

§493.1299 Standard: Postanalytic 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 postanalytic systems specified in §493.1291.

Interpretive Guidelines §493.1299(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 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 investigation, 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 has 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 **Postanalytic System** includes assessing practices/issues related to test reports. Examples include monitoring and evaluating the accuracy and completeness of the

laboratory's test reports (i.e., patient information, test results, normal ranges, and the disposition of unacceptable specimens), and the laboratory's turn-around times and procedures for notification of test results e.g., routine tests, STATS, abnormal or panic values.

Review a cross-section of patient test reports for accuracy of patient information, test results and normal ranges to verify that the laboratory is effectively monitoring and evaluating the quality and accuracy of the information supplied to its clients.

Verify that the laboratory has a system in place to monitor and evaluate its established reporting time frames and procedures for notification of test results, routine tests, STATS, abnormal or panic values.

If the laboratory uses an LIS, the laboratory must have a mechanism to periodically verify the accuracy of:

- Its calculated data;
- Its results sent to interfaced systems; and
- Patient specific data.

In the event that the laboratory becomes aware of information that reasonably suggests that an in vitro diagnostic device may have caused or contributed to a patient death or serious injury, verify that the laboratory has reported such instances to the FDA.

Reports must be submitted on FDA Form 3500A (<https://www.fda.gov/medwatch/getforms.htm>) or an electronic equivalent as soon as practical, but no later than 10 days from the time personnel become aware of the event. For more information on reporting requirements, contact the FDA: Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration, HFZ-440, 2098 Gaither Road, Rockville, MD 20850, Phone: 240-276-0450, Fax: 240-276-0652.