THE METHOD DETECTION LIMIT: FACT OR FANTASY?

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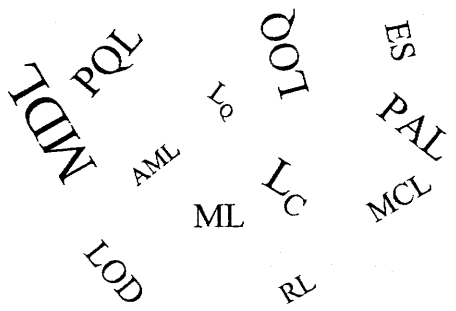

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MDL

- The minimum concentration of an analyte that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix type containing the analyte.

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MDL

- If the true concentration is zero, then a false positive at or above the MDL level should be obtained in 1% of determinations
- If the true concentration is at the MDL, then a concentration greater than the MDL should be determined 50% of the time and a concentration less than the MDL 50% of the time. (Assuming 100% recovery)

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DRIVERS TOWARDS LOW MDLs

- Regulatory limits
- Used to judge "quality" of lab
- Method and QAP MDLs

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RESULTS OF DRIVERS

- Labs committing to unrealistic reporting limits.
- Databases contaminated with false positives and negatives
- Estimated values(J) and None Detects(ND) have lost meaning on real world samples

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PURPOSE OF MDLs

- Definitely not to create the Drivers
- Ascertain the reproducible level of detection of the method
- Evaluate the various matrices for the level of detection

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WHY FANTASYLAND?

- Data users (Risk Assessors) are causing the Drivers
- Desire for more Confidence in the MDL
- Purpose of MDLs being ignored
- Instead of changing the Methods to get better MDLs we select unrealistic items to achieve a lower MDL.

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MDL DETERMINATIONS AND ROUTINE ANALYSIS

Instrument specific MDL	*Routine sample analysis*
Analyst knows which analytes are present and what the concentrations are expected.	*Analyst does not know which analytes/ concentrations may be present*
Reagent water or a solid matrix that generates no interferences is used.	*Matrix generates varied and unpredictable interferences*

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MDL DETERMINATIONS AND ROUTINE ANALYSIS

Instrument specific MDL	Routine sample analysis
Test is generally performed on an instrument in pristine condition.	Test is performed on an instrument that meets routine calibration criteria, and may have been affected by previous samples.
Test is performed on a single instrument	Tests are performed on multiple instruments.
Test is repeated if analyte is not detected or has poor recovery or excessive variability.	Test is not repeated if QC criteria are met.

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INCREASING CONFIDENCE IN MDLs?

- Analyst specific MDLs?
- Instrument specific MDLs?
- Multiple iterations?
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Generally reduce variability and therefore the MDL

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INSTRUMENT SPECIFIC MDLs

- Shows that each instrument can meet a certain detectability level?
- Increases confidence that the lab is not "hiding" a poor instrument?
- Minimize variation, MDLs

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POSSIBLE MDL COMBINATIONS

- BTEX Compounds = 5
- Number of dual column GCs = 6
- Number of MDLs = 5 * 6 * 2 = 60
- Number of possible MDL combinations = 12^5 = 248,832

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POSSIBLE MDL COMBINATIONS

- 8270 Compounds = 85
- Number of GC/MS = 4
- Number of MDLs = 85 * 4 = 340
- Number of possible MDL combinations = 4^{85} = 1.49E+51

Since the complexity is too great for data management systems, generally the "worst case" MDL is used

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INSTRUMENT AND ANALYST SPECIFIC MDLs

- If the SOP is followed, MDL should be analyst independent
- MDL is a snapshot - different analysts and instruments will have different MDLs on different days.
- Ongoing QC should demonstrate that instrument can meet required level of detection

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REAL VS. FANTASY MDLs

1,1,1-Trichloroethane			
	Published MDL	Interlab MDL	Mult.
502.2	0.03, 0.01	8.96	299, 896
524.2	0.08	6.35	79

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REAL VS. FANTASY MDLs

Aroclor 1016 / 1242			
	Published MDL	Interlab MDL	Mult.
608	0.065	0.98	15

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REAL VS. FANTASY MDLs

1,1,1-Trichloroethane			
	Published MDL	Quanterra MDLs	Quanterra WS-037 MDL
524.2	0.08	0.05-0.10	2.68

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OPTION 1 - USE LOW LEVEL CALIBRATION STANDARDS

- Collect seven replicate low level standard results for each instrument
- Calculate IDLs for each instrument
- Perform the MDL study on the worst case instrument

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USE LOW LEVEL CALIBRATION STANDARDS

- Pros
  - Uses existing data that demonstrates instrument performance over extended period of time
  - Demonstrates that each instrument can meet the MDL
- Cons
  - Still a "fantasy " MDL

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OPTION 2 - PERFORM THE MDL REPLICATES ACROSS ALL INSTRUMENTS

- Pros
  - Demonstrates that all instruments detect the analyte at the MDL spike level
  - Increases variability, thereby increasing MDL, bringing MDL closer to real world situation
- Cons
  - Still far removed from routine sample analysis experiment

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OPTION 3 - USE MULTI LAB PERFORMANCE EVALUATION DATA

- Pros
  - Much closer to real world routine analysis experiment
- Cons
  - MDLs will be higher than many regulatory compliance levels

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SUMMARY

- Current procedures for determining MDLs do not reflect the routine sample analysis experiment and result in MDLs that are much too low.
- Efforts to increase confidence in MDLs by making them analyst or instrument specific only exacerbate the situation, since the MDLs will be even lower.

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SUMMARY

- Let's travel back to reality and concentrate on the purpose of MDLs
  - Encourage industry to improve on the methods to lower MDLs
  - Run MDLS on site specific matrix samples
  - Educate all on the risk of the Fantasy approach to MDLS

ACKNOWLEDGMENTS AND REFERENCES

- 40 CFR Part 136 Appendix B
- Routine QC Standards Used as a Guide to Conducting MDL Studies, Larry Penfold, Quanterra Inc., In Preparation
- Availability, Adequacy, and Comparability of Testing Procedures for the Analysis of Pollutants Established Under Section 304(h) of the Federal Water Pollution Control Act, EPA/600/9-87/030