

OUTCOME ORIENTED SURVEY PROCESS

CMS' objectives in developing an outcome oriented survey process is to not only determine the laboratory's regulatory compliance but to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results. The surveyor meets the objectives by employing an outcome-oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

The quality assurance (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart P) are the appropriate guide surveyors use for organizing their review. The surveyors select a cross-section of information (from all aspects of the laboratory operation) for review to assess the laboratory's ability to produce quality results as well as its ability to identify and correct problems. Emphasis is placed on overall laboratory performance and the structures and processes contributing to the reliability of the testing. The surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor can direct the laboratory to the requirements and the relevant sections for its particular setting, thereby accomplishing the educational aspect of the survey process.