

**\*\*\* DRAFT – NOT FOR FILING \*\*\***

3745-506-330

**Performance standards for statistical analysis methods.**

Each statistical analysis method included within the statistical analysis plan shall meet the following performance standards:

(A) A statistical analysis method shall be designed to allow an owner or operator to detect a release.

(B) For the ground water detection program, a statistical analysis method shall be conducted separately for each of the parameters required to be statistically evaluated in accordance with rule 3745-506-400 of the Administrative Code.

(C) For the ground water assessment program, if statistical analysis is to be performed, a statistical analysis method shall be appropriate for determining the extent or concentrations of a release in accordance with rules 3745-506-500 and 3745-506-510 of the Administrative Code and for determining the need for corrective actions for remediating the release in accordance with rule 3745-506-600 of the Administrative Code.

(D) For a corrective action being implemented under the ground water corrective actions program, if statistical analysis is to be performed, a statistical analysis method shall be appropriate for determining the effectiveness of the corrective action being implemented in accordance with a corrective action implementation plan required by paragraph (G) of rule 3745-506-600 of the Administrative Code.

(E) Test for normality. A statistical analysis method selected shall be appropriate for the distribution of parameters. If the distribution of the parameters is shown by an owner or operator to be inappropriate for a normal theory test, then the data shall be transformed or a distribution free theory test shall be used. If the distributions for the parameters differ, more than one statistical analysis method may be used.

(F) Individual and multiple well comparison procedures shall conform to the following:

(1) Comply with at least one of the following:

(a) If an individual well comparison procedure is used to compare an individual monitoring well parameter concentration to background parameter concentration or a ground water concentration level, the test shall be conducted at a type I error level not less than 0.01 for each testing period. If multiple comparison procedures are used, the type I experimentwise error rate for each testing period shall be not less than 0.05; however, the type I error rate of not less than 0.01 for individual monitoring well comparisons shall be maintained.

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(b) Achieve at least fifty per cent power at a three standard deviation increase and at least eighty per cent power at a four standard deviation increase for the parameter.

(c) For control charts with up to one re-sample, the following requirements with regard to parameter limit values:

(i) Decision internal limit value equal to or less than five.

(ii) Shewhart control limit value equal to or less than five.

(iii) Reference control limit value equal to or less than one.

(2) Comply with the following:

(a) If conducting more than one re-sample as a part of the statistical analysis method or exceeding one or more control chart parameter limit values in paragraph (F)(1)(c) of this rule, the statistical test shall meet the power requirements in paragraphs (F)(1)(b) and (F)(2)(c) of this rule.

(b) Any alternative statistical analysis method selected in accordance with paragraph (D) of rule 3745-506-310 of the Administrative Code shall meet the power requirements in paragraphs (F)(1)(b) and (F)(2)(c) of this rule.

(c) If a human health standard for ground water ingestion has been determined for a parameter and the statistical limit or a GWAS calculated for that parameter is greater than or equal to the human health standard, then the statistical method shall be adjusted to achieve ninety-five per cent power at a four standard deviation increase.

(G) All statistical analysis methods selected shall account for data below the limits of detection and quantitation with one or more statistical procedures. These procedures shall be in accordance with the following:

(1) Each practical quantitation limit (PQL) used in the statistical analysis method shall be the lowest concentration that can be reliably achieved during routine laboratory operating conditions that are available to the owner or operator. If a lower PQL is available to the owner or operator for use in the statistical analysis method in accordance with this paragraph, the owner or operator shall update the background data set in accordance with rule 3745-506-320 of the Administrative Code.

(2) Any censored estimation technique used to estimate the summary statistics for the statistical limit shall meet the following requirements:

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- (a) The censored estimation technique shall be appropriate for the distribution and percentages of censored and uncensored data in the background data set.
- (b) The censored estimation technique shall be prescribed in the statistical analysis plan completed in accordance with rule 3745-520-300 of the Administrative Code and shall be selected from the following techniques:

  - (i) Kaplan-Meier.
  - (ii) Robust regression on order statistics.
  - (iii) Parametric regression on order statistics.
  - (iv) Cohen's adjustment.
  - (v) Substitution of one-half the method detection limit (MDL) or the whole MDL when censoring at the MDL and one-half the PQL or the whole PQL when censoring at the PQL.
  - (vi) An alternative censored estimation technique. If an alternative is chosen, a written demonstration justifying that the alternative technique is appropriate for the distribution and percentages of censored and uncensored data in the background data set shall be submitted to Ohio EPA and the approved board of health at least thirty days prior to submission of the first statistical comparison utilizing a statistical limit derived from this technique.
- (H) If there is only a single detection equal to or above the PQL in the background data set, the single detection equal to or above the PQL shall not be used as the statistical limit unless justified in a demonstration submitted in accordance with paragraph (F) of rule 3745-506-320 of the Administrative Code.
- (I) If area-wide ground water corrective actions have been implemented or are scheduled for implementation, the statistical limit shall not be greater than the area-wide clean-up standard for a parameter.
- (J) If necessary, the statistical analysis method selected shall include procedures to control or correct for seasonal and spatial variability as well as temporal correlation in the data.