TNI Board of Directors Meeting Summary
April 8, 2015

1. Roll Call

Directors	Present
Jordan Adelson	X
Aaren Alger	X
Steve Arms	X
Justin Brown	
Scot Cocanour	X
George Detsis	
Zonetta English	X
Jack Farrell	X
Keith Greenaway	---
Myron Gunsalus	X
Sharon Mertens	X
Judy Morgan	X
Lara Phelps	X
Patsy Root	X
Scott Siders	X
Alfredo Sotomayor	X
Dave Speis	X
Elizabeth Turner	X
Staff	
Lynn Bradley	X
Carol Batterton	X
Ken Jackson	X
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

2. 2015 Officer Election

The Officers shall be a Chair, Past-Chair, Vice-Chair, Secretary and Treasurer. Other Officers may be established by the Board of Directors. The Officers, with exception of the Past-Chair, shall be elected annually at the first meeting of the newly elected Board of Directors, from among its members

Turn meeting over to Steve Arms – Past Chair and Nominations Committee Chairperson for officer elections:

Chair: Sharon Mertens
Vice-Chair: Aaren Alger
Secretary: Alfredo Sotomayor
Treasurer: Dave Speis

Motion to accept slate as presented – Lara Phelps
Second – Judy Morgan
Approved – Unanimous

3. Approval of March 2015 Minutes

Changes: Change title to Summary instead of Agenda.

Motion to Approve: Myron Gunsalus
Second: Judy Morgan
Approved: Unanimous

Lara made some comments from the EPA about the MUR for the BOD's benefit. This was also discussed during Advocacy Meeting last week. Going forward Lara will recuse herself from any discussion

Regarding sending comments back to the EPA: The EPA puts documents in the federal registry and makes them available for comments to truly get comments and understand when something is creating a problem for their stakeholders. It is more than appropriate for our community and organization to provide those comments about something that is potentially going to impact our stakeholders in any way. Also, as we share our comments with our stakeholders so they can share them forward, this is looked upon favorably. What needs to be thought about is how those comments are transmitted. It's okay to make the same comments, but consider making each cover letter to make it unique. Make it known that we are on board with a set of changes that are going to be made. This will benefit our organization just like it would benefit another organization. Lara is encouraging TNI to do what we think is best for representing our stakeholders.

4. 2016 Board Election

A total of 37 votes were cast. And while every candidate was overwhelmingly elected, there were some disturbing trends. As many as 5 negative votes were cast for some candidates, and it could have been very easy for a small group of individuals to overturn the recommended slate. Write-in votes were cast for individuals not eligible to serve on the Board and at least one individual who is not qualified. The TNI Executive Committee met on April 3 and is proposing the Board consider an action to improve this process, and that would be to move the election back into the January-February timeframe to allow voting to occur during the winter meeting. The Committee even considered a "meet the candidates" session. All voting would still be done electronically, but a computer could be provided to allow those at the meeting to cast their vote while they were there. The table below shows how the timeline would change.

Election Timeline	**2015**	**2016**
Announcement of election process		November 15
Deadline for submission of application by potential candidates.	March 2	January 2
Based upon a review of applications, the Nominating Committee develops a slate of candidates	March 16	January 16
The slate is officially announced on the TNI website.	March 23	January 23
Deadline for election.	April 1	March 1
Newly elected Directors assume office.	April 8	March 9

Note: The timeline that has been used by TNI since 2007 was based on the fact that the interim board created in November 2006 was charged to act on behalf of TNI until an election would occur after the first meeting of the new organization. That meeting was in Denver in late January 2007.

Historically, there has been a low turnout for voting. It may be a good idea to move the timeframe back from March, to the time of the winter meeting, as a way to stimulate more votes. This does not require a change to the Bylaws.

Motion to Move the Board election timing back to coincide with the winter conference:

Motion: Steve Arms
Second: Dave Speis
Approved: Unanimous

In the future we will have a larger discussion about the voting process and some potential new ideas such as "Meet the Candidates" sessions.

5. 2014 Financial Statement and 2015 Proposed Budget (Attachment 1)

2014 financials and 2015 budget information was reviewed. A summary table and charts are provided in Attachment 1.

Motion to approve the 2015 budget: Patsy Root
Second: Jack Farrell
Approved: Approved
Abstentions: Jordan Adelson

6. SOP 2-100

On the recommendation of the Policy Committee, minor revisions were made to SOP 2-100 (Procedures Governing Standards Development). These changes were agreed by the Consensus Standards Development Executive Committee, and the SOP was returned to the Policy Committee. Following its sign-off by the Policy Committee and endorsement by the Board, the SOP will be submitted to ANSI for approval. When accepted by ANSI, this will complete all aspects of the recent audit of the standards development program.

Note: This is a very complex SOP that has been through extensive review and is being provided to the Board for informational purposes. The Board retains the right to conduct its own review.

This SOP provides more flexibility (more routes to getting approval) and allows for more work to be done upfront before the committees even put a standard to a vote. Such standards will go directly to a VDS. With approval, this SOP is ready to go to ANSI – Ken will take care of this.

Motion to Approve SOP 2-100: Scot Cocanour
Second: Judy Morgan
Approved: Unanimous

7. Method Update Rule (Attachments 2 & 3)

From the March 2015 minutes:

The MDL procedure was developed by TNI's Chemistry committee. The Advocacy Committee is recommending TNI provide comments on this rule, in particular the proposed MDL procedure.

Encourage the Board to that TNI should send in comments, in particular on the MDL procedure. Jerry is working on a document that has his thoughts. The changes to part 136 is all correcting technical errors and adding clarification and updating method versions so there's no problem with that. And the Chemistry Committee developed the MDL procedure so we should support that.

What will be controversial are the three methods – maybe TNI should stay out of this since our mission is not to establish methods. Technology is great in the new methods, but they've imposed a lot of QC requirements and the stipulation that if you fail any QC, you cannot report data, including MSMSD's. We have the laboratory community, ACIL, WET, ELAB, etc. to argue those points.

Should our EC or Exec committees be looking at this document for conflicts with our Standard (PT-type stuff)? Is there something that we're going to need to think about doing to support this when this goes through, or do we wait until it's finalized? Comments are due April 20. Important that we alert our committee chairs to take a close look at this and encourage them to comment individually.

Suggestion: Try to get our comments out early enough so other organizations can use them as a sort of template. Being a leader and encouraging others to respond.

We will develop some substantive comments on the MDL procedure that we can share with people, and also revisit the comments we submitted in 2010 on the mandatory quality control in 136.7 and consider resending those. We can draft and share these with people before the next Board call and then decide if we want to send them in.

Jerry will work on comments on the methods as a Catalyst Information Resources effort. See Attachments 1 and 2. Areas where TNI might provide comments on the 600 series methods are highlighted in yellow.

We would like a few people to review the draft comments: Judy Morgan, Zonetta English, Scott Siders, Alfredo Sotomayor. Jerry needs feedback early next week – Tuesday, the 14th.

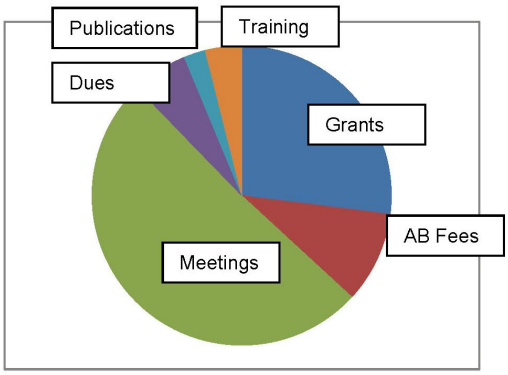
We will contact the Chemistry Committee and make sure any MDL comments come through TNI and include ELAB as well. Comments will be posted on the website asap, and will be in the newsletter next week.

8. Program Reports (Attachment 4)

Attachment 1
2014 Financial Summary

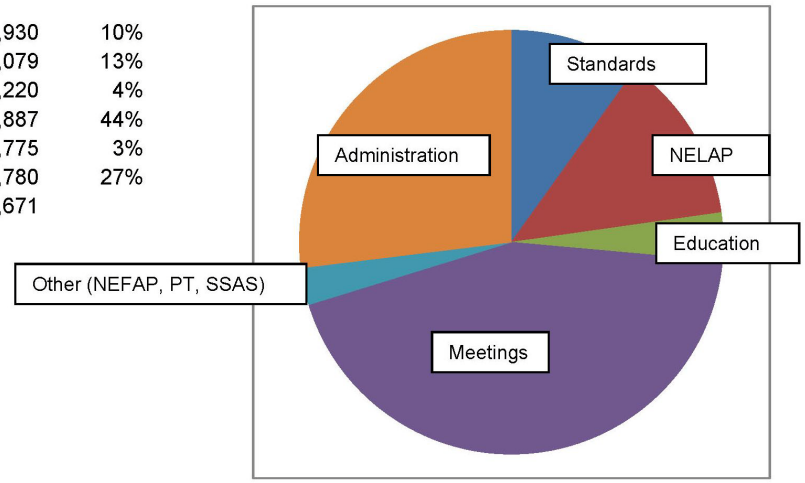
Table 4. 2014 SUMMARY

INCOME		
Grants	$268,297	31%
AB Fees	$98,066	11%
Meetings	$505,908	59%
Dues	$59,680	7%
Publications	$23,225	3%
Training	$38,999	5%
Total	$855,469	



EXPENSE

Consensus Standards	$86,930	10%
NELAP	$113,079	13%
Education	$32,220	4%
Meetings	$384,887	44%
Other (NEFAP, PT, SSAS)	$24,775	3%
Administration	$236,780	27%
Total Expenses	$878,671	



Attachment 2
Draft Comments on the 2015 Methods Update Rule
Courtesy of Catalyst Information Resources

Changes to Sections 136.2 through 136.6 are all good except for a few minor typographical errors and some document control issues.

Comment 1. Footnote 52

Recommendation: The citation to 300.1 (1997) should be changed to 300.1, Rev 1 (1999). The cover page to 300.1, Rev 1 should be changed and the text in the errata sheet incorporated into the method. This method should be posted on the OST website.

Discussion: Footnote 52 was proposed to be added. This footnote vaguely mentions 300.1-1 and then states "EPA Method 300.1 is Revision 1.0, 1997, including errata cover sheet April 27, 1999." Method 300-1, which was not in the docket or the OST website) is an exact copy of Method 300.1, Revision 1 published in 1997, except for the addition of the word 300.1-1 on the cover page and an errata sheet dated 1999 that appears as the second page. This errata contains minor changes to sections 4.1.1, 11.9, 9.3.2.2, 9.4.1.5, 9.4.3.2 and 9.4.3.3, which have all been made to the method. Thus, this method is not Revision 1 to Method 300.1. It is revision 1.1.

Comment 2. Table 1C, methods for analytes 35, 36, and 37 (dichlorobenzenes)

Recommendation: The approved EPA methods for these three analytes should be Methods 601, 602, and 624.1

Discussion: Table 1C shows Method 625.1 approved for 1,2-dichlorobenzene. This should be 624.1. The 2007 MUR removed Method 625 for dichlorobenzenes stating "significant losses of these volatiles can occur using the prescribed sample collection procedures in the LLE methods, resulting in relatively low recovery of these compounds" If this is true, 1625 should be not allowed either since the same analyte loss during storage could occur.

Comment 3. Errata Sheet for WET Methods

Recommendation: EPA should revise the Whole Effluent Toxicity methods manuals to reflect changes in two errata sheets.

Discussion: There are now two errata sheets associated with the Whole Effluent Toxicity Methods. One was referenced in the 2007 Method Update Rule and the second one in this proposed rule. Neither Table 1A nor the list of references in the text following Table 1H indicate the existence of these errata sheets. Laboratories who do not read the preamble would not know of the existences of this second errata sheet. These changes need to be incorporated into the methods. In the interim, the two errata sheets should be readily accessible of the OST website and footnotes 26, 27 and 28 to Table !A should be revised to show that these errata sheets are part of the referenced methods.

Comments on Methods 608.3, 624.1 and 625.1

General Comments
The technical aspects of these methods represent a great improvement over the current methods. There is much more flexibility in the application of the methods to allow laboratories to take advantage of advancements in technology. The removal of specific procedural details help ensure laboratories can adjust the methods to fit their specific needs. The division of analytes into two groups, a default list that is used for Quality Control purposes in lack of other specific guidance and an expanded list of additional analytes that may be measured is also useful.

The specific comments below are focused on these areas:

- Ensure these methods are somewhat comparable to similar methods to allow laboratories to meet the challenges of analyzing samples using different methods using one Standard Operating Procedure
- Correct inconsistencies among the three methods
- Correct technical errors

MDLs and MLs
All three methods contain Method Detection Limits (MDLs) and Minimum Levels (MLs) for most of the default analytes, but not all. The MDLs are those published in the earlier versions of these methods, or in the case on Method 608.3, a comparable method. The MLs are the MDL multiplied by three.

Because the published MDLS were calculated using a procedure that is widely known to misrepresent the actual MDL that is achievable, these MDLs should be shown as guidance only and there should be no requirement for a laboratory to obtain MDLs that are at or below these numbers. Furthermore, since the ML is a simple multiplication of a number that may not be realistic, then this number may not be realistic as well. For example, the MLs for two compounds that are isomers of each other, anthracene and phenathrene are shown as 5.7 and 16.2 ug/L, differing by almost a factor of 3.

The MLs as published will create many logistical issues for laboratories in trying to customize calibration standards that are at or below these widely varying MLs because of the requirement that the low point of the calibration standard be at or below the ML. Because these MDL and ML values do not represent typical laboratory performance, they can be provided as guidance as to what is the expected sensitivity of the method but should not be used to set the low end of the calibration curve. Laboratories should not be required to achieve these levels.

Expanded Analyte Lists
The concept of having a default list of analytes, and then an expanded list is good. However, caution must be exercised to ensure the expanded lists are appropriate. For example, Table 2 in Method 624.1 list methanol as an analyte. Methanol is used as the primary reagent in this method because under the normal conditions of the method, this analyte is not detectable. Another example is phthalic anhydride in Method 625.1. This compound decomposes in water to phthalic acid, and thus would never be measurable. Most of the analytes in these expanded tables have no published method performance data. If the Agency is to list an analyte in one of these tables, it should have some data to indicate the method is in fact capable of measuring the analyte.

Standards
There are inconsistencies in the section on standards in terms of storage, traceability, and replacement. The table below highlights these differences.

608.3	624.1	625.1
Store neat standards or single analyte standards in the dark at -20 to -10 °C. Store multi-analyte standards at 4°C or per manufacturer's recommendations.	Store standard solutions at - 10 to -20°C, protected from light, in fluoropolymer-sealed glass containers with minimal headspace.	Store at <6 °C and protect from light.
Place a mark on the vial at the level of the solution so that solvent evaporation loss can be detected.		Check frequently for degradation or evaporation, especially just prior to preparing calibration standards from them.
Stock standard solutions must be replaced after 12 months or sooner if comparison with quality control check standards indicates a change in concentration.	Replace after one month, or sooner if the concentration changes by more than 10 percent.	Replace purchased certified stock standard solutions per the expiration date. Replace stock standard solutions after one year, or sooner if comparison with QC check samples indicates a problem.
Analyze all standard solutions within 48 hours of preparation. Replace purchased certified stock standard solutions per the expiration date. Replace stock standard solutions		

prepared by the laboratory or mixed with purchased solutions after one year, or sooner		

The differences appear to be arbitrary and these sections in the methods need to be revised for more consistency.

Second Source Standards

Second source standards are used in many methods for organics and their primary purpose has always been to verify the identification and purity of the primary standard.[1] Method 608.3 uses a second source standard for this purpose. It is defined in the Reagents section of the method and used to verify the initial calibration. Methods 624.1 and 625.1 do not take this approach. Second source standard is not defined or listed in the Reagents section of each method, and rather than using this standard to verify the initial calibration, it is later equated with a laboratory control sample (Method 624.1) or a calibration check standard (Method 625.1) and is not used to verify the initial calibration, but instead is used as a daily calibration check. This is not the intent of a second source standard. Additional error can be brought into the analytical system because it is a different source and the calibration standards were prepared independently. These methods need to differentiate between a second source calibration check and a daily calibration check.

Instrument Calibration

The initial instrument calibration for Methods 624.1 and 625.1 reflect the best practices in use today, a minimum of 5 calibration points (6 for quadratic) and if a curve is used, then it must be inversely weighted to concentration. Method 608.3 requires a minimum of 3 points but recommends 5. This should be changed to 5 for consistency. The methods then have RSD limits to be used to determine if an average response fact can be used. If these limits are not achieved, calibration curves may be used with the measure of fit using either relative standard error or correlation coefficient. For 35 years, this community has known the correlation coefficient is not a good statistic to be used for evaluating instrument calibrations.[2] As stated in the reference:

> One practice which should be discouraged is the use of the correlation coefficient (r) as a means of evaluating goodness of fit of linear models. Thorough statistical analysis of analytical calibration data should be used to provide optimal evaluation of results. The correlation coefficient is not an effective statistic for this purpose.

The initial calibration is to be verified each day by a calibration check standard. (This should not be called a Laboratory Control Sample in Method 624.1 to avoid confusion with that commonly used term.) The acceptance limits for this QC check are found in the QC Acceptance Criteria tables in the methods (608.3 - Table 4; 624.1 – Table 7; 625.1 – Table 6). These tables include all sample processing steps and in general, are way too lenient to be used for a calibration verification check. For example, the acceptance limits for benzo(ghi)perylene in Method 625.1 is 19-195%; the limits for chloromethane in Method 624.1 is D (for detected) to 205%. Using limits such as these will greatly increase the laboratory error and greatly increase the probability the laboratory will be able to achieve expected performance for QC samples.

Note: Method 608.3 is poorly organized, with part of the discussion of this QC check occurring in the Calibration section (Section 7) and part occurring in the System and Laboratory Performance section (Section 14).

These methods should be rewritten to establish a fixed QC limit for this calibration check, e.g., 30%, but with an allowance for corrective action and limited data reporting as described in the National Environmental Laboratory accreditation Program (NELAP) laboratory accreditation standard and repeated below.

> If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, corrective actions must be performed. If documented routine corrective action procedures are followed immediately with a calibration verification that is within acceptance criteria, analysis may proceed. If that calibration verification analysis is not within acceptance criteria the laboratory shall demonstrate acceptable performance, after additional corrective action measures, with two consecutive calibration verifications, or a new initial instrument calibration. If samples are

analyzed using a system on which the calibration has not yet been verified, the results shall be qualified. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

i. when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

ii. when the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Quality Control

All three methods have an appropriate level of Quality Control (QC) checks embedded in the methods, and as discussed in more detail below, there are only a few minor issues related to these QC checks that need to be addressed. However, fundamental to this discussion is a new concept that is not contained in Part 136 and has never been subjected to public comment. This phrase "Results from tests performed with an analytical system that is not in control (i.e., that does not meet acceptance criteria for all of QC tests in this method) must not be reported or otherwise used for permitting or regulatory compliance purposes, but do not relieve a discharger or permittee of reporting timely results." This statement would ensure these methods are never selected since alternative methods exist for all analytes that do not carry this very stringent clause. This statement also supercede other language elsewhere in the existing proposed method in the QC section.

If the Agency truly believes all QC checks must always be met, then this language should be added to Part 136 and subjected to public review and comment. Such a requirement would be impossible to achieve for many reasons, and would greatly lead to laboratory fraud if implemented.
The specific recommendations below on each QC check recognize that sometimes all a laboratory can legitimately do is report the sample results along with the QC results and let the regulated entity and permitting authority determine the appropriate course of action.

Demonstration of Capability
The earlier versions of these methods indicated this test was to be per analyst. This has now been changed to laboratory. The current accepted industry practice, and a requirement for laboratory accreditation under NELAP, is per analyst. To be in harmony with many other methods, current practice and NELAP, the DOC should be per analyst. The inclusion of an MDL study as part of this DOC is appropriate and consistent with current industry practice and a requirement in NELAP. However, to require laboratories to meet MDLs published in these methods that may or may not reflect the true MDL is inappropriate. The Agency should either conduct new MDL studies using these revised methods with the new MDL procedure, or drop the requirement to achieve the published MDLs. The DOC should be verified on an annual basis. The NELAP standard allows flexibility in meeting this requirement:

> The laboratory shall have a documented procedure describing ongoing DOC that includes procedures for how the laboratory will identify data associated with ongoing DOCs. The analyst(s) shall demonstrate on-going capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an Initial DOC shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.
>
> This on-going demonstration may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst) or successful analysis of a blind performance sample on a similar method using the same technology;

b) another initial DOC;

c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs or reference sample(s) for each method for each analyst each year;

d) a documented process of reviewing QC samples performed by an analyst or groups of analysts relative to the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;

e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

Blanks

Given that the definition of the MDL is "the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results" it is not reasonable to expect all blank results will be less than the MDL. Also, since the reporting section of these methods all require results less than the ML to be reported as <ML, there would never be a reported results that is greater than the MDL and less than the ML. This section should be rewritten to mimic the language in the NELAP standard:

> The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:
>
> a) the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample;
> b) the blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives; and
> c) a blank is determined to be contaminated. The cause shall be investigated and measures taken to minimize or eliminate the problem. Samples associated with a contaminated blank shall be evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes). In all cases the corrective action shall be documented.

Laboratory Control Samples

These methods introduce a troubling concept in allowing duplicate measurements of the LCS to occur with the laboratory able to use the second results to demonstrate compliance if the first one fails. This "pick and choose" concept is not allowed under NELAP. A better approach is to use the marginal exceedances concept developed by Tom Georgian of the US Army Corps of Engineers that is contained in the NELAP Standard and described below:

> Allowable Marginal Exceedances. If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (three standard deviations), but within the ME limits. ME limits are between three (3) and four (4) standard deviations around the mean. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and

corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than eleven analytes.

The number of allowable marginal exceedances is as follows:

Number of Analytes in LCS	Number Allowed as Marginal Exceedances
> 90	5
71 – 90	4
51 – 70	3
31 – 50	2
11 – 30	1
< 11	0

If the same analyte exceeds the LCS control limit consecutively, it is an indication of a systemic problem. The source of the error shall be located and corrective action taken. Laboratories shall have a written procedure to monitor the application of marginal exceedance allowance to the LCS.

In addition, the method should allow for the circumstances described below.

Samples analyzed along with an LCS determined to be "out of control" shall be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

i. when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported with data qualifying codes; or

ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes.

Matrix Spikes
The 1984 versions of these methods required matrix spikes to be analyzed, but for those analytes that did not meet the QC criteria, a QC check sample could be used to demonstrate laboratory control. The requirement to not use results for compliance purposes only applied if the results from both the MS and QC check failed. This practice is consistent with the long-standing understanding of the purposes of the LCS and MS[3,4]. This section should be revised to be consistent with the earlier versions of the method and accepted practice, where the LCS is used to document laboratory performance and the MS used to document the performance of the method on that matrix.

Accuracy Assessment
The 1984 version of these methods, and the proposed revisions both contain a requirement to generate statements of accuracy for wastewater. This section does state what this statement is to be used for and it is unclear as to whether this is for all wastewaters from multiple sources, or segregated by discharger. In any event, there does not seem to be any use for this requirement. This section references 136.7 (c)(1)(viii), but that section merely states "Control charts (or other trend analyses of quality control results)," which could be many other charts such as LCS.

Reporting

The requirement to report quantitative data down to the ML to three significant figures is not appropriate given the precision of these methods. The requirement to report results less than the ML as <ML is not consistent with accepted practice and reflects a lack of understanding of the relationship of the MDL and ML. The mathematical relationship of these two numbers is based on Currie's Limit of Detection L_D and Limit of

Quantitation L_Q.[5] Results above the ML should be reported as quantitative results. Results below the ML, but above the MDL should be shown as detected, typically with a quantitative value and a data qualifier to indicate the result is an estimate only. Results below the MDL should be reported as ND, not detected, at the stated MDL. The methods allow for blank subtraction. This sentence should be removed as such a technique increases the measurement uncertainty due to the uncertainties of both the sample and blank results.

Specific Method Comments

Method 608.3
The requirement to report an analyte as not detected if the results from two columns differ by more than a factor of 2 if an "intereferent" is not detected will be difficult to implement and likely lead to false negative results.

Method 624.1
The recommendation to go down to mass range of 25-250 for four analytes ignores the fact that the recommended characteristic ions for these four analytes are all above m/z 50 and going below m/z 35 introduces many interferences. See the table below:

Analytes recommended for low mass scan and m/z	**Interferences below m/z 35**
Acrolein (m/z 56, 55, 58)	Methanol (m/z 29, 31, 32)
Acrylonitrile (m/z 53, 52, 51)	Nitrogen (m/z 28)
Choloromethane (m/z 50, 52)	Oxygen (m/z 32)
Vinyl chloride (m/z 62, 64)	Argon (m/z 40)

The requirement to achieve a 25% resolution between 1,2-dibromoethane (characteristic ions 107 (109, 188)) and chlorobenzene (characteristic ions 112 (77, 114)) ignores the fact that GC/MS can correctly identify and measure these two compounds even if they coelute. The same principle applies to most other target analytes. Any requirement for GC resolution can only apply to compounds that have the same characteristic ions.

Methods 624.1 and 625.1
The change in the requirement for relative intensities from ± 20% to -50% to +200% will likely increase false positives. The new requirement appears too broad and is not consistent with other similar methods. The statement to account for "m/z's present in the acquired mass spectrum" presumes mass spectra are obtained, but this is not a requirement if the laboratory uses extracted ion current profiles for identification and quantification as allowed by the method and furthermore could lead to false negatives due to the practical difficulty of meeting this requirement where the analyte is obscured by high concentrations of interferences.

References:

1. An Independently Prepared Second Source Lot Reference Material – Where Did This Come From and What Does It Really Mean? Joe Konschnik 2013 National Environmental Monitoring Conference http://www.nemc.us/meeting/2013/load_abstract.php?id=210
2. Correlation Coefficients for Evaluation of Analytical Calibration Curve; *Anal. Chem. 1981* (C.L. Grant)
3. Carlberg, K.A., R.C. Hanisch, J.L. Parr, *Quality Assurance in the Environmental Laboratory - A Practical Approach*, Presented at the Fourth Annual Waste Testing and Quality Assurance Symposium, Washington, D.C., July 1988
4. THE APPROPRIATE USE OF MATRIX-SPECIFIC QUALITY CONTROL SAMPLES, Environmental Laboratory Advisory Board, June 2008
5. Principles of Environmental Analysis, Keith, L.H., et.al; Anal Chem 1983 (55) 2210

Attachment 3
ELAB Comments on the MDL Procedure

Background

The detection limit of an analytical procedure is a critical property and vital to understanding the capability of the method and the range of data quality objectives that can be supported. The MDL serves the purpose of determining the single laboratory detection limit for methods approved under 40 CFR 136, and the importance of accurate estimates can hardly be overstated because incorrect compliance decisions are likely to result from an inaccurate estimate. Unfortunately, the current MDL procedure is widely recognized to have serious flaws that can and do result in incorrect detection limit estimates.

There have been previous efforts to update or replace the MDL procedure. In 2003, EPA issued a proposed update that was withdrawn after receiving considerable negative comment in the public review period. Subsequently, a federal advisory committee developed a replacement for the MDL that was generally considered technically sound, but implementation difficulties were such that it was never implemented.

In the Board's opinion, the TNI procedure strikes a good balance between technical validity and ease of implementation. Detailed comments are provided below, and suggestions for language changes are included marked as revisions in the attached copy of the procedure.

Definition: ELAB supports the change in definition to reference method blanks rather than zero. For the purposes of determining compliance, it is important to identify the lowest level that can be reliably distinguished from a blank rather than zero.

Section 2.a Selection of spiking level: Changing the initial spiking level from 1 to 5 times the estimated MDL to 2 to 10 times is beneficial. Spiking at only 1x the MDL is likely to result in many results below the MDL (i.e., the spiking level would be too low). It may be helpful to point out that spiking levels 10x the anticipated MDL should only be needed if the specific analyte is a poor performer in terms of recovery.

Section 2.b Blanks: The Board strongly supports including an assessment of blanks in the MDL procedure. As the objective is to identify the lowest level that can be distinguished from a blank, using actual blank data makes sense.

Section 2.b.i Multiple instruments: The guidance for multiple instruments is valuable. This is a very common situation and lack of previous guidance has resulted in a wide and confusing range of different approaches.

Section 2.c.iii Computation of the MDL based on blanks: ELAB supports calculation of the MDL based on blanks as mean plus Student's t times the standard deviation. Incorporation of the mean is very important.

Section 2.d Set the MDL: The Board believes that EPA should consider favoring the blank-calculated MDL over the spike-calculated MDL, assuming that there is more blank data than spike data.

Section 3. Ongoing data collection: ELAB believes that spreading data collection over time is important, and the requirement for a minimum of two spikes per quarter is a reasonable compromise between collecting sufficient data and having a procedure that is not too onerous. EPA may want to consider providing clearer guidance regarding what is meant by "per quarter."

Section 4. Ongoing annual verification: Although an annual recalculation of the MDL is not in the current procedure, the Board believes that this recalculation (annual verification) is a sound practice for maintaining MDLs that reflect the current capability of the laboratory; therefore, ELAB believes that it is a good addition to the procedure. EPA may wish to consider clarifying the annual requirement. For example, "recalculation of the MDL must be performed within 13 months of the previous MDL determination or recalculation."

Section 4.f. Adjustment of the MDL: No justification is provided for the factor of three used as a limit for determining whether the current MDL needs to be adjusted. Some degree of justification would be useful and ELAB notes that the upper 99% confidence interval for a population standard deviation based on 6 degrees of freedom is 2.98.

Addressing Previous Objections to the MDL

ELAB has reviewed objections to the 2003 MDL update that were received in the public comments, with a view to determining whether they have been addressed in the new draft. Many comments were received on each of the following general issues.

Variability:

Long-Term Variability—The new draft does a good job of incorporating longer term variability.

Interlaboratory Variability—There is no additional material covering interlaboratory variability; however, the procedure is intended as a single laboratory detection limit determination. Recently, EPA has set MDLs based on the highest MDL from participating laboratories, after removal of outliers, and the same approach could be used with the new draft. Another option for estimating the interlaboratory variability would be to calculate a pooled MDL from a large population of laboratories. ELAB would be able to assist EPA in gathering this data once the revised MDL has been in use for a year or more.

Analyte Concentration, Calibration and Analytical Range—Determining the spiking concentration is similar in the current and new drafts, but the new draft has the benefit that there are steps to verify the MDL determined.

Definitions: Many concerns were raised regarding the definition of the MDL. ELAB believes that adjusting the definition to refer to blanks, and clarifying that the MDL is based on results rather than true concentrations, will be beneficial in removing some of the current confusion. The MDL does not purport to be equivalent to the IUPAC limit of detection, but is more similar to the critical level because it only controls false positives.

Precision and bias: Concerns were raised especially concerning bias, and the new draft addresses these well by incorporating the mean of the blanks into the MDL_b calculation.

Error types: The current MDL does nothing to control false negatives. The revised draft addresses false negatives to some extent through the requirement that the ongoing spikes return positive results. The Board would encourage EPA to consider further control of false negatives through a subsequent effort to provide better definition of a single laboratory quantitation limit, which could be used to replace the minimum level.

Iterative procedure: There were many complaints regarding the proposed iterative procedure in the 2003 proposed update. This iterative procedure has fortunately been removed from the current draft and replaced with ongoing evaluations of the MDL.

Outlier testing: There were various comments both in favor and opposed to outlier testing. The new draft does not include an outlier test, but the nonparametric option for method blanks could be considered a useful alternative.

Spike levels: The new draft includes options and requirements for adjusting spike levels if needed based on the ongoing data collection.

Use of blanks: Many comments concerned the lack of consideration of blanks in the 2003 draft; these are fully addressed in the new draft.

Number of replicates: Some comments noted that more replicates would be desirable. The new draft still allows starting with seven replicates (a reasonable compromise), but in most cases many more replicates would soon be available through the ongoing data collection.

Tolerance vs. confidence intervals: Some comments stated that tolerance intervals should be used for the MDL. This is a point of contention between statisticians, and ELAB does not take a position on which is preferable. However, retaining Student's t will certainly make implementation of the new draft easier, and in many cases, the increased number of replicates will reduce the difference between the confidence and tolerance intervals. Also, the use of nonparametric statistical tools when possible eliminates this contentious issue.

Sensitivity check: Comments in favor of a sensitivity check are addressed by the requirement for ongoing data collection and the requirement that the spikes return positive detections.

Attachment 4
PROGRAM REPORTS

CONSENSUS STANDARDS DEVELOPMENT

- The following steps towards finalizing the "2012" Quality Systems Standard have been completed. The Quality Systems Expert Committee that was in place when the Voting Draft Standard comments were discussed, and the standard was modified to resolve persuasive comments, have voted to approve the decisions it made at that time. These decisions have been published as committee minutes. The only remaining step, which will be completed within the next 1-2 weeks, will be publication of a response-to-comments document and the revised standard. Those final modules will be merged into the 2015 standard.

- The Quality Systems Committee has published a Working Draft Standard (WDS) on Volume 1 Module2, Section 5.5.13.1 and is planning to do a webinar for this section on April 20th. This is to correct an inconsistency between that standard and the proposed Microbiology Module 5. The conflict involves thermometer verifications. Following the requisite 30 day posting of the WDS, the proposed change will be discussed during a webinar on April 20th. A Voting Draft Standard will then be presented. If the proposed change is non-controversial, it is expected to be finalized in time for the 2015 standard. The final votes were received from committee members that voted in the 2012 standard. The result was posted on the TNI website in the committee minutes. Each person who commented on the VDS for the 2012 standard was contacted with a description of the committee's action on their comment and information on the appeals process. The committee has started work again on the Handbook.

- The Chemistry Expert Committee's standard on calibration is now a final TNI Standard. It will be published shortly, together with the interim standard response-to-comments document. A Voting Draft Standard on detection/quantitation is scheduled to be ready in May.

- The EPA is soliciting comments on the proposed modified EPA Method Detection Limit procedure, developed by the Chemistry Committee. The chair of the Chemistry Committee, Richard Burrows, is offering to meet with stakeholders to answer any questions before they submit their comments to EPA.

- The Laboratory Accreditation Body Committee LAB Expert Committee needed to reverse the change to its meeting time, since our sole "other" stakeholder category member cannot be available at the preferred time. For meetings where Carl Kircher, the Chair, must depart early, there is now a Vice Chair, Nilda Cox, who can continue the remainder of the meeting. There are membership opportunities available for stakeholders of the "other" category; until more "others" are added, other categories cannot be considered for membership. LAB has undertaken the 5-year review of Volume 2, and realizes that consolidating Modules 1 and 3 will eliminate the tremendous overlap between the two modules presently. A draft of the consolidated modules is ready to distribute to the committee for discussion at its April meeting.

- With its newly approved charter, the WET Expert Committee will begin meeting on April 15 to transition from a subcommittee of Quality Systems to a full-fledged committee in its own right.

- The Radiochemistry committee has posted a Voting Draft Standard. The voting period will close May 15, 2015. The committee has started discussing tools to help with the implementation of the new standard.

- The Microbiology standard is being reviewed by the SRC. Any comments will be reviewed and considered at the next meeting and then the VDS will be voted on by the committee for posting on the TNI website.

NEFAP Executive Committee

- The Mobile Lab Subcommittee has a regrouping meeting set for Friday, April 17th.
- The committee followed up with William on updates needed to the NEFAP pages.
- The contract for L-A-B has been drafted and sent to Doug Leonard for approval. Still waiting to hear back.
- The committee has started forming a Marketing/Advocacy Subcommittee to develop a plan to increase NEFAP exposure, number of FSMOs, etc.
- The Nomination Committee has been formed. NEFAP EC members have been asked to reach out to potential candidates. The nomination period closes April 12th.
- Calista Daigle has been nominated to represent NEFAP on the Policy Committee.
- Final comments have been submitted to Jan for the Brochure. The committee hopes to have the brochure ready to use at a few upcoming conferences.
- The committee will start work on its Charter once it receives strategic planning direction from the Board of Directors.

Field Activities Expert Committee (FAC)

- The committee did not meet this last month.
- Three FSMO tools were sent to William for posting on the NEFAP EC website. The committee followed up with William on other updates needed to the NEFAP pages.
- The Container Subcommittee. This discussion will be tabled until closer to the Chicago meeting. There are still concerns about whether this is something the committee should work on. Most feel its use needs to be expanded for it to make sense to work on.
- The committee will begin work on the Scope Guidance document.
- The committee is still looking for a Vice-Chair.
- Progress has been made on ANSI approval. Ken sent off the information the committee prepared.

NELAP

Accreditation Council

- Five evaluations are complete with renewals approved. An additional seven are in various stages of the process, with the remaining two to start later this year.
- Another of the AC's Assessor Calls took place for the first meeting of April. These are valuable opportunities for both state and contract assessors to share best practices.
- Alfredo Sotomayor will join the AC at its second call to continue the discussion of a possible shared logo with the non-governmental ABs.
- The AC is modifying the NELAP Mutual Recognition Policy 3-100, provided by LASEC, to address "home state" applications. It already addressed secondary accreditations, and will thus accomplish several identified policy needs with one document, when complete.

Laboratory Accreditation System Executive Committee (LAS EC)

- LAS EC members have reviewed Volume 1, Modules 2, 3 and 7 (the 2012 revisions) and these will be discussed at the April committee meeting.
- Now that the CSDEC's Standards Development SOP 2-100 is before the Board for endorsement, LASEC will once again revise its Standards Review for Suitability SOP 3-106 to accommodate the changes to SOP 2-100. LASEC will also review the NELAP Standards Acceptance SOP 3-103, to affirm that no additional changes are needed there.
- LASEC will have an updated charter for the Board, soon.
- **Standard Interpretation Request Quarterly Report**

Total Number	279
Closed Out	240
LASEC Review	6
NELAP AC Voting	9
Expert Committee	14

PROFICIENCY TESTING

- The committee has a number of requests to add analytes to FoPT tables:
  - (Carl Kircher – FL) SCM FoPT Table: Aroclor 1221, Arochlor 1232 and Arochlor 1248 to PCBs in Oil.
  - (Jeff Lowry) SCM FoPT Table: DBCP, EDB and 1,2,3-Trichloropropane.
  - (Jennifer Best - EPA) DW FoPT Table: Subdivision of current codes to: MPN – Multiple Tube ad MPN – Multiple Well. The code for MPN encompasses different methods that have different sample volumes analyzed – therefore different reported values. This is a PT problem.
- Still in progress: The committee has started work on two old SIRs that were returned. They center around asking labs to run PTs for methods that that they were not designed for. Usually a concentration issue. The committee will plan to respond to the request and will work with the FoPT Table Format Subcommittee to resolve the longer term issue.
- Work is still progressing on the finalization of the new WET FoPT table. Maria is continuing to work with the subcommittee to possibly delete Footnote 3. The committee received a response from the subcommittee and will be reviewing it this next month.
- The Microbiology FoPT Subcommittee has had their first meeting and they have elected Jennifer Best as Chair of the subcommittee.
- The FoPT Table Format Subcommittee is continuing work on updating the format of the DW FoPT table. The NELAP AC has asked for what the benefits are for adding methods to the table.
- The Chemistry FoPT Subcommittee is continuing the review of SCM data.
- The committee is still working on the compound naming and identification inconsistency ((2,2'-osybis (1-chloropropane) vs. bis (2-chloroisopropyl) ether).
- The committee will finish work on its Charter in April.

ADMINISTRATION

Advocacy Committee

- The Advocacy Committee approved the PT Position statement at their last meeting. The position paper will be forwarded to the Policy Committee.
- Target publication date for the next newsletter is early April.
- The Advocacy Committee reviewed and discussed comments prepared by Jerry on EPA's proposed Method Update Rule (MUR). The committee recommended that two sets of comments be prepared. One set to be submitted by TNI will deal with direct impacts of the rule on TNI standards. Another set of comments dealing with the methods will be available for members to review and use as they wish.

Non-Governmental Accreditation Bodies

- TNI did not receive any proposals in response to the RFP issued for Lead Evaluator. The NGAB and TNRC will meet at a later date to review/modify the implementation strategy for this program.

Policy Committee

- Policy Committee has approved the revised SOP 2-100 (Standards Development,) and that is presented for Board endorsement at the April meeting, today.
- The review of all NEFAP updated SOPs is complete but awaiting a quorum to approve comments on the final document, after which all comments on all SOPs will be returned to NEFAP as a set.

- The draft TNI Quality Management Plan is the next item on Policy Committee's priority list. Review of that document should begin later this month.

Training

- The updates to the Ethics and Data Integrity webcast have been sent to William.
- A training webinar was held March 26th regarding the MUR update proposal. There were close to 500 participants between individual and group sign-ups. Certificates will be out by April 16th. CEUs were offered for this webinar.
- Another training webinar is planned for April 8th regarding the MDL update proposal in the MUR. We already have over 180 registrations. There are 48 groups participating at this point, so we will likely have over 400 people participating in this webinar. CEUs will be offered for this webinar.
- A QS Working Draft Standard Webinar is planned for April 20th.
- Three technical Webinars are planned with Metrohm starting in mid May.

NEMC

- NEMC 2015 abstracts have been placed and notifications to presenters went out last week.
- The Symposium brochure is in development and should be mailed next week.
- Registration will open around April 15.
- The NEMC Facebook Group has been set-up and is operational (https://www.facebook.com/groups/NEMCmail/). Various updates and presentation features will go out each week. Linked In will be operational this week with invitations still going out.

Membership Report

- There were 2 new committee applications. One is for the PTPEC and will be considered at their next meeting. The other was for the NEFAP EC, but it is from the same organization as another member on the NEFAP EC.

- **Active Members:** 856