Coalition for Responsible Waste Incineration

CRWI comments on the Commercial and Industrial Solid Waste Incineration Units proposed rule (EPA-HQ-OAR-2003-0119)

Appendix A: The Texas Commission on Environmental Quality guidance on variability allowed during testing.

Guidance for Determining Maximum Allowable Operating Rates for an Emission
Performance Test and Requesting a Retest
02/21/2005

Guidance for Determining Maximum Allowable Operating Rates for an Emission Performance Test and Requesting a Retest

A June 4,1980, Texas Air Control Board (TACB) memo from Mr. James Draper, P.E. to the TACB regional supervisors, team leaders and all source evaluation personnel established guidance for determining maximum allowable operating conditions during performance tests and when the agency should request a company to retest. Representatives from Field Operations Division, Compliance Support Division, Environmental Planning and Implementation Division, Chief Engineer's Office, and Air Permits Division provide this guidance for determining maximum allowable operating conditions during compliance performance testing and when the agency should request a company to retest. When using this guidance consideration should be given to the type of process, the specific operating parameter(s), and how close the actual emissions are to the regulatory limit in determining that a retest should or should not be required. Each test event should be considered on a case-by-case basis.

This is guidance provided for use by Texas Commission on Environmental Quality (TCEQ), is for determining maximum allowable operating conditions in pretest planning activities, during test observations, and in the review of test reports.

1. When a source is being tested for a state and/or federal regulatory requirement, the operating rates during an individual test run cannot vary by more than +/- 10% from the average operating rate of the run. The average operating rate of each run cannot vary more than +/- 10% from the average operating rate of all test runs. This requirement is not applicable for the purposes of a continuous emissions monitoring systems (CEMS) certification relative accuracy test audit (RATA), unless an emission performance test is being performed concurrently with the RATA.
2. In the absence of state and/or federal regulatory requirements establishing specific operating rate limitations, the actual average operating rate during a state and/or federal regulatory performance test should be the maximum allowable operating rate.
3. In the absence of state and/or federal regulatory requirements addressing a facility operating above the maximum allowable operating rate, retesting should be required to demonstrate compliance with the applicable state and/or regulatory requirements, if the facility operates above the maximum allowable operating rate.

This guidance supersedes the James Draper memo revised June 4, 1980.

CRWI
Coalition for Responsible Waste Incineration

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Appendix B: The graphs (and their references) showing the relationship between carbon monoxide and nitrogen oxides during combustion.

ISSN 0280-5316
ISRN LUTFD2/TFRT--5769--SE

Modelling NOx-Formation in Combustion Processes

Christian Schwerdt

Department of Automatic Control
Lund University
June 2006

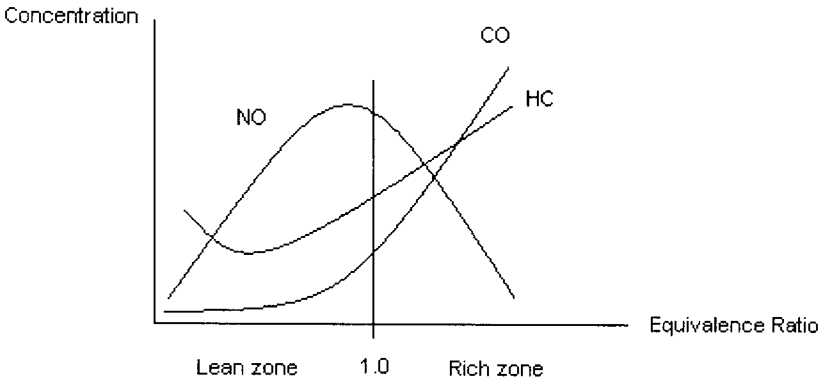

Figure 2.1: *Figure shows different emission substance concentrations qualitative dependence on the equivalence ratio*

In the figure the variations of other emission substances concentration can also be seen. It clearly shows the difficulty of trying to decrease all the emission substance concentrations with a strategy of only changing the equivalence ratio. In the far fuel-lean region, NOx and carbon oxide (CO) concentrations are low, but the concentration of hydro carbon (HC) is large. And when HC has a minimum and CO is relatively small, NOx has a maximum. And the more fuel-rich the condition gets, the higher the concentration of both HC and CO even though NOx is decreasing. [4]

FUNDAMENTALS OF AIR POLLUTION ENGINEERING

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Library of Congress Cataloging-in-Publication Data

Flagan, Richard C. (date)
Fundamentals of air pollution engineering.

Includes bibliographies and index.
1. Air—Pollution. 2. Environmental engineering.
I. Seinfeld, John H. II. Title.
TD883.F38 1988 628.5'3 87-7322
ISBN 0-13-332537-7

Editorial/production supervision and
interior design: *WordCrafters Editorial Services, Inc.*
Cover design: *Ben Santora*
Manufacturing buyer: *Cindy Grant*

A Division of Simon & Schuster
Englewood Cliffs, New Jersey 07632

Printed in the United States of America

10 9 8 7 6 5 4 3 2 1

0-13-332537-7

Prentice-Hall International (UK) Limited, *London*
Prentice-Hall of Australia Pty. Limited, *Sydney*
Prentice-Hall Canada Inc., *Toronto*
Prentice-Hall Hispanoamericana, S.A., *Mexico*
Prentice-Hall of India Private Limited, *New Delhi*
Prentice-Hall of Japan, Inc., *Tokyo*
Simon & Schuster Asia Pte. Ltd., *Singapore*
Editora Prentice-Hall do Brasil, Ltda., *Rio de Janeiro*

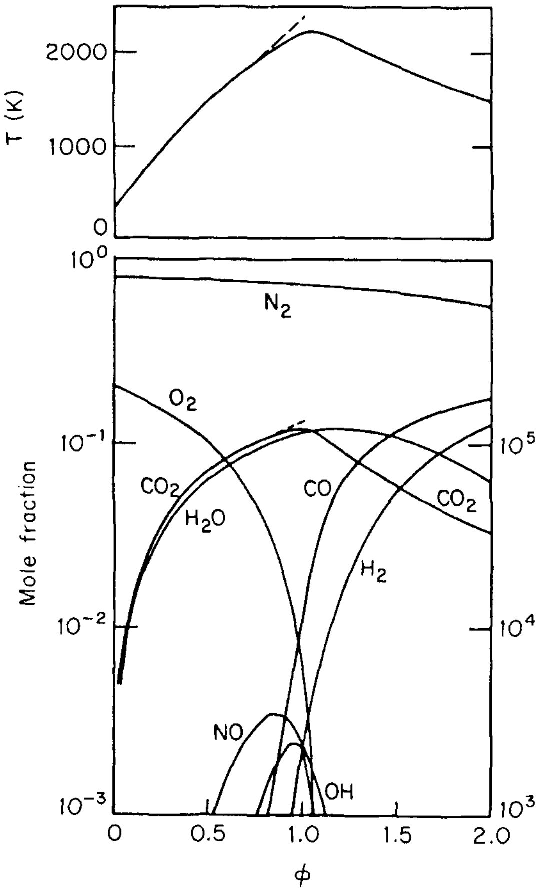


Figure 2.6 Equilibrium composition and temperature for adiabatic combustion of kerosene, $CH_{1.8}$, as a function of equivalence ratio.

stants for combustion reactions using the integrated form of van't Hoff's relation,

$$K_p = B \exp\left(-\frac{\Delta h_r(T_l)}{RT}\right)$$

where T_l is a reference temperature at which the preexponential factor B, is evaluated. The dissociation reactions, for example,

$$CO_2 \overset{1}{\rightleftharpoons} CO + \tfrac{1}{2}O_2$$

$$H_2O \overset{2}{\rightleftharpoons} H_2 + \tfrac{1}{2}O_2$$

have large positive heats of reaction,

$$\Delta h_{r1} = 283{,}388 \text{ J mol}^{-1}$$

$$\Delta h_{r2} = 242{,}174 \text{ J mol}^{-1}$$

Coalition for Responsible Waste Incineration

CRWI comments on the Commercial and Industrial Solid Waste Incineration Units proposed rule (EPA-HQ-OAR-2003-0119)

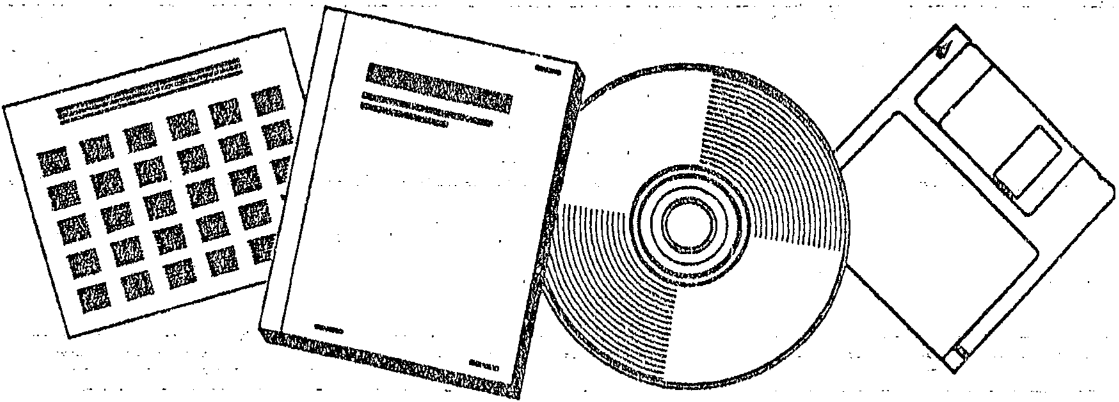
Appendix C: A copy of EPA's 1995 Engineering and Analysis Division paper entitled: Development of Compliance Levels from Analytical Detection and Quantification Levels.

PB95-216321

DEVELOPMENT OF COMPLIANCE LEVELS FROM ANALYTICAL DETECTION AND QUANTITATION LEVELS

(U.S.) ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC

1995



U.S. DEPARTMENT OF COMMERCE
National Technical Information Service

PB95-216321

DEVELOPMENT OF COMPLIANCE LEVELS FROM ANALYTICAL DETECTION AND QUANTITATION LEVELS

This issue paper provides an overview of the use of analytical detection and quantitation levels as compliance limits and a rationale for use of the Minimum Level (ML) as the quantitation level appropriate for such limits. This paper also provides strategies for clarification of the Method Detection Limit (MDL) and the ML to mitigate concerns by industry and others about the use of these measurements for regulatory compliance.

BACKGROUND

The lowest level of an analyte that can be detected using an analytical method is generically termed the "detection limit." EPA's commonly-used specific term for the detection limit has been the MDL, which was promulgated at 40 *CFR* Part 136, Appendix B. Above the detection limit is the level at which reliable quantitative measurements can be made. This level is generically termed the "quantitation limit" or "quantitation level."

In the early 1980s, EPA's wastewater program established the ML as the quantitation level, and in the mid-1980s, EPA's drinking water program established the practical quantitation level (PQL) as the lowest level at which reliable measurements can be made. In the mid to late 1980s, EPA's solid waste program adopted the PQL as the quantitation level, although the version adopted was different from the version used in EPA's drinking water program.

In recent years, the varied concepts of detection and quantitation levels have come under scrutiny by the regulated industry, by municipalities, and by others. Much of the concern has been focused on the difficulties associated with implementing these diverse concepts in the analytical and regulatory arenas; others, however, have challenged the scientific assumptions on which the concepts are based. Comments and criticism regarding the varied approaches within EPA have reached new levels in recent months as a result of the Agency's effort to develop a strategy regarding the enforcement of water-quality based effluent limits (WQBELs) that are set below detection and quantitation levels.

The purpose of this document is to provide the reader with an overview of the issues relating to analytical detection and quantitation levels and the impact that these issues have on regulatory compliance levels. In addition, this paper suggests a strategy for adoption of a single approach to these issues within EPA.

COMPLIANCE LEVELS

In setting regulatory compliance levels, EPA is often faced with situations that require monitoring near or below analytical detection or quantitation levels. In such situations, permittees often argue that the compliance level should be set with a large safety factor to make absolutely certain that measurements are reliable. Environmental groups frequently argue that a zero level or the level at which a single researcher can demonstrate that the pollutant can be detected should be used as the compliance level. EPA must weigh the advantages and disadvantages of each approach and choose a solution that reflects both good science and good policy.

Within the Office of Water (OW) alone, EPA is responsible for setting standards and issuing guidance concerning regulatory compliance levels associated with the requirements of the Safe Drinking Water Act and with technology-based and water-quality based permitting under the Clean Water Act. Three recently drafted OW documents that explicitly address these standards and provide guidance are:

- *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring* (EPA 821 B-93-001, June 1993);
- The *Draft Final National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limitations Set Below Analytical Detection/ Quantitation Levels* (March 22, 1994); and
- *Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria* (a memorandum from Martha Prothro to Regional Water Management Division Directors and Environmental Services Division Directors, October 1, 1993).

Compliance monitoring issues similar to those addressed by OW must also be addressed by decision makers in other EPA Program Offices. Consequently, it is appropriate to consider the applicability of any proposed analytical measurement as a regulatory compliance level across all Agency programs. Because measurements that are made below analytical detection and quantitation levels are associated with increased measurement uncertainty, an understanding of these concepts is essential to a thorough comprehension of the impact that they have when they are applied as regulatory compliance levels. The following sections describe these concepts and their impacts.

DETECTION AND QUANTITATION LEVELS

Numerous terms have been created to describe detection and quantitation levels. These include:

- Method Detection Limit (MDL);
- Method Detection Level (MDLVL);
- Limit of Detection (LOD);
- Reliable Detection Level (RDL);
- Compliance Monitoring Detection Level (CMDL);
- Limit of Quantitation (LOQ);
- Practical Quantitation Level (PQL);
- Reliable Quantitation Level (RQL);
- Compliance Monitoring Quantitation Level (CMQL); and
- Minimum Level (ML).

The significance and applicability of the more important and widely used of these detection and quantitation levels are summarized in the paragraphs below.

Method Detection Limit (MDL)

EPA's lynchpin for the lowest level at which a pollutant or contaminant can be reliably *detected* is the MDL. The MDL is defined as the lowest level at which an analyte can be detected with 99 percent confidence that the analyte concentration is greater than zero. Although EPA has not used the MDL as a compliance level in any of its nationwide standards, it is believed that the MDL has been incorporated as a compliance level in some permits by individual State and Regional permit writers.

Detection of pollutants at parts-per-billion, parts-per-trillion, or lower levels in effluent or drinking waters is not a simple process and is accompanied by a degree of uncertainty. Consequently, nearly all definitions of detection limits, including the MDL, are based on statistical analyses of laboratory data. To determine an MDL, for example, at least seven replicate samples with a concentration of the pollutant of interest near the estimated MDL are analyzed. The standard deviation among the analyses is determined and multiplied by 3.14. The result of this calculation becomes the MDL[1]. The factor of 3.14 is based on a t-test with six degrees of freedom and provides a 99 percent confidence that the analyte can be detected at this concentration.

The MDL was introduced in the technical literature in 1981[2] and promulgated in 1984. More than 130 EPA analytical methods for the determination of several hundred analytes incorporate the MDL. Such methods have been promulgated at 40 *CFR* Parts 136, 141, 143, 260 - 270, and 403 - 499.

Minimum Level (ML)

EPA uses the ML as a compliance level in its nationwide technology-based standards for wastewater discharges. The ML is a quantitation level that corresponds to the lowest level at which the entire analytical system gives reliable signals and an acceptable calibration point. The ML was introduced in EPA Methods 1624 and 1625 in 1980 and was promulgated in these methods in 1984 at 40 *CFR* Part 136, Appendix A.

EPA's Engineering and Analysis Division (EAD) has recently clarified the procedure for establishing the ML in order to support use of this level as a regulatory compliance level across EPA programs. The refined procedure is now being utilized in EPA's strategy for enforcement of WQBELs set below the analytical limit of detection, and is described in the draft WQBEL document cited above. The clarified procedure establishes an "interim ML" as 3.18 times the MDL; the result is exactly equal to the limit of quantitation (LOQ) established by the American Chemical Society (ACS)[3].

To ensure reliable quantitation, the analytical instrument used for compliance monitoring must be calibrated at or below the interim ML so that the exact interim ML is included in the calibration

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[1] 40 *CFR* Part 136, Appendix B.

[2] *Environmental Science and Technology* **1981** *15*, p. 1427.

[3] *Analytical Chemistry* **1980** *52*, p. 2242.

range. Laboratories may find it helpful and less error prone to round the exact interim ML to a whole number for calibration purposes.

The "final ML" for a given analytical method will be established by EPA in method validation studies. These studies will be directed at determining the level at which quantitation can be performed reliably. The final ML will then be published in the EPA method.

Practical Quantitation Level (PQL), Reliable Detection Level (RDL), and Reliable Quantitation Level (RQL)

The PQL has been used in drinking water and solid waste programs and defined to be the level at which reliable measurements can be made under routine laboratory operating conditions (50 *FR* 46908; 52 *FR* 25699). The PQL is constructed by multiplying the MDL, derived as above, by a factor usually in the range of 5 - 10. However, PQLs with multipliers as high as 50 have been proposed.

The PQL has been criticized because of the ambiguous nature of the multiplier and because the resulting levels have been perceived as too high for regulatory compliance purposes. In response to this criticism, the Drinking Water Standards Division (DWSD), the Environmental Monitoring Systems Laboratory in Cincinnati (EMSL-Ci), and the ACS Committee on Environmental Improvement (CEI) have introduced the concepts of the RDL and the RQL.

In the EMSL-Ci embodiment of the RDL and the RQL, the RDL is 2.623 times the MDL and the RQL is 3.623 times the RDL. Thus, the RQL is 2.623 x 3.623 x MDL or 9.5 times the MDL. EMSL-Ci has stated that this multiplier is necessary to allow for all sources of variability. In the DWSD embodiment, multipliers of 2 and 2 are used, resulting in an RQL that is 4 times the MDL. We understand that DWSD may propose one of these embodiments of the RDL/RQL for public comment by the end of calendar year 1994.

Multiples of the Standard Deviation

All of the various detection and quantitation levels commonly used by EPA, including those described above, are based on an estimate or a calculation of the measurement error associated with a particular analyte, matrix, and analytical method. Calculated measurement errors are based on the standard deviation of replicate determinations. The principle difference between each of the concepts is the multiplier that is used on the standard deviation.

Figure 1 illustrates the detection and quantitation levels proposed and the number of standard deviations on which these levels are based. Included in this illustration are the concepts of a "compliance monitoring detection level" (CMDL) and "compliance monitoring quantitation level" (CMQL), which have been proposed by the Utility Water Act Group (UWAG) and are discussed later in this paper.

IMPACT OF QUANTITATION LEVEL ON REGULATORY COMPLIANCE LIMITS

Table 1 lists the various detection and quantitation level concepts, the number of standard deviations on which these concepts are based, and the compliance limits that could result for two pollutants of environmental concern: 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (dioxin); and "oil and grease" (O&G). The detection limit concepts are presented in Table 1 for information purposes only; it is generally accepted that the quantitation limit should be used for regulatory compliance purposes. Figure 2 illustrates the effect that each of the quantitation limit concepts shown in Table 1 would have on the regulatory compliance limits for dioxin and for oil and grease.

Dioxin is regulated under several environmental programs, including the Clean Air Act, the Safe Drinking Water Act, and the Clean Water Act. Under the Clean Water Act, dioxin is regulated as toxic (priority) pollutant (40 *CFR* 401.15) and is controlled through water quality-based standards and through technology-based effluent guidelines. Recently, for example, EPA proposed technology based guidelines that would regulate Pulp, Paper, and Paperboard industry dioxin discharges at 10 parts-per-quadrillion (58 *FR* 66078). This 10 parts-per-quadrillion compliance level corresponds to the ML associated with the proposed analytical method. The impact of using quantitation limit concepts other than the ML can be seen from Table 1 and Figure 2. Except for the ACS LOQ, all other concepts result in a significantly higher compliance level.

Oil and grease (O&G) is regulated under the Clean Water Act as a conventional pollutant (40 *CFR* 401.16), and is controlled through the Storm Water Discharge Program, the Effluent Guidelines Program, and the Water Quality Criteria and Standards Program. EAD is in the process of establishing the MDL and ML for O&G. Initial results indicate that the MDL will be in the range of 3 - 5 milligrams per liter (mg/L) and the ML will be approximately 10 mg/L, as shown in Table 1 and Figure 2. EAD believes that an ML of approximately 10 mg/L is reasonable based on the analytical technology employed. However, EAD is aware of existing permit limits for oil and grease in the 5 - 10 mg/L range. Setting the compliance level no lower than 10 mg/L in a nationwide standard and justifying this level with regulatory language may cause re-evaluation and possible re-openers for these permits. EAD does not believe that an increase to 10 mg/L is excessive, particularly if it supports a consistent regulatory strategy on the use of the ML as a compliance limit. Higher levels based on alternative quantitation limit concepts, however, are not justified. Indeed, as shown in Table 1 and Figure 2, some of these alternative concepts would unacceptably increase existing regulatory compliance levels if they were to become entrenched in the regulatory process.

Of greatest concern to EAD are proposals for compliance levels that are based on the pooled interlaboratory standard deviation and on prediction or tolerance intervals. These include the RQL proposed by EMSL-Ci and the CMQL proposed by industry groups and associations [led primarily by the Electric Power Research Institute (EPRI), but including UWAG, ASTM, TRW, and others]. These concepts would lead to regulatory compliance levels based on the regulated community's perception of what the analytical technology will achieve. As is illustrated in Figure 2, such levels will be well above existing proposed or promulgated compliance levels.

State of New York Approach

In 1988, the Division of Water of the New York Department of Environmental Conservation published *Analytical Detectability and Quantitation Guidelines for Selected Environmental Parameters*.[4] In the New York approach, the compliance level is set at the MDL of the most sensitive EPA analytical method, or at the water-quality based level, whichever is higher. The New

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[4] Document 0080, December 1988.

York approach also recognizes the uncertainty introduced when the water-quality based level is above the MDL but below the ML or PQL, but does not provide relief to the ML if the water-quality based limit falls in this range. EAD believes that this approach is open to criticism based on the uncertainty of quantitation at the MDL and below the ML.

Soundness of the ML

EAD strongly believes that the use of the MDL-derived ML as a compliance limit represents a scientifically sound approach that allows EPA to provide maximum protection of human health and the environment while recognizing the uncertainty associated with analytical measurements at very low concentrations. EAD recognizes, however, that widespread consensus on this approach may not be possible unless some concerns about the current MDL procedure are addressed and resolved. EAD has evaluated the concerns voiced by MDL critics, and has developed a strategy for refining the MDL procedure in order to mitigate these concerns. This strategy is described below.

STRATEGY FOR REFINEMENT AND AGENCY-WIDE ADOPTION OF THE MDL

The MDL for a variety of analytes is given in wastewater methods promulgated at 40 *CFR* 136, Appendix A; in wastewater methods specific to a given effluent rule promulgated at Parts 403 - 499; in drinking water methods promulgated at Parts 141 and 143; and in Office of Solid Waste methods promulgated at Parts 260 - 270 (SW-846 by reference). Many of these methods have been used for more than a decade for monitoring in the drinking water, wastewater, and solid waste programs. Changing from the MDL to another concept or revising the MDL would require revision of these methods and may require revision of the regulations that they support. If there were consensus among the scientific, regulatory, regulated, and environmental communities for a concept other than the MDL, the reasons for revising or replacing the MDL might be compelling. However, the opinions concerning detection and quantitation levels are far from unanimous and are nearly as varied as the number of people consulted on the detection/quantitation limit issue.

We have concluded that there is a subjective component to each of the detection limit concepts presented here and elsewhere, that the MDL serves the concept of the detection limit well, that the MDL is based on a sound statistical foundation, and that the fundamental concept of the MDL should not be altered. The MDL concept can, however, be clarified to address the concerns of its critics. These concerns are that:

- The existing procedure for determining the MDL may result in an overstatement of the MDL;
- The procedure for determining the MDL is a single-laboratory procedure that does not reflect interlaboratory variability; and
- MDLs in EPA methods are based on determinations made in reagent water that do not reflect method performance in real-world sample matrices.

Each of these concerns is addressed in the paragraphs below.

Iterative Determination of the MDL

The 1984 procedure for the determination of the MDL contains iterative steps to assure that the MDL is neither overstated nor understated. Specifically, the procedure requires that the MDL achieved be within a factor of five of the level spiked. If not, the spiking level must be adjusted and the procedure repeated until the resulting MDL is within a factor of five of the spike level. This factor of five was recently criticized by a presenter at the detection level workshop held in conjunction with PittCon '94[4]. The presenter argued that the factor of five allows the MDL to be overstated.

EAD believes that the solution to this criticism is to narrow the iteration window to a factor of two or three, rather than five. This solution does not alter the MDL principle and does not require fundamental changes to any existing methods or regulations.

Interlaboratory Variability

The regulated community has raised the issue that the MDL is a single-laboratory concept. This single-laboratory limitation has been acknowledged in the rulemaking for drinking water (50 *FR* 46908; 52 *FR* 25699). As an alternative, some members of the regulated community have developed and advanced the concepts of a compliance monitoring detection level (CMDL) and a compliance monitoring quantitation level (CMQL).[5] These levels are calculated based on the pooled interlaboratory standard deviation and result in levels much higher than the MDL, the ML, the PQL, and either version of the RDL and RQL.

To overcome the single laboratory limitation of the MDL, EAD's analytical methods now contain the requirement that, prior to use of a method for data gathering or compliance monitoring purposes, each laboratory must demonstrate that it can achieve the MDL for each analyte to be determined using that method. EAD's methods also require use of the ML as the lowest calibration point. Dr. Henry Kahn of the Economic and Statistical Analysis Branch within EAD points out that the required demonstration in each laboratory makes the MDL, and thus the ML, an interlaboratory concept.

EAD has also issued *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring*.[6] This guidance states that performance of an MDL study is a means of demonstrating proficiency with an analytical method and that if the ML is not achieved, data are considered not valid. EAD has suggested the addition of the demonstration of the MDL as a requirement for equivalency in the performance-based methods system now under consideration by EPA's Environmental Monitoring Management Council. EAD believes that establishment of minimum standards is a necessary part of the regulatory process, and believes that

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[4] The Detection/Quantitation Workshop, March 4, 1994, held in conjunction with the *Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy*, Chicago, Illinois, February 28 to March 3, 1994. Presentation of Dr. Robert Gibbons, University of Illinois, Chicago.

[5] *Water Environment & Technology*, 1993, *5(1)*, 41-44.

[6] EPA 821-B-93-001, June, 1993.

the ML represents the best compromise between setting a low level that is acknowledged to be associated with high measurement error, and a high level that is not reflective of the Agency's mission to protect human health and the environment.

The regulated community is likely to argue that a requirement for demonstration of the MDL in each laboratory is not equal to performing an interlaboratory study to learn what the MDL should be. However, EAD believes that the Agency must set minimum standards that are demonstrable, and that a demonstration in each laboratory proves that the MDL can be achieved under routine conditions.

Matrix Interferences

The regulated community has also argued that the MDLs in EPA's analytical methods are based on the use of reagent water[7], and that these MDLs cannot be achieved in a real-world sample matrix. In response, EAD asserts that, for drinking water there is no matrix problem, and that for wastewater, the effluent from a well-designed, well-operated Best Available Technology (BAT) treatment system behaves nearly identically to reagent water in the analytical process. For some indirect dischargers required to meet effluent limits equal to those for direct dischargers, EAD acknowledges that there may be a few rare instances in which a detection level equivalent to the MDL in reagent water cannot be achieved. In instances brought to EAD's attention to date, there is no example in which the strategies provided in the *Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring* have not ultimately resolved the problem. However, EAD recognizes that there may be a few cases in which matrix problems are intractable. In these cases, EAD recommends that the discharger be allowed to use the matrix-specific MDL procedure option in 40 *CFR* 136, Appendix B, and if the sample remains intractable, EAD is willing to investigate alternative, interference-reducing options.

Advances in Analytical Technologies

EAD believes that use of the MDL-derived ML as a regulatory compliance level has the added advantage of addressing improvements in analytical technology. Most methods used for regulatory compliance purposes are no longer state-of-the-art by the time they are promulgated, and EPA has not made any attempt to establish levels that will be achieved at the time of promulgation of its regulations. An example of the lowering of detection levels by improvements in technology is provided by comparing the MDLs in the gas chromatography/mass spectrometry (GC/MS) methods for volatile organic pollutants promulgated in 1984 (49 *FR* 43234) and those proposed in 1993 (58 *FR* 65622). In that period, MDLs for these pollutants have been lowered by a factor of 50 - 100. Although the projection of advances in technology is probably not a prudent regulatory development or compliance monitoring strategy, it should be recognized that the technology advances nonetheless, and monitoring at lower levels is possible by the time regulations take effect. Therefore, in setting compliance levels, use of a smaller multiplier on the MDL is more reflective of the advancing analytical technology than a larger multiplier.

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[7] Reagent water is water in which the analyte of interest and potentially interfering substances are not detected.

ARGUMENTS FOR AGENCY-WIDE ADOPTION AND USE OF THE ML

The ML is based on the scientific concept of the LOQ developed by ACS and the International Union of Pure and Applied Chemistry (IUPAC). EAD has relied upon these concepts because they were developed by a committee of knowledgeable analytical and environmental scientists. EAD believes that the concepts underlying the LOD and LOQ are equally valid concepts today. EAD believes that ACS and IUPAC will support the LOQ, and therefore the ML, as a reasonable estimate of the lowest level that can be quantitated reliably.

Clarification of the ML Procedure

In order to support multi-program use of the ML, the process of setting the ML has now been refined into an exact procedure that is based on the scientific concepts of the ACS and IUPAC LOQ, incorporates the operational procedure of the EPA MDL, and employs the pragmatic concept of instrument calibration. EAD has now tested the refined MDL in several laboratories using several analytical methods with single and multiple analytes, and finds that the ML neither over- nor under-states the level that can be measured reliably with an analytical method.

EAD has made the observation that increasing the multiplier by a larger factor than that required for the ML has the practical disadvantage of shortening the dynamic range of the analytical instrumentation. For example, the practical dynamic range over which existing GC/MS instruments are calibrated is approximately a factor of 20. Increasing the multiplier between the MDL and the ML to the factors stated for the PQL, RQL, or CMQL reduces this dynamic range. This decrease in dynamic range can increase the number of dilutions required when pollutants are detected, thereby increasing the cost of analysis. Further, the movement of the quantitation level higher into the dynamic range renders unusable that perfectly valid portion of the dynamic range between the ML and the alternate quantitation level. EAD acknowledges that laboratories can "desensitize" their instruments to move the alternate, higher quantitation level closer to the low end of the dynamic range, but argues that this action violates the reason for the higher alternate quantitation level in the first place; i.e., to move the quantitation level higher into the dynamic range to allow a greater safety factor for reliable quantitation. The ML obviates this problem by matching the lowest calibration point to the level at which reliable quantitation begins.

Demonstration of the ML

A key concept behind the philosophy of the ML is that the laboratory must demonstrate that the ML can be achieved before the analytical method can be practiced in that laboratory. EAD believes that this demonstration is consistent with the regulatory process in which EPA must establish minimum standards for performance, whether those standards are for the performance of a treatment system or an analytical method. These "built-in" controls in the analytical method assure that reliable measurements can be made and make the ML suitable for use as the compliance limit in EPA rules. EAD also believes that demonstration of the ML is consistent with the performance-based methods system envisioned by EPA's Environmental Monitoring Management Council, in that the ML becomes a specification that must be met in any reference method.

Flexibility for Permit Writers

The use of a specific MDL-derived procedure for calculating MLs also provides a mechanism by which individual permit writers can recognize advances in analytical technology. Since the ML can be determined by a single laboratory for a given analyte in a given matrix, State and Regional permit writers are free to require determination of matrix-specific or method-specific MDLs at any time or point in the permitting process. Because the procedure for establishing the ML is based on the MDL, State and Regional permit writers are allowed to re-evaluate method-specific and matrix-specific MLs at any time, on an as-needed basis. Ultimately, this approach not only provides permit writers with the ability to recognize advances in analytical technology, it also provides local authorities with the flexibility to set regulatory compliance levels that are more stringent than those promulgated at the national level, as needs dictate.

CONCLUSIONS

EAD believes that the widely used concept of the MDL should not be altered, but should be refined to improve its efficacy. EAD further believes that the ML represents the quantitation level most consistent with the levels set by EPA for compliance in existing regulations. EAD believes that the ML approach should be adopted by all EPA programs.

EAD urges the Office of Research and Development, the Office of Enforcement and Compliance Assurance, and all affected Program Offices and their supporting counsels to come to closure on the MDL/ML issue. The inconsistencies between the various detection and quantitation limit concepts are apparent to the public and the regulated community. It is no longer satisfactory for each Office or Division within EPA to claim that the needs of that Office or Program are sufficiently different to warrant different approaches to detection/quantitation levels.

Figure 1

Detection/Quantitation Level Concepts

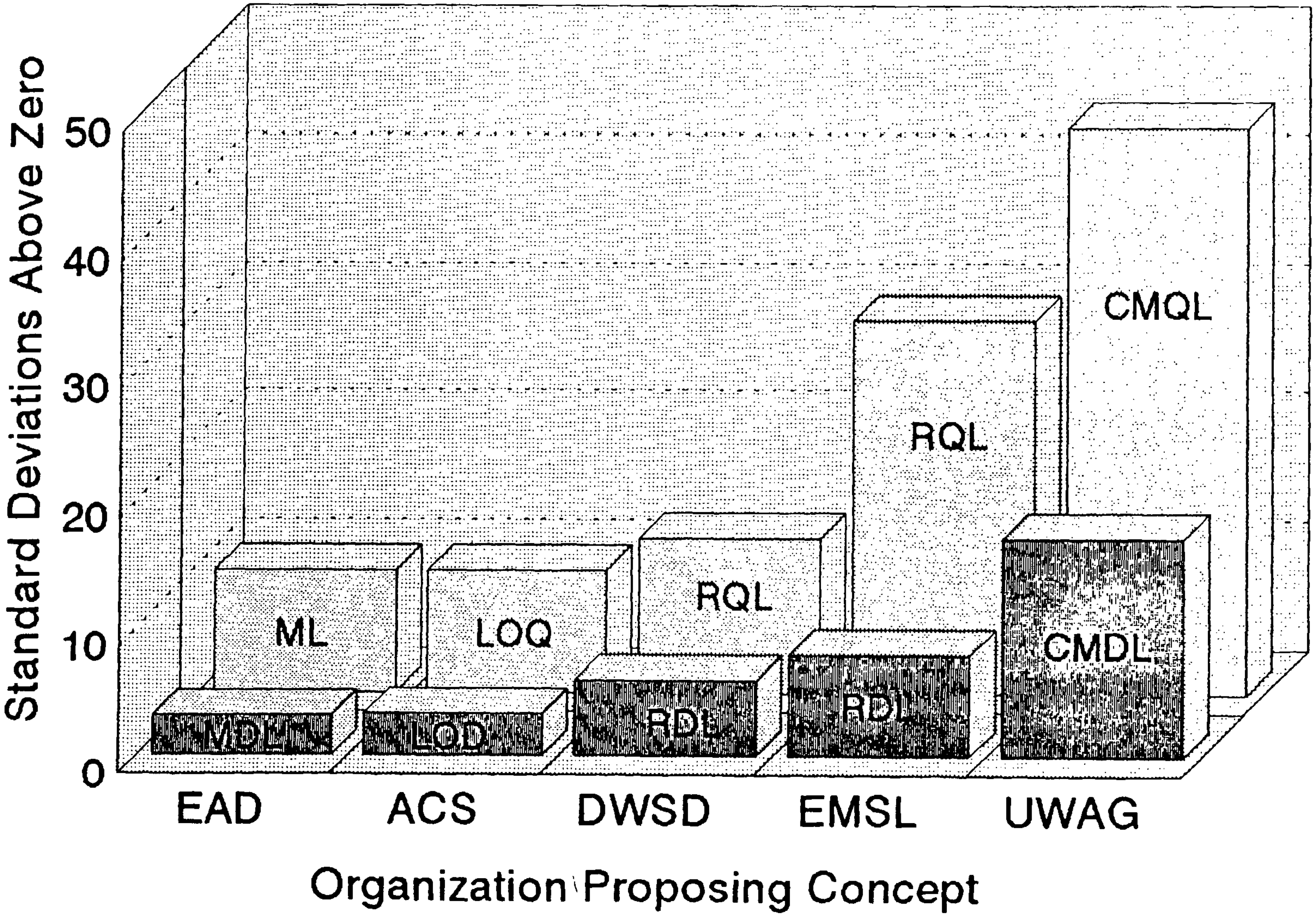

Table 1

Impact of Various Detection/Quantitation Limit Concepts on Possible Regulatory Compliance Levels for 2,3,7,8-TCDD and for "Oil and Grease"

Detection/ Quantitation Limit Concept	Proposing Organization	Number of Standard Deviations	Derived Compliance Level	
			Dioxin[a] (ppq)[b]	Oil & Grease (mg/L)[c]
Detection Levels				
MDL	EAD	3.14	4.4	4.0 est
LOD	ACS	3.00	4.2	3.8
RDL	EMSL-Ci	8	11	10
RDL	DWSD	6	27	7.6
CMDL	UWAG	22[d]	31	28
Quantitation Levels				
ML	EAD	10	10[e]	10[e]
LOQ	ACS	10	14	13
RQL	EMSL-Ci	30	42	38
PQL	DWSD	15 - 31	21 - 43	19 - 39
CMQL	UWAG	45[d]	63	57

[a] 2,3,7,8-Tetrachlorodibenzo-p-dioxin.
[b] Parts-per-quadrillion.
[c] Milligrams per liter.
[d] Back calculated from data provided by EPRI.
[e] Rounded per ML procedure.

Figure 2

Effect of Quantitation Limit Concepts for 2,3,7,8-TCDD and "Oil and Grease"