



WHAT TO EXPECT DURING SUBSEQUENT SURVEYS

State surveyors, acting on behalf of the Centers for Medicare and Medicaid Services (CMS), are expected to review laboratories for compliance with all CLIA standards and regulations biennially (every two years).

Similarly, laboratories enrolled in a CMS-approved accreditation organization, such as COLA, are surveyed once every two years by that organization to determine compliance with their CLIA-equivalent standards of accreditation.

By now, most laboratories that have been testing since CLIA '88 took effect in 1992 have had at least four surveys. Newer clinical laboratories may have only participated in one CLIA-related on-site survey. All laboratories will continue to be re-surveyed for the purpose of re-certification during subsequent CLIA survey cycles, with increasing expectations for the level of compliance demonstrated. This CLIA Facts discusses what might be expected of laboratories by their state survey agency or accrediting organization during the second and subsequent rounds of biennial surveys.

Many labs experienced their first CLIA survey sometime during the initial phases of CLIA '88 implementation (between 1992 and 1994). These initial surveys were aimed at making newly regulated laboratories familiar with the regulations, noting any glaring and significant deficiencies, and promoting good laboratory practice through the use of quality control and quality assessment plans.

The next round of surveys are reflective of the time that has passed, the collective experience and learning of laboratorians and surveyors, and refinements to the CLIA regulations. While the second (or subsequent) cycle survey is still a CLIA compliance check, expectations of accrediting organizations are higher and will focus on more specific areas of laboratory practice.

You can count on having the lab thoroughly reviewed for compliance with all aspects of the CLIA regulations. Special attention will be given to reviewing those areas of the laboratory where deficiencies were noted during the previous survey.

When preparing for a second or subsequent cycle survey, it is helpful to review any past survey reports in advance of the upcoming survey. This is especially important when there has been a change in staff since the previous survey.

State surveyors or accrediting organizations will want to see that the laboratory took the steps necessary to resolve previous problems and that any needed improvements have been maintained. Most importantly, they will check to see that the laboratory has a written quality assessment process in place and that those systems are being implemented to prevent the problems from recurring.

The laboratory director is expected to take an active role by standardizing laboratory activities and seeking quality improvement through error prevention. The commitment of the laboratory director to develop written policies, provide training to employees, and then hold them accountable for following these policies, is essential.

Surveyors are likely to note the laboratory director's level of involvement with the laboratory during the second and subsequent survey cycles. If the laboratory has a good quality assessment plan, proper training of staff, good quality control and documentation practices, and effective error prevention in place, the survey will reaffirm these excellent laboratory practices.

Expectations for Second and Subsequent Surveys

- Laboratories are expected to be in compliance with deficiencies noted in their previous statement of deficiency. Plans of correction should be implemented and those improvements continuously maintained. Repeat deficiencies are considered a serious matter.
- Laboratories must meet all condition-level criteria. Accrediting organizations may use a different term such as "essential criteria."
- Laboratories should have a written and signed procedure manual that includes complete and up-to-date procedures for all tests performed in the laboratory.
- Laboratories must have a written quality assessment plan and it must be followed on a regular basis.
- Surveyors are likely to emphasize the responsibility of the laboratory director to operate a laboratory that values error prevention. This focus stresses the importance of following standardized laboratory processes through the development of laboratory quality policies and procedures, and appropriate staff training.