

## Initial Demonstration of Capability

In addition to the Quality Manual and Method SOPs, the new code also requires that the laboratory explicitly define what constitutes an Initial Demonstration of Capability (IDC) for each test and method the laboratory performs.

IDC criteria can be included as part of the method SOP or the entire IDC criteria can be documented in a separate SOP. Each of the methods used to analyze compliance samples must have an IDC completed for them by each analyst that will conduct that analysis.

The intent of the IDC is to have a formal documented program that defines exactly what the laboratory has decided must be accomplished in order for an analyst to be considered qualified to perform testing. Think of it as, what will the lab require in the way of training and testing in order to feel comfortable that the analyst could analyze compliance samples unsupervised.

The laboratory must document what the criteria are for the IDC, for each parameter/method that is analyzed in the laboratory for compliance. Elements of note regarding the IDC:

- If the analytical method specifies an IDC procedure then it must be followed as written in the method.
- If the method does not have a specific IDC procedure, then the lab must decide what criteria they will use. The criteria the lab comes up with must be clearly documented.
- Once the analyst completes the IDC and meets the established criteria, then the laboratory has shown that this analyst is qualified to analyze samples for that method. This only has to be done once for each analyst.
- Make sure that the data that supports that the analyst met the IDC criteria is easily accessible for an auditor to review. An easy way to do this would be to maintain a file by analyst or by method that contains the data that shows the analyst or each analyst performing that test - has passed the IDC.

Remember that the IDC does not need to be something “new” that the analyst must do. If the analyst has been working on a test for a long time already the data needed to support an IDC may more than likely already have been completed. In those cases, all that needs to be done is to track down the data and organize it so it can be easily retrieved in the future when requested.

Examples of IDC criteria that could be used (one or several of these could make up your criteria)

- ◆ Read the method.
- ◆ Passed the annual PT sample.
- ◆ Passed a QCS sample.
- ◆ BOD – passed to method blanks and 2 GGA samples on 2 separate analysis days.
- ◆ Passed a split sample with an already qualified analyst
- ◆ Passed a method blank and LCS and calibration curve on two separate days.