



## Frequently Asked Questions regarding "Lowest PQL" in OAC 3745-27-10(C)(7)(e)

\*This document supersedes the documents by the same title that were issued on January 8, 2008 and revised on April 21, 2008.

OAC 3745-27-10(C)(7)(e) requires that:

"The statistical method shall account for data below the limit of detection with one or more statistical procedures that ensure protection of human health and the environment. Any practical quantitation limit (PQL) used in the statistical method shall be the lowest concentration level that can be reliably achieved within the specified limits of precision and accuracy during routine laboratory operating conditions that are available to the facility."

**Question Set #1:** How is a new, lower PQL to be used in the statistical method in accordance with the rule? Is the owner/operator (O/O) required to re-establish a new background data set each time a new, lower PQL is achieved? Does this mean that every time a new, lower PQL is achieved for a given parameter that non-detects censored at the older, higher PQLs in background must be removed from the background data set? Or are the non-detects censored at the older, higher PQLs simply now assumed to be non-detect at the new, lower PQL?

**Response:** These questions will be addressed in more detail below.

### General Requirements

The OAC 3745-27-10(C)(7)(e) rule language is copied directly from RCRA Subtitle D, and it should be pointed out that the rule is regarding how "...data below the limit of detection..." are to be "...used in the statistical method...", and specifically how PQLs are used in the statistical method. Therefore, the rule is regarding only those cases where a statistical limit is based on a background data set that could include non-detects at multiple PQLs. In some cases the background data set may be composed of a mixture of detects and non-detects, whereas in other cases the background data set may be composed entirely of non-detects. OAC rule 3745-27-10(C)(7)(e) does not typically involve cases where the background values are all or nearly all detections (i.e. naturally-occurring parameters that are ubiquitous in ground water like sodium, chloride, potassium, etc.).

In cases as described above where non-detects make up a substantial portion of the background data set and the statistical limit is based on this background, Ohio EPA interprets the requirements of OAC rule 3745-27-10(C)(7)(e) to be generally: 1) that the O/O utilize current laboratory technology to obtain the lowest available PQL for the parameter; and, 2) that the O/O incorporate this current laboratory technology into the statistical method as soon as possible through updating the background data set with the new, lower PQLs.

### Updating Background and Statistical Limits

#### Inorganic Parameters

Ohio EPA does not interpret OAC rule 3745-27-10(C)(7)(e) as requiring the O/O to conduct special sampling each time a new, lower PQL is achievable for an inorganic parameter or an organic parameter detected in background. Ohio EPA interprets the

rules as pertaining to scheduled ground water monitoring samples, re-samples and any additional samples the O/O elects to collect. Therefore, apart from special circumstances or a Director's Findings and Orders, Ohio EPA would not require the O/O to establish a new background by collecting eight new samples under the new, lower PQL. However, Ohio EPA does think that the rule requires the O/O to update the background data set with the new, lower PQL when a sufficient number of samples are obtained to update background.

OAC 3745-27-10(C)(7)(g) requires at least four statistically independent samples to update a background data set. Therefore, apart from re-sampling or from voluntary sampling conducted at the O/O's discretion, it would take approximately two years of semi-annual sampling to accumulate the four statistically independent samples using the new, lower PQL necessary for a background update. Ohio EPA considers this as a standard for all inorganic parameters and any organic parameters detected in background.

However, it is possible that a facility-wide background update after exactly four samples would put some monitoring wells "off schedule" from that of most other wells for the same parameter (e.g. resamples, replacement wells) and inadvertently require frequent statistical analysis plan revisions. Therefore, Ohio EPA thinks it is more practical to require background updates of this nature based on a time limit rather than merely the number of available samples. Based on this, if an O/O fails to update the background data set for an inorganic parameter or for an organic parameter detected in background with the new, lower PQL within two years of the date of the sampling event at the new, lower PQL, a violation regarding OAC 3745-27-10(C)(7)(e) may be issued.

If an inorganic parameter background data set is comprised of 100% non-detects and a new, lower PQL becomes available and is being utilized, the O/O should take the following steps, in order:

- A. Update background when four data points at the lower PQL are available;
- B. Base the statistical limit on the highest PQL in background (i.e. such that a detection *at or above* the highest PQL is considered to be a statistically significant increase above background) until eight data points at the lower PQL have been updated into background;
- C. When eight data points at the lower PQL have been updated into background, change the statistical limit or method accordingly:
  - i. If the background data set remains 100% non-detects after eight data points at the lower PQL have been updated into background, change the statistical limit to be based on the lower PQL (i.e. such that a detection *at or above* the lower PQL is considered to be a statistically significant increase above background).
  - ii. If the background data set contains detects after eight data points at the lower PQL have been updated into background, the O/O should either:
    - a. Change the non-parametric statistical limit to an appropriate large order statistic (i.e. typically the highest or second highest detection in background);

- b. Utilize a control chart or parametric statistical method, as appropriate if a sufficient number of detects are now present in background for the method.

#### Organic Parameters Not Detected in Background

Compared to inorganic parameters or organic parameters detected in background, organic parameters that are not detected in background require a different approach as their presence indicates an impact to ground water. For such an organic parameter not detected in background Ohio EPA interprets OAC 3745-27-10(C)(7)(e) to require that a detection at or above *any* PQL be considered a statistically significant increase above background. Therefore, the O/O should use language in the statistical analysis plan requiring that the non-parametric statistical limit for such an organic parameter not detected in background be set at either zero or at less than the current PQL such that a detection at or above any PQL is a statistically significant increase above background.

If such an organic parameter is detected after utilizing the new, lower PQL the O/O may make a false positive demonstration in accordance with OAC 3745-27-10(D)(7)(c) either by re-sampling in accordance with the sampling and analysis plan following OAC 3745-27-10(D)(7)(c)(i) or by a demonstration in accordance with OAC 3745-27-10(D)(7)(c)(ii) to show that the organic parameter can be expected to occur in background or that an alternate source or error caused the initial detection. If the resample result disproves the initial detection or the Director approves the 3745-27-10(D)(7)(c)(ii) demonstration the O/O may return to detection monitoring.

**Question Set #2:** How do the Target PQLs found in Ohio EPA, Division of Materials and Waste Management Guidance Document #406 relate to the “lowest PQL” requirements in OAC 3745-27-10(C)(7)(e)? What if a PQL used in the statistical method is already at or below the Target PQL but an even lower PQL becomes available to the O/O? If analysis is conducted using the new, lower PQL, must background be updated and/or the statistical limit changed to reflect the new, lower PQL even though the PQLs in the existing background are already at or below the Target PQL?

**Response:** As described in the Ohio EPA, Division of Materials and Waste Management Guidance Document #406 released by DMWM on April 24, 2007, Ohio EPA will generally interpret a PQL that is equal to or less than the “Target PQL” for that parameter as being in compliance with OAC rule 3745-27-10(C)(7)(e) and thus the “lowest concentration level that can be reliably achieved” provided proper laboratory protocols were followed. Therefore, if the PQL used by the O/O is at or below the Target PQL for that parameter the O/O is not required to change laboratories or laboratory analytical methods or procedures to achieve an even lower PQL. Furthermore, non-detects at a higher PQL that is at or below the respective Target PQL can be retained in the background data set.

However, if background data used in determining statistical limits contains censored data at a PQL greater than a Target PQL, that higher PQL may not meet the requirements of OAC Rule 3745-27-10(C)(7)(e) and may need to be removed from the background data set. Two exceptions to this would be:

- If the O/O demonstrates that a PQL at or below the Target PQL is not reasonably obtainable on a routine basis due to matrix interference;

- If the O/O is utilizing a non-detect adjustment method capable of accommodating multiple PQLs (e.g. Kaplan-Meier, Robust ROS) in calculating summary statistics. In such a case, older, censored data at a higher PQL can be retained in the background as long as that higher PQL is not unreasonably high (e.g. multiples above the Target PQL).

Otherwise, to achieve compliance the background data set would need to be updated with data meeting the Target PQLs and censored data at PQLs above the Target PQLs should be removed from the background data set.

Additionally, if all censored background data meet Target PQLs but the O/O finds that their laboratory is now routinely achieving new, lower PQLs, the O/O should update background to include the data at the new, lower PQL when four data points at the lower PQL are available for updating and follow the appropriate protocols in the answers to Question Set #1 above. .

The laboratory should conduct analysis and report data down to the new, lowest PQL. It is understood that PQLs can vary from laboratory to laboratory, vary within a laboratory based upon equipment used, etc., and vary from event to event. Analysis for solid waste facilities should be conducted at a PQL meeting minimum Target PQL levels, unless justified by documented matrix interference.