

17.0 Preventive Action / Complaints and Corrective Action

17.1 Preventive Action

17.1.1 The laboratory participates in annual NTEP laboratory meetings. Discussion at these meetings includes the interpretation of type evaluation test procedures. The information from these meetings is documented and used to improve the quality of test in the laboratory. The laboratory obtains information from laboratory meetings and internal reviews and uses this information to examine its technical and quality system to identify needed improvements and potential sources of nonconformance. If preventive action is required, action plans are developed, implemented, and monitored. Procedures for preventive action are maintained in the laboratory (see Appendix H, AP No. 6).

[NOTE: If the laboratory has a control chart process, this can be referenced in this section as a means of preventive action]

17.2 Complaints and Corrective Action

17.2.1 The laboratory promptly investigates complaints, adverse findings during audits, or any other circumstance that raises doubts concerning the laboratory's competence or compliance with required procedures. The laboratory determines the root cause, identifies potential corrective actions, and follows a corrective action procedure to resolve the adverse situation promptly and, where necessary, conducts a retest. Procedures for handling complaints are maintained in the laboratory (see Appendix H, AP No. 6, AP No. 10, and AP No. 16).

17.2.2 The laboratory quality manager examines all documents and records associated with complaints, and the laboratory technical manager investigates adverse audit findings and other circumstances. If deficiencies are discovered during these reviews, they are documented. After review of the deficiencies with the laboratory staff and management, corrective actions are documented for each deficiency appropriate to the magnitude and risk of that deficiency and likely to eliminate or prevent recurrence. Deadlines are set for each corrective action. The laboratory manager monitors the corrective action to ensure that it is effective (see Appendix H, AP No. 6).

- 17.2.3 Records of deficiencies and corrective actions are maintained in the laboratory (see Section 13, Records and Appendix O, Forms).