

## Statement of Interest

As a Member of the F AC on Detection and Quantitation (D/Q)

By Tom Mugan -Wisconsin Department of Natural Resources (DNR)

June 16,2005

The primary interest of the Wisconsin **DNR**, a state regulatory agency, is to protect the environment, more specifically in this case, to protect water quality. We do that by identifying and regulating sources of pollution, including those that impact water quality at very low concentrations.

A secondary interest is to minimize regulatory burden. This interest supports the primary interest because we generally accept that we have limited funds for environmental protection. We must therefore prioritize our efforts to achieve results in the most cost- effective way possible. I include in regulatory burden, expenditures of time and resources by both regulated entities and regulatory agencies.

To support the primary and secondary interests for the D/Q issue, the Committee should:

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Develop a standard set of terms (and definitions) to describe data qualifications that result from pushing limits of test sensitivity.

Establish procedures for determining D/Q limits that:

0 Realistically measure the best a method can do under normal operating conditions 0 Minimize false positives -

Because Wisconsin regulates down to the limit of

detection, a "hit" sets in motion a series of responses that greatly increases effort and resources by both the permittee and the agency

0 Allow for customizing for a specific matrix (not just determined in lab water)

0 Provides for a "reality check" step

Standardize protocols laboratories must use to report data near D/Q limits to avoid rejection by different regulatory agencies.

Consider costs associated with means of determining D/Q limits.

Suggest regulatory approaches that reward a regulated entity for attaining lower D/Q limits.

## Interests Related to MDL and ML Procedures

Florida Dept. of Environmental Protection

Presented by Timothy W. Fitzpatrick

In Florida, protection of the environment is regarded as a high priority by its citizens and is considered a critical component in maintaining the State's healthy tourism industry. Consequently, the State of Florida regulates

surface water dischargers using water quality-based limits that, in some cases, are below levels that can be routinely quantified or detected in analytical laboratories. The Florida Department of Environmental Protection (FDEP) requires monitoring and reporting of pollutants down to the laboratory limit of detection. Thus, issues surrounding the concept of analytical 'detectability' have broad implications for FDEP's regulatory policy.

To satisfy its interests, FDEP would (ideally) prefer that this committee recommend procedures for determining detection and quantitation limits that meet the following criteria:

1. Defensible -Procedures should be based on statistically sound techniques and produce detection and quantitation limits that are valid within the context of laboratory operations. Limits established with the procedure should a) have a low frequency of Type I errors (false positives) using established laboratory practice, b) address bias in the population distribution used to establish limits (i.e., address measurement populations that are not centered around zero concentration units), c) address both quantitative and qualitative interpretation of supporting data, and d) be verifiable, repeatable and yield results that professional chemists can support.
2. Practical -Procedures should be cost effective, achievable and compatible with routine laboratory operations.
3. Useful -Detection limits established with the recommended procedures should serve the needs of the agencies charged with protecting the environment.
4. Understandable -The procedures and underlying concepts should be logical and should be easily communicated to stakeholders. An understanding of the advantages and limitations of the procedures should be understood and documented.
5. Consistent -To the extent possible, the nomenclature, terminology and concepts embodied by the procedures should be consistent with those of other regulatory programs and with those defined by standard setting and professional organizations such as the Institute for National Environmental Laboratory Accreditation (INELA), the International Organization for Standardization (ISO) or the American Chemical Society (ACS). Ideally, analytical data collected to establish detection limits in support of the Clean Water Act should also be useful to support requirements for other regulatory programs that use similar analytical methodologies.

#### Statement of Interest

Advisory Committee on Detection and Quantitation

Colorado Department of Public Health and Environment

June 20, 2005

The Colorado Department of Public Health and Environment is responsible for protecting the state's environment and the health of its citizens and visitors. Central to this mission are water quality standards, adopted by Colorado's policy-making body, the Water Quality Control Commission, to protect beneficial uses. These include standards for the protection of aquatic life and drinking water quality. The standards are adopted based on an acceptable level of risk and the integrity of the program depends on the ability to characterize water quality at, or as close as possible to, the level of any given standard.

Where standards have been adopted at levels below that which analytical laboratories can reliably quantify, the ability to make definitive determinations regarding the quality of a discharge or a water body is diminished. It is these situations that challenge the state to establish detection limits that approach the standard while not exceeding the capability of a competent analytical chemist. To that end, Colorado suggests that the following be considered in developing recommendations for appropriate methods for detection and quantitation:

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The highest level of performance that can be consistently replicated;

Options to conduct matrix specific studies to determine the required level of D/Q;

Rigorous laboratory *QA/QC* protocols;

Flexibility for states to adopt statewide D/Q levels;

Cost of the method and a process to periodically revisit cost; and

Approaches, such as adjusting the monitoring frequency or other alternatives, that may be used to address total cost of implementing more expensive methods.

Statement of Interest  
FACA on Detection and Quantitation  
Approaches and Uses in the Clean Water Act  
June 20, 2005



Bob Avery, Chief of Laboratory Services  
Environmental Science and Services Division  
Michigan Department of Environmental Quality

## Responsibilities.:

Oversee various state programs under the umbrella of Laboratory Services, including the state Environmental Laboratory, Drinking Water Laboratory, Drinking Water Laboratory Certification Program, and the Laboratory Recognition Program. In addition, provide scientific support to other state programs such as permitting, civil and criminal investigations, public and private laboratory sector outreach and assistance, review of A TP's, and providing emergency testing for catastrophic events and suspected chemo-terrorism activities.

## POSITION:

To have a scientifically acceptable and legally defensible protocol for the determination of the lowest possible method detection and quantitation limit.

**INTEREST** is to have the MDL/QL protocol be:

1. Sensitive enough to protect the interests of public health concerns
2. Easy to use with defined uniform criteria (i.e. acceptable recovery limits, established confidence limits, consistent definitions, etc.)
3. Understandable so that everyone will know how to use and apply it
4. Achievable during routine laboratory operations
5. Practical and defensible in application and use
6. Cost efficient and easily utilized within the current analytical QC requirements
7. Traceable for auditing/confirmation purposes
8. Be a continuous ongoing process vs. a one time annual snapshot of the method/instrument capability. This continuing process or check would take into consideration the daily variables that impact methodology/instrument sensitivity over time.
9. Independent and based on the individual laboratory's capability, NOT influenced by outside laboratory data (inralab vs. interlab).
10. Flexible to address different matrices as well as matrix interference problems.
11. Flexible to address new technology that may allow for lower detection/quantitation limits

## CONCERNS

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How to determine permit levels when some of the Water Quality Based Effluent Limits (WQBEL) are lower than the MOL & QL? 40 CFR Part 136 Appendix B is used by many other state and federal programs other than CWA:

- a.
- b.

How will the change to MDL/QL impact the other programs? Will other federal programs accept the change?