



MANAGEMENT | LAB SAFETY

Fostering a culture of continual preparedness in the laboratory

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Compliance surveys are a regular part of operating a laboratory. On-site visits are the best way to ensure that laboratories are performing testing within the guidelines of the CLIA regulations, but they are unfortunately a source of great anxiety to many a laboratorian and Laboratory Director. Surveys are intended to help laboratories improve their processes and documentation, and ensure that quality results are being reported every day. That said, it is still stressful to have an outsider come into your laboratory, flip through your QC manuals, and watch you perform testing.

A survey-ready laboratory

With a little preparation and effort, surveys don't have to be a source of angst for your laboratory. Any laboratory team can reach a state of year-round survey-readiness and take some of the pressure out of the process; it just requires a shift in thinking. If you are always ready, then you are not going to be caught off-guard when survey time comes up again. You can think of it like keeping up with the assigned reading for an advanced-level class instead of trying to get through 15 chapters in the week before the final exam.

Fostering a culture of continual preparedness in your laboratory is one of the best ways to assure that your scheduled surveys will go more smoothly. When a lab is operating with an inspection-ready mindset, laboratory staff is less stressed about surveys because they know what is expected of them, and how to meet those expectations. A prepared lab is less likely to encounter surprises during the post-survey summation; the staff know their strengths and is already working on their weaknesses in order to improve quality.

Communication with your accreditor

Generally, a new laboratory has its first visit from a laboratory surveyor nine to 11 months from the date the initial CLIA certificate is issued. After that, routine surveys are biennial, generally scheduled 18 to 24 months apart. Depending on the circumstances and your accreditor, your laboratory may or may not be given advance notice of the expected survey date. Either way, it is very important to make sure that your laboratory accreditor has current contact information for the laboratory personnel so that any important pre-survey information can be shared with you. Notifications are most often made by telephone or email, so be sure that your accreditor knows whom to reach as your survey window approaches.

In addition to keeping contact information current, be sure to keep your accreditor up-to-date on personnel changes or changes to your test menu. Laboratory surveyors use this information to plan their surveys so that they can be as effective and efficient as possible. A surveyor may not be able to complete a survey during the scheduled timeframe if they discover unexpected significant changes to your staff, instrumentation or test menu when they arrive. Check with your accreditor about the best way to keep them apprised of changes in your laboratory, and make it a habit to review your test menu and personnel roster regularly to be sure you haven't missed notifying your accreditor of changes.

Familiarize yourself with expectations

It is important to be familiar with the regulatory requirements for your laboratory. The requirements you must meet are based on your CLIA certificate type, the complexity of the

testing you perform, and the specialties and specific test systems that are represented in your lab. The CLIA regulations are the basis of all laboratory compliance, but depending on your accreditation organization, you may be required to meet standards that are more stringent. If you have a manual or checklist provided to you by your accreditor, take the time to review it carefully as a team, and understand the specific expectations for your laboratory. If any of the requirements are unclear, contact your accreditor for guidance.

Some states also have requirements for labs operating within their borders or testing specimens that were collected there. These can include personnel licensure, proficiency testing requirements and record retention timeframes. Always check with CLIA or state laboratory agencies for these requirements, especially if you receive specimens from states other than your own.

Self-assessment

What better way to have your lab ready for a survey than to survey it yourself? Most accrediting organizations offer some sort of self-assessment checklist to their labs, and this can be an invaluable tool for teasing out your laboratory's weak spots. Reviewing all of the accreditation criteria and applying them to your lab can be a very enlightening and educational process for the entire laboratory team.

Assign staff to different sections of the checklist and have them use the listed criteria to check those areas for compliance. Is anything missing? Are records disorganized, incomplete or hard to find? What can your laboratory be doing better? Discovering problems during a self-assessment may seem disappointing at first glance; however, discovering them prior to survey leaves you plenty of time to investigate and implement meaningful corrective actions for any lapses in compliance.

Think like a surveyor

Self-assessment is even more effective when the staff performing it take it seriously and try to approach it as a surveyor would. For example, refer back to previous survey reports to look for any non-compliances or suggestions for improvement that were noted. A corrective action plan was likely submitted after those previous surveys, but how has the laboratory been performing in those areas since then? Were the corrective actions effective? Would the lab be at risk for a repeat non-compliance if a surveyor were to arrive unexpectedly?

Surveyors also target areas where changes have been made in your laboratory. For example:

1. If you have added new testing, have you signed up for the correct proficiency testing modules, if required?
2. Were all staff trained on the new tests and have competency assessments been performed at the correct intervals?
3. Were validation studies performed prior to implementation, and is quality control being performed at the correct frequency?
4. How about new staff members who have joined you since your last survey?
5. Do you have copies of documents showing that their education and experience is sufficient for the positions they hold?

Any person performing moderate complexity testing needs to have at least a high school diploma available for the surveyor's review. Higher degrees such as Associates or Bachelors are also acceptable, but beware of professional licenses and certifications, which in most cases are not sufficient *on their own* as evidence of education level. It is also important to remember that any degrees earned outside of the United States will need to be accompanied by an equivalency report showing that they meet U.S. educational standards. This is more than simply a language translation. These reports can take some time to obtain, so it is best to get an early start on them.

Preparing the team

Most staff reports that the most stressful portion of any laboratory survey is when the surveyor speaks to them directly and asks questions. Testing personnel, especially those who have never experienced a survey, can be very intimidated by the process, and worry that they will say something wrong. Including staff interviews in your self-assessment process can help them become more comfortable with discussing their work and learn which types of questions to refer back to the Technical Consultant or Laboratory Director. Remind them that they should always answer truthfully, and only answer what was asked without volunteering extra information. They should know that it is always acceptable to admit they are unsure of answers or need to refer to a procedure or to a supervisor for guidance.

While interviewing team members, make sure that they know where to find important documents, like the laboratory safety manual, exposure control plan, procedure manual and safety data sheets. This is also a good time to organize the laboratory space; check that manuals are current, stored in a logical way, and contain what they are supposed to. Check that employee files have all required documentation in them, including degrees, evidence of training on the testing they perform and copies of regular competency assessments.

Importance of a solid quality assessment plan

You may have noticed that many of the suggestions outlined above sound like items you would find in an average laboratory's Quality Assessment (QA) plan. There's a reason for that: a robust QA plan, properly implemented, creates an environment of constant assessment and improvement. Regularly assessing how your lab is handling pre-analytic, analytic and post-analytic activities is the best way to ensure that you are staying compliant with all regulatory requirements and are providing the best possible care to your patients. In a sense, regular quality assessment reviews are mini-surveys that you are performing on selected areas of your lab. Every completed review is its own partial survey report, with data highlighting areas where you are performing well and areas where you may need to rethink your approach. These reviews should always be shared with the whole laboratory team, so that you can share in successes and in planning improvements.

Any laboratory can be a survey-ready laboratory, with a dedicated team focused on consistent improvement. Make quality assessment a priority and you are likely to find that survey season doesn't hold all the stress for your team that it once did. You have been studying for this final all year. You've got this!

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