Summary Guidance for Reviewing Environmental Monitoring Data

Standard Operating Procedure # - BEP-WR-1

1. **APPLICABILITY.** This SOP applies to all DEM programs where staff review environmental monitoring data for use in various environmental regulatory decisions. This summary guidance can be applied to the review of environmental data generated by the Department or by entities in fulfillment of environmental regulatory requirements, as well as to secondary data. It is anticipated that individual programs will modify the checklist (Appendix A) as necessary to meet their DQOs. Appendix C is an example of a checklist that focuses on data verification / validation issues.

2. **PURPOSE.** This SOP is intended to serve as a primer on the procedures for reviewing environmental data and data reports for DEM programs. Depending on the needs of the project, the intended use of the final data and the degree of confidence required in the quality of the results, data review can be conducted at many levels. This document provides general guidance on verification and validation procedures and usability assessments and informs staff of available references to utilize. Data verification ensures that reported results accurately depict work performed. Data validation confirms that these verified results meet the overall quality requirements of the project. Usability assessments define acceptance criteria by which environmental data are evaluated for ultimate use in decision-making.

3. **DEFINITIONS.**

Data Quality Objectives (DQOs) – Description of the intended use of the data and some of the requirements that must be attained (quality and quantity) to meet the intended use.

Data Validation – A technical review performed to compare data with established quality criteria to ensure that data are adequate for the intended use. Data validation confirms that the verified results meet the overall quality requirements of the intended use.

Data Verification – The first step in data review, data verification entails an evaluation of the completeness, correctness, consistency and conformance/compliance of a data set against pre-determined requirements given in a document such as the Quality Assurance Project Plan (QAPP), and to ensure that the records associated with a specific dataset actually reflect what was conducted.

Detection Limit (DL)/Method Detection Limit (MDL) – the lowest concentration of a substance that can be measured with 99% confidence that the substance is present in the sample, i.e., greater than zero.

Metadata – Informational data about the data.

Quality Control (QC) –technical activities intended primarily to control errors. The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the established requirements.

Quantitation Level (QL) – (quantification level, practical quantitation level) – the lowest concentration of a substance that can be reliably measured and reported with some degree of confidence.

Secondary Data – Data collected for purposes other than the current intended use.

4. RESPONSIBILITY.

All staff involved in reviewing environmental data are responsible to determine the applicability of this SOP to their work. Supervisors are responsible for ensuring that staff are familiar with and adhere to any SOPs affecting their project or program functions.

5. GUIDELINES AND PROCEDURES

5.1 General

A primary goal of DEM is to ensure that environmental decisions are supported by data of the type and quality needed and expected for their intended use. Data review is the process by which data are examined and evaluated to varying levels of detail and specificity to ensure that only sound data that are of known and documented quality and meet project quality objectives are used in making environmental regulatory decisions. Although a certain level of verification and validation occur during field sampling and analytical procedures in the laboratory prior to data/report submittal to DEM staff, there is an internal need to review submitted data/reports which will ultimately be used to make environmental regulatory decisions.

The review of environmental data occurs in two phases. The first phase consists of 2 steps in reviewing and determining the validity of the analytical data (data verification and validation). The second phase consists of interpreting the data to determine its applicability for an intended use (usability assessment). Generally, the data verification and validation procedures are outlined in the project's QAPP or Quality Assurance (QA) documentation. Details regarding data verification and validation procedures can be found in EPA's *Guidance on Environmental Data Verification and Data Validation* (EPA 2002). Data verification and validation can be conducted using a checklist or other systematic approach (see Appendix A checklist adapted from EPA's *Requirements for Quality Assurance Project Plans, EPA QA/R-5).* (EPA 2001).

When considering the use of secondary data, the metadata associated with the secondary data should be evaluated for consistency with the Data Quality Objectives and quality criteria of the current intended use similarly to the steps outlined below.

5.2 Data Verification

Data verification is the process of evaluating the completeness, correctness, and consistency of a laboratory data package or final data/project report, against specified requirements usually outlined in project/program QAPPs. This completeness check is performed first to determine whether the required information (the complete data package) is available for further review. The process verifies the information for consistency with project/program specifications, including but not limited to:

- Completeness of the data package as prescribed in the QAPP or other QA documentation;
- Inclusion of sample collection records including field logs;
- Sample collection methods, location(s) and list of analytes are reported in accordance with QAPP or other QA documentation requirements, or documentation of deviations;
- Integrity of samples as determined by complete and proper sample chain-of-custody documentation;
- Adherence to appropriate holding times, preservation, transport or handling protocols;
- Proper sample preparation and documentation such as instrument logs, bench notes, calculation worksheets;

- Sample analysis documentation such as methods and instruments utilized;
- Proper and sufficient documentation of quality control measures and criteria including calibration standards, method blanks, duplicate and replicate samples, spiked samples and blanks, precision, accuracy and data qualifier codes;
- Documentation of Detection Limits and Quantification (reporting) Levels including methods of calculation;
- Documentation of all generated data

5.3 **Data Validation**

The primary focus of data validation is the accuracy and integrity of individual data values so that the numbers can be trusted. Data validation is 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. The intensity of the data validation effort can vary depending on the needs of the project, program, and/or use of the data.

Data validation should:

- Establish that required sampling methods were used and that any deviations were noted;
- Ensure that the sampling procedures and field measurements met performance criteria and that any deviations were documented;
- Establish that required analytical methods were used and that any deviations were noted.
- Verify attainment of required QC measures and criteria, and that deviations were documented.
- Review data for the level of precision, accuracy, representativeness, comparability and completeness;
- Determine that the laboratory data qualifiers are defined and applied as specified in methods, procedures, or the QAPP;
- Verify attainment of required DLs and QLs;
- Identify any deviations from procedures and methods that may require corrective actions or limit the use of the data collected.

5.4 Data Usability Assessment

Data Usability Assessments determine the adequacy of the verified and validated data as related to the data quality objectives (DQO) outlined in the QAPP or for the intended use of the data. Many aspects of a project affect data quality, therefore, all types of data and associated information (e.g., sampling design, sampling technique, analytical methodologies) are evaluated to determine if the data appears to be appropriate and sufficient to support decision-making based upon the original project needs.

A Data Usability Assessment has an analytical and a field component. An Analytical Data Usability Assessment is used to evaluate whether analytical data points are scientifically valid and defensible, and of a sufficient level of precision, accuracy, and sensitivity to support the DQOs. The Field Data Usability Assessment evaluates whether the sampling procedure (e.g., sampling method, sample preservation and hold times) ensures that the sample that is collected and delivered to the laboratory is representative of the sampling point.

Verification and validation processes may result in identifying data that do not meet predetermined QC measures or criteria (e.g., flagging quantitative data that must be considered qualitative only) or in the ultimate rejection of data from its intended use. The Data Usability Assessment considers whether all aspects of the final data meet project/program quality objectives as they relate to the decision to be made, and evaluates whether verified and validated data are suitable for making that decision. Usability of verified and validated data for environmental regulatory decisions is project/program specific and details of the usability criteria may be outlined in the project/program QAPP. Appendix B of this SOP contains the Office of Water Resource's data use rules for water quality assessments.

6. REFERENCES

U.S. EPA, 2001. *EPA Requirements for Quality Assurance Project Plans,* (EPA QA/R-5) EPA/240/B-01/003, March 2001, Office of Environmental Information. (http://www.epa.gov/quality/qs-docs/r5-final.pdf)

U.S. EPA, 2002. *Guidance on Environmental Data Verification and Data Validation*, (EPA QA/G-8), EPA/240/R-02/004, November 2002, Office of Environmental Information. (http://www.epa.gov/quality/qs-docs/g8-final.pdf)

Appendix A

Checklist for Review of Environmental Data and Data Reports

This checklist is based on the elements in *EPA Requirements for QA Project Plans* (QA/R-5) (EPA, 2001). This checklist can be used to review a final data report developed in accordance with a QAPP or other QA documentation.

PROJECT TITLE: _____

Date Submitted for Review: _____ **Date of Review:** _____

Preparer: _____ **Organization:** _____

Reviewer: _____ **Organization:** _____

☐ Accepted as is	☐ Accepted, if minor issues addressed	☐ Major revision needed

Reviewer Signature _____

Note: A = Acceptable U = Unacceptable NI = Not Included NA = Not Applicable

Element	A	U	NI	NA	Page #/ Section #	Comments
A1. Title and Approval Sheet						
Contains project title						
Indicates revision number, if applicable						
Indicates Organization's name						
Dated signature of organization's project manager						
Dated signature of organization's QA manager						
Other signatures as needed						
A.2. Table of Contents						
Lists QA Project Plan information sections						
Document Control Information indicated						
A.3. Distribution List						
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization						

Element	A	U	NI	NA	Page #/ Section #	Comments
A.4. Project/Task Organization						
Identifies key individuals involved in all major aspects of the project, including contractors						
Discusses their responsibilities						
Project QA Manager position indicates independence from unit generating data						
Identifies individual responsible for maintaining the official, approved QA Project Plan						
Organizational chart shows lines of authority and reporting responsibilities						
A.5. Problem Definition/Background						
States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained						
Clearly explains the reason (site background or historical context) for initiating this project						
Identifies regulatory information, applicable criteria, action limits, etc., necessary to the project						
A.6. Project/Task Description						
Summarizes work to be performed, for example, measurement to be made, data files to be obtained, etc., that support the project's goals						
Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments						
Details geographical locations studied/sampled, including maps where possible						
A.7. Quality Objectives and Criteria						
Identifies performance/ measurement criteria for all information collected and acceptance criteria for information obtained from previous studies, including project action limits and lab detection limits and range of anticipated concentrations of each parameter of interest						
Discusses precision						

Element	A	U	NI	NA	Page #/ Section #	Comments
Addresses bias						
Discusses representativeness						
Identifies the need for completeness						
Describes the need for comparability						
Discusses desired and achieved method sensitivity						
A.8. Special Training/Certifications						
Identifies any project personnel specialized training or certifications						
Discusses how and if this training was provided						
Indicates personnel responsible for assuring these are satisfied						
Identifies where this information is documented						
A.9. Documentation and Records						
Identifies report format and summarizes all data report package information						
Lists all other project documents, records, and electronic files that will be produced						
Identifies where project information is kept and for how long						
Discusses back up plans for records stored electronically						
States how individuals identified in A3 will receive the most current copy of the approved QAPP, identifying the individual responsible for this						
B.1. Sampling Process Design (Experimental Design)						
Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample						
Details the type and total number of sample types/matrix or test runs/trials expected and needed						
Indicates where samples should be taken, how sites will be identified/located						
Discusses what to do if sampling sites become inaccessible						
Identifies project activity schedules such as each sampling event, times samples should be sent to the lab, etc.						

Element	A	U	NI	NA	Page #/ Section #	Comments
Specifies what information is critical and what is for informational purposes only						
Identifies sources of variability and how this variability should be reconciled with project information						
B.2. Sampling Methods						
Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken						
Indicates how each sample/matrix type should be collected						
If *in situ* monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data						
If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages						
Indicates how samples are to be homogenized, composited, split, or filtered, if needed						
Indicates what sample containers and sample volumes should be used						
Identifies whether samples should be preserved and indicates methods that should be followed						
Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of						
Identifies any equipment and support facilities needed						
Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented						
B.3. Sample Handling and Custody						
States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for *in situ* or continuous monitoring, the maximum time before retrieval of information						

Element	A	U	NI	NA	Page #/ Section #	Comments
Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)						
Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible						
Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan						
Identifies chain-of-custody procedures and includes form to track custody						
B.4. Analytical Methods						
Identifies all analytical SOPs (field, lab and/or office) that should be followed by number, data, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures						
Identifies all analytical SOPs (field, laboratory and /or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures						
Identifies equipment or instrumentation needed						
Specifies any specific method performance criteria						
Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation						
Identifies sample disposal procedures						
Specifies laboratory turnaround times needed						
Provides method validation information and SOPs for nonstandard methods						

Element	A	U	NI	NA	Page #/ Section #	Comments
B.5. Quality Control						
For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency						
Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented						
Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data						
B.6. Instrument/Equipment Testing, Inspection, and Maintenance						
Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this						
Identifies testing criteria						
Notes availability and location of spare parts						
Indicates procedures in place for inspecting equipment before usage						
Identifies individual(s) responsible for testing, inspection and maintenance						
Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented						
B.7. Instrument/Equipment Calibration and Frequency						
Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration						
Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment						
Identifies how deficiencies should be resolved and documented						

Element	A	U	NI	NA	Page #/ Section #	Comments
B.8. Inspection/Acceptance for Supplies and Consumables						
Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials						
Identifies the individual(s) responsible for this						
B.9. Non-direct Measurements						
Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used						
Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project						
Indicates the acceptance criteria for these data sources and/or models						
Identifies key resources/support facilities needed						
Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing						
B.10. Data Management						
Describes data management scheme from field to final use and storage						
Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs						
Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately						
Identifies individual(s) responsible for this						
Describes the process for data archival and retrieval						
Describes procedures to demonstrate acceptability of hardware and software configurations						
Attaches checklists and forms that should be used						

Element	A	U	NI	NA	Page #/ Section #	Comments
C.1. Assessments and Response Actions						
Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates						
Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process						
Describes how and to whom assessment information should be reported						
Identifies how corrective actions should be addressed and by whom, and how they should e verified and documented						
C.2. Reports to Management						
Identifies what project QA status reports are needed and how frequently						
Identifies who should write these reports and who should receive this information						
D.1. Data Review, Verification, and Validation						
Describes criteria that should be used for accepting, rejecting, or qualifying project data						
D.2. Verification and Validation Methods						
Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any						
Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.						
Identifies issue resolution process, and methods and individual responsible for conveying these results to data users						
Attaches checklists, forms, and calculations						

D.3. Reconciliation with User Requirements						
Describes procedures to evaluate the uncertainty of the validated data						
Describes how limitations on data use should be reported to the data users						

Appendix B

Final Decisions on Use of Low Level Ambient Data for Water Quality Assessments

January 24, 2007

Definitions

- Ambient data result/value – analytical results as determined by the laboratory with data qualifiers (ie, additional associated information that must be taken into account during any interpretation of the result).
- Reported value – final data results/values after consideration of DLs and QLs as described below. Reported values are to be used for assessments, TMDLs and other analyses by OWR.
- DL/MDL – detection limit/method detection limit – the lowest concentration of a substance that can be measured with 99% confidence that the substance is present in the sample, i.e., greater than zero. The MDL is determined through analyses of at least seven replicate samples containing the target analyte(s) at a concentration near the estimated detection capabilities of the method. To calculate the MDL value, the standard deviation of the replicate measurements is multiplied by critical values from the Student t-statistic table for the 99 percent confidence level (1-tailed) with n-1 degrees of freedom. For example, in the case of 7 replicates, the critical value for the 99% confidence level with 6 degrees of freedom (n-1), is 3.143.
- QL – quantitation level – the lowest concentration of a substance that can be reliably measured and reported with some degree of confidence. (EPA's current working definition - The smallest detectable concentration of an analyte greater than the detection limit where the required accuracy (precision & bias) is achieved for the intended purpose.) No standard methodology for QL determination exists but most current approaches follow a calibration procedure similar to, or even based upon, the MDL determination.

Environmental Data Review for Water Quality Assessments:

1. QAPPs will describe: the analytical method to be used for each parameter; the MDL for each parameter (preferably generated through a minimum of 7 replicate samples as noted above), including results of the MDL calibration determination; the QL for each parameter, including how the QL was determined (Because a standardized methodology for determination of the QL does not exist, a complete description of the approach followed should be submitted.)

2. QAPPs should ensure that adequately sensitive analytical techniques are utilized to meet a project's data quality objectives. The analytical method implemented and MDLs and QLs which must be achieved will be driven by the criteria for each parameter analyzed. In other words, OWR staff should ensure that every attempt is made to choose and utilize the analytical method and the lowest detection limit needed to evaluate results relative to criteria. In addition, the lab should achieve quantitation levels as low as possible and as low as necessary to evaluate results relative to criteria. The MDLs and QLs should be routinely achievable by HEALTH certified laboratories to assure the reliability of the measurements and be cost effective for the OWR project.

3. Due to the low hardness of many RI freshwaters, metals criteria may be extremely low in some waterbodies. To account for this issue and implement consistency in metals data review, QLs of at least the following values should be achieved for the listed metals of concern:

Metal	Required QL
a. Dissolved Cd	1.0 ug/l
b. Dissolved Pb	1.0 ug/l
c. Dissolved Cu	1.0 ug/l
d. Dissolved Zn	2.5 ug/l

4. Ambient data resulting in a value below detection limit (i.e. <DL), will be reported as zero. This guideline is in accordance with the determination of the MDL/DL as defined above, where the variance associated with results observed at these levels is such that the concentration cannot be distinguished as different from zero.

5. Ambient data resulting in values which are equal to or greater than the DL but less than the QL, constitute uncertain values. Such data will be deemed invalid and excluded from analyses (e.g. assessments) because the measured concentrations do not meet the required accuracy for the intended purpose(s)/data quality objectives.

6. All ambient data results/values will be submitted to OWR (along with the DL and QL). OWR staff will be responsible for determining the reported values including the validity of the data as described above. OWR staff will maintain both the ambient data value and the reported value within RISWIMS.

7. The aquatic life criteria were developed by reliable EPA laboratories and will be used to evaluate all valid ambient data results even if the criteria is less than DL or less than QL for a given parameter.

Appendix C

Checklist for Review of Environmental Data & Data Reports

Project Title: Date Submitted for Review: Date of Review:

Preparer: Organization:
Reviewer: Organization:

☐ Accepted as is ☐ Accepted with minor revisions ☐ Major revision required

Please respond to each question. Indicate if any question is not applicable to this set of environmental data being reviewed.

Checklist for Review of Data Verification Issues in Environmental Data & Data Reports				
	Data Verification Issues			
No.	Question	Comment	Yes	No
1	Was all the information/data included in data package?			
1a	If no, identify any missing data.			
2	Were sample collection records/chain of custody /sample loss included in data package?			
2a	If no, identify any missing data.			
3	Were all samples collected and analyzed?			
3a	If no, identify any missing samples.			
4	Were holding times and preservation of samples and transportation and handling protocols met?			
4a	If no, identify any nonconformance.			
5	Is all analytical documentation included in the data package?			
5a	If no, identify any missing documentation.			
6	Were the correct analyses performed and were the correct reporting limits (quantitation and detection) reported?			
6a	If no, identify any nonconformance.			
7	Is QC information provided (i.e. duplicates, spikes, blanks, surrogates) with acceptance criteria?			
7a	If no, identify any nonconformance.			
8	Can the decisions be made for the project DQOs based on this environmental data report?			
8a	If no, have the field and/or lab personnel been contacted to obtain any missing information or data.			
9	Has a data usability report/narrative been completed? (i.e., can you complete/close this project?)			
9a	If no, should any missing data be collected in order to complete the report?			

Checklist for Review of Data Validation Issues in Environmental Data & Data Reports

	Data Validation Issues			
No.	Question	Comment	Yes	No
1	Were required sampling methods used?			
1a	If no, note deviations from sampling methods used.			
2	Were there any deviations noted in the sampling methods used?			
2a	If yes, note deviations from the sampling methods.			
3	Did the sampling procedures and field measurements meet performance criteria?			
3a	If no, document any deviations from the performance criteria.			
4	Were the required analytical methods used on the samples?			
4a	If no, note deviations from the analytical methods.			
5	Were attainment of required QC measures and criteria verified?			
5a	If no, document any deviations from the required QC measures and criteria.			
6	Did the data review indicate the level of precision, accuracy, representativeness, comparability and completeness were met?			
6a	If no, note deviations found in the review.			
7	Were the laboratory data qualifiers defined and applied as specified in methods, procedures, or in the QAPP?			
7a	If no, explain why they were not defined and applied as specified in methods, procedures, or in the QAPP			
8	Was attainment of the required detection limits and quantification limits verified?			
8a	If no, indicate problems found in the review of the data.			
9	Were there any deviations from procedures and methods that may require corrective actions or limit the use of the data collected?			
9a	If yes, indicate corrective actions conditions that limit the use of the data collected.			

Summary Guidance for Reviewing Environmental Monitoring Data

Standard Operating Procedure # - BEP-WR-1

Originator:

Connie Carey _____ Connie Carey _____ Date: 7/27/07
Print Name Signature

APPROVALS:

Quality Team Chair:

Tom Getz _____ _____ Date: 7/27/07
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Assistant Director of Water Resources

Alicia Good _____ _____ Date: 8/15/07
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