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3745-506-320

Background data in the statistical analysis plan.

(A) An owner or operator shall ensure that the background data set in the statistical analysis plan includes a minimum of eight, statistically independent data points for each parameter for each ground water monitoring well and that the number of data points is consistent with the statistical analysis methods and procedures as documented in the statistical analysis plan.

(B) If an owner or operator updates the background data set, the background data set shall be updated in accordance with the following requirements:

(1) A background data set shall not be updated more frequently than once a year.

(2) Analytical data from each ground water monitoring well contributing new background data shall be added to the background data set only in blocks of four or more statistically independent samples.

(3) When updating control charts there shall be at least three post-background data points after the update is complete or the statistical parameters shall be adjusted to provide adequate statistical power to detect a release.

(4) Appropriate statistical outlier tests and trend analyses shall be performed in accordance with paragraphs (D) and (E) of this rule on the background data set including the new background data.

(5) If a lower practical quantitation limit (PQL) is available to the owner or operator for use in the statistical analysis method in accordance with paragraph (G) of rule 3745-506-330 of the Administrative Code, then an owner or operator shall do the following:

(a) For organic parameters not detected in background at the facility, base the background data on the lower PQL.

[Comment: Pursuant to rule 3745-520-300 of the Administrative Code, for organic parameters not detected in background at the facility, a quantifiable detection in a downgradient ground water monitoring well is a statistically significant change from background.]

(b) For inorganic parameters or organic parameters that are detected in background at the facility, update the background data set with all appropriate data points collected using the lower PQL not later than two years after the date of the first sampling event that the lower PQL is utilized. The type and number of data points to be included in the background data set for these parameters shall be further determined as follows:

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- (i) All previous detections meeting the requirements of paragraphs (D), (E), and (F) of this rule shall be retained in the background data set.
- (ii) All censored data points at a higher PQL shall be removed from the background data set unless one or more of the following conditions are met:

 - (a) The censored data points at a higher PQL include values that have been estimated by a laboratory to be between a method detection limit (MDL) and a PQL. The owner or operator may elect to retain the censored data points at a higher PQL in the background data set if the estimated values are used in place of the corresponding PQLs to represent background concentrations.
 - (b) The number of data points at the lower PQL to be updated plus the number of detects plus the number of estimated values in the background data set is less than eight. The lowest and then the most recent censored data points at a higher PQL shall be retained in the background data set such that the updated background data set is comprised of eight data points.
 - (c) A censored estimation technique that can accommodate multiple PQLs is used to estimate the summary statistics in accordance with paragraph (G) of rule 3745-506-330 of the Administrative Code.
- (C) Prior to conducting the first statistical analysis utilizing any background data set, an owner or operator shall demonstrate within the statistical analysis plan that background data are representative of background ground water quality in accordance with rules 3745-506-100 and 3745-506-120 of the Administrative Code and that background data are not affected by the following:

 - (1) Laboratory or sampling error. This demonstration shall include the following:

 - (a) Verification that rejected data or data with unacceptable bias are not included in the background data set.
 - (b) The results of the performance of an appropriate statistical outlier test conducted in accordance with paragraph (D) of this rule.
 - (2) A release from potential sources of contamination. This demonstration shall include the following:

 - (a) A description of the results of trend analyses conducted in accordance with paragraph (E) of this rule.

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- (b) A comparison of background data to the range of facility data and, if available, appropriate regional data.
- (D) An appropriate statistical outlier test shall be performed on the background data set for each parameter, including data from all ground water monitoring wells contributing data to the background data set. A statistical outlier shall be excluded from the background data set unless a demonstration is submitted to Ohio EPA and the approved board of health that justifies that the data point is representative of background ground water quality in accordance with paragraph (F) of this rule. Statistical outlier testing shall be conducted in accordance with the following requirements:
- (1) If censored data comprise less than seventy-five per cent of the background data set, a statistical outlier shall be determined as follows:
- (a) A statistical outlier test shall be performed on high and low suspect values at a type I error rate of not less than 0.01 for each parameter. Any data point identified as being statistically significant shall be considered a statistical outlier.
- (b) If the highest value data point in the background data set exceeds by an order of magnitude the value of the second highest data point, the highest data point shall be considered a statistical outlier.
- (2) If censored data comprise greater than or equal to seventy-five per cent of the background data set, a statistical outlier shall be determined as follows:
- (a) If there is a single detection greater than or equal to the PQL, and detections greater than or equal to the MDL comprise greater than or equal to fifty per cent of the background data set, any value greater than or equal to two times the median of the background data set shall be considered a statistical outlier.
- (b) If there is a single detection greater than or equal to the PQL, and detections greater than or equal to the MDL comprise less than fifty per cent of the background data set, any value greater than the highest PQL among the background data shall be considered a statistical outlier.
- (c) If there are two or more detections greater than or equal to the PQL, and detections greater than or equal to the MDL comprise greater than or equal to fifty per cent of the background data set, any value greater than or equal to three times the median of the background data set shall be considered a statistical outlier.
- (d) If there two or more detections greater than or equal to the PQL, and detections greater than or equal to the MDL comprise less than fifty per cent

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of the background data set, the highest value shall be considered a statistical outlier.

[Comment: Flowcharts to aid in understanding of paragraphs (D)(1) to (D)(2)(d) of this rule are provided in the appendices to this rule.]

(E) After performing outlier tests, statistical trend analyses shall be performed on the background data set, including data from all ground water monitoring wells contributing data to the background data set. Data causing a statistically significant change or increasing trend shall be excluded from the background data set unless a demonstration is submitted to Ohio EPA and the approved board of health that justifies that the data point is representative of background ground water quality in accordance with paragraph (F) of this rule. Statistical trend analyses shall be performed in accordance with the following:

(1) Trend analyses shall be performed at 0.01 level of significance or greater per tail for each parameter at each ground water monitoring well contributing data to the background data set.

(2) Trend analyses shall be performed using Sen's Estimate of Slope, Spearman's Rank Correlation Test, the Mann-Kendall Trend Evaluation, or another appropriate trend analysis method.

(F) Prior to conducting the first statistical analysis utilizing any background data set, an owner or operator shall submit documentation and justification for statistical outliers, data causing an increasing trend, and data causing a statistically significant change to be included into the background data set. This documentation and justification shall be received by Ohio EPA and the approved board of health at least thirty days prior to submitting the results of the first statistical comparison of ground water analytical data to the background data set, and shall include the following:

(1) Documentation. All data and results from each outlier test or trend analysis conducted in accordance with paragraphs (D) and (E) of this rule including the following:

(a) A list of identified statistical outliers, data causing an increasing trend, or data causing a statistically significant change that the owner or operator intends to include in the background data set.

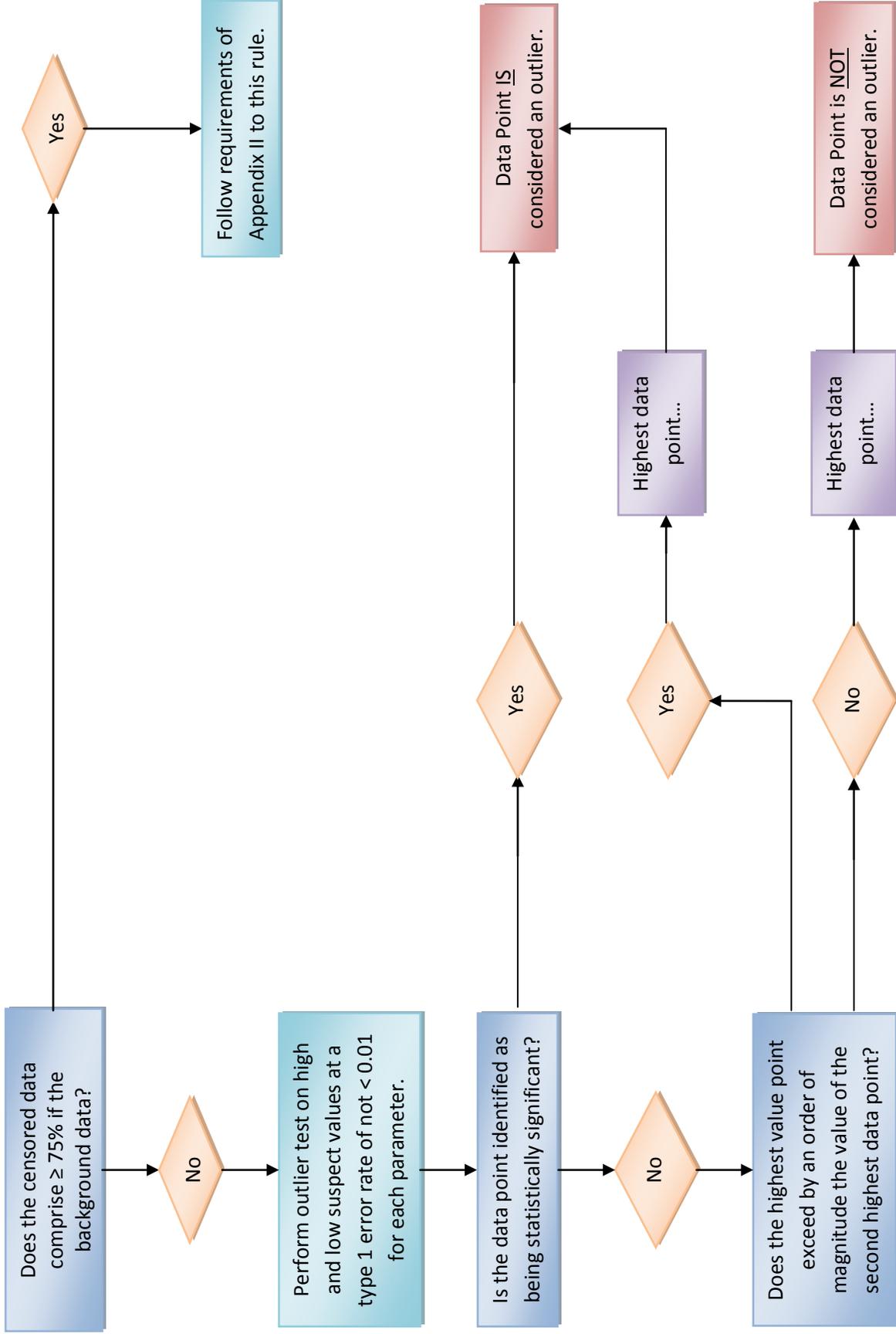
(b) A description of the statistical outlier tests or trend analyses that were run on the background data set.

(c) A demonstration that the statistical outlier tests and trend analyses were run accurately and at the appropriate level of significance.

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- (2) Justification for the inclusion of statistical outliers. If the owner or operator intends to include a statistical outlier in the background data set, the owner or operator shall submit written justification of the representativeness of the statistical outlier that considers, as appropriate, the following:
- (a) Proximity in concentration of the statistical outlier to other detections or to available estimated data that is greater than or equal to the MDL but less than the PQL from that sampling location.
 - (b) Supporting evidence found in relevant, professional literature that the statistical outlier concentration is within the normal range of background concentrations expected for the parameter at the facility.
 - (c) A comparison of the statistical outlier concentration to background data from other sample locations that are located upgradient or downgradient and are unaffected by a potential source of contamination. This comparison shall consider the range, standard deviation, and spatial variability present in background at the facility and shall demonstrate that the statistical outlier concentration is within the normal range of background concentrations expected for the parameter at the facility.
 - (d) Use of an appropriate outlier testing procedure not previously identified in the statistical analysis plan demonstrating that the data point previously identified as a statistical outlier in accordance with the statistical analysis plan is not an outlier.
- (3) Justification for the inclusion of data causing a statistically significant change or increasing trend. If the owner or operator intends to include data causing a statistically significant change or increasing trend in the background data set, the owner or operator shall submit written justification of the representativeness of the data causing a statistically significant change or increasing trend that considers, as appropriate, the following:
- (a) Similarity of background data to other site data from other sample locations that are located upgradient or downgradient and are unaffected by a potential source of contamination.
 - (b) Similarity of background data to appropriate regional data, if available.
 - (c) Information or data indicating that a source other than the facility is responsible for the change in concentration.
 - (d) Supporting evidence found in relevant, professional literature that the concentration is within the normal range of background concentrations expected for the parameter at the facility.

Appendix I



Appendix II

