

are trapped in difficult to clean areas not effectively cleaned by the CIP system (e.g., dome nozzles or dead-legs).

Consideration of the following is suggested as part of the development of a manual cleaning methodology:

- The inspection of major equipment following or during manual cleaning should take place prior to the analytical rinsing or swabbing to provide a greater probability that target residues are removed prior to sampling.
- The inspection should not substitute for the final visual inspection that would typically take place following analytical sampling. The final visual inspection determines the success or failure of the validation execution.
- For those areas that will be inspected again for final determination of visual cleanliness, this in-process inspection may be less stringent than the final visual inspection. For instance, flashlights and mirrors might not be necessary, complete absence of visible residues might not be required, and complete disassembly of equipment might not be justifiable. The justification for this approach being that this type of inspection is not the final inspection and once a residue has been acted upon in some manual manner (e.g., scrubbing, power washing) it is more likely to be effectively removed subsequently by the CIP system.
- The inspection is at the discretion of the process designer(s) and is not required. The purpose of inspection after manual cleaning is to measure the effectiveness of the manual methodology before resuming CIP cleaning. It might not be justified for example, if the manual methodology has been shown to be rugged in the past, or is simply a precautionary measure to provide a greater probability of passing acceptance criteria at the conclusion of the cleaning process.

Inspection of equipment that is cleaned manually and can be 100% visually inspected prior to release back to production (e.g., mills and minor equipment) is not the subject of this specific section. Rather, the inspection of these examples should follow the guidance of “final visual inspection” detailed below.

2 (a). Visual Inspection of Dedicated Equipment – Interval Cleaning:

Interval cleaning, or cleaning processes that take place within a campaign of the same product, are appropriate when an evaluation of the material being cleaned has been completed and there are no quality concerns (e.g. degradation of material) about carryover of some amount of one batch into the next batch.

Although the intent of this section of the procedure is focused primarily on dedicated equipment it may also be applied to interval cleaning that takes place between batches within a campaign using multi-purpose equipment.