STANDARD OPERATING PROCEDURE

CORRECTIVE ACTION DOCUMENTATION AND PROCEDURES

DHHS PHE Laboratory SOP #8500.1G

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Public Health Environmental Laboratory

Written by: _Laurie Wieting_   Date: _6-19/13_
QA Manager

Approved by: _Mary J. Boden_   Date: _6/19/13_
Laboratory Manager

SOP Review

Reviewed by:	Approved by:	Date:
Sandra Irons 10/1/14	*Laurie Wietting* / *Mary Boder*	10-1-2014 / 10-1-14
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Laurie Wietting	*Mary Boder*	2-20-18

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1.   Policy

It is the policy of the DHHS PHE Laboratory to ensure continuous acceptable quality levels for all lab services provided. This SOP was developed to address the proper course of action if an out of control event is observed in laboratory operations. Each analytical process is equipped with a self-correcting QC procedure as an integral part of every analytical SOP. The QA Manager and Laboratory Manager will monitor the implementation of corrective action and ensure that the root cause has been addressed. All corrective action reports (CAR's) will be tracked from imitation to conclusion on the lab shared drive and the final CAR will be signed and a signed paper copy will be archived in the QA office when completed. Of several possible out of control occurrences, four well-recognized events and their associated plans of corrective action and documentation are set forth below.

2.   Levels of Corrective Action

The initial responsibility to monitor the quality of a function or analytical system lies with the individual performing the procedure. Additional responsibility lies with the Team Leaders, QA Manager and the Laboratory Manager.

2.1   Corrective Action at the Customer Service Level

2.1.1. If a complaint is received from a customer or quality control problems are encountered, a logbook is kept of the problem and the corrective action taken.

2.1.2   Customer Service personnel will document and notify clients of any discrepancies in samples received. Instructions on handling discrepancies are documented in current version of *DHHS SOP #1900.1, Customer Service Procedures*. Relevant information on that sample will be disseminated to the analyst involved in the project.

2.1.3   These are discussed with appropriate Customer Service staff so that any problems can be corrected, and won't be repeated.

2.1.4   The Laboratory Manager, as the Customer Service team leader is responsible for seeing that the Customer Service Team corrects problems or complaints that have occurred. He/she reports problems and corrective action to the QA Manager.

2.2   Corrective Action at the Bench Level

2.2.1   Daily Quality Control Monitoring. Quality control samples (blanks, standards, LFBs, QCs, etc.) and calibration steps must meet specific acceptance limits. These limits are found in the specific method's SOP. If any of these fail, the corrective action is documented in the data package or on the bench sheet. The analysis is stopped until the problem can be resolved and the quality control samples are within the acceptance limits again.

2.2.2   Control charts, are used by the analyst to determine if any trends or shifts are occurring with his/her analysis. Control charts are used as a tool to detect problems before they become severe and have an adverse affect on the quality of the data. The statistical rules listed here can also be found in the current version of *SOP # 8200.1, Documenting Data Quality.*

2.2.2.1 If one measurement exceeds a control limit (+/-3 SD) repeat the analysis immediately. If the repeat measurement is within the control limits continue the analysis; if it exceeds the control limits, discontinue the analysis and correct the problem.

2.2.2.2 If two out of three successive points exceed a warning Limit (+/-2SD) analyze another sample. If the next point is within the warning limit continue the analysis; if the next point exceeds the warning limit, evaluate potential bias and correct the problem.

2.2.2.3 If four out of five successive points exceed one standard deviation, or are in decreasing or increasing order, analyze another sample. If the next point is less than 1 standard deviation or changes the order, continue the analysis; otherwise, discontinue the analysis and correct the problem.

2.2.2.4 If seven successive points are on the same side of the mean, discontinue analysis and correct the problem. Trending could be caused by deterioration of standards or reagents or a change in extraction efficiency. It could also indicate an instrument component failure such as a lamp failure with an AA.

2.2.2.5 Trends indicate systematic error. Shifts of data points above or below the mean can indicate serious systematic error; random error is revealed when measurements randomly exceed warning or control limits.

2.2.2.6 If necessary, complete corrective action for control charts using the above rules. A copy of the control chart with problem highlighted and C.A. written on chart, is submitted to the QA

office. This will be kept in the QA files. At the end of each quarter, the analyst has 10 days to update control charts. However, control charts should be kept current and corrective action taken throughout the quarter as problems occurred.

2.2.2.7. Review: the first level of corrective action is completed by the analyst and approved by the data reviewer.

2.2.2.8 Requirements: Minimum requirements for control charts is described in the Manual for the Certification of Laboratories Analyzing Drinking Water. Charts are developed from the mean (X) % recovery of the laboratory reagent blank(LRB) and/or other appropriate QC. The data are used to establish upper and lower control limits as follows: acceptance limits = X +-3 SD and warning limits = X +- 2 SD.

2.2.2.9. A minimum of 20 to 30 points should be used. Periodically new acceptance limits are calculated. The acceptance range must always meet or be more stringent than the method acceptance range. (When recalculating the acceptance range, the limits should not change very much from the previous limits. If the change is significant, there is a problem with the analytical system that needs to be investigated before analysis continues.)

2.2.2.10. The control limits determined by the analyst should not exceed the control limits established in the method. If any of these control limits are tighter than the method specifications, the laboratory should use the tighter criteria.

2.3   Corrective Action at the Management Level.

2.3.1 In the following situations, the analyst must bring the quality control problem to the attention of the QA Manager and/or the Laboratory Manager.

2.3.1.1 Quality control or instrument problems that last longer than 3 days.
2.3.1.2 Samples that go over the "holding time" (Samples that will not meet the established "turnaround time" must be reported to the lab manager or the Laboratory Manager).
2.3.1.3 Problems with sample(s) or instrumentation that causes the data to be unacceptable.

2.3.2 The QA Manager and Laboratory Manager will work with the analyst to develop a corrective action plan. This will be documented on the CAR (Corrective Action Report). The QA Manager will keep the Lab

QA Team updated on the quality control problems and the corrective action that has taken place.

2.3.3 When the corrective action has been completed and quality control issues resolved, the CAR is signed by the analyst and approved by appropriate manager. This report will become part of the permanent records in the QA office.

2.4 Corrective action initiated by the Management Team

2.4.1 Corrective action will be initiated for the following:
2.4.1.1 Customer complaint logs reveal a significant trend which may adversely affect quality.
2.4.1.2 A technical complaint is received from clients, auditors, or Regulatory representatives indicating problems associated with quality.

2.5 Corrective action initiated by the QA Manager

2.5.1 Unacceptable PT studies, study failed.
Two PT studies will be completed each year, at a minimum of 6 months apart. When an analyst fails a study, the QA Manager initiates the corrective action process when the final report is received. The analyst shall determine the cause of the failure and take the necessary corrective action. For the steps that are followed, see section **3.2, Formal Documentation.**

2.5.2 Unacceptable PT studies, two out of the three most recent studies failed.
If the analyst fails two out of the three most recent studies for his/her test method or analyte, performance is considered unacceptable and analysis is stopped. Certification will be removed from the analyst for that specific test method. The steps followed for corrective action are taken from the NELAC standard, Proficiency Testing.

2.5.1.1. The analyst will participate in two PT studies producing acceptable results. The studies are designated as the **corrective action** PT studies. The studies must be at a minimum, 15 days apart or the closing of one study to the opening of the next. The studies will not be analyzed concurrently. At this time, a work improvement plan will be developed and signed by the analyst and lab manager. The corrective action plan will be completed and become part of the work improvement plan.

2.5.1.2 When the PT provider issues reports for both studies, the analyst will become "recertified". The analyst must obtain acceptable results for both studies and must pass the next scheduled PT study. This will be either the official spring study or official fall study.

2.5.1.3 During this time, to prevent samples from outdating, the secondary or backup analyst will assume responsibility of the test method. He/she must be "certified". This can be accomplished by analyzing a PT blind sample producing acceptable results.

2.5.3 Other unacceptable quality control.

2.5.3.1 Failed external or on-site inspections completed by EPA or NELAC. The problem can be found with any of the following: entire analytical area, a specific method or analyte, or a analyst's technique.

2.5.3.2 Failed internal inspections, spot checks, or audits that reveal circumstances that may adversely affect quality. Procedures outlined in analytical SOP's, administrative SOP's and QA Plan must be followed. If not followed, it would be noted on an inspection report for that area/test method or analyte. Deadlines will be set for the corrective action to be completed.

2.5.3.2 Problems discovered during intra-laboratory blind sample audits that reveal circumstances that may aversely affect quality. Depending on the situation corrective action may be required to eliminate a problem. Deadlines will be set for any corrective action to be completed.

2.5.4 Unacceptable double blind studies.
Depending on the situation, double blinds can be treated as an unacceptable PT study.

3. Documentation

3.1 Routine documentation.

Routine corrective action (CA) is documented in the routine flow of daily activity. The CA is recorded on the maintenance logs, data review checklists, sample data packets, customer service logs or other relevant documents. Routine monitoring of control charts is required, also. Any data points falling outside acceptance limits indicate problems to the analyst. The corrective action taken by the analyst is documented. Corrective action taken due to problems occurring with control charts will be submitted as they occur.

3.2   Formal Documentation.

The progress of corrective action is documented through the Corrective Action Report. (CAR). The person starting the corrective action process should generate a new CAR form on the lab's shared drive. The CAR form template can be located on the I drive, in the #0 current year (example 2013) CAR TEMPLATE folder. The CAR template must be opened and saved as CAR # (always use the next available number for the year), what the CAR is For & the current Date. (Example #20 Metals WS-3PT 6-21-13). This starts a new CAR in the computer tracking system. The new CAR is filled out on the shared drive as the corrective action process proceeds through the investigation, problem solving and prevention stages. For example:

3.2.1   The QA Manager initiates the corrective action for the failure of a PT study. A deadline is given to identify the problem and develop a corrective action plan. This timeframe is 7 working days from the receipt of the report by the analyst.
The analyst and QA Manager both must sign the C.A. report.

3.2.2   The analyst implements the above corrective plan, including re-analysis of the missed PT sample and analysis of a new blind sample, known as a quick response sample. This sample is used to establish acceptable performance again immediately. The dead-line for corrective action is 25 days from the approval of the C.A.R.

3.2.3   The analyst will evaluate the effectiveness of the corrective action in preventing further events that may impact adversely on data quality. This will be discussed in the report.

3.2.4   The analyst will submit the report to the QA Manager and it will be signed and placed in the permanent QA files. The corrective action may be discussed with the remaining management team members and/or the QA team.

3.2.5   The QA Manager will maintain the corrective action reports in the QA office.

3.2.6   If the analyst has missed 2 out of the three most recent PT studies, a work improvement plan may be included with the C.A. report. The analyst and the Lab Manager will discuss and sign the Work Improvement Plan.

3.3   Finalization of CAR

All follow-up documentation is attached to the CAR once the CAR is completed and approved by management. The person performing the corrective action signs

Describe how the laboratory will monitor itself to ensure the effectiveness of newly implemented policies and practices.

Identify the individual(s) responsible for monitoring the effectiveness of implemented policies and practices.

Conclusion. (Discuss the effectiveness of the corrective action): ☐ **See attached**

C.A. completed by:_____**Date**_____

QA Manager Approval: _____**Date**_____

Corrective Action Closed by QA Manager: Signature_____**Date:**_____

Save Typed Reports by CAR # & <u>date</u> to I:\Corrective Action Reports (EXAMPLE #20 Metals WS-3 PT 6-21-12)