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EPAs New MDL Procedure
What it Means, Why it Works, and How to Comply

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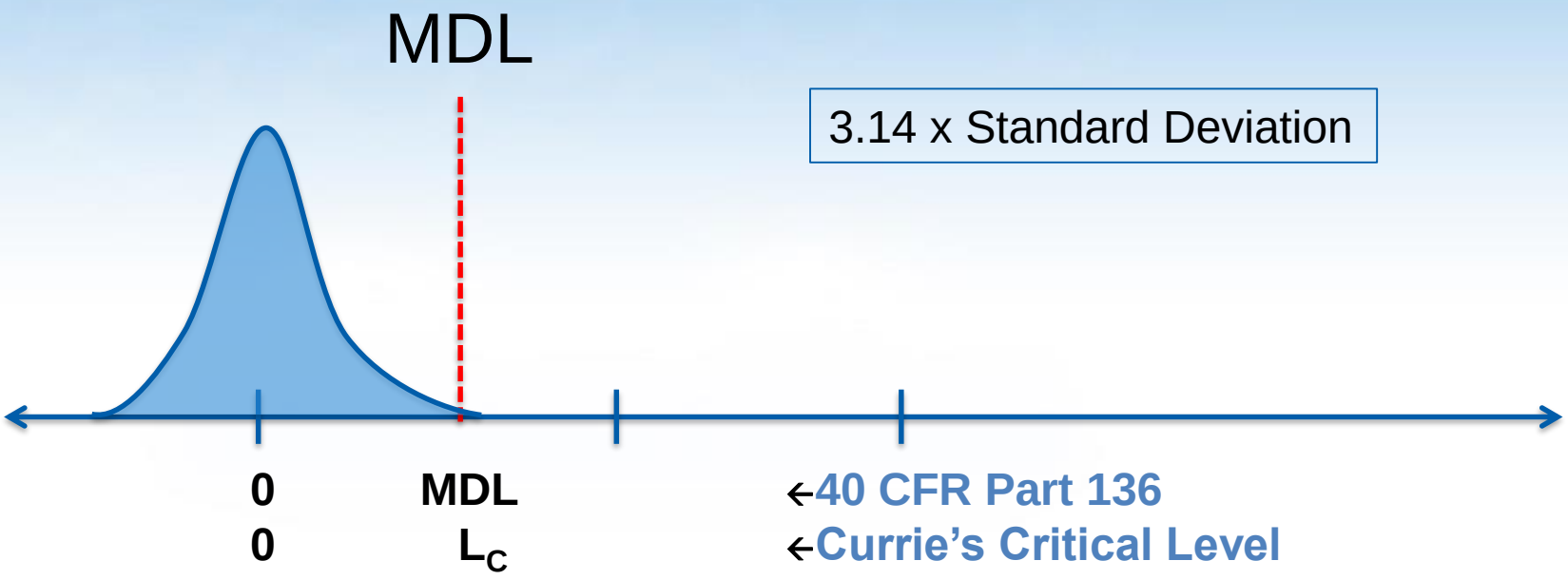
What is the MDL?

MDL

MDL The method detection limit (MDL) is defined as the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results



What the MDL is (and is not):

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MDL = Lowest result that can be distinguished from blanks

Or, lowest result that means there is actually something in the sample

MDL ≠ Lowest amount in a sample that can be reliably detected

What does this mean regarding verification?

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- MDL **can** be verified by examining blank results
- MDL **cannot** be verified with spiked samples
  - (Curries L_D could be verified with spiked samples)

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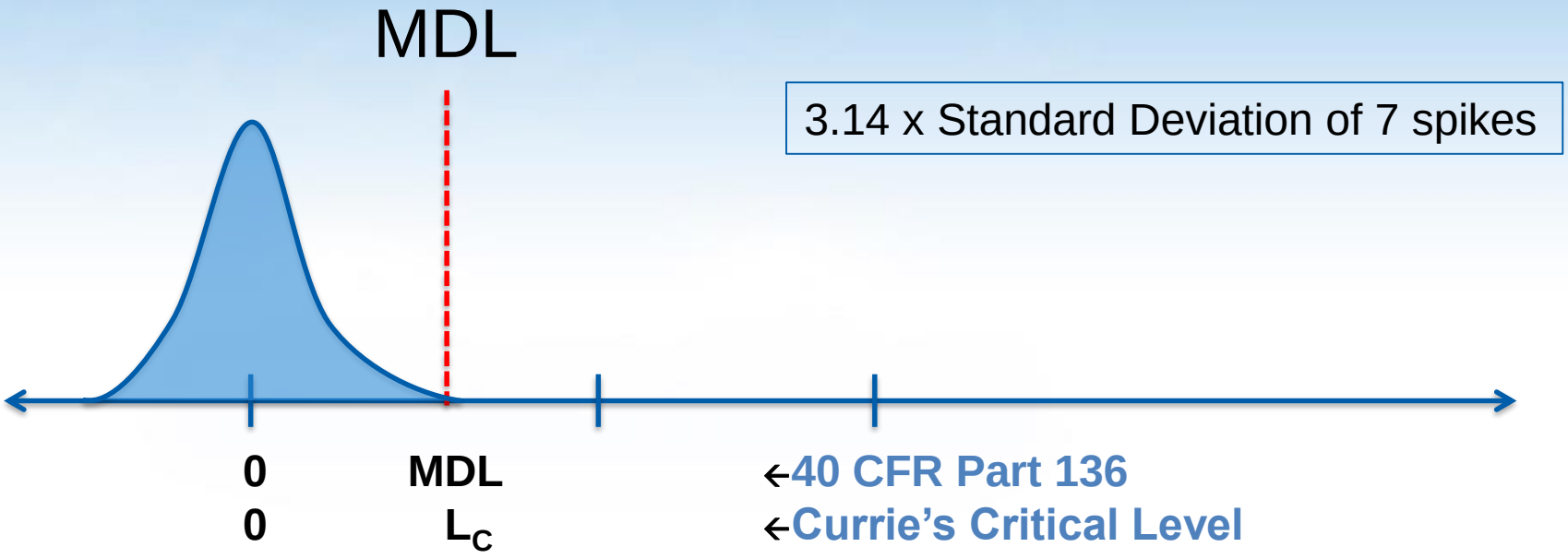
Problems with the Current MDL

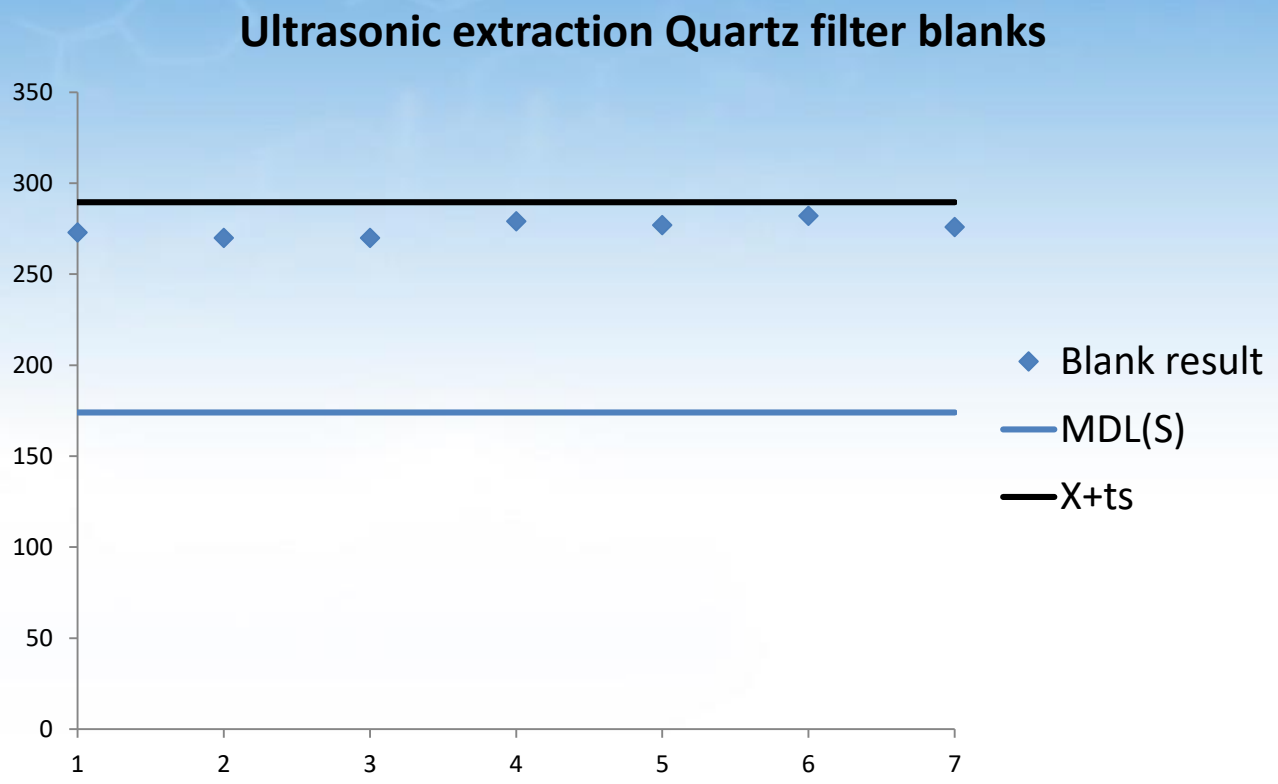
Blank bias

Current MDL assumes blank results are centered around zero

If blanks are not centered around zero, then the MDL will be too low and many false positives will result



Lead in Particulate Matter



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Details of the Modifications

First, what stays the same?

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- Fundamental concept is unchanged
  - What is the lowest result that is qualitatively reliable, i.e., the lowest result that reliably indicates the analyte is in the sample?
- Fundamental approach is unchanged
  - Describe the distribution as Student's t times the standard deviation of results

What is different?

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- Requires calculation of a MDL based on blanks as well as a MDL based on spikes (the higher of the two becomes the MDL)
- Incorporates longer term variance
- Includes checks for reasonableness
- Works effectively with various quantitation limit concepts and procedures

Details, details

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- Spiking level
  - 2-10 times estimated MDL
- Run spiked replicates in at least 3 separate preparation and analysis batches
- Multiple instruments
  - At least 2 spike replicates on each instrument
- If blanks give ND, MDL_B does not apply
- Addendum for MDL determined on a specific matrix
- No 10X rule
- Use all method blanks unless batch was rejected

How the modifications improve the procedure

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- Sensible MDLs when there is blank bias
  - **1980 Lead in tuna** results overstated by 1000X due to blank contamination
  - **2004 EPA Episode 6000 data** Chromium by ICPMS, 1400% recovery at the MDL and 600% recovery at the ML due to blank bias
  - **2013 Multi-lab blank** detection rates
    - ~ 8270 SIM 6.4%
    - ~ 8021B 16%
    - ~ ICPMS 8%
  - **2014 Lead in particulate matter**
    - ~ All blanks in the validation study exceeded the MDL

This problem is getting worse because of the need for low level data and increasing sensitivity of instrumentation

How the modifications improve the procedure

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- Long term vs. short term bias
  - The difference varies from method to method and lab to lab, but can be large
  - Long term bias is what matters when it comes to the MDL
- Ongoing verification
- Very consistent with EPA office of Water MRL, EPA ORCR LLOQ and the proposed TNI LOQ

What do we expect from a LOQ?

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Known precision? 

Known accuracy? 

Ability to detect and report? 

- Freedom from false negatives? 

Freedom from False positives? 

What do we expect from a MDL?

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Freedom from false positives (99%)? 

Known accuracy? 

Ability to detect and report? 

Freedom from false negatives? 

How much will MDLs change?

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- Analytes with minimal or no detects in blanks, eg most GC/MS analytes at normal levels:

Not Much

- Analytes with frequent detects in blanks, eg, metals, very low level PAH, some general chemistry tests:

Depends

  - If the lab is currently adjusting MDLs to avoid excessive false positives, not much
  - If the lab has been pushing MDLs below levels justified by the blanks, potentially quite a bit

Frequently asked Questions

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https://www.epa.gov/cwa-methods/method-detection-limit-frequent-questions

Three significant changes:

1. Use of blanks
2. Uses data gathered throughout the year
3. Option to pool data from multiple instruments

Frequently asked Questions

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Are more samples needed?

Old procedure

7 spiked samples per year

Zero blanks samples

New procedure

8 spiked samples per year (2 per quarter)

Zero additional blanks (use routine method blanks)

Frequently asked Questions

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- Is the lab required to recalculate the MDL every quarter?
  - No, spiked samples are analyzed every quarter, MDL is recalculated once per year
- If the lab does not use a method during a quarter will the laboratory still need to analyze low level spikes samples?
  - No, the minimum requirement is 7 spikes samples and 7 method blanks over a 2 year period

Frequently asked Questions

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- Could a high blank drastically elevate the MDL?
  - Depends – a method blank can be ignored if it is associated with an instance of gross failure. If the samples associated with a bad method blank are not used (i.e. are rejected) then the blank need not be included.
- A lab might have hundreds or even thousands of blanks over a two year period
  - Which is fine – however there is an option to use the most recent 50 blanks or last six months of data, whichever yields the greater number of blanks.

Frequently asked Questions

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Many more answers at:

https://www.epa.gov/cwa-methods/method-detection-limit-frequent-questions

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Questions?