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An Alternative Swab Recovery Procedure

The traditional approach to swab recovery studies is to perform them prior to approving a cleaning validation (or cleaning verification) protocol. They may be done either as part of an analytical method validation or as a separate study after the analytical method is validated. There may be situations where this is not practical (because of scheduling or timing of activities). Fortunately there is another way to determine swab recovery percentages simultaneously with the protocol execution. It depends on certain assumptions, but I believe the assumptions are reasonable.

Here is the technique. Let's assume you are required to perform a cleaning verification on short notice, and perhaps you don't have recovery data for the specific material of construction you will be swabbing. You can get a reasonable estimate of the percent recovery by swabbing the same surface area twice, with a different swab each time. But, make sure you put each swab in a separate vial for extraction and for measurement by the analytical method. Now comes the critical assumption, that the recovery percentage from the second swab is essentially the same as for the first swab. If that is true, then we can do the following based on the analytical data for each swab. For simplicity, I will use as an example a case where I express the amount recovered by each swab as a total amount per swab (μg per swab).

Let Q be the amount (μg) of residue on the swabbed area before swabbing.
Let R be the amount (μg) per swab for the first swab.
Let S be the amount (μg) per swab for the second swab.
Let P be the recovery expressed as a decimal (that is, a recovery of 75% will be expressed as 0.75)

Remembering my assumption that the recovery is essentially the same for the first swabbing as for the second swabbing, we can generate two equations that will allow us to solve for the value of P (reminds me of my college days).

For the first swab,

$$R = PQ \qquad \text{(Equation I)}$$

For the second swab,

$$S = P(Q-R) \qquad \text{(Equation II)}$$

We can then solve for Q in Equation 2, as follows:

$$Q = S/P + R \qquad \text{(Equation III)}$$

We then substitute the value for Q from Equation III into Equation I:

$$R = P\,(S/P + R) \qquad \text{(Equation IV)}$$

We can then solve for P as a function of R and S to obtain the following equation:

$$P = (R - S)/R \qquad \text{(Equation V)}$$

In other words, by measuring the residue from the same swabbed area, using two swabs and measuring the amount of residue from each swab independently, we can calculate the recovery percentage (okay, technically

the equation calculates the recovery as a decimal, but I'm sure you can convert it to a percentage).

For those of you who might be skeptical, let's provide an example. Suppose I clean my equipment, and then select an area to sample that is 100 cm^2. I swab that area with one swab, and the analytical result is 83 µg per swab. I then swab the identical 100 cm^2 with a second swab, and the analytical result is 28 µg per swab. Using Equation V above, I can calculate the recovery as:

$$P = (R - S)/R = (83 - 28)/83 = 0.66$$

In other words, the amount of residue that was on the surface before I started swabbing was 126 µg (calculated as 83/0.66). After the first swab, the amount of residue left on the sampled area was 43 µg (calculated as 126 minus 83). Therefore, if the recovery was the same for each swabbing, for the second swab I should obtain (43 µg)(0.66) = 28 µg. Which (of course) was what I actually obtained.

As you are aware, the key assumption is that the recovery is essentially the same for the first swab as for the second. You might review my October 2010 Cleaning Memo on the subject of swab recovery as function of the amount on the surface. In that Cleaning Memo I state that recovery differences "based on spiked levels that differ by a factor of 2 or 3 would be minor". This may be even truer in the analysis of measuring recovery percentage in this way, because the two swabbing events are done by the same person, hopefully only separated by a short time frame (thus reducing the variability).

Certainly there are some potential downsides to determining recovery percentages in this way. One is that it assumes that you will get recovery percentages above your minimum acceptable (such as 50%). What happens if your recovery is only 25% because you chose the wrong solvent for wetting the swab? There are certainly some risks in the use of this alternative method, and those should be considered.

Others may be uncomfortable with the assumptions about recovery being the same. However, this can be "tested" by performing a traditional recovery study in the lab using a known level of spiked residue. Following swabbing with one swab, that swab is analyzed to allow you to calculate the recovery percentage in the traditional manner. However, you then continue to use a second swab on the same surface, and measure the residue form that swab. From the results of each swab, you can calculate the recovery percentage by this alternative method. You can then compare the percentage obtained by the traditional method with the percentage obtained by this alternative method. If they are reasonably close (say, within 10% absolute of each other), then the alternative method may be used.

One potential "problem" with this approach is what happens if the first swab gives results that are below the limit of detection by the analytical procedure. With such results, one cannot tell whether the issue is an extremely low residue level or just poor recovery. There may be several options to deal with this situation. One option is to swab soiled surfaces (before cleaning) with the same two-swab approach. If the results are non-detectable, then clearly the swabbing procedure is inadequate. On the other hand, if a measureable recovery above 50% is obtained, then that recovery can be used. Of course, that negates one advantage of this two-swab approach for cleaned equipment surfaces, in that sampling of equipment before cleaning must also be done. In such cases, it may be simpler just to perform a regular swab recovery with a known amount of spiked residue. Perhaps the possibility of getting "non-detectable" results can be mitigated by driving the LOD as low as practical.

Another issue with this approach is that it can work if a specific analytical procedure is used. If the analytical method is TOC, then the measurements are subject to so much interpretation as to be useless. By this I mean