

## For Interested Party Review – September 2010 Draft

### 3745-4-05 Level 2 data requirements and reporting.

- (A) Except as provided by paragraph (D) of rule 3745-4-01 of the Administrative Code, all data submitted to the director for consideration as level 2 credible data shall be collected and submitted by level 2 or level 3 qualified data collectors (QDCs) approved by the director pursuant to rule 3745-4-03 of the Administrative Code. The director shall accept the data as level 2 credible data provided the requirements of this rule are met. The director shall have sole authority in determining whether data meet these requirements. Data reporting shall be in a format consistent with the requirements listed in this rule. Data submitted by a QDC determined to meet these requirements shall be included in a computerized database maintained by Ohio EPA and made available for sharing with other agencies and interested persons.
- (B) Data submitted by a QDC must meet the requirements in this paragraph to be accepted as level 2 credible data.
- (1) Adherence to a study plan. Persons submitting data to Ohio EPA as a QDC under section 6111.53 of the Revised Code must prepare and adhere to a project study plan or, alternatively, use a generic study plan as described in this paragraph.
- (a) The QDC shall prepare and submit to the director for approval a project study plan using the guidelines presented in appendix A of this rule. Upon completion of the plan review, the director shall send written notification of deficiencies in the plan, if any are found, to the QDC thereby disapproving the plan for use in the credible data program. A plan submitted by a QDC ~~or qualified data collection organization~~ (level 2 or level 3) not disapproved within sixty days shall be considered to have been approved. The director will disapprove a site-specific plan that does not include the certification statement in paragraph ~~(B)(4)(f)~~ (B)(4)(e) of this rule.
- (b) Generic study plan. The director may from time to time make available generic study plans suitable for certain project objectives and utilizing appropriate methods. After such time that a generic study plan is available, the QDC may elect to collect data using the generic study plan appropriate to the data quality objectives for the specific study. The level 2 QDC shall submit to the director a notification of the level 2 QDC's intent to utilize a generic plan or generic plan component under this paragraph. The QDC is encouraged to submit the notification to the director at least ninety days prior to the first anticipated sampling activity. The QDC may submit credible data to the director in

accordance with a generic study plan without prior approval from the director.

[Comment: QDCs are encouraged to submit notification of intent to use generic study plans at least ninety days prior to sample collection to allow time for consultation with Ohio EPA. The objective of the consultation is to ensure that Ohio EPA and the QDC agree that the generic study plan is suitable for the project and the stated data quality objectives, thereby allowing the data generated to be deemed credible at the level intended by the QDC.]

- (2) Use of appropriate test methods. In preparing the project study plan, the QDC shall be responsible for selecting the appropriate field and laboratory methods, including quality assurance and quality control steps that fit the objectives and purpose of the project. All methods should be commensurate with the purposes of level 2 and the need for sufficient rigor and sensitivity to detect relatively small differences in water quality over time or from sampling site to sampling site. The QDC may select from parameters and test methods published by the director pursuant to paragraph (C) of this rule or similar methods published in the scientific literature. Explicit approval of the specific methods employed shall occur when Ohio EPA reviews project study plans or whenever Ohio EPA makes available a generic study plan.
- (3) All laboratories that perform analysis under a level 2 study plan must implement a quality assurance program and must document all elements of the program in a quality assurance manual (QAM) or quality assurance plan (QAP). Guidelines for the elements that should be addressed in the QAM or QAP are presented in appendix B of this rule.
- (4) Data reporting. QDCs choosing to submit their data to Ohio EPA must submit all collected data. Submission of data may be done at any time, but must be done no later than one year after completion of the study identified in the project study plan. For ongoing sampling programs, data submission should begin no later than one year after the initial phase of study identified in the project study plan. Additional data reporting requirements are:
  - ~~(a) Wherever possible, a paper copy of all sample data shall be on forms made available by the director, but may be submitted on forms developed for the project. In lieu of a paper copy, data may be submitted electronically in a format mutually acceptable to the QDC and the director;~~
  - (a) Level 2 sample data shall be submitted using the online credible data database;

- (b) Submission of documentation demonstrating adherence to an approved project study plan, generic study plan, or generic plan component;
  - (c) ~~Copies~~ Online submission of the results from all quality assurance and quality control samples collected during implementation of the approved project study plan, generic study plan, or generic plan component;
  - ~~(d) Documentation of the person's status as a level 2 or level 3 QDC;~~
  - ~~(e)~~(d) A statement attesting certification that, to the best of the QDC's knowledge and belief, the data were collected in accordance with the procedures required by the approved project study plan, generic study plan, or generic plan component; and
  - ~~(f)~~(e) A certification that the persons conducting data collection have signed statement from each QDC working on the project certifying that the QDC has not been convicted of or pleaded guilty to a violation of section 2911.21 of the Revised Code (criminal trespass) or a substantially similar municipal ordinance within the previous five years.
- (5) Reporting laboratory quality assurance and quality control plans. In addition to the information required by paragraph (B)(4) of this rule, the QDC, upon request of the director, shall provide quality assurance and quality control documentation for all laboratories that were used to analyze any data collected pursuant to the approved project study plan, generic study plan, or generic plan component. The QDC is responsible for providing this documentation in the form of a laboratory QAP that meets the content guidelines presented in appendix B of this rule.
- (6) Data approval process. The director shall review data submissions to verify that they were submitted by a QDC, that appropriate test methods and quality control quality assurance practices were used, and that the data reporting requirements are complete. The review will ensure that all components of the plan for the collection of data were followed. If substantial discrepancies are found, the director may decide not to approve the data. The director will provide written notification to the person submitting the data as to whether the data have been approved and at what level the data qualify as credible data.
- (C) Publication of acceptable methods.

The director from time to time shall publish examples of acceptable level 2 analytical methods for commonly sampled parameters. Appendix C is the published list of such examples as of the effective date of this rule.

Effective:

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Certification

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Date

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