Lab Director Approval: Mark Tolbert / 08/19/2021

QA Manager Approval: Jeffrey Moore / 08/19/2021

Georgia EPD Laboratory Standard Operating Procedure (SOP): Data Integrity, Verification and Validation and Fraud Prevention

Access to this SOP shall be available within the laboratory for reference purposes; the official copy of this SOP resides on the official Georgia EPD website at https://epd.georgia.gov/about-us/epd-laboratory-operations. Printed copies of this SOP will contain a watermark indicating the copy is an uncontrolled copy.

1 Purpose:

1.1 To describe the Georgia Environmental Protection Division Laboratory's (EPD Lab) Data Integrity System.
1.2 To emphasize the importance of ethics in the performance of all analytical work.
1.3 To ensure that the laboratory staff consistently meets the ethical requirements outlined in this data integrity plan.
1.4 To describe processes and procedures intended for the protection of the integrity of laboratory data and which prevent even the appearance of improper data handling.

2 Scope and Application:

2.1 This procedure applies to all analyses performed by the EPD Lab.

3 Summary:

3.1 Valid data requires a defined knowledge of the data quality and integrity. Data may have less than perfect quality, but if the integrity of the data is intact, it can be usable for many purposes. If there is any doubt about the integrity of the data, then the usability of the data is in question.
3.2 To ensure confidence in the integrity of the data, even the appearance of improper activity must be avoided.

4 Definitions:

4.1 Laboratory Fraud[1]**:** The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.
4.2 Data Verification[2]**:** The process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements.
4.3 Data Validation[2]**:** An analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set.

[1] See 11.1
[2] See 11.2

4.4 Data Integrity: The ability to define and defend the entire analytical process by documenting and adhering to Quality System requirements.

4.5 Real-Time Data: Data that is collected and recorded as it is created. Real-time data is not limited to data automatically collected during instrumental analyses. Preparation or extraction of samples, testing chemical and physical characteristics (pH, color, alkalinity, etc.) and spike witnessing all produce real-time data.

5 Personnel Responsibility:

5.1 The Laboratory Director, and Quality Assurance Manager provide initial data integrity training and on-going annual training to Laboratory Managers and staff.

5.2 Laboratory Managers provide on-going data quality and integrity training throughout the year. Laboratory Managers ensure each staff member agrees to and signs the ethics agreement[3] and that only staff members who sign the ethics agreement can work in the laboratory.

5.3 All staff members involved in the generation, collection, reduction, review, and validation of laboratory data are responsible for maintaining the integrity of data while within the scope of their duties.

6 Training:

6.1 Ethics and data integrity training are part of new employee orientation and is provided within three months of initial employment. It is the responsibility of each Laboratory Manager to ensure that no new employee who has not received this initial training and signed an ethics agreement is allowed to work without close supervision. Until these requirements have been met, the employee status is the same as if they have not passed in Initial Demonstration of Capability[4].

6.2 Throughout the year, Laboratory Managers will include data integrity training during staff meeting training sessions by reinforcing the principles and procedures set forth in this document.

7 Data Integrity:

7.1 Corruption of data, whether intentional (fraudulent) or unintended impacts the usefulness of data. Any appearance of impropriety impacts the value of the data. Any activity that could be interpreted as inappropriate must be avoided. Data corrections and how laboratory notebooks are handled are two critical activities that must be performed correctly to avoid the appearance of impropriety.

7.2 Corrective action, manual integration, documentation of procedures, and many other topics are all related to data integrity. Other topics, such as corrective action and manual integration are covered in other EPD Lab SOPs.

7.3 Laboratory Logbooks:

7.3.1 The EPD Laboratory uses 3-ring binders for logbooks for most documentation in lieu of pre-printed, pre-bound and paginated notebooks that are typically required for laboratory documentation. The EPD Lab can use 3-ring binders by the EPA because the laboratory has agreed to treat these binders very much as if they were pre-printed, pre-bound and paginated volumes with minimal and specific exceptions.

7.3.2 Pages that are placed in the binders must be immediately paginated. Depending on the orientation of the binder (new pages are either added to the front/top of the binder or to the bottom/rear) each new page is added before/following any previous pages. New pages may never be inserted in between existing pages.

7.3.2.1 One exception to the above is adding attachments to an existing page, especially in the case of corrective actions. The primary page is marked with the word “See Attachments”. The

[3] See Attachment A

[4] SOP 6-001 – Georgia EPD Laboratory Standard Operating Procedure (SOP): Initial Demonstration of Proficiency – online revision

attachments must show the primary page number, the number of sheets attached and the number of that specific attachment page. Attachments should be stapled to the primary page.

7.3.2.2 Example: A corrective action, number 6-040310-009, requires an attachment consisting of 4 pages to fulfill documenting the problem and resolution. The corrective action page will include the words "See Attachments" (initialed and dated if added after the corrective action was added to the logbook). Every attachment page will have "6-040310-009" and "page x of 4" where x is a number from 1 to 4 indicating the specific number of each page of the attachment.

7.3.3 Once a document is placed in a 3-ring binder, it may not be removed for any purpose except for making photocopies and archiving as outlined below. *Removal and destruction of a document that has been previously inserted into a 3-ring binder could be considered an act of fraud by the EPA.* Such actions may be done with the best of intentions, but they give rise to suspicions that data may have been changed to affect a more favorable outcome.

7.3.4 Blank forms for sample extraction/preparation, data collection, and other activities are to be inserted into appropriate 3-ring binders and immediately paginated prior to the initiation of sample extraction/preparation, data collection, etc. Static data, such as Sample IDs, standard or lot numbers, standard volume of spikes, etc., may be entered prior to insertion and pagination. Once inserted into the binders these forms become a permanent part of the binder, until the pages are archived.

7.3.5 Real-time data entry must only occur after the form has been inserted into the binder.

7.3.6 The only exception to the above is when a situation exists where more than one person or persons need to enter data at the same time into extraction/preparation forms. For example, if two groups are extracting HAAs at the same time, one group will take possession of the binder and follow the rules above. The second group may fill out an extraction form outside the binder for so long as the first group requires access to the binder. The second group must insert and paginate their form at the earliest possible opportunity. Please note that once real-time data has been entered on any form, that form becomes part of the permanent record, whether it is in a logbook or not.

7.3.7 If a staff member requires a copy of a page or pages in a 3-ring binder log, they must physically take the binder to the copier, remove the page(s) to be copied, make the copies and immediately return the pages to the binder. If multiple pages are to be copied, only one group of *continuously numbered* pages may be removed at any one time.

7.3.8 Pages that have been inserted into 3-ring binders may not be removed if there is a reason to generate a replacement form or the information on the form becomes invalid, but they may be voided if the situation warrants.

7.3.9 To void a log page, draw a diagonal line from one upper corner of the page to the opposite lower corner. Write the word "Void" in large, conspicuous characters parallel to the diagonal line and initial and date the correction.

7.3.10 NOTE: When voiding a log page, the page number is not voided. Any replacement pages must be added as new pages and paginated with the most current page number. For example, pages 156, 157 and158 are the most recent pages in a logbook. A situation exists such that page 156 should be voided and a new page inserted to replace it. Page 156 is voided as described above and the replacement page is inserted *at page position 159* and is so numbered.

7.3.11 Upon completion of a binder page, the primary user initials and dates the page. This indicates that the form has been completed and to verify that the data has been reviewed for completeness and correctness. Any information that is updated, corrected *or added* after that time should be initialed and dated at the time of entry.

7.3.12 Occasionally, pages in binders must be archived to make room for new pages. While not bound in a notebook, archived pages are to be treated as if they were in a bound volume except as noted above for making photocopies. Typically, archived pages will be bound by a rubber band and/or

placed in a folder in a file cabinet. All the pages bound by the rubber band or folder are considered one volume and are to be treated as a single bound volume.

7.3.13 Exceptions to the above are limited to instrument sequence logs. Sequences for instruments are often edited one or more times while the sequence is being processed. Because of this, only the most recent version of a log is required to be kept in sequence logbooks. This copy must accurately reflect the samples, QC, and calibrations that have been processed up to the current sample being processed at the time of printing. Upon completion of a sequence, the sequence in the logbook must accurately reflect every sample etc. that ran in that sequence.

7.3.13.1 Current copies of sequence logs must be initialed and dated by the analyst most recently preparing or modifying the sequence. If the sequence has been modified after initiation, the date of the modification and printing should be noted as well.

7.3.13.2 Sequences are given logbook numbers by sequence, not by page. Unless unique identifiers appear on each page, the logbook number must be on every page.

7.3.13.3 Each page of the sequence must be manually numbered from 1 (or A) to the end, if not numbered by the software.

7.4 Corrections to data:

7.4.1 Wherever there is handwritten data and often even printed information, there will be a need for corrections. The following sections discuss proper and improper corrections.

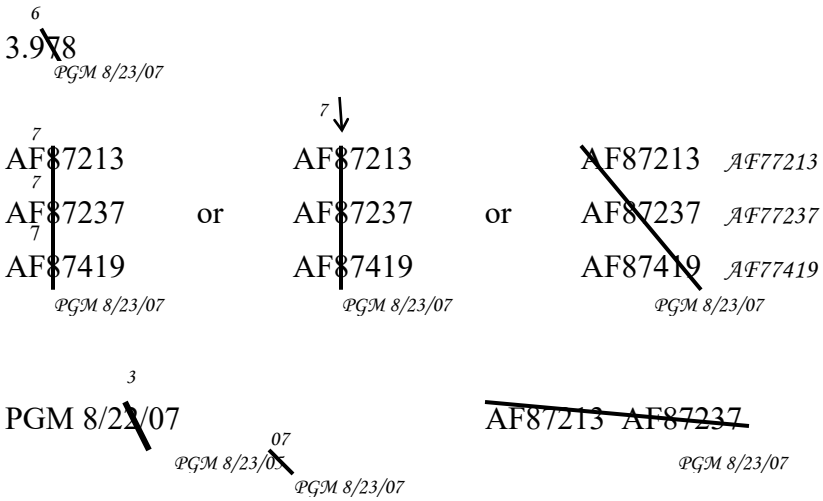
7.4.2 At a minimum, improper data corrections can raise questions as to the validity of data. At worst, improper corrections can result in lost court cases. Improper corrections that obscure the original data may even be considered an act of fraud where it appears that an analyst was attempting to hide information or mislead end users of the data.

7.4.3 Draw a single line through the data to be corrected. Write the correct value or text near that point to make it obvious the connection between the correction and the data being corrected. Initial and date the correction. Repeat for each correction made. This includes corrections to initials and dates. There must be one and only one correction and one set of initials and dates for each line drawn.

7.4.4 If a single straight line can be used to line through several mistakes (for example, several words in a row, or a column of data in which the same character is wrong in each row) a single line and one initial and date is acceptable.

7.4.5 **Never** use correction fluid (White-out), correction tape or anything else to hide the original data. Do not “black out” the original data. Do not write the correction on top of the original data (one of the most common errors when making corrections). In other words, make the corrections in such a way that would allow a reviewer to see what was changed.

7.4.6 The following are examples of **proper** corrections (note: script font and correction lines represent handwritten items):



7.4.7 The following are some examples of **improper** corrections:

7.4.8 Drawing a line through an empty field to indicate that it was not used (i.e. “nulling the field”) is not the same as a correction. A single line in the field or writing “NA” in the field is acceptable and does not require initials and dates. If nulling a block of unused fields, a single line preferably from top left down to the bottom right is used. If there is pre-printed text in some of the fields, it is acceptable for these fields to be included in the block if none of the fields in the block contain written information. Initials and dates are not required but are preferred for this action. Do not “X” out a block of unused fields.

Correct:

LCS2	*PGM 8/23/07*		
LCSD2			

$MeCl_2$ *JTB C49466* Acetone ——— Na_2SO_4 *NA*

Incorrect:

LCS2	*PGM 8/23/07*		
LCSD2			

$MeCl_2$ Acetone Na_2SO_4

Ok, but prefer like Acetone in the "Correct" examples.

8 Data Verification and Validation:

8.1 Data verification and validation are parallel processes and are considered one and the same for the purposes of this discussion.

8.2 Self-validation of data is the lowest level of data validation and should be performed by each staff member anytime he/she generates, records or transcribes data.

8.3 Self-validation is the act of reviewing one's own work to assure that no mistakes have been made in recording analytical data or in the process of transcription of data.

8.4 For each activity for which an analyst records or transcribes data, he/she should develop a routine of double-checking each entry for errors. Time should be taken to make sure that experimental data is correct and accurate. Upon entering one or more items into a spreadsheet, table or LIMS data field, the analyst should take a few moments to compare the entry(s) to the source, looking for transcription errors.

8.5 Analysts should develop personal procedures that assure that correct samples are spiked and that correct standards are used. An example would be to line up samples to be processed, setting samples to be spiked a little further back or forward than the rest. Upon processing each sample, that sample is moved behind the unprocessed samples.

8.6 Each form, instrument report, checklist, etc. produced by an analyst must be initialed and dated by that analyst to certify that the analyst has reviewed the data for accuracy and is taking responsibility for that data.

8.6.1 For computer printouts for which each page is uniquely identified and paginated, the analyst need only initial and date the one page of the printout, usually the first page. It is preferred, however that each page be initialed and dated.

8.7 Each individual laboratory of the EPD Lab should develop SOPs for the review and validation of data within that laboratory. These SOPs should be up to date, reviewed annually and provide sufficient guidelines to ensure thorough review and validation of data.

8.8 Validation procedures include checklist, peer review, supervisor review and laboratory manager review of data packets. Other validation procedures may include, but are not limited to, quarterly internal audits by the supervisors and manager of that lab.

8.9 Each level of validation beyond self-validation should be performed and documented. Such documentation may include checklists and should be outlined in data validation SOPs specific to that lab and, if appropriate, to an analysis.

8.10 Data that has not received complete validation, including LIMS validation of test and samples, is ***never*** to be reported to clients by verbal, physical (printed reports) or electronic (email) means without prior approval of both the Laboratory Director and the QA Manager.

9 Recording Real-time Data:

9.1 Real-time data is data that is generated and/or collected as it occurs. When an analyst measures the pH of a group of samples, he/she does not measure the pH of all the samples then record it all at once. Rather, he/she records the value for each sample as it is tested. This is real-time data collection.

9.2 Many forms of real-time data that are often incorrectly recorded all at once and after the fact instead of as it is generated.

9.2.1 The addition of spikes to samples should be recorded as each individual sample is spiked. The analyst should look at sample and standard labels and confirm that he/she is about to spike the correct sample with the appropriate spiking solution. Similarly, bringing samples to final volume, filtering, and other such information should be recorded as it is performed on each individual sample.

9.2.2 Checklists are intended to prompt the user to perform certain tasks and to certify to reviews that the tasks have been performed. Checklists items are live data and should be checked off as each action is performed. Alternately, upon completion of a project, each item is double checked and marked completed as they are checked. Completing a project then simply filling out a required checklist without confirming that each action item has been completed is not acceptable practice. By initialing and dating the checklist, the analyst is verifying that all action items on the list have been completed and verified by the analyst.

9.2.3 Spike witnessing is real-time data collection. The witness should verify that the standard and lot numbers listed on the sample extraction/preparation sheet match the standards that have been presented to the witness by the analyst and that the appropriate delivery device is being used. The analyst is to verbally and clearly declare the sample that is to be spiked and which spiking solution is to be used. The witness confirms, observes and upon completion of the spiking of that sample, records such on the form.

9.2.3.1 It is the responsibility of the spiking analyst to choose the correct spiking solutions and indicate the correct amount to be used.

9.2.3.2 It is the responsibility of the spike witness to verify that the spiking solution(s) indicated and amounts on the form is the actual solution and amount used.

9.2.3.3 It is *not* the spike witness's responsibility to determine if the appropriate spiking solutions were selected for use by the analyst, only that the solutions indicated were the ones actually used.

10 Criteria:

10.1 This document is based on the information found in references 11.1, 11.2 and 11.3.

11 References:

11.1 Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water – US EPA - EPA 815-F-08-006 - June 2008

11.2 Guidance on Environmental Data Verification and Data Validation – US EPA – EPA QA/G-8 – November 2002

11.3 Best Practices for the Detection and Deterrence of Laboratory Fraud – California Military Environmental Coordination Committee – March 1997 version 1.0

11.4 Georgia EPD Laboratory Quality Assurance Plan – online revision.

12 Attachments:

Attachment A:

Data Integrity and EPD Laboratory Ethics Policy
2021 Annual Renewal Training

_____
EPD Staff Member (print) Date

_____
Laboratory Operation

The Management of the EPD Laboratory is committed to keeping the staff informed of the need to conduct all Laboratory related business with the highest ethical standards. As part of the program, we are required to conduct an annual review of our policy.

Examples of improper or unethical Laboratory practices are, but not limited to:

1. Intentional misrepresentation of analytical results by presenting calibration or Quality Control data as though acceptance criteria was met, when approved and documented acceptance criteria was not met.
2. Modification of a measurement system clock or intentionally recording an incorrect time to make it appear as though a time sensitive application was conducted within the method requirement.
3. Application of acceptable batch Quality Control results in place of failed batch Quality Control results from another batch. Either by entering incorrect data in the computer or substitution of actual Quality Control samples in the measurement system auto sampler.
4. Intentional and improper modification of chromatographic peaks (peak shaving or addition by manual integration) to meet calibration or method required Quality Control criteria.
5. Failure to initiate Corrective Action and notify supervisor of failed measurement system or Quality Control criteria. Full explanation of failure required.
6. Intentionally modifying the analytical process required by an EPD Laboratory SOP when processing samples without the expressed written permission of the Laboratory Quality Assurance Manager and Laboratory Manager.
7. Utilization of any non-controlled SOP documentation for sample processing such as shortcut summary pages or method review sheets. Only approved and controlled documentation is utilized for sample processing.
8. Misrepresentation of yourself as another analyst, as in signing or stamping another analyst's initials, on bench sheets or other sample processing and Laboratory documentation.
9. Intentionally misrepresenting measurement system maintenance records to make it appear as though a system is meeting method required Quality Control acceptance criteria during sample analysis. Failure to properly "red tag" an inoperative measurement system.
10. Reporting analytical results when the sample has not been actually analyzed (dry- labbing).
11. Failing to document sample preparation on batch digestion or extraction logs, including the documentation of all information required on the log page. Or the intentional misrepresentation of any information required by the log.

Data Integrity

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Georgia EPD Laboratory
Ethics Policy

- The EPD Laboratory and staff are committed to the highest ethical standards in all aspects of our Laboratory mission and assigned duties. The EPD Laboratory will provide the highest quality analytical services to our Customers.
- Analytical data will be accurate, precise, traceable, and legally defensible by current established standards. Each staff member is committed to the requirements of the Laboratory Quality System and the generation of analytical data in an environment of complete honesty and integrity.
- All analytical procedures are clearly and completely documented in an unambiguous manner. By documenting all procedures, each staff member is able to demonstrate their compliance with Quality System requirements.
- EPD Laboratory staff is required to immediately notify the Laboratory Director and Quality Assurance Manager if they become aware of unethical activity in the Laboratory.

I have attended the initial data integrity presentation or annual renewal presentation of the EPD Laboratory's Data Integrity and Ethics Policy. I understand and agree to the requirements of the Policy.

_____
Staff Members Signature