Part 136 Method Update Rule
Revisions to Appendix B – MDL Procedure as Applied to Drinking Water

Office of Ground Water and Drinking Water, Technical Support Center
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In the revised Part 136, Appendix B procedure, method detection limits (MDLs) are determined by analyzing seven method blanks (i.e. laboratory reagent blanks, LRBs) along with seven low-level laboratory fortified blanks (LFBs). Laboratories then use the higher MDL calculation derived from either the LRB or LFB replicates. ***From a drinking water perspective, if a laboratory practices good hygiene by keeping their laboratory clean (i.e. sample prep areas, glassware, instrumentation, etc.), the method blanks should never indicate a recurring background as nearly all blank failures would invalidate analytical results. Consequently, the revised procedure should have little to no impact, and MDLs will be calculated in the same way as described in the original MDL procedure used over the last thirty years.*** The question then becomes whether the revised MDL procedure has any significance for the drinking water program. The short answer is "yes," with careful consideration for the following:

1. <u>Specific citations to Part 136, Appendix B in the drinking water regulations.</u> Such citations will require a laboratory to follow the new procedure. There are three such regulatory citations related to the analysis of VOCs and laboratory certification:
   a. For all VOCs, except vinyl chloride. 40 CFR 141.24(f)(17)(i)(E) – "Achieve a method detection limit of 0.0005 mg/L, according to the *procedures in appendix B of part 136."*
   b. For vinyl chloride. 40 CFR 141.24(f)(17)(ii)(C) – "Achieve a method detection limit of 0.0005 mg/L, according to the *procedures in appendix B of part 136."*
   c. For all VOCs. 40 CFR 141.24(f)(20) – "Each certified laboratory must determine the method detection limit (MDL), as defined in *procedures in appendix B to part 136*, at which it is capable of detecting VOCs. The detectable MDL is 0.0005 mg/L. This concentration is the detection concentration for purposes of this section."

   There is also such a citation in the lead and copper rule:
   d. 40 CFR 141.89(a)(1)(iii) – "To obtain certification to conduct analyses for lead and copper…Achieve the method detection limit for lead of 0.001 mg/L according to *procedures in appendix B of part 136* of this title." There is not a similar explicit specification for copper, but it is implied: 40 CFR 141.89(a)(3) – "All lead and copper levels measured between the PQL and MDL must be either reported as measured or they can be reported as one-half the PQL specified for lead and copper in paragraph (a)(1)(ii) of this section. All levels below the lead and copper MDLs must be reported as zero."

2. <u>EPA methods and MDL procedure</u>. A few of the older EPA methods (e.g. 515.1, 548.1, 555) and various methods evaluated through the alternate test procedure (ATP) program and approved for drinking water analysis (e.g. OIA-1677 OW cyanide method) specifically cite the Part 136, Appendix B MDL procedure. Labs using those methods will need to follow the new procedure. Many of the newer EPA drinking water methods, however, either describe the specific steps for the 'old' MDL procedure without referencing Part 136, Appendix B or they reference the 1981 Glaser/Budde paper that was the basis for development of the old MDL procedure. Options for dealing with these methods are:
   a. <u>Apply the new MDL procedure across all methods</u>. From the standpoint of consistency, this would be a logical choice. Laboratories that analyze wastewater samples will be required to

follow the new procedure and it may be simpler to revise all their SOPs to specify the new procedure for both drinking water and wastewater methods. *Do not* penalize a lab if they choose to implement the new MDL procedure even if the drinking water method only describes the old procedure for determining MDLs (provided of course that their method blanks meet the method criteria).

b. Follow methods as written. If Part 136, Appendix B is not cited in a regulation and its associated methods, and a method contains the steps for determining MDL following the old procedure, it becomes a judgement call. Just be consistent in applying such judgement across the region.

3. Standard Methods. Similar issue as the EPA methods discussed above. Rather than incorporating QC within each method which would result in a massive unwieldy book, Standard Methods consolidates the common QC requirements within specific sections (e.g., Sect. 4020 contains the QC that pertains to the Part 4000 methods). ***The separate QC section is considered an intrinsic part of each method***. In the 22nd edition of *Standard Methods for the Examination of Water and Wastewater*, the QC section references the MDL Revision 1.11 in Part 136. That's the 'old' MDL determination. But the recently published 23rd edition incorporates the requirements of the 'new' MDL procedure (the editors apparently had anticipated publication of the CWA methods update rule prior to publication of the 23rd edition). We will be reviewing the methods within the 23rd edition for subsequent approval in a *Federal Register* notice at a later time. So, again, a laboratory may choose to apply the new MDL procedure across all methods or use the old procedure as described in the older editions.

The following represent some highlights from the new procedure:

1. Read the revised procedure and especially the frequently asked questions (FAQs) on the CWA webpage at:
   https://www.epa.gov/cwa-methods/method-detection-limit-frequent-questions.

2. The value calculated from the seven low-level LFBs is called the MDL_s. The MDL_s is the same as the 'old' MDL. The seven method blanks are used to calculate the MDL_b, which involves a similar evaluation of contamination/noise associated with the measurement. The final MDL is the higher of the two values. ***From the standpoint of conducting drinking water analyses, the MDL_b should not be the higher value***. If it is, that's a sure sign the lab needs to take corrective action.

3. The new procedure requires that the LFBs used to calculate the MDL are representative of laboratory performance throughout the year, rather than determined from a single analysis batch. Thus, the laboratory needs to analyze at least seven low-level LFBs and seven LRBs for an instrument in a two-year period (spread over at least three batches), but there is also a requirement to analyze two LFBs per quarter in separate batches for any quarter in which samples are analyzed. There are several nuances to this; read the FAQs.

Under Part 136, laboratories have the option to pool data from multiple instruments to calculate one MDL that represents multiple similar instruments. That is not considered a reasonable option for drinking water:

1. Chapter IV, Sect. 7.2.9 (Initial Demonstration of Capability) in the Laboratory Certification Manual states: "Before beginning the analysis of compliance samples, an initial demonstration of capability (IDC) must be performed for each method as required by the method. The IDC includes a demonstration of the ability to achieve a low background, the precision and accuracy required by the method, and determination of the method detection limit (MDL). ***An IDC should be performed***

for each instrument." This specification of determining the MDL per method and per instrument precludes the option of determining a multi-instrument MDL for instruments that will be used to analyze drinking water compliance samples.

2. For some drinking water contaminants, e.g. the SOCs identified in 40 CFR 141.24(h)(18), qualification for reduced monitoring is based on specified low threshold levels. In order for a laboratory to meet those low levels, they will need to optimize *lower* detection levels. Pooling data from multiple instruments will have the net effect of increasing variability, resulting in *higher* calculated MDL values.

As discussed in the FAQs on the CWA web page, while the rule becomes effective 30 days after publication in the *Federal Register*, "EPA recognizes that it is not possible for any laboratory to make this change instantaneously. The laboratory should comply with the requirements of its control authority or permitting authority to implement Revision 2 of the MDL procedure." No one needs to start from scratch, cease operations and conduct new MDL studies. The revised procedure is structured to allow labs to use existing batch LRBs and low-level LFBs to calculate their initial MDL under the new procedure.