Guest Lab Consultant Libby Knollmeyer: What to Expect When You're Expecting (or Not Expecting) a Lab Inspection

Prior to CLIA '88 (Clinical Laboratory Improvement Amendments of 1988) only laboratories participating in interstate commerce underwent inspections. Since the enactment of CLIA '88, all laboratories are subject to inspection, and **all non-waived laboratories are inspected**. CLIA has the right to appear at any point in time to inspect a lab.

There are two types of inspections for non-waived labs: routine and non-routine

Routine inspections take place every two years as mandated by CLIA, regardless of which agency is responsible for the inspection. If a lab has a Certificate of Compliance, CLIA will be the inspecting agency. If the laboratory has opted for a Certificate of Accreditation from one of the approved accrediting agencies, that agency will perform the inspection. Either way, the inspections are set on a two year cycle and the renewal of the laboratory's certificate is dependent upon successful completion of the inspection. If no deficiencies are cited, the certificate will be renewed very soon after the inspection is completed. If deficiencies are cited during the inspection, the laboratory will receive a deficiency report and will be given a timeline to submit a plan of correction. Once the plan of correction is accepted by the inspecting agency, the certificate will be renewed. Failure to achieve a successful conclusion to the inspection process will result in the cancellation of the lab's certificate, and therefore loss of privileges to do lab testing and to bill for lab testing.

The inspection cycle differs slightly for a newly set-up laboratory. CLIA or the accrediting agency will come in to do an inspection after the lab has been in operation for 3 – 6 months to ensure everything required is in place and all regulations are being followed. CLIA and the accrediting agencies do not inspect prior to the lab starting testing operations because they want the lab to generate data for them to review upon their inspection.

It should be noted that states which require state lab licensing in addition to CLIA certification frequently require inspection of the lab before the license number can be assigned and before the lab has begun operating. The CLIA application will not be released to CMS until the state is satisfied that the lab has everything in order, so both state lab licensing and CLIA certification will be dependent on this inspection. Check with your state to determine if it has regulations for laboratories in addition to CLIA regulations.

Non-routine inspections include validation inspections, off-cycle inspections, and inspections generated by a complaint against the laboratory.

Validation inspections occur when the primary inspection is performed by an accrediting agency, and CLIA opts to inspect the lab again behind the accrediting agency. CLIA has an assigned number of validation inspections to perform each year, but the selection process is random for the most part. So being selected for a validation inspection doesn't necessarily mean CLIA thinks there are any problems. A lab could have been selected for a validation inspection merely because it was convenient in location and scheduling for the CLIA inspector.

Off-cycle inspections occur when there have been problems identified in the lab and the routine inspection led to serious deficiencies. CLIA and COLA (Commission on Office

Laboratory Accreditation) will frequently follow-up a routine inspection that generated deficiencies with a second inspection to satisfy the inspector that the plan of correction (Plan of Required Improvement if COLA) was actually put into place and effective. Sometimes labs do so poorly on an inspection that they request an off-cycle inspection to get back in good standing and get the Certificate of Accreditation renewed. Regardless of when an off-cycle inspection takes place, the routine inspection will remain on the established every-two-year cycle tied to the expiration date of their certificate.

Any complaint against a laboratory can generate an inspection, and usually does. The agency to which the complaint was sent will usually do the inspection. The extent of the inspection will depend on the severity of the complaint, but the inspector has the right to look into any part of the laboratory on a complaint-generated inspection.

Waived Labs do not generally undergo inspections by CLIA, but are subject to be inspected at any time if there is a complaint generated, or if they are selected as one of the small percentage of waived labs that CLIA inspects routinely. There has been discussion of including waived labs in the routine inspection cycle, but to date that has not occurred. CLIA and COLA follow the same policies regarding waived labs; CAP (College of American Pathologists) does not recognize the "waived" test category and treats all tests with the same regulations as for moderate or highly complex laboratories. The Joint Commission (TJC) operates almost exclusively in the hospital arena where waived labs are nonexistent; it is unlikely that any Physician Office Laboratory (POL) would opt for TJC accreditation so inspection of waived labs is a non-issue for TJC.

Should I bring in a consultant to prepare for an inspection?

The answer to that question depends on the training and experience of the staff running the laboratory, but in general getting a consultant's opinion and input on the lab's preparedness for an inspection is a good idea. The time to benefit most from a consultant's input, however, is early on in the setup of the laboratory. If the lab is set up in compliance with all lab regulations, if the staff is educated adequately about those requirements, and if good processes for maintaining regulatory compliance are established from the beginning, then passing an inspection becomes just another day's work.

Want more information about inspections? Libby has a wonderful checklist called **"I'M YOUR CLIA INSPECTOR – WHAT AM I GOING TO LOOK FOR?"** that she will be glad to share with MMP readers who email her with a request (eknollmeyer@triad.rr.com).

Consultant Elizabeth "Libby" Knollmeyer, B.S., MT (ASCP) has over 40 years experience in the laboratory industry and has set up many laboratories! She specializes in financial, operational management and compliance issues for both hospital and physician office laboratories. Libby has a wide variety of experience with her areas of special expertise including financial review and management, Quality Management protocols, outreach development, compliance and regulatory assistance, lab design and up fitting, lab remodeling, and market research for IVD manufacturers. She works independently and with large consulting groups to provide interim management for hospitals, and serves as adviser to lab equipment and supply distributors. She consults (and enjoys traveling) throughout the US and internationally. She can be reached at (336)

288-5823 or at eknollmeyer@triad.rr.com.