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§493.1239 Standard: General laboratory systems quality assessment

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1239(b)

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1239(b)

When problems are identified in personnel competency, what corrective actions are instituted to improve employee performance?

When the laboratory identifies a problem, are corrective actions taken? Are these actions documented and monitored for effectiveness?

How does the laboratory prevent reoccurrences of problems?

How does the laboratory identify and document potential communication problems and any corrective actions that are taken (e.g., with staff, referral laboratories)?

Have the corrective actions that were taken as a result of failures in proficiency testing (PT) and/or verification of accuracy testing (as required under subpart H) improved performance?

(c) The laboratory must document all general laboratory systems quality assessment activities.

Interpretive Guidelines §493.1239(c)

Laboratories must document the steps taken to identify and correct problems, and any efforts to prevent recurrences. This includes laboratory policies amended due to QA activities.

PREANALYTIC SYSTEMS