

§493.1239 Standard: General laboratory systems quality assessment

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.

Interpretive Guidelines §493.1239(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and other non-laboratory areas or departments of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be **written** as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the General Laboratory System includes assessing practices/issues related to:

- Patient confidentiality;
- Specimen identification and integrity;
- Complaint investigations;
- Communications;
- Personnel competency; and

- Proficiency testing performance.

An example would be monitoring the type and number of complaints received by the laboratory such as a particular client continuously complaining about the laboratory's failure to promptly respond to STAT test requests. The laboratory must have documentation that the complaint was investigated and appropriate action taken to correct the problem.

Verify that the laboratory has a system in place for monitoring and evaluating confidentiality of patient information.

Probes §493.1239(a)

How does the laboratory ensure that an individual who had problems in performance is competent after appropriate retraining and technical assistance is completed?

How does the laboratory determine which complaints require investigation and which do not?