

Virginia Division of Consolidated Laboratory Services
ENVIRONMENTAL LABORATORY CERTIFICATION PROGRAM
GUIDANCE DOCUMENT

May 1, 2015 (Revised June 22, 2015)

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

This document is provided as guidance and, as such, sets forth standard operating procedures for the Virginia Environmental Laboratory Accreditation Program (VELAP). 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). This document refers to DEQ as the predominant data user; however the data user may also be DMME.

This guidance document does not mandate or prohibit any particular action not otherwise required or prohibited by law or regulation. If alternative proposals to satisfy regulatory requirements are made, such proposals will be reviewed and accepted or denied based on their technical adequacy and compliance with appropriate laws and regulations.

The U.S. Environmental Protection Agency (EPA) issued revisions to 40 CFR Part 136 in July 2012. This Methods Update Rule (MUR) removed approval of the 18th edition of *Standard Methods for the Examination of Water and Wastewater (Standard Methods)*. The fixed limit table for quality control acceptance criteria published in this edition was not transferred to later editions. *Standard Methods* provides that laboratories generate laboratory-based performance criteria for quality control acceptance of data. These changes have resulted in challenges in evaluating acceptability of testing results for many laboratories.

VELAP provides this guidance to assist laboratories in compliance with these changes. VELAP has worked cooperatively with DEQ to establish minimum QA/QC acceptance criteria (“fixed limits”) for analyses where *Standard Methods* requires laboratory performance-based quality control limits or a fixed limits alternative. (“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) Laboratories will be compliant with VELAP requirements when the quality control evaluation criteria used by the laboratory meets the information provided in the VELAP 40 CFR 136.3 (Table 1B) Fixed Limits Table (hereafter, “Fixed Limits Table”) for the Analyte/Method listing that matches the laboratory’s Field of Certification or Field of Accreditation.

The Fixed Limits Table has been prepared from “equivalent” 40 CFR 136-approved EPA methods (same analyte, same/similar methodology), where available, and from limits formerly published in *Standard Methods* 18th Edition where no “equivalent” approved EPA method is available as a reference for fixed limits. The Fixed Limits Table is available for download on the VELAP web page at www.dgs.virginia.gov/dcls.

For analyses used for compliance purposes where *Standard Methods* requires performance-based quality control limits, the Fixed Limits Table may be used as the acceptance criteria where data must

be qualified and at which corrective action must be taken for failed QA/QC. Alternative proposals (for example, another table of fixed limits, or performance-based quality control limits exceeding those in the Fixed Limits Table) will be reviewed by VELAP in coordination with DEQ and/or DMME and accepted or denied based on their technical adequacy and compliance with appropriate laws and regulations.

Laboratories will be assessed in accordance with information in this guidance document effective November 1, 2015.

Regulations regarding requirements for quality control data to be “recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of QA/QC results” remain in effect and laboratories will continue to be assessed according to these regulatory requirements. [See 1VAC30-45-750A and NELAC 2003 5.5.9.1.] All laboratories are encouraged to continually monitor data for trends as predictors of influences on the laboratory’s quality system which, if not addressed with root cause analysis, can cause future QA/QC failures.

Whenever the accredited method specifies minimum data quality objectives, those quality objectives within the accredited method must be met. This guidance does not impose new requirements or change existing requirements.

Any questions regarding fixed data quality objectives for methods not addressed by the VELAP 40 CFR 136.3 (Table 1B) Fixed Limits Table must be directed to the data user.