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TITLE: Data Verification and Validation

PREPARED BY: Marshall K. Cheung, Ph.D., Laboratory Director _____

REVISED BY: Marshall K. Cheung, Ph.D., Laboratory Director _____

REVIEWED BY: Anne Cheung, Laboratory Manager _____

APPROVED BY: Marshall K. Cheung, Ph.D., Laboratory Director _____

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***Copy provided to*:**	**Marshall K. Cheung, Ph.D.** 29 Palms Tribal EPA Environmental Coordinator 47-250 Dillon Road Coachella, CA 92236
***Copy provided by*:**	Marshall K. Cheung, Ph.D.
***Title*:**	Laboratory Director
Date:	August 4, 2004

1. Scope and Application

1.1. The following procedures describe the process of examination applied to both tribal laboratory generated analytical results and outside laboratory results once final data packages are available.

1.2. These procedures are intended to detect issues with sampling design and implementation, laboratory analytical procedures, QC results, and conformance to the needs of the 29 Palms Tribal EPA.

1.3. This SOP describes the process to be taken and the responsibility of the 29 Palms Laboratory and Tribal EPA Quality Assurance Officer (QA Officer), primarily.

2. Summary of procedure

2.1. During sampling events, the QA Officer will fill out Field Audit Checklist.

2.2. The QA Officer will prepare Field Audit Reports within two weeks for Project Manager (Environmental Coordinator).

2.3. Samples analyzed by the 29 Laboratory will be subjected to three levels of review, involving the Laboratory Manager, the QA Officer and Laboratory Director.

2.4. Upon completion of analysis of samples and receipt of final data package, the QA Officer will go through the Data Audit Checklist, noting any deficiencies.

2.5. The QA Officer will prepare a Data Audit Report within two weeks for the Project Manager (Laboratory Director).

2.6. The Project Manager will have the responsibility of instituting corrective action and applying supplied reports to program needs and data quality objectives for final decision making.

3. Comments

3.1. This procedure is applicable to all activities of the Tribal EPA and all federally funded programs carried out by the 29 Palms Tribal EPA.

3.2. This procedure coincides with Option 3 of the tiered validation approach summarized in the table, “Region 9 QA Office’s General Guidelines for Superfund Data Validation/Review”.

3.3. Qualifiers/flags used by the 29 Palms Tribal EPA/29 Palms Laboratory are as follows:

3.3.1. Green flag (g): note issue, but accept result as valid unless other problem indicators arise

3.3.2. Yellow flag (y): note issue, results suspect and/or data inclusion requires caution

3.3.3. Red flag (r): note issue, results invalid or unacceptable for inclusion in decision-making

4. Procedure

4.1. In the field, during sampling, the QA Officer has the responsibility of overseeing activities of sampling staff and documenting deficiencies through the use of the Field Audit Checklist (see attached).

4.2. The QA Officer must stop sampling activities that may compromise sample, and therefore, data quality.

4.3. Based on observations in the field, the QA Officer will prepare a Field Audit Report within two weeks to keep the Project Manager informed of sampling events.

4.4. The Field Audit Report will summarize the event, including a table of samples collected, a description of any deviations from procedures, and notes of all issues surrounding samples that could lead to data quality issues (from Field Audit Checklist):

4.4.1. If data is recorded in pencil, the author will be requested to rerecord data and initial the correction.

4.4.2. Any deviation from SOPs will be flagged appropriately depending on the gravity of the issue and noted in the Field Audit Report.

4.4.3. Lack of trained personnel or QA oversight will be noted in report and data will be assigned a yellow flag.

4.4.4. Sample containers that are not certified clean will not be used. If they are mistakenly used to collect samples, a red flag will be assigned to resulting data.

4.4.5. Lack of preservative in samples will be noted in report and data assigned a yellow flag.

4.4.6. Samples collected from incorrect locations are assigned red flags and this is noted in report.

4.4.7. If not all samples are collected; a green flag is assigned so that the issue of completeness can be examined.

4.4.8. If expired standards are used this will be noted in the Field Audit Report. The field analysis is invalid (adequate purge questionable) and data resulting from collected samples will be assigned a yellow flag.

4.4.9. Field calibration and documentation issues raise the same question as 4.4.8 and if uncorrected, data will be assigned a yellow flag.

4.4.10. If samples are kept cold by sampling personnel, the mistake will be corrected in the field or the time elapsed will be noted and the Project Manager will make a decision concerning level of concern.

4.4.11. Chain-of-Custody issues will be resolved prior to sample shipment. If uncorrected, flags will be assigned to data based on the seriousness of the mistake.

4.4.12. Samples not delivered within holding times will be noted in Field Audit Report and data will be assigned red flags.

4.5. Samples submitted to 29 Palms Laboratory are subjected to three levels of review that include recalculation and a check of transcription from logbooks to electronic form.

4.6. After the 29 Palms Laboratory performs the analysis and submits a final report or final results are received from an outside laboratory, the QA Officer will use the Data Audit Checklist (see attached) as a guide to examine whether the measurement quality as well as all other requirements of the QAPP have been met.

4.7. The QA Officer will prepare, within two weeks, a Data Audit Report based on the checklist, deliverable to the Project Manager.

4.8. The Data Audit Report will include, in addition to details from the Data Audit Checklist, information from the Field Audit Report that has relevance to sample results and possible data quality (e.g. all flagged samples will be noted and described or referenced back to field documentation, corrective actions at any stage of sampling or analysis).

4.8.1. If Chain-of-Custody forms are not included, the lab is contacted. If forms are lost, unsigned or unavailable, this will be noted in the Data Audit Report and the sampling data will be assigned a red flag.

4.8.2. If custody seals are broken in transit, this will be noted in the Data Audit Report and the sampling data will be assigned a red flag.

4.8.3. If samples are not received cold by the laboratory, the time elapsed in transit will be noted and the Project Manager will make a decision what level of concern is appropriate.

4.8.4. QA/QC reports are required in the final data package, if not received, the lab will be contacted and a note will be included in the report. If no QA/QC info is supplied, the data will be assigned a red flag.

4.8.5. Method blank information is not required of outside laboratories, but is required in 29 Palms Laboratory final data package.

4.8.6. Calibration curves are not required of outside laboratories, but are required in 29 Palms Laboratory final data package.

4.8.7. Calibration curves containing less than 5 points will be noted and data assigned a green flag (use spikes as accuracy indicators). If curve does not bracket samples, data will be assigned a red flag.

4.8.8. If calibration checks differ by more than 15%, this will be noted and the data will be assigned a red flag.

4.8.9. If QC samples are not included in each batch, this will be noted and the data will be assigned a yellow flag.

4.8.10. If blanks show contamination, this will be noted and the data will be assigned a red flag.

4.8.11. For surrogate and matrix spike recoveries:

4.8.11.1. If there is no detection, a red flag is warranted.

4.8.11.2. If the compounds are detected, but below ranges, a yellow flag is assigned (quantitation suspect).

4.8.11.3. If the compounds are recovered above the specified ranges, a green flag will be given.

4.8.12. If the matrix spike duplicate differs by more than 15%, this will be noted and the data will be assigned a yellow flag.

4.8.13. If not all target analytes are included, the lab will be contacted and requested to reanalyze if the holding time has not expired (no flag). If the holding time has expired, this issue will be noted in reference to completeness of monitoring (green flag).

4.8.14. If methods used by the laboratory were inappropriate, the lab will be contacted and reanalyzed requested if holding times have not expired (no flag). A yellow flag will be assigned if samples cannot be reanalyzed.

4.8.15. Samples analyzed outside of holding times will be assigned a red flag.

4.8.16. The lab will be contacted to describe report flags and detection limits if not included in analytical report. This information will be included in Data Audit Report.

4.8.17. If the results are not reported in agreement with listed detection limits, the lab will be contacted for clarification or the result will be recalculated. If results are less than the limits provided by the lab, the data will be assigned a red flag.

4.8.18. A yellow flag will be given to all data that differs by more than 15% from data from another lab.

4.9. Annually, the Project Manager will compile the reports for federally funded projects for decisions on sample design and collection, choice of laboratory and overall program execution.

4.10. The QA Officer will resolve issues (with Project Manager oversight) encountered in the field or with laboratories if the problem pertains to quality assurance/quality control.

4.11. The Project Manager confirms the proper resolution of issues in the field, resolves administrative problems uncovered in Field or Data Audits or in the annual review, and decides what data to use for decision-making based on profession judgment and all available information.

5. Bibliography

5.1. EPA Guidance for Quality Assurance Project Plans, EPA QA/G-5, February 1998.
5.2. Region 9 Tiered Approach to Validation
5.3. 29 Palms Pesticide Monitoring Program Quality Assurance Project Plan (FIFRA), Revised April 2001.

6. Appendix

6.1. Appendix A - Field Audit Checklist

Sampling Project: _____

Date of sampling: _____

_____ All relevant information is recorded in bound logbooks using ink.

_____ Sampling personnel are in possession of relevant, current Standard Operating Procedures.

_____ Standard Operating Procedures are followed or deviations are noted in logbooks with appropriate flags for samples involved.

_____ All samplers are trained or are supervised by trained personnel.

_____ Quality Assurance oversight is provided during sampling activities.

_____ Sample containers are appropriate for the intended analyses and certified clean, either by laboratory or manufacturer.

_____ Sample containers have preservatives if needed for the intended analyses.

_____ The samples are collected from the proper sites.

_____ All required QC samples are collected.

_____ Standards for field analyses are fitting for the intended use and not expired.

_____ Field calibrations performed successfully within QC limits.

_____ Field calibration and calibration verification data recorded in bound logbook.

_____ Field sample analysis results recorded in bound logbook.

_____ Samples are stored at 4°C.

_____ All Chain-of-Custody documentation is complete and included in sample delivery.

_____ Custody seals are present and intact at the time of delivery.

_____ Samples are delivered within prescribed holding times.

Printed name of auditor: _____

Signature of auditor: _____

Title of auditor: _____

Address and Phone Number: _____

Date of Field Audit: _____

6.2. Appendix B - Data Audit Checklist

Sampling Project: _____
Date of sampling: _____
Analytical laboratory: _____

_____ Copies of Chain-of-Custody forms are included in final data package.

_____ Chain-of-Custody is signed by all parties involved in sample transit.

_____ Custody seals listed as intact upon receipt by laboratory.

_____ Sample condition listed as cold upon receipt by laboratory.

_____ The final data package includes a QA/QC Report. Check the following:

- _____ Method blank information is included and results are acceptable.
- _____ Calibration curve is supplied (not required from outside laboratories).
- _____ Calibration curve contains at least 5 points and brackets concentration of samples unless impractical for method.
- _____ Calibration checks are listed and relative percent differences are within 15%.
- _____ Calibration checks, matrix spikes and duplicates are analyzed with each batch of twenty samples.
- _____ Field and equipment blanks show no contamination with analytes of interest or with contaminants that interfere with target analyte.
- _____ Surrogate recoveries are listed and are within the ranges specified by the QAPP.
- _____ Matrix spike results are listed and are within the ranges specified by the QAPP.
- _____ Matrix spike duplicate results are within 15% of MS results.

_____ All target compounds are included in laboratory analytical report as stated in the QAPP.

_____ Proper analytical methods were employed by the laboratory to analyze samples as stated in the QAPP.

_____ Samples were extracted and analyzed within holding times.

_____ Descriptions of qualifiers/flags provided in report.

_____ Method detection or practical quantitation limits listed on report.

_____ Results reported in agreement with listed method detection or quantitation limits.

_____ If 2+ laboratories analyzed samples, results are within 15%.

Printed name of auditor: _____

Signature of auditor: _____

Title of auditor: _____

Address and Phone Number: _____

Date of Data Audit: _____