

September 2004
Issues in the Visual Examination of Equipment Surfaces

The issues that will be discussed include the extent of the visual examination, the training/qualification for those people doing the visual examination, the need for second person verification, and the need for a written SOP. What is required for each issue will depend on the nature of the visual examination. There are at least four different circumstances in which visual examination of equipment surfaces may be utilized.

Case I is visual examination of equipment surfaces during protocol execution to supplement rinse/swab testing.

Case II is visual examination of equipment surfaces during protocol execution as the sole acceptance criterion (with no rinse/swab testing).

Case III is visual examination of equipment surfaces as a routine monitoring practice (following completion of validation).

Case IV is visual examination of equipment surfaces at the beginning of manufacturing.

Clearly, one would expect the requirements for each case to be different. In terms of the extent of visual examination, one would normally expect it to be most rigorous for Case II, since no swab or rinse testing is done. It is probably least rigorous for Case IV, because examination of only the assembled equipment is required (for Case III, there may be inspection of unassembled equipment in manual cleaning, for example).

In terms of training/qualification, one might expect that Case II is the most rigorous again. However, that is *not necessarily* the case. In all cases, it is required to qualify people in terms of visual acuity (vision corrected by glasses, “not color blind”). It is also required to train people to distinguish between “residues on the surface” and “imperfections/blemishes in the surface” (or at least contact a supervisor when a suspected “residue” is found to determine its true nature). But, the required training/qualification should be the same for each case. What is different for Case II is that for the *laboratory* aspect of determining the correlation of visually clean to a specific residue level, there may be special training/qualification required.

In terms of second person verification, there is clearly the greatest need for second person verification for Case II. However, Case I ordinarily should involve second person verification, since it does involve an acceptance criterion in the protocol. For Case III and Case IV, it is less critical that there be second person verification. For those two cases, it may be adequate to specify a second person only if there is a “questionable” residue.

Finally, in terms of a written SOP for visual examination, this is a must for Case II. The SOP should specify (or should allow to be specified in the protocol) things like the distance, the lighting, and specific sites to examine. For the other cases, a detailed SOP may not be required, but is helpful. For Case I, the visual examination is supplementary to the rinse/swab testing. Specific locations for examination are not necessarily specified (although clearly it is an expectation that any swabbed location is visually examined before swabbing). In Case I one is doing a general observation over all readily-visible equipment surfaces. In one sense, if one is using Case II, one should also include aspects of Case I in the Case II SOP to make sure that a general overall observation of equipment surfaces is done. For Cases III and IV, a separate SOP for visual examination may be helpful, if for no other reason than to help convey the importance of a good visual

examination in helping to insure consistency. One way to address these needs is to have one procedure, but have different sections in terms of applying certain practices to the different cases.

As used in this Cleaning Memo, the term “require” or “requirement” is not necessarily to be taken as a *regulatory* requirement. Most regulatory guidelines are silent on this subject. The purpose of the Cleaning Memo is neither to specify nor prohibit certain practices, but rather clarify issues that should be considered in the different cases of visual examination.