

Cleaning Memo for December 2015

Special Cases in Determining “Visually Clean”

It is well known that there are a lot of variables in determining whether a surface is visually clean or not. Those variables include lighting, distance, surface roughness, angle of viewing, residue sheen, residue color, operator eyesight, and the contrast between the residue and the surface. This Cleaning Memo will focus on the last issue in that list, the contrast between the residue and the surface. It will focus on two specific cases, and possible ways to deal with appropriate evaluation as to whether the surface is “visually clean” or “visually soiled”.

In the first situation, suppose we are dealing with a residue that is clear (transparent), and further that the residue has a sheen (and that sheen is different from the sheen on the surface itself). If the residue is only on a small portion of the surface, then the visual presence of that residue may be established by the difference in sheen of the surface itself in contrast to the sheen of the residue on the surface. That’s the easy case. The more difficult case is what happens if the residue covers the *entire* surface, remembering that the residue is transparent. We may look at the surface and not be able to identify it as visually soiled; that is, the surface looks the same over all areas viewed. How do we deal with that situation?

One way is to take a swab and wet it with a solvent the residue is known to be soluble in. The swab is then moved across a portion of the surface (back and forth several times). The surface is then allowed to dry. If the swabbing dissolves and removes the residue on the surface, it may now be possible to see any contrast between the surface itself (the portion of the surface swabbed) and the cleaned (or spiked) surface. If there is no difference in appearance between the swabbed area and the non-swabbed area, then the surface (before swabbing) could be considered visually clean. On the other hand, if there is a visual difference between the swabbed area and the non-swabbed area, then the surface (before swabbing) was not visually clean.

There may be some variation on this procedure, such as using two solvent-wetted swabs in succession. The reason for two swabs might be that one might only remove 70% of the residue on the surface, and the second swab might provide an assurance of > 90% removal of residue, thereby enhancing the difference (if any) in appearance between the two areas.

A second situation involves a residue that is the same color as the surface. The most common example of this is where the residue is white and the surface itself is also white, such as would be the case with PTFE (polytetrafluoroethylene). In that situation, there may be large amounts of residue on the surface ($> 20 \mu\text{g}/\text{cm}^2$), but the surface appears visually clean. One way to deal with this is to use an artificial situation to examine the surface, such as wiping it with a black (or other dark color) cloth or swab. If the cloth appears visually soiled with white residue, then perhaps the surface is not visually clean. I include the word “perhaps” because whether I see a white residue on the cloth depends

on the surface area wiped and the surface area of the cloth the residue is transferred to. It certainly is possible to increase the ratio of wiped surface area to cloth (or swab) surface area such that the cloth will always appear soiled. It would be appropriate to control (for consistent results) the area wiped and the cloth or swab surface area. It also may be appropriate to do some spiking studies (with the white residue spiked at different levels in terms of $\mu\text{g}/\text{cm}^2$) to determine at what level the cloth would be visibly soiled.

For this second situation, remember that the regulatory requirement (or at least my understanding of the regulatory requirement) is not that the cloth be visibly clean; it is that the equipment be visually clean when viewed by the unaided eye. If you use a “black cloth” evaluation, make sure you carefully define the objective and what is acceptable (or what is unacceptable) in such an evaluation. For example, it might be used in routine monitoring of a process, whereby a visibly soiled cloth wipe requires that the equipment be sampled with measurement by a validated analytical method (such as UHPLC or TOC). On the positive side, if the cloth is visually clean, it might be an measure of the consistency of the cleaning process.

The purpose of this Cleaning Memo is not to advocate for use of either of these options in determining if a surface is visually clean. It is merely to present alternatives that may be useful in certain situations, and to provide some cautions in their use.