



Standard Practice for Determination of the 99 %/95 % Critical Level (WCL) and a Reliable Detection Estimate (WDE) Based on Within- laboratory Data¹

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Note—Balloted information was included and the year date changed on March 28, 2013.

1. Scope

1.1 This practice provides a procedure for computing a 99 %/95 % Within-laboratory Detection Estimate (WDE) and the associated critical level/value (WCL). The WDE is the minimum concentration, with false positives and false negative appropriately controlled, such that values above these minimums are reliable detections. The WCL is the point at which only false positives are controlled appropriately. A false positive is the reporting of an analyte as present when the analyte is not actually present; false negatives are reports of analyte absence when the analyte is actually present. This practice is distinguished from the Interlaboratory Detection Estimate (IDE) practice in that the IDE Standard utilizes data from multiple, independent laboratories, while this practice is for use by a single laboratory. The IDE would be utilized where interlaboratory issues are of concern (for example, limits for published methods); this practice (and values derived from it) are applicable where the results from a single laboratory, single operator, single instrument, etc. are involved (for example, in understanding, censoring and reporting data).

1.2 The establishment of a WDE involves determining the concentration below which the precision and bias of an analytical procedure indicates insufficient confidence in false-positive and false-negative control to assert detection of the analyte in the future analysis of an unknown number of samples. Most traditional approaches attempt to determine this detection “limit” by estimating precision at only a single, arbitrary point. The WDE approach is intended to be a more technically rigorous replacement for other approaches for estimating detection limits. The WDE practice addresses a number of critical issues that are ignored in other approaches.

1.2.1 First, rather than making a single-point estimate of precision, the WDE protocol requires an estimate of precision

at multiple points in the analytical range, especially in the range of the expected detection limit. These estimates are then used to create an appropriate model of the method’s precision. This approach is a more credible way to determine the point where relative precision has become too large for reliable detection. This process requires more data than has been historically required by single-point approaches or by processes for modeling the relationship between standard deviation and concentration.

1.2.2 Second, unlike most other approaches, the WDE process accounts for analytical bias at the concentrations of interest. The relationship of true concentration to measured concentration (that is, the recovery curve) is established and utilized in converting from as-measured to true concentration.

1.2.3 Third, most traditional approaches to detection limits only address the issue of false positives. Although false negatives may not be of concern in some data uses, there are many uses where understanding and/or control of false negatives is important. Without the false-negative-control information, data reported with just a critical-level value are incompletely described and the qualities of data at these levels incompletely disclosed.

1.2.4 Fourth and last, the WDE standard utilizes a statistical-tolerance interval in calculations, such that future measurements may reasonably be expected to be encompassed by the WDE 90 % of the time. Many older approaches have used the statistical confidence interval, which is not intended to encompass individual future measurements, and has been misunderstood and misapplied. Procedures using the confidence interval cannot provide the stated control when the detection-limit value is applied to future sample results; such application is the primary use of these values.

1.3 To summarize, the WDE is computed to be the lowest true concentration at which there is 90 % confidence that a single (future) measurement (from the studied laboratory) will have a true detection probability of at least 95 % and a true non-detection probability of at least 99 % (when measuring a blank sample). For the laboratory in the study, the critical value

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