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Additional Considerations in Recovery Studies: Part 2

Last month's Cleaning Memo covered several issues in designing sampling recovery studies. This month's memo continues with three more considerations.

Drying time: Since in most cases, swabbing of equipment surfaces will involve swabbing of dry equipment surfaces, it is a reasonable expectation that the spiked residue be allowed to dry on surfaces for a recovery study. The question then arises, "How long should it dry?" The answer is not straightforward. However, once most spiked residues are dry, there are no further changes in the difficulty of removal. One exception to this might be residues that could crosslink over time, but these are probably rare. As a practical matter, it makes sense to set both a minimum time and a maximum time. The minimum time will depend on whether the residue is spiked in water (in which case 12 hours might be a reasonable minimum) or a volatile organic solvent (in which case 1 hour might be a reasonable minimum). One might ask why a maximum is specified when no further change is expected once the residue is dry. The answer is that it just makes good practical sense (from a laboratory processing viewpoint) to have the surface sampled within 12-24 hours after it dries. A reasonable scheme may be something like no less than 12 hours, but no more than 24 hours. That way, the coupons can be spiked in the afternoon of one day, and sampled the next morning.

If a dry time is recommended for the swabbing of spiked residues based on the fact that the equipment surfaces are sampled dry, then one might ask why is drying necessary for recovery studies involving rinse sampling. After all, rinse sampling is not typically done on dried surfaces (although it can be for small parts). And that is a good question! However, the answer is that it is not only the drying of the residue on the surface after cleaning that is important, it is also the drying before cleaning that might better represent the nature of the residues to be removed in sampling. Therefore, even for rinse sampling, setting an appropriate range for drying times for spiked residues is appropriate for recovery studies.

Coupon size: There are several issues here, and they are slightly different with swab and rinse recovery studies. For swab studies the coupon should be of sufficient size to encompass the surface area and shape of the area to be swabbed. If 100 cm^2 (10 cm x
10 cm square) is to be sampled, clearly the coupon should be at least a 10 cm x 10 cm square. It may be a circle with a diameter of 20 cm. However, it probably should not be a circle with a diameter of 5.64 cm (so that the surface area is exactly 100 cm^2). If the swab procedure calls for swabbing a specific pattern (10 cm x 10 cm square), then that swab procedure cannot be followed exactly on the circular surface with an area of 100 cm^2.

The second issue for swab recovery studies revolves around the issue of whether coupons should be exactly the surface area swabbed (10 cm x 10 cm square, for example), or whether the coupon should be slightly larger (12 cm x 12 cm square, for example). If the coupon is exactly 10 cm x 10 cm, the advantage is that the surface area sampled is exactly 100 cm^2. One possible disadvantage of this exact size is that there may be some unknown edge effects as the swab head touches the coupon edge. For example, a small amount of liquid may "fall over" the edge and not be captured. Alternatively, the edge of the coupon may be sampled during the swabbing procedure. Swabbing a coupon with a larger area than the swabbed area may actually better reproduce an actual equipment swabbing situation. However, it should be noted that these suggestions of what

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might happen are purely theoretical (at this time). These slight difference may not be significant when one considers the overall variability of surface swabbing (which after all is a type of manual cleaning).

For rinse studies, the issue is not so much the size and/or shape of the coupon, as it is the ratio of the volume of the rinse sampling solution to the surface area sampled. This ratio should be the same or lower than the actual ratio of sampling solution to surface area in equipment sampling. Other things being equal, one would expect the same results whether one sampled 50 cm^2 with 75 mL of water or 100 cm^2 with 150 mL of water. Which one is utilized for a rinse recovery study would be a matter of convenience and practicality.

Coupon rotation in swab sampling: A third issue involves the positioning of the coupon relative to the person swabbing. Most presentations on swabbing techniques discuss the need to swab in one direction, and then flip the swab head and swab in a direction 90° to the first swabbing step. The temptation in the lab is to take the coupon and turn it 90° and swab exactly like what was done in the first part of the swabbing procedure. In many cases of actual equipment sampling, however, it is not possible to rotate the sampled equipment 90° to make swabbing simpler. If neither the equipment nor the person swabbing can change their position, then the hand motion for the second swabbing step will be slightly different from the motion in the first step. It is this motion that should be approximated in the lab swab recovery study. In other words, as much as possible keep the positions of the coupon and the operator fixed in the recovery study, with only the operator's hand/wrist/arm motions varying between the first swabbing step and the second swabbing step. The extent to which this will make a difference is again theoretical. However, it requires no additional effort, so therefore should at least be considered for swab recovery studies.

The purpose of this memo is not to say that certain techniques are (or should be) mandated. Rather, these are three items that should be considered in the design of recovery studies.

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