Cleaning Memo for November 2018
More Swab Sampling Issues

Last month's Cleaning Memo addressed the issue of "timing" in performing swab sampling in a protocol. This month we will consider four miscellaneous topics in swab sampling.

Controlling the swabbed area in protocols
There are basically two techniques used to control the swabbed area *in protocols*. One is what I call the "eyeball" method. That is, the operators are trained to swab a defined area (plus or minus) without any template. Companies may utilize a diagram (typically 25 or 100 square centimeters) in the swab SOP to assist in that process. Another option to assist in the eyeball method is to have a coupon (preferably a translucent plastic) cut to the desired surface area. These adjuncts are *never* placed on the surface, but may be held near the surface to assist in swabbing the correct area.

A second option is to use a template *placed on the surface* to be sampled. Traditionally a template is a plastic sheet with a defined area (typically 25 or 100 square centimeters) cut out *within* the template. The template is placed on the surface to be sampled, and the swabbed area is controlled by the area of the cut-out section of the template. A possible variation in the template method is to have template with an area *slightly larger* than the area to be swabbed. For example, if my swabbed area was to be 10 cm X 10 cm, the template might have a cut-out area of 11 cm X 11 cm. That way, once I place my template on a surface, my swab strokes would stop about 0.5 cm from the edge of the template. There is still some element of variability as in the "eyeball" method, but the variability is significantly reduced. This *larger* template avoids the issue of the swab head contacting the template edge, perhaps leaving behind some liquid at the surface/template interface.

My recommendation between the eyeball and template method has generally been to use the eyeball method. The reason is that the worst-case swabbing locations are typically not flat surfaces. Templates can be problematic if the surface is not flat (or perhaps gently curved). That said, if all sampled surfaces are flat, the template certainly controls the swabbed area better, and the use of the slightly larger template avoids contact of the swab head with the template itself.

Controlling the swabbed area in recovery studies
The same two methods discussed above for protocols can also be used *for recovery studies* for *larger* coupons. However, there are two more possibilities to consider for recovery studies. One is to use a coupon the exact size of the area to be swabbed. That is, if the swabbed area is 100 square centimeters, my coupon is cut exactly 10 cm X 10 cm. The main concern with this option is having the swab head touch the coupon edges, which can lead to loss of liquid and a corresponding low recovery percentage. This issue can be overcome by having a coupon slightly larger than the area to be swabbed (much like having a slightly larger area for the template discussed previously). For example, I

might use a coupon that is 11 cm X 11 cm. When I swab the coupon, I would stop my swab strokes about 0.5 cm from the edges of the coupon. That way I can control my swabbed area reasonably without having the swab head touch the edges of the coupon.

Use of an extension pole for swabbing inaccessible location
This is one of my *major* "pet peeves". I know many companies use this technique, but I see little reason for its use in most cases. If I have a swab on the end of a three meter pole, how do I control the pressure applied to the swab head? And, how do I control the surface area sampled? Furthermore, if I am sampling through an opening in the top of a large vessel, I may be able to sample the sidewalls of the vessel, but how do I sample under the agitator blades, certainly a more significant worst-case location. In such a situation, unless I am willing to have a person enter the tank for swab sampling, I would much prefer to depend on rinse sampling (by setting limits appropriately for my rinse sample and by having recovery studies done for the rinse sampling procedure).

Use of multiple swabs for the same surface
The issue here is that I may be able to increase the recovery percentage by swabbing the same surface twice (or even thrice). That is, I use one swab first over a specified area (for example, a 10 cm X 10 cm surface) with that first swab being a wetted swab. Then I swab that same 10 cm X 10 cm surface with a second swab, and place both swabs in the same vial for extraction. In some cases, the second swab may be a dry swab, based on the fact that the second swab will "mop up" the liquid left on the surface from the first swab. In other cases, I might want that second swab to also be a wetted swab, based on the possibility that the limiting factor is dissolution of the residue onto the swab (with a second wetted swab allowing a greater percentage recovery).

If I wanted to investigative whether two swabs gives me a significantly better recovery, there are two possible options. One is to perform a recovery study with two swabs, but putting the swabs in separate vials for separate extraction and analysis. The second option would be to do two separate coupons (spiked the same), one coupon with one swab and a second coupon with two swabs, and then compare the recoveries.

My preference for a given facility is to *always* use one swab for sampling, or to *always* use two swabs. While it is possible to set up a sampling SOP using one swab for certain specified products and two swabs for other specified products, this requires more attention and care to make sure the correct number of swabs is used in a given protocol.

If multiple swabs are used for a given surface area, then it is important, particularly if TOC is the analytical method, to make sure that my blank is also with multiple swabs.

This Cleaning Memo does not exhaust all the concerns with swab sampling, but it does point out concerns and options with certain practices.