D5205

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1233 Standard: Complaint investigations

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

Interpretive Guidelines §493.1233

Verify that the laboratory documents all complaints and problems reported to the laboratory, and that it has a mechanism to determine which complaints require investigation.

Probes §493.1233

What mechanism does the laboratory have that allows individuals to report complaints or problems to the laboratory?

How does the laboratory inform laboratory personnel of mechanisms to anonymously report complaints about laboratory quality to outside agencies, e.g. State survey agencies?

Does the laboratory have a mechanism to refer complaints or problems to its reference laboratory(s), or other offices or agencies, when appropriate? Does the laboratory document this activity?