

**Virginia Division of Consolidated Laboratory Services  
Virginia Environmental Laboratory Accreditation Program**

**FREQUENTLY ASKED QUESTIONS**

**PERFORMANCE-BASED AND FIXED LIMITS FOR LABORATORY QUALITY CONTROL**

**June 22, 2015**

**This document reflects responses to Frequently Asked Questions regarding the Guidance on Performance-Based and Fixed Limits For Laboratory Quality Control.** The guidance document is located on the VELAP web page at [www.dgs.virginia.gov/dcls](http://www.dgs.virginia.gov/dcls). The guidance provides a table: “VELAP 40 CFR 136.3 (Table 1B) Fixed Limits Table” or simply “Fixed Limits Table”, also available on the VELAP web page.

**Does the guidance document regarding fixed limits pertain to my laboratory?**

VELAP certification or accreditation is applicable for testing used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the Code of Virginia). The end users of testing data generated for these purposes are the Virginia Department of Environmental Quality (DEQ) and the Virginia Department of Mines, Minerals, and Energy (DMME)<sup>1</sup>.

The guidance document pertains to laboratories using 40 CFR 136 approved inorganic test methods from ***Standard Methods for the Examination of Water and Wastewater (Standard Methods or SM)*** for compliance purposes reported to DEQ or DMME.

**What part of the agency’s regulations does the guidance document interpret?**

Laboratories certified or accredited under 1VAC30-45 or 1VAC30-46 may be required to use methods approved in 40 CFR 136.3 Table 1B (List of Approved Inorganic Test Procedures) for testing performed for compliance purposes under the Clean Water Act (CWA) and State Water Control Law including approved methods from *Standard Methods*.

*Standard Methods* refers to requirements in SM 1020 or chapter-specific quality control (QC) sections (SM 2020, 3020, 4020, 5020, etc.) for information on control limits applicable to quality control samples. These methods include a reference to fixed limits from a database as an alternative to generating limits from control charts. (“As an alternative to constructing control charts, use fixed limits from a database or list for WLs [warning limits], CLs [control limits], and trends.” [SM 1020 B 13 c-2011])

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<sup>1</sup> Generally, State Water Control Law compliance is managed by Virginia Department of Environmental Quality (DEQ). In selected cases, permits are managed by Virginia Department of Mines, Minerals, and Energy (DMME). As such, the data user of analyses done per 40 CFR 136 for the regulations cited above may be either DEQ or DMME. Both DEQ and DMME have concurred with the May 1, 2015 guidance document and fixed limits table as amended on June 22, 2015. This document refers to DEQ as the predominant data user; however the data user may also be DMME.

### Why was the Fixed Limits Table needed?

The 2012 40 CFR 136 Methods Update Rule (MUR) caused the Standard Methods 18<sup>th</sup> edition, published in 1992, to no longer be an option for laboratories. SM 18<sup>th</sup> edition included a table of fixed limits which were used as evaluation criteria for duplicates and for known additions. [“Known additions” includes Laboratory Fortified Blank (LFB) or Laboratory Control Sample (LCS), and Laboratory Fortified Matrix (LFM) or Matrix Spike (MS)].

When the 2012 MUR became effective, laboratories using *Standard Methods* were directed to use statistical measures to calculate control limits for evaluating acceptable quality control data, when the method did not specify limits for known additions and for duplicates. The *Standard Methods* also referenced an alternative fixed limits table that could be used to evaluate quality control data but did not provide a table. As a result, the quality of data being used for Clean Water Act (CWA) and State Water Control Law compliance purposes could potentially be reported with greater uncertainty. In response to requests from laboratories seeking guidance on this point, VELAP provided the Fixed Limits Table for use in evaluating QC data.

When the approved methods contained no definitions of the minimum QC, the QC acceptance criteria could vary greatly from laboratory to laboratory. These ranges in acceptance criteria were contingent upon both the laboratory’s historical data and the practices used to calculate limits.

For example, the Laboratory Fortified Blank (LFB) acceptance limits from two laboratories for the same analyte may be as follows:

Lab A	91-107%
Lab B	70-130%

Using this illustration:

- Lab A was required to perform corrective action and, if the issue was not resolved, to qualify data for samples in a batch with **<91% or >107% recovery**.
- Lab B was required to perform corrective action or qualify data for samples in a batch with **<70% or >130% recovery**.

### This issue indicates potential weakness in data quality because:

- The data user, DEQ, lacked sufficient information to fully understand the data being received for work being done for CWA and State Water Control Law compliance purposes after the MUR changes were implemented.
- The variations in evaluation limits impacted the responsibility for laboratories to qualify data and caused inequalities in the requirements for performance of corrective action and qualification of data among laboratories.
- The lack of minimum evaluation criteria made possible the acceptability of data with greater uncertainty than had been acceptable for compliance purposes for more than two decades.

### How were the limits in the Fixed Limits Table determined?

The Fixed Limits Table was prepared from “equivalent” 40 CFR 136-approved EPA methods (same analyte, same/similar methodology), where available. When no “equivalent” approved EPA method is available as a reference for fixed limits, the limits formerly published in Standard Methods 18<sup>th</sup> Edition were used.

**Is the Fixed Limits Table an *alternative to calculating laboratory generated limits* or is using the table a *requirement*?**

The Fixed Limits Table is a practical solution to a multi-faceted issue. Its use is guidance and not regulation. The use of the Fixed Limits Table is not binding on either the laboratories or the agencies. VELAP and DEQ believe however that the use of the Fixed Limits Table will benefit the laboratories as well as the agencies by providing reasonable and defensible data by using limits of comparable approved methods (exceptions noted above).

Note that laboratories certified or accredited are still required to record data in such a way that “trends are detectable, and, where practicable, statistical techniques shall be applied to the reviewing of QA/QC results.” [1VAC30-45-750A, NELAC 2003 5.5.9.1]

VELAP encourages laboratories to continue to record and evaluate data using control chart techniques because of the numerous benefits to laboratories to identify bias or trends such that preventive or corrective action can be taken.

**Because guidance documents are not regulation, alternative proposals which satisfy regulatory requirements are considered. If alternative proposals are made, such proposals are reviewed and accepted or denied based on their technical adequacy and compliance with appropriate laws and regulations. Alternative proposals are to be submitted to Lab\_Cert@dgs.virginia.gov. The Department of Environmental Quality, and/or if applicable, the Department of Mines, Minerals, and Energy, will be consulted regarding any alternative proposals.**

**What will be VELAP’s role regarding this guidance?**

During VELAP assessments, assessors will review evaluation criteria used by the laboratory.

When laboratories are performing tests by *Standard Methods* under 40 CFR 136.3 1B, assessors will review the laboratory’s QC acceptance criteria as stated in their SOP(s) and in practice. If the assessors observe instances where the QC limit in the Fixed Limit Table have been exceeded, then more data may be requested during the assessment to evaluate the laboratory performance of a method(s) over a longer period. When the laboratory has shown a pattern or history of not achieving the quality control acceptance limits VELAP will provide this information to DEQ and/or DMME. DEQ and/or DMME will use this information to evaluate whether data reported to support an individual permit is representative of the monitored activity.

**When will VELAP begin its assessments with regard to this guidance?**

On November 1, 2015.

**How does the Fixed Limit Table benefit laboratories?**

- 1) The Fixed Limits Table allows laboratories to use the option in SM 1020 for a fixed limits table, instead of using statistical processes for calculating and maintaining control limits for reporting data in compliance with State Water Control Law (§62.1-44.2).
- 2) For laboratories using statistical measures to calculate their control limits, the Fixed Limits Table provides information to evaluate the laboratory’s own calculated limits to determine whether the method performance is meeting minimum established acceptance criteria as stated in the parallel EPA method for the technology/analyte combination.

- 3) This requirement “evens the playing field” for laboratories regarding the acceptability of data or reporting of results with or without qualification. The concept of an “even playing field” benefits laboratories as follows:
  - a. All laboratories are required to qualify data at the same low or high limit.
  - b. A laboratory with a strong quality system, and with tighter calculated limits than its competitor laboratory, is not required to perform corrective action and qualify data at a more stringent limit than its competitor laboratory.

**How does the Fixed Limit Table benefit DEQ?**

- 1) When all data submitted to DEQ are evaluated by the same evaluation criteria, data are more comparable and the uncertainties are more similar.
- 2) Fixed Limits assure DEQ that data used for compliance purposes in 2015 and beyond will not be of lesser quality than the data produced by previous revisions of these methods over the last two decades.

**If a specific method does not require a QC element, but the element (for example, matrix spike) is listed on the table, is the QC element now required?**

No, the table adds no new requirements regarding QC practices.

**The Fixed Limits Table includes evaluation criteria for duplicates that require evaluating low-level samples separately from high-level samples. Are there any alternatives to this approach for duplicates?**

Yes, DEQ has agreed that a  $\pm 20\%$  Relative Percent Difference (RPD) evaluation criterion for evaluation of duplicates at all concentration levels is an acceptable alternative to the two-tier evaluation of duplicates. This additional option was added to a revision of the Fixed Limits Table on 6/22/2015

**If the table is updated, how will I know? Will I know what changed?**

Should *Standard Methods*, EPA, or DEQ change the fixed limits requirements, VELAP will notify laboratories of the change by e-mail and update the materials on the website accordingly. Current information is located on the VELAP web page at [www.dgs.virginia.gov/dcls](http://www.dgs.virginia.gov/dcls).