

Technical Work Group Recommendations on Procedures

Agreement was reached on the following recommendations at a Technical Workgroup Meeting. Not all members were present (although all caucuses were represented) and there was insufficient time to obtain further input and consensus from TWG members not at the meeting.

Single Laboratory Detection Limit Procedure

- 1. The ACIL procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC procedures, is recommended for a single laboratory detection limit procedure.**
 - i. The ACIL procedure performed as well or better than the other candidate procedures.
 - ii. The ACIL procedure incorporates 14 of the 15 “What Do We Need a Procedure to Do?” criteria, more than any other procedures.
 - iii. The most important modification to the ACIL procedure suggested by the Pilot Study data is incorporation of a technique to deal with intermittent blank contamination.
 - iv. The Technical Work Group, including the primary sponsors of the Consensus and LabQC procedures, agrees that the ACIL procedure, with some modifications informed by their procedures, is most appropriate.
 - v. The Technical Work Group, including the primary sponsors of the Hubaux Vos procedure, agrees that the ACIL procedure is preferable for detection.

Single Laboratory Quantitation Limit Procedure

- 2. The ACIL procedure, with modifications indicated by the Pilot Study results and informed by concepts from the Consensus Group and LabQC procedures, is recommended for a single laboratory quantitation limit procedure.**
 - i. The MQOs for the ACIL procedure have not been finalized. A number of different options can be accommodated with slight changes to the procedure.
 - ii. The ACIL procedure performed as well or better than the other candidate procedures.
 - iii. The ACIL procedure incorporates 14 of the 15 “What Do We Need a Procedure to Do?” criteria, more than any other procedures.
 - iv. The Censored ACIL procedure is essentially the same as the MRL (different MQOs are used in the current drafts).

- v. The Technical Work Group, including the primary sponsors of the Consensus and LabQC procedures, agrees that the ACIL procedure, with some modifications informed by their procedures, is most appropriate.
- vi. If it is necessary to determine the lowest possible quantitation limit, then the iterative steps or multi level initial spiking determinations in the ACIL procedure should be used.

Multiple or Interlaboratory Quantitation Limit Procedure

3. The LCMRL is amenable for determining either interlaboratory or multiple-laboratory quantitation limits. The ACIL procedure is only amenable for determining multiple-laboratory quantitation and detection limits. The LCMRL provides characterization of the method across a broader analytical range than the ACIL procedure. The IDE/IQE is only amenable for determining interlaboratory detection and quantitation limits.

- i. The Technical Work Group and the primary sponsors of the LCMRL procedure agree that the LCMRL is most appropriate for determining multi-laboratory or interlaboratory method reporting limits.
- ii. For the purpose of assessing the performance of a new method, the Technical Work Group recommends either the LCMRL or use of the iterative concentration steps in the ACIL procedure. If several laboratories are involved, then a multi-laboratory assessment of performance is recommended, unless it is assured that the performance of the participating laboratories is similar enough to make use of inter-laboratory LCMRL or IDE/IQE procedures reasonable.
- iii. If it is necessary to characterize performance of a method across the analytical range, the Technical Work Group recommends the LCMRL procedure.

4. Future Study Recommendations

i. Future method validation studies

If resources are available, the Technical Work Group recommends that the FACDQ-selected procedure(s) be piloted. It would also be beneficial to collect data for some of the more recent, highly-sensitive technologies, for example, methods 200.8 and 1631.

ii. Additional analysis of Pilot Study data

The analysis of the Pilot Study data that has been performed is quite comprehensive. The Technical Work Group believes that there is more to be gained by further review of the existing data analysis than from further data analysis. The existing Pilot Study data should be used to evaluate any modifications to the selected procedure(s) to the extent possible.