

**September 2003**  
**Correlation of Swab and Rinse Sample Results?**

Sometimes the question is asked, "Should my swab and rinse sample results be correlated?" Like a lot of things, the answer to this depends on what you mean by "correlated". If it just means that every time you've performed a cleaning study, you have obtained either (1) all good (passing) results on both swab and the associated rinse samples, or (2) bad (failing) results on at least one swab sample and on the associated rinse samples, then it may be appropriate to say the results correlate. In this case, the "associated rinse sample" must involve sampling the same surface that is swabbed. If you are using swab sample for the 1,000 L vessel and rinse samples for the associated piping, then it makes no sense to talk about "correlation" because you are evaluating two different things. Of course, if a rinse sample is used to sample the same surface as a swab sample, that means that it generally must be "grab" sample at the end of the final process rinse.

However, if what you mean by "correlation" is that a necessary relationship must exist between swab and rinse sample results, then the answer is somewhat different. It should be recalled that swabbing focuses on sampling a (relatively) small portion of the equipment surface. In addition, swab locations should include the worst-case locations (that is, those areas most difficult to clean). If a failure occurs in swab sample results, it should not be surprising that perhaps only one sample (or a few samples) -- one of the worst-case locations out of the many taken -- has failing results. On the other hand, rinse sampling effectively "averages" the residue over all sampled locations. In most cases of rinse sampling, this is the entire surface of the equipment rinsed (or the entire surface sampled).

If that is the case, then it is entirely possible that one might have passing results with the rinse sample (the "average" over the entire surface sampled), but have one or more failing swab samples (here again, the swab samples must be associated with the same surfaces sampled by rinsing). If the residue after cleaning is unevenly distributed throughout the equipment, it does make sense that one could have high (failing) levels in certain locations, but still have acceptable (passing) overall results in rinse sampling (when all surfaces are "averaged").

The opposite is not true. Generally if you have failing results in rinse sampling, you will have at least one (most likely, more than one) failure in swab sampling results. This assumes (additionally) that you have calculated your limits for swab sampling and rinse sampling correctly, and that any assumptions used for the rinse sampling limits calculation are reasonably accurate. If the assumptions for rinse sampling limits are extremely conservative (an extreme worst case), then it is possible (but still unlikely) that you could have a failure for rinse sampling, but that all swab samples gave passing results.

The purpose of this Cleaning Memo is to neither promote nor discourage the use of either swab or rinse sampling. Rather the purpose is to point out differences and how those differences might affect whether results are, or should be, correlated.