

Cleaning Memo for October 2015 Comparing Swab and Rinse Results

In the past, I have written (see Cleaning Memo of September 2005) that as a general rule, I expect it more difficult to get passing results with swab sampling as compared to rinse sampling. My rationale had been that when one does swab sampling, one selects worst case locations, those most difficult to clean, for sampling. Those worst case locations are more likely to have higher levels of residues as compared to easier to clean locations. I should note here that if my cleaning process is robust enough, I might get the *same* analytical results at all locations, including difficult to clean and easy to clean locations. Those same results might be <LOD or <LOQ. But if there are differences, any higher result, including any failing result, is more likely to show up in a worst case swabbed location.

In contrast, rinse sampling effectively integrates residue levels over the entire surface area sampled (the entire surface area rinsed). Therefore, while a swab result for a worst case location might exceed the swab limit, the contribution of that one high residue amount in a swabbed location might be effectively diluted by lower residue levels at other locations sampled by the rinse solution.

Now, if I were effectively comparing the same situations, I believe it is a reasonable conclusion that I would be more likely to get failing results with swab sampling. By “same situations”, imagine a case where I have two identical equipment items (A and B), and I make the same product on each of A and B. And then I clean A and B separately with the same cleaning process, to arrive at situation where the total residue and the residue distribution in each of A and B were exactly the same (okay, I realize this is not likely, but I asked you to *imagine* it). So, for the imagined situation, I might have some failing results for swab sampling for A but have passing results for the one rinse sample for B. In that imagined scenario, I was effectively sampling identical situations by two different sampling methods, and could compare the results.

What is really the case is that I am generally never in a situation where I am sampling by two different methods (swab and rinse) on the same situation such that results could be compared. Let’s take a look at the two typical situations.

The first situation involves the situation where my rinse sample is a grab sample of the final process rinse, and then my swab samples are taken after completion of that process rinse and any subsequent drying of equipment surfaces. In that case, the “rinse sample” is not sampling the residues on equipment surfaces after completion of the process rinse (remember that for swab sampling I am measuring residues on surfaces after completion of the process rinse). If I am using a series of pulse rinses, then the final pulse rinse is measuring residues on surfaces left after the penultimate (that is, next to last) pulse rinse. So realistically, I am not comparing sampling of the same situation in this case. Now, I still might expect that swab sampling is more likely to give me a failing result, because in that grab sample of the process rinse, I am effectively integrating residue results over all

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rinsed surfaces. But, I am more open to the rinse sampling results being the more critical measurement, because I realize that what I am sampling with a grab sample is a worst case as compared to a separate sampling rinse, that is, a sampling rinse *after* the completion of the process rinse.

The second situation is where I am performing a separate sampling rinse *after* the final process rinse is completed. There is also a difficulty in comparing swab and rinse results in this situation. Let's say I first perform swab sampling, and then perform a separate sampling rinse. If I have sampled my worst case locations (and presumably removed a large portion of residues from those sampled sites), won't this alter any rinse sampling I might subsequently do. That would be a situation where I might expect a greater possibility that rinse would pass, while at least some swab samples might fail. But what if I reverse the order and perform my separate sampling rinse first, and then follow that up with swab sampling for the worst case locations. What I have effectively done is reduced any residues on those locations to be swabbed by performing my separate sampling rinse *before* I actually swabbed the surfaces.

Note that in the latter case, not only can I not *compare* rinse and swab results, but I should not *perform* the swab sampling after the separate sampling rinse because the swab results will appear cleaner. In the former case it is acceptable to perform swabbing after a grab rinse sample of the process rinse, because in that case the rinse sample I collect will provide the same or a worst case result as compared to a separate sampling rinse.

Note that I am not making a case that one type of sampling is inherently better (or worse) than another. The point is that rinse and swab measure different things about a given residue on equipment surfaces, and I should not expect some kind of *direct correlation* of the two.