

Quality Qorner

Knock-Knock—Here We Are!

The biggest change to laboratory accreditation since the introduction of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) kicks off the 2006 New Year. Both the JCAHO and the CAP have publicized that their respective organizations will conduct *unannounced* laboratory inspections. Are you uneasy with this change? Should you be?

What's wrong with the following picture? Your laboratory has just had its most recent inspection. The cited deficiencies (by whatever name) now need corrective action. In the next 30 days there's a lot of rewriting of old procedures, writing of new procedures, developing of new forms, and issuing of new or revised policies to close the deficiency gap. All the paperwork is sent in to the accrediting organization. Your laboratory then exhales a collective sigh of relief. You're off the hook for the next 2 years and it's back to business as usual; you know—solving problems, fighting fires, finding resources, and keeping it all together.

Time goes by and then... gosh!! It's time for reinspection again! Time to write more procedures, rewrite old ones, get the medical director's signature on all the procedures, move things, hide things, put things back in some semblance of order, spit-shine and polish up the laboratory. Here they come again; there they go again; now to deal with the new deficiencies. Except... haven't we seen these deficiencies before?

What is wrong with the picture described above is that laboratory inspection is mostly looked at as an interruption to be endured and survived. It's often perceived as a necessary annoyance and a game of "What can we keep the inspector from finding?" What is wrong with this picture is that this reactive approach to inspection involves using the laboratory's human and financial resources to *get ready* for the event rather than to *be ready* for it. What's also wrong is that the focus is on the inspection instead of constant compliance to serve the patients!

The role of quality.

Quality cannot be inspected into the laboratory's services. Inspections by accreditation organizations do not reduce the number of misidentified patients, mislabeled samples, lost samples or reports, or wrong results. Accreditation inspections do not improve staff competence, or the appearance, understanding, and use of the laboratory's procedure documents. Biannual inspections do not improve laboratory performance on proficiency testing, nor do they improve patient safety. True improvements in quality in all the areas described above can only start from within the laboratory itself.

Quality needs to be built into each process that contributes to the laboratory's services. Your laboratory's limited human and financial resources are best spent proactively designing, building, validating, implementing, and monitoring new and changed processes and procedures to ensure that all the necessary requirements are met in the routine performance of the processes and procedures by the staff every day.

There's a 180-degree difference in the philosophy of "getting ready for an inspection" versus "being ready at all times." The opportunity to continue living in the former paradigm has now been removed by the CAP and the JCAHO. Laboratories

that continue to "put it off for the next 2 years" have set a course that ensures problems ahead.

Quality management to the rescue.

In the movie *City Slickers*, the grizzled veteran cowboy tells his greenhorn to find the one thing that makes a difference. Is there *one* thing that laboratories can do to chart a proactive course for managing unannounced inspections? You bet! It's called a quality management system (QMS)—a systematic means to manage laboratory quality as part of the daily routine of laboratory work. In such a system, your laboratory's policies, processes, and procedures for management activities and for preanalytic, analytic, and postanalytic technical activities are designed, implemented, and executed in a manner that meets all regulatory and accreditation requirements. The QMS includes proactive self-assessment—through monitoring quality indicators and performing process audits—that alerts your laboratory's management to process problems so that preventive action can be taken before the inspectors arrive. The QMS also includes a nonconformance-monitoring program so that complaints, work issues, and patient safety problems can be captured, analyzed, and removed through corrective action. In a QMS, your laboratory's management team actively reviews the status of the laboratory's processes and services so that timely improvements can be made and documented—and thus immediately available for the inspectors.

CLSI (formerly NCCLS) guidelines HS1-A2,¹ GP26-A3,² and GP22-A2³ provide all the information your laboratory needs to learn about and begin implementing a quality management system. In a properly implemented QMS, your laboratory won't have to worry about unannounced inspections because you'll be ready anytime. It's the one-stop-shopping approach that treats quality as integral to daily laboratory life, rather than incidental to inspection findings.

So the next time you hear "knock, knock," will you be ready?

1. CLSI. A Quality Management System for Health Care; Approved guideline HS1—Second edition. Wayne, PA: Clinical and Laboratory Standards Institute, 2004.
2. CLSI. Application of a Quality Management System for Laboratory Services; Approved guideline GP26—Third edition. Wayne, PA: Clinical and Laboratory Standards Institute, 2004.
3. CLSI. Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved guideline GP22—Second edition. Wayne, PA: Clinical and Laboratory Standards Institute, 2004.

This Month's Quality Quote:

"In an ideal world, inspection should not be necessary and the goal should always be to minimize the need for inspection through the continuous improvement of processes."

—Greg Hutchins

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