

QAM-Q-105

Corrective Actions

Revision 16


Approval:



Laboratory Manager

3-13-24

Date



Concurrence

3/13/2024

Date

Effective Date

3-15-24

Renewal Date: _____ Initials: _____

Texas Institute for Applied Environmental Research

1.0 Applicability

This procedure applies to all analyses, samples, data collection, data management, standard operating procedures and activities that affect laboratory data quality at the Texas Institute for Applied Environmental Research (TIAER), Tarleton State University, Stephenville, Texas.

2.0 Purpose

The purpose of this procedure is to provide a method for the identification, documentation, tracking, and resolution of problems associated with quality-related data collection and reporting. Corrective actions are a proactive part of the quality control/quality assurance program of dynamic organizations that strive to improve by learning from and correcting mistakes and problems.

3.0 Definitions

- 3.1 Corrective action report (CAR): a document that gives specifics of situations in which all quality control (QC) requirements were not met, all approved procedures were not followed, deficiencies were found during internal or external audits, or some other deviation from normal data collection, production, or management protocols occurred. CARs are electronically generated using a TIAER-designed database module that can be linked to TIAER's laboratory information management system database, but may be handwritten on a printed form in unusual circumstances.
- 3.2 Nonconformance: an item, reagent, instrument or piece of equipment that does not meet specifications originally used to declare it as acceptable for quality data generation or management.
- 3.3 Out-of-control situation: an occurrence of failure of quality control measures used to validate data generation. Examples are duplicate precision, spike and standard recoveries, or instrument variances that are out of established acceptance limits
- 3.4 Tier reporting level: one of three levels of CAR designation indicating the varying degrees of potential effect on data quality.

4.0 Equipment, Reagents and Standards

Not Applicable

5.0 Procedure

5.1 Overview of CAR initiation and routing:

5.1.1 All personnel who deal with samples and sample data are responsible for promptly initiating a CAR when a nonconformance, out-of-control situation, or other situation affecting final data integrity is discovered. CARs may also be written to document problems that do not ultimately affect final data integrity. If personnel are not trained in starting the CAR, they should contact their immediate supervisor for assistance.

5.1.2 The CAR is then routed to the Laboratory Manager.

5.1.3 The Laboratory Manager will route the CAR to the pertinent TIAER Project/Technical Manager(s) for situations possibly affecting data integrity. More immediate modes of communication are also used, as necessary.

5.2 Tier Designation. The problem described by the CAR is designated as Tier 1, 2, or 3. The Laboratory Manager makes initial determination for tier based on the following:

5.2.1 A Tier 3 designation indicates that the final data integrity may be affected.

5.2.2 A Tier 2 designation indicates that the quality of the sample is acceptable, but the data may need to be qualified, as appropriate, when being submitted or used.

5.2.3 Tier 1 CARs document situations that are resolvable and do not ultimately affect final data integrity.

5.2.4 Project managers may determine the tier needs to be changed if project requirements require it.

5.3 Tracking CARs. The Laboratory Manager is responsible for tracking Corrective Action Reports related to the laboratory. Project managers or the Project QAO may maintain paper copies of completed CARs, if needed, including attachments, and make electronic backups.

5.4 Implementing Corrective Actions. The Laboratory Manager is responsible for implementing Corrective Actions in the laboratory and may assign duties to other personnel as required.

5.4.1 QC samples not meeting criteria

5.4.1.1 If sufficient sample volume and holding time remain, another analysis may be completed, where appropriate. A second analysis may be routinely performed when duplicates, spikes, standards, or blanks do not meet criteria.

5.4.1.2 If the second analysis does not meet criteria, other corrective actions are taken. These include equipment adjustment or maintenance, review of analytical procedures, examination of reagents, check of cleanliness of labware, and other appropriate actions. A third analysis may be undertaken after corrective measures have been taken.

5.4.2 Missing Samples

5.4.2.1 If a sample is spilled or otherwise lost, efforts should be made to complete as many of the requested analyses as possible with the remaining amount of sample. The decision on priority of analytes rests with the project manager in consultation with the Laboratory Manager.

5.4.2.2 If sufficient analyses cannot be completed for a sample, resampling should be done, where possible and/or practical, if the client or project manager requests such.

5.4.3 Missing Data. When data required for sample analysis are missing, reasonable efforts should be made to obtain as much data as possible.

5.4.4 When other types of situations occur that may affect final data integrity, the appropriate client project manager should make the decision with respect to corrective actions.

5.5 Based on recommendations from the Laboratory Manager, client project manager may decide whether to use and/or submit data containing nonconformances.

5.6 Completing Initial Section of a CAR

5.6.1 Open the CAR module and click on File, then Create New CAR. A list of general CAR categories (below) pops up from which to choose the specific deviation. Select the general category, then, where applicable, the more specific type, and finally the specific deviation. New deviations may be added judiciously after

checking to see if the deviation exists with alternate wording or in another category. Attachments 3 and 4 list common procedures, QC types, and problems for which laboratory CARs are written.

5.6.1.1 Analytical CARs (QC analysis and environmental sample analysis)

5.6.1.2 Sample Collection CARs (non-laboratory)

5.6.1.3 Sample Login CARs (sample handling, sample receipt, documentation on COCs, or compositing documents)

5.6.1.4 Compositing CARs (inclusion of all samples in the composite, availability of flow data, documentation for running the compositing program, correct running of the compositing program)

5.6.1.5 General CARs (QAPPs, SOPs, forms, database, computer programs or systems, audit findings, other issues)

5.6.2 Affected Samples. After the specific deviation is chosen, check boxes to indicate whether samples are affected and whether the sample numbers are known may be displayed. Be sure the correct boxes are checked.

5.6.2.1 If sample numbers are known, numerous samples can be written on the same CAR. Enter the sample numbers in numerical order. Commas and dashes can be used. Spaces are optional and are ignored by the program.

5.6.2.2 Be sure to exclude samples in the sample number sequence that were not affected.

5.6.2.3 For QC samples that do not meet criteria, all samples in the pertinent batch are identified on the CAR, with the following exceptions.

5.6.2.3.1 Calibration standards at the limit of quantitation (LOQ) are run once daily at the beginning of an analytical run batch, prior to sample analysis. LOQ calibration standards that do not meet criteria are rerun with a batch. If the LOQ standard passes upon rerun, sample numbers do not need to be included with the CAR.

However, if samples are analyzed without a passing LOQ calibration standard, for whatever reason, the associated samples in the analytical run are identified on the CAR.

5.6.2.3.2 If field duplicates do not meet criterion, only the sample duplicated in the field is affected, not the entire batch.

5.6.2.3.3 If matrix spikes exceed criterion, only the spiked sample is affected, not the entire batch, as long as the LCS is acceptable.

5.6.2.4 For equipment malfunction or failure, identify all affected samples.

5.6.2.4.1 When temperatures fall outside specified ranges in ovens, refrigerators, etc., all samples in the malfunctioning unit are identified on the CAR. Additionally, all samples that had used the unit since the last acceptable temperature documentation are also identified in the CAR.

5.6.2.4.2 If no samples are in the malfunctioning equipment, the CAR states specifically that no samples were in the equipment when the malfunction was identified.

5.6.3 Analyte. CARs can be written for one or more analytes or all analytes. New analytes may be added, as needed.

5.6.3.1 If specific samples are affected, the sample numbers must be entered before the analyte(s) can be selected.

5.6.3.2 Click the Select Analytes button to bring up a list of analytes. Only analytes that are analyzed for all listed samples are included on the list.

5.6.3.3 If the deviation affects the entire sample(s), there is an option to select All for the analyte. Examples include login documentation, compositing, and sample retrieval.

5.6.3.4 For situations that involve equipment (maintenance, malfunction, temperature), include the specific analytes that would be affected by the equipment problem.

- 5.6.3.5 For situations that do not involve analytes, such as those listed in Attachment 2, analyte does not need to be selected.

5.6.4 Deviation details

- 5.6.4.1 Avoid including causes and corrective actions when describing the problem.
- 5.6.4.2 Specify the date, time, or procedure during which the problem was identified, if other than during sample analysis. Examples: during log-in, while running the compositing program, monthly calibration check.
- 5.6.4.3 If the CAR is written for a temperature excursion, equipment malfunction, or similar situation, include the time at which the excursion is discovered and the most recent (previous) time for which an acceptable measurement was made. When the situation has been brought under control, the time should be added to the CAR. This is useful in determining the length of time of the excursion. For temperature excursions, document the unacceptable temperature in the CAR.
- 5.6.4.4 Specify which bottles or aliquots are affected, where pertinent.
- 5.6.4.5 For QC excursions, provide QC ID, sample ID (where pertinent), analytical values, calculated QC results, and criteria. Additional details are important in evaluating the acceptability of the QC or batch.
 - 5.6.4.5.1 If a laboratory duplicate fails, indicate whether the LCSD for the batch passed.
 - 5.6.4.5.2 Indicate whether or not any other QC samples in the batch did not meet criteria.
- 5.6.4.6 A separate CAR is completed for each failing batch if the QC values are different. Example 1: Several batches are in an oven with a temperature exceedance. Only one CAR needs to be written for the excursion. Example 2: Two NH₃ method blanks fail. They have different IDs and represent different batches. Two CARs are written.

- 5.6.5 Possible Causes. The analyst should make an effort to determine the root cause of the deviation. If a root cause cannot be determined provide any information that could assist in determining the cause of the excursion. There may be times when the cause is unknown, routine, or unavoidable, but an effort should be made to identify a root cause.
- 5.6.5.1 Determining Root Cause requires the analyst to think about why the deviation occurred. The excursion may be a symptom of a deeper problem. Ineffective cause analysis will only address the symptoms of a deeper root cause.
 - 5.6.5.2 One practice that may be used to dig deeper into the root cause is the Five Whys. Ask “Why” five times to avoid simply identifying a symptom and not a cause. Note: You may get to a root cause before asking “Why?” five times.
 - 5.6.5.3 It may help to assign the cause of the deviation to one of the following categories: Product, Process, People or Performance.
 - 5.6.5.4 Note: This is a possible cause. The assigned cause may not be correct. Corrective actions taken and monitoring of those actions will determine if further corrective action is needed.
- 5.6.6 Corrective Actions Taken. Include only those actions that have already been completed. Notification of the supervisor may be considered a type of corrective action. If no corrective action has occurred, write “None”. For situations other than immediate reanalysis of samples, include the date and/or time the corrective actions were taken.
- 5.6.7 Corrective Actions Suggested. If the person who initiates the CAR has a suggestion for corrective action that should be taken, enter it in this section. An entry in this section is not required.
- 5.6.8 Project name(s) are automatically input by the CAR module, based on sample number. If the CAR is initiated prior to completion of the sample data entry in the database, the project name might not be added to the CAR. The Database Manager may add it at a later date.

- 5.6.9 Project/Technical Manager name(s) are automatically added for Tier 3 CARs so that the appropriate Project/Technical Manager(s) may be included in the routing.
- 5.6.10 Attached documentation. For some CARs, attachments can help evaluate the effect on data quality, provide a broader understanding of the problem, describe or document corrective/preventive actions, and the like. In addition, attach copies of memos, emails, data sheets, logbook printouts, and other documents to accommodate lengthy explanations that will not fit on the CAR form. Scans or electronic files can be attached to an electronic CAR. This may include emails pasted into the Notes section.
- 5.6.10.1 The electronic CAR form has a section for indicating attachments. Check the pertinent box(es) on the electronic CAR. Select “Attachments” and then “Add.” Browse to select the file to be added.
- 5.6.10.2 Types of tier 2 and 3 CARs for which documentation is required are listed below.
- 5.6.10.2.1 CARs written for COC documentation excursions should have a COC copy attached to the CAR, plus pertinent data sheets.
- 5.6.10.2.2 CARs for login temperature excursions have a copy of the COC and Flow Link printout, on which the time of sample retrieval is written.
- 5.6.10.2.3 CARs for other login problems have a copy of the COC and any other pertinent document attached.
- 5.6.10.2.4 Inclusion of information on the electronic CAR that may be useful in evaluating data is recommended, even if the information is also on an attachment.

5.6.11 Routing the CAR

5.6.11.1 When the Create CAR Screen has been completed, click “Save and Close” or “Save and New”. A CAR ID number is automatically assigned to the CAR and will be displayed on the screen. The CAR will automatically be routed to the queue of the Laboratory Manager. Record the CAR ID number on any log or document where it applies.

5.6.11.2 The Laboratory Manager will route the reviewed CAR to the appropriate Project Manager.

5.7 Completing Laboratory Manager Section of the CAR

5.7.1 Tier. The Laboratory Manager selects the appropriate tier. If there is any question, the higher tier is selected.

5.7.2 The Laboratory Manager addresses Tier 3 CARs within 1 week of notice. Tier 1 CARs are addressed within 1 month. All CARs are completed as efficiently and effectively as possible.

5.7.3 Deviation Details. The Laboratory Manager reviews the deviation details in the initial section of the CAR and adds any information that may assist in understanding the details and/or scope of the problem and in evaluating associated data for acceptability. It is recommended that additions to another person’s comments include the Laboratory Manager’s initials and that the first person’s comments not be deleted, except in atypical circumstances.

5.7.4 Possible Causes. The Laboratory Manager reviews the section on Possible Causes in the initial section of the CAR and lists any additional potential causes of the excursion. Relevant possible causes that have been ruled out are listed in this section. If necessary, the Notes section of the CAR can be used to provide additional information on possible causes.

5.7.5 Corrective Actions Taken for Specific Incident. Document any corrective actions that have already been taken to assure the quality or evaluation of the sample(s) or quality system component. If the person who initiated the CAR has already documented all corrective action taken, write “See above” in the supervisor’s section on corrective action.

5.7.6 Correction Actions Taken to Prevent Recurrences. Document any actions taken to ensure similar excursions do not happen again.

- 5.7.6.1 Be specific in distinguishing between corrective actions that have been taken as opposed to actions that will be taken.
- 5.7.6.2 If the situation for which the CAR was written is a result, fully or in part, from an action or lack of action by a person, include documentation that the responsible person has been informed of the cause and effect associated with the situation and has been given proper information to prevent recurrences.
- 5.7.6.3 If the problem is caused by a situation that cannot be avoided in the future, such as a matrix spike failure, write "Unavoidable situation" (or similar explanation) as the corrective action.
- 5.7.6.4 If recommended actions or other information written by the person who initiated the CAR are not appropriate, the supervisor may revise or add to the initial part of the CAR. The Edits icon on the toolbar of electronic CARs may be clicked to view any changes made to the CAR, the person making the revision, and the date of revision.

5.7.7 Monitoring for Effectiveness

- 5.7.7.1 This section is used to document follow-up measures to corrective actions that are necessary in some cases, but have not been completed as part of remediation for the specific incident or to prevent recurrences.
 - 5.7.7.1.1 Completed actions are not included in this section, but suggestions on compliance may be. If a corrective action proves to not be effective, new steps are taken by management to correct the issue or noncompliance.
 - 5.7.7.1.2 Word the monitoring action so that it can be completed. For example, "LQAO will check the log at monthly intervals for a year to ensure

compliance with the corrective action and document in the comments section with initials and date.”

5.7.7.2 The Laboratory Manager documents the required actions in the Monitoring for Effectiveness section, may designate the staff member responsible for completion, provide a proposed completion date, and describe how the monitoring will be documented.

5.7.7.2.1 The staff member designated as being responsible for completing the action is responsible for documenting the completion and outcome of the monitoring.

5.7.7.2.2 CARs remain “open” until all corrective action has been documented as being complete.

5.7.7.2.3 The LM or LQAO reviews the CAR module at least monthly and, if necessary, alerts people to whom corrective action has been assigned to make them aware of the assignment and their need to complete the task in a timely manner.

5.7.8 Effect on data quality

5.7.8.1 The information in this section is used to qualify data, so be as specific as possible.

5.7.8.2 For most Tier 1 CARs, the effect on data should be none. Additional information, such as “Rerun and passed” or “Corrected before compositing”, should be added for additional clarity.

5.7.8.3 Be specific in documenting that data are missing, deleted, or used as estimates only.

5.7.8.4 A list of common effects on data quality is included as Attachment 5.

5.7.8.5 The effect on data supplied by the Laboratory Manager may be revised by the project manager following review of the CAR based on project objectives. Laboratory Manager signature on CARs, thus, does not necessarily reflect the final decision regarding the effect on and use of

data. Any changes to the effect on data are documented in the Edits section of CARs. If needed, the Laboratory Manager will be sent a list of CARs associated with some client quarterly data submissions to review any changes regarding effect on data.

5.8 (TIAER) Project Manager Approval

5.8.1 For tier 3 CARs, Project/Technical Manager (PM) approval is required. The Laboratory Manager may be the Project Manager for certain laboratory projects.

5.8.2 If the tier 3 CAR includes samples from more than one project, the CAR will be automatically routed to all pertinent PMs. Because different projects have different requirements, the effect on data quality may differ according to project on the same CAR.

5.8.3 The PM reviews the deviation details and adds any information to document the details and/or scope of the problem and assist in evaluating associated data for acceptability.

5.8.4 The PM reviews the section on Possible Causes. If potential causes are known but are not listed, the PM lists them. If relevant potential causes have been ruled out but are not listed, the PM lists them. If needed, the Notes section of the CAR can be used to provide additional information on possible causes.

5.8.5 The PM may request the addition of Corrective Action to be Taken, changes in the Effect on Data Quality, and other items on the CAR. The PM may add Notes to the CAR.

5.9 Quality Assurance Officer Approval

5.9.1 The Laboratory Quality Assurance Officer (LQAO) must sign all laboratory CARs before they are considered complete and official. Completed CARs in the electronic database are considered the official version and have security measures against subsequent changes by users.

5.9.2 The LQAO may add Corrective Action to be Taken, change the Effect on Data Quality, add information concerning Possible Causes, and add additional information at any location on the CAR.

- 5.9.3 The LQAO reviews the deviation details and adds any information to document the details and/or scope of the problem and assist in evaluating associated data for acceptability.
- 5.9.4 The LQAO reviews the section on Possible Causes. If potential causes are known but are not listed, the LQAO lists them. If any relevant potential causes have been ruled out but are not listed, the LQAO lists them. If needed, the Notes section of the CAR can be used to provide additional information on possible causes.
- 5.9.5 For Tier 3 CARs, the LQAO will perform another review after a reasonable amount of time for the corrective action to be implemented. This Monitoring of Effectiveness will be signed by another staff member for concurrence and dated. Should the actions not be proven to be effective, the CAR will be reopened and corrective action will begin again until the problem is solved.

6.0 Quality Control and Safety Aspects

- 6.1 Corrective actions are performed in accordance with this procedure and under the guidelines established in QAM-Q-101, "Laboratory Quality Control", QAM-W-101, "Disposal of Laboratory Waste", and QAM-S-101, "Laboratory Safety".
- 6.2 Project-specific requirements may dictate the types of situations that require the completion of a CAR.
- 6.3 If problems occur while working with electronic CARs that cannot be resolved at the individual level, contact the Database Manager or the Data Supervisor.

7.0 References

- 7.1 Standard Methods for the Examination of Water and Wastewater, Latest or Online Edition (EPA approved), ed. by Arnold E. Greenberg, et al., APHA, AWWA, Washington, D.C.
- 7.2 TNI Standards, 2016

8.0 Attachments

- 8.1 Example of Corrective Action Report, Q-105-1
- 8.2 Example of CARs for which analyte selection is not necessary
- 8.3 Example of QC Types and Procedures for which CARs are written

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- 8.4 Example of Common Problems, Nonconformances, and Out-of-Control Situations for which CARs are written
- 8.5 Examples of Effects on Data Quality Documented by Tier 2 and 3 CARs

Attachment : Example of Corrective Action Report

Corrective Action Report

SOP-Q-105

CAR #: _____

Report Initiation Date: _____ Reported by: _____ Sampling Station: _____

Analyte: _____ Procedure or QC Type : _____

State the nature of the problem, nonconformance or out-of-control situation:

Affected sample #s / date(s) of sample collection ¹:

Project(s) : _____ Attached documentation: COC FDS SampLink Flow8 Logbook QC Table

Possible Causes:

Corrective Actions Taken:

Suggested Corrected Actions:

CAR routed to: _____ Date: _____

Supervisor: Circle one: **Tier 1** (does not affect final data integrity) **Tier 2** (data accepted but flag required²) **Tier 3** (possibly affects final data integrity)

Corrective actions taken for specific incident: _____

Corrective actions taken to prevent recurrences: _____

Corrective actions to be taken: _____

Responsible Party³ _____ Proposed completion date _____

Effect on data quality: _____

Responsible Supervisor: _____ Date: _____

Concurrence: Program/Project Manager: _____ Date: _____
(Tier 3 CARs only)

Quality Assurance Officer: _____ Date: _____

Monitoring for Effectiveness: Quality Assurance Officer: _____

Concurrence: _____ Date: _____

Attachment 2
Examples of CARs for which analyte selection are not necessary

Documentation
COC storage
Login Procedures
QA Manual
QC Procedures
QA/QC Review
Standard Operating Procedures
Equipment Maintenance/Repair
Equipment Monitoring
Computer Systems
Database

Note: "All" is appropriate for many types of problems that involve specific samples but do not apply to specific analytes.

Attachment 3

Examples of Common QC Types and Procedures for which CARs are Written

Common QC Types

CCB (continuing calibration blank)
CCV (continuing calibration verification)
Duplicate (laboratory sample duplicate)
FS (field split)
LCS (laboratory control standard; % recovery)
LCS/D RPD (relative percent difference between LCS and LCSD)
LOQ (limit of quantitation) check standard
MB (method blank)
MS (matrix spike)
MSD (matrix spike duplicate)

Common Procedures for which CARs are Written

ANALYTICAL

completion of analysis
sample results
reasonableness
standards preparation

MULTIPLE CATEGORIES

COC completion
sample submission/login
equipment maintenance
instrument calibration
sample filtration
sample preservation
temperature maintenance
holding time
sample container

DOCUMENTATION

data entry
computer use
database program
QA/QC procedures

Attachment 4
Examples of Common Problems, Nonconformances, and Out-of-Control
Situations
for which CARs are Written

QC Problems/Nonconformances/Out-of-control Situations

LOQ ck std. < 70% rec.	LOQ ck std. > 130% rec.
FS RPD > 30%	Duplicate RPD > 20%
CCV recovery < 90%	CCV recovery > 110%
could not generate valid calibration curve	MB > LOQ
LCS recovery < 80%	LCS recovery > 120%
MS < 75% rec.	MS > 125% rec.

Analysis Problems/Nonconformances

insufficient sample for duplicate analysis	sample spilled
OPO ₄ > TP	NH ₃ > TKN
TSS > TS	HTEL (holding time exceeded in the lab)
sample inadvertently discarded	sample not refrigerated

Equipment and Instrument Problems/Nonconformances

- monthly maintenance not performed
- pipetters not relabeled
- temperature not checked (include type of equipment and frequency of scheduled check)
- temperature > range
- temperature < range
- thermometer did not have current calibration tag

Documentation Problems/Nonconformances

COC misplaced	data entered incorrectly
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Sample Collection/Submission Problems/Nonconformances

low volume of liquid in bottles	pH > 2 at login
samples not iced	temperature > 6° at login
sample in wrong bottle type	

Compositing Problems/Nonconformances

incorrect end time	incorrect start time
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Attachment 5
Examples of Effects on Data Quality Documented by Tier 2 and 3 CARs

SAMPLE COLLECTION/RETRIEVAL

Sample not field-filtered
Storm grab collected instead of automated sample
Transparent bottle used instead of dark bottle
Sample container not sterile
Insufficient sample for complete data analysis
No data - HTEF (holding time exceeded in the field)

SAMPLE SUBMISSION/LOGIN

Samples received > 6° C with no ice
pH > 2 at login
No data - Samples not identified properly

COMPOSITING

Flow data not available
Bottle(s) missed for compositing
Sample not composited correctly

ANALYSIS

LOQ not used in curve
LOQ did not pass
CCB > LOQ
CCB not run at end of batch
Estimate only - CCV > limit
Estimate only - CCV < limit
Estimate only – control limits exceeded but concentration > PQL
Field split > 30% but concentrations < 5*LOQ
Field split > 30% and concentrations > 5*LOQ
No data - Control limits exceeded for bacteria duplicate
Duplicate RPD exceeded 20%
No data – Sample duplicate RPD exceeded 20%
No data - HTEL (holding time exceeded in lab)
Incorrect standard run with batch
Incubator temperature > maximum recommended temperature
No data – LCS% rec. > 125
No data – LCS% rec. < 75
No data – LCS/D RPD. > 20
Matrix spike % rec. > 125
Matrix spike % rec. < 75
MB > LOQ
Estimate only – sample temperature not maintained in lab
No data for OPO4; OPO4 > TP
No data for TSS; TSS > TS