct your team to proven solutions that are customized to address your organization’s specific barriers. The TST is located on Joint Commission Connect under “Resources and Tools.”

Joint Commission Resources (JCR) Customer Service Center (Toll Free) (877) 223-6866

We realize your laboratory may need more in-depth assistance and educational resources. Joint Commission Resources (JCR), is an affiliate of The Joint Commission and can provide resources such as educational programs, publications and other options. A full list of their available resources can be found at jerinc.com.