

42 C.F.R. § 493.1804

General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

- (1) To protect all individuals served by laboratories against substandard testing of specimens.
- (2) To safeguard the general public against health and safety hazards that might result from laboratory activities.
- (3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) CMS's decision to impose sanctions is based on one or more of the following:

- (i) Deficiencies found by CMS or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)