THE METHOD DETECTION LIMIT: FACT OR FANTASY?

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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.

DRIVERS TOWARDS LOW MDLs

• Regulatory limits
• Used to judge “quality” of lab
• Method and QAP MDLs

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

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
**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.

**MDL DETERMINATIONS AND ROUTINE ANALYSIS**

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

**INCREASING CONFIDENCE IN MDLs?**

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

**POSSIBLE MDL COMBINATIONS**

- 8270 Compounds = 85
- Number of GC/MS = 4
- Number of MDLs = $85 \times 4 = 340$
- 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

**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
REAL VS. FANTASY MDLs

<table>
<thead>
<tr>
<th>1,1,1-Trichloroethane</th>
<th>Published MDL</th>
<th>Interlab MDL</th>
<th>Mult.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aroclor 1016 / 1242</td>
<td>608</td>
<td>0.065</td>
<td>15</td>
</tr>
<tr>
<td>1,1,1-Trichloroethane</td>
<td>502.2</td>
<td>0.03, 0.01</td>
<td>896</td>
</tr>
<tr>
<td></td>
<td>524.2</td>
<td>0.08</td>
<td>79</td>
</tr>
</tbody>
</table>

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REAL VS. FANTASY MDLs

<table>
<thead>
<tr>
<th>1,1,1-Trichloroethane</th>
<th>Published MDL</th>
<th>Quanterra MDLs</th>
<th>Quanterra WS-037 MDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aroclor 1016 / 1242</td>
<td>524.2</td>
<td>0.08</td>
<td>2.68</td>
</tr>
<tr>
<td>1,1,1-Trichloroethane</td>
<td>524.2</td>
<td>0.05-0.10</td>
<td></td>
</tr>
</tbody>
</table>

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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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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.
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(b) of the Federal Water Pollution Control Act, EPA/600/9-87/030