

July 2011
Manual Cleaning Issues – Part 2

This Cleaning Memo is a continuation of last month's Cleaning Memo on the subject of special issues for manual cleaning. Last month I gave a definition for manual cleaning, and discussed issues related to classification of cleaning processes based on their degree of automation and the location of cleaning. One reader brought up the question of where a "static soak" fits into that categorization. A static soak may involve disassembling small parts, placing them in a sink with cleaning solution, and then without any operator intervention (no scrubbing or brushing, for example), allow the part to be cleaned. The part may then be removed and rinsed by any of a variety of processes. The question is, "where does such a static soak fit on the continuums discussed last month?" Well, if this process involves disassembly and moving the parts to a sink, then clearly this is "out of place" cleaning (at least according to the usage in last month's Cleaning Memo). However, is this automated or manual cleaning? Well, the washing step itself is not dependent on operator manipulation to a high degree. However, while I would ordinarily be hesitant to call this an "automated" cleaning process, if "push comes to shove" I would probably classify it as a semi-automated (or partially automated) process. My preference, if I am not forced to categorize such static soak processes, would be just to say that is a unique situation which doesn't easily fit into my categorization system. Note that this same concern arises with an "in-place" static soak, where an operator fills a process vessel with cleaning solution, and then in a static soak allows the soil to be dissolved or emulsified.

Now, the main issue I wanted to cover in this Cleaning Memo was what to do for routine monitoring for manual cleaning processes. The most common problem with a manual process is operator error, usually involving lack of overlapping strokes in the manual wiping/brushing/scrubbing process. While it is possible that the evidence of this problem may be visually apparent during the washing or rinsing step, it is more likely to be apparent after the equipment surfaces are dry. This problem will show up as streaks of visible soil on the surfaces corresponding to the direction of scrubbing/wiping/brushing strokes. If this occurs, what should be done?

Well, one option is to treat it as a deviation, performing an investigation which hopefully results in corrective and preventive actions. Another option, however, is to incorporate that possibility into the cleaning procedure itself. That is, allow for the possibility that if after a manual cleaning process, the equipment is visually examined and found to be "not visually clean", then the equipment can be cleaned by the same manual cleaning procedure again. I would try to put some constraints on what "not visually clean" might be. For example, if the entire (or even the majority of the) equipment surfaces were not visually clean, I would not allow the equipment to be automatically recleaned again to correct the problem. In the case where a significant portion of the equipment surfaces are still visually dirty, it should be clear that something major has happened, and I would prefer to handle this as a deviation. On the other hand, if there are just random areas where the equipment is visually soiled, and the soiled pattern is suggestive of improper coverage (perhaps due to not using overlapping strokes), then I could handle it outside the deviation procedure, but within the cleaning SOP itself. Note that I might put another constraint on doing this, and that would be allowing it to be recleaned only once. In other words, if I cleaned it once and it was still visually dirty, I could reclean again. If after that recleaning the equipment surfaces were still visually dirty, then clearly something seriously is different, and I would want to capture that under my deviation procedure.

Here are some additional constraints.

1. I would not necessarily require retraining of the operator prior to the recleaning, since the cause has been identified as lack of overlapping strokes (or something similar). However, some companies may want the recleaning done by a different operator.
2. If after the initial cleaning, the equipment is visually dirty, I would recommend that the procedure require examination of the surface by a second person (a supervisor, for example) to confirm that the soiled pattern is suggestive of improper coverage in the manual cleaning process.
3. If I allow recleaning under certain conditions, I would want to capture on a batch record or a cleaning log whenever that was done. The purpose is to identify any trends, such as frequent recleaning by a specified operator. If such trends are observed with a given operator, then mandatory retraining should be considered. If the frequency of recleaning is high, but is not associated with a given operator, then the cleaning procedure should be reviewed.

It is certainly acceptable to treat such situations described here as deviations, and handle them using the firm's deviation procedures. However, taking this situation outside the deviation system may help avoid unnecessary paperwork and investigations that add little to product quality (in this situation).

The purpose of the Cleaning Memo is to help clarify some key issues in manual cleaning processes and their validation.