



Discussion:

- Identify how internal audit findings will be addressed and documented. One method would be to document the findings and then follow the non-conformance procedure to address these findings. This must be documented in accordance with that policy and procedure. Refer to EL-V1M2 Section 4.11 - Corrective Actions.

4.14.5 Additional Items



Key Points:

- A policy detailing the timeframe for notifying a customer of events that impact their analytical data is needed.
- Management must accomplish the notification within the timeframe that has been established in each particular laboratory.
- The internal audit schedule is to be completed annually.



Discussion:

- The laboratory must develop a policy to identify the process that will be followed in the event an internal audit identifies issues that impact the data quality of customer results. Identify a timeframe within which customer notification will be completed.

4.15 Management Reviews

Requirements in this section should ensure the continued suitability and effectiveness of the quality system, policies and testing procedures.

4.15.1



Key Points:

- Develop a procedure and schedule for the completion of a review of the laboratory's management system, including testing and/or calibration activities to ensure their continued suitability. Address all items listed in EL-V1M2 Section 4.15.1.



Discussion:

- This is not an internal audit. Rather, it is an opportunity to assess the laboratory's performance in general and identify areas that require attention, and is to be completed on an annual basis. It can be seen as an opportunity to identify areas of

the lab that experience increased sample load as well as to identify areas requiring attention, whether it be facility related, equipment issues, or staffing.

4.15.2



Key Points:

- Record the findings from the management review and the actions that will be taken to address the issues that were identified.
- Management must verify that the actions are carried out within the appropriate time frame.
- The management review must be completed on an annual basis.



Discussion:

- As the report is compiled, it will identify issues that require further investigation or corrective action. The members of the laboratory management will determine the best course of action to address those. Some may not be within the ability of the laboratory management to address entirely, depending upon the overall structure of the organization. In these circumstances, the management report can be a highly useful communication between the laboratory management and the overall organization's management.

4.16 Data Integrity Investigations

Data integrity investigation is a simple inclusion in the TNI Standard that requires that a process be in place to investigate data integrity issues and to monitor data integrity within the laboratory. Actual data integrity training is covered in EL-V1M2 Section 5.2.7.



Key Points:

- All investigations resulting from data integrity issues are to be conducted in a confidential manner until they are completed.
- All investigations are to be documented including any necessary notifications to customers if it has been determined that their analytical results are affected.



Discussion:

- On occasion, it will become necessary to investigate potential issues calling into question the actions of a laboratory staff member. These types of situations are