EDUCATIONAL COMMENTARY – CAP & JCAHO UNANNOUNCED SURVEYS – NEW REQUIREMENTS

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Learning Objectives
Upon completion of this exercise, the participant will be able to:

- Discuss the primary reason(s) that the College of American Pathologists (CAP) and the Joint Commission (formerly JCAHO) moved to unannounced routine inspections in 2006.
- Discuss the basic programs that all laboratories should focus on to ensure that they are in continuous compliance with all regulations.
- Discuss ways the laboratory can link to other departments in the hospital to test the process by which they deliver comprehensive quality care to all patients.

In December 2005, an article appeared in the Los Angeles Times entitled “Lab Mistakes Threaten Credibility, Spur Lawsuits.” The article noted various examples of poor-quality laboratory practices across at least three states and inferred that “laboratory mistakes are a growing national problem.” The author stated that the laboratories that produced the poor-quality testing were fully accredited and in good standing with the leading laboratory accrediting agencies. This article and other similar articles tainted the public’s perception of the quality of laboratory testing.

Elected officials also questioned the effectiveness of the laboratory accreditation process. About the same time as the reports appearing in the media, the United States Government Accountability Office (GAO) was asked to investigate the quality of laboratory testing and the effectiveness of surveys and enforcement actions in detecting and addressing issues. It was also asked to study the quality of CLIA oversight by CMS. The GAO report, published in June 2006, had 3 major recommendations, which have led to some of the changes in the accreditation process. The foci of these recommendations are: (1) standardizing the reporting of survey results across accrediting organizations and regulatory agencies, (2) ensuring that surveys identify and report deficiencies, and (3) renewing emphasis on CMS’s statutory responsibilities.

As a result of these activities, laboratories today are faced with the uncertainty of unannounced inspections. The priority of the survey process is shifting from educating the staff to identifying and reporting deficiencies that can affect the quality of the testing. The intention is to shift from a specific focus on survey preparation to a continuous approach of improving overall laboratory operations by consistently identifying and reducing errors.
Previously, the focus of surveys and survey preparation was on reviewing documentation to ensure compliance with published standards. In today’s environment, the focus throughout healthcare is on outcomes related to the quality of patient care. In this new environment, surveyors are charged with analyzing the actual service processes to evaluate the systems in place that impact patient outcomes. In the hospital setting, they examine operational systems that are critical to safety and the delivery of care, with an emphasis on the interaction of the various departments of the hospital. The primary examples used by the accreditation agencies are the use of system or specimen tracers in the laboratory and the patient tracer methodology throughout the hospital.

Preparing Your Laboratory for Unannounced Inspections

If a proper Quality Management System is the core of the laboratory’s operational program, it will ensure staff compliance with regulatory requirements and laboratory policies and procedures. Every laboratory should have a strong Quality Management System in place and should consistently manage that process. The Quality Management System cannot simply be typed and put in a binder, ready for a surveyor to review. It must be a continuous process embraced by the entire staff and allowing them to focus on customer service and quality patient outcomes. If approached correctly, it will serve as the basis to create a “culture of quality” in the laboratory.

Many resources are available to help laboratories implement or enhance their Quality Management System. However, for real success the entire staff must consistently incorporate the program into the work environment. One process that will ensure that the staff is involved is to develop an internal self-audit team as an integral part of the program. Self-audit teams are charged with identification of errors, and should be set up to allow for participation by the entire staff over time. When not on a self-audit team, staff members can rotate to a project team.

Project teams are responsible for correcting issues that have been identified. After significant issues are identified, the next step is to develop a corrective action plan. Some options for correcting issues are:

- Change the process
- Retrain staff
- Redesign the process and monitor the outcome

This process allows peer review to evaluate the staff’s technical competency as well as their knowledge of regulations and standards as related to the internal processes established by management.
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Conclusion
The laboratory oversight environment is in the midst of change. However, progressive laboratory managers are not waiting for an unsuccessful survey before making operational changes. The best managers, both medical directors and administrative directors, are proactively involving and educating their staff and taking steps to create a culture of quality. In such a culture, the entire staff works as a team to continuously identify, correct, and monitor the outcome of internal processes to constantly improve the delivery of quality patient care. Those laboratories focused on providing the best quality of care will also be consistently prepared for unannounced inspections.

Suggested Resources
Approximately 36,000 laboratories are surveyed biennially by either their state agency or one of the 6 private accrediting organizations. The three largest accrediting organizations—CAP, Joint Commission, and COLA—survey about 97% of privately accredited laboratories. With this in mind, the websites of accrediting organizations are a primary resource for a laboratory. In addition, the following documents are recommended references for a laboratory about to embark on establishing a Quality Management System or in the process of reviewing an existing program:

- International Standard ISO 15189 – *Medical laboratories – Particular requirements for quality and competence*

- CLSI Document K2Q – *The Key to Quality*

- CLSI Document (GP22-A2) – *Continuous Quality Improvement: Integrating Five Key Quality System Components*

- CLSI Document (GP26-A3) – *Application of a Quality Management System Model for Laboratory Services*

- CLSI Document (HS1-A2-C) – *CLSI Quality System Toolkit*


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