

February 2003 Using Sampling Recovery Percentages

Three recent Cleaning Memos (October, November, and December 2002) discussed sampling recovery studies. What is an acceptable recovery percentage for sampling a chemical residue is dependent on how that recovery percentage is used. There are basically two ways that companies can handle those specific recovery percentages in dealing with actual analytical values obtained from swab or rinse samples.

Option 1: The first option is to utilize the recovery percentage to correct (transform) the measured analytical values. For example, if a recovery for an active using a TOC procedure on stainless steel is 78%, then any analytical value obtained with that method for that active with that sampling procedure will be corrected by dividing it by 0.78 (the percentage expressed a decimal). If this is the manner of using recovery percentages, then generally an acceptable percentage recovery should be 50% or greater. If recoveries of 50-65% are obtained, I generally encourage clients to try to improve the sampling procedure to increase the recovery. But, that is not absolutely required. In general, any recovery of less than 50% should have a written justification of why this is acceptable a correction factor (and this justification should refer to studies where you tried to improve the sampling/analytical method). Just for clarification, for any recovery above 100% (for example 106%), a correction factor of 100% is used (or stated another way, no correction factor is used).

Option 2: A second way to use recovery percentages is to require that the sampling percentage be within a certain range so that no correction is required. For example, a requirement might be that if the sampling percentage is within the range of 75% to 125%, no correction factor is required for measured analytical values. In the example in the previous paragraph, if the recovery percentage is 78%, then no correction factor would be required. If a recovery percentage is below 75%, companies have one of two choices. First is that the sampling method can't be used until it is improved to a recovery of at least 75%. A second strategy would be to use the percentage in the same way as it is used in Option 1 above, namely to use that percentage (of less than 75%) to correct the measured analytical values. This latter choice may or may not require a written justification (although if the recoveries were below 50%, a written justification would certainly be prudent).

It should be noted that one will generally find that the range selected for Option 2 recoveries "not requiring corrections" is generally narrower than the range for Option 1 recoveries "not requiring written justification". For example, in Option 1 an acceptable range ("may be used without written justification") may be greater or equal to 50%. For Option 2, an acceptable range ("not requiring correction of measured values") may be greater or equal to 75%.

The purpose of this Cleaning Memo is not to proscribe either option, nor to specify acceptable ranges in which each may be used. It should be noted that the objective of most cleaning processes is to be well below the acceptance limits. An assumption about what is an acceptable recovery is just one factor affecting the true safety factor in the cleaning process. If one believes that the difference between 65% recovery and 70% recovery in a swab sampling procedure is going to be the difference between passing and failing a validation protocol, then more effort should be put into designing a more robust cleaning procedure rather than in designing a better swab sampling procedure.