

Translating Laboratory-Developed Visual Residue Limits to Process Area Applications



Keith Bader



Kelly Scalva

By

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While considerable attention has been given to the development of visual residue limits (VRLs) in a laboratory setting, translating the bench scale values to the assessment of process surfaces has not yet been thoroughly assessed. However, knowledge of both the critical parameters that impact the determination of VRLs and the influence of those parameters on visual inspection can provide a framework for the development of a robust visual inspection program. Development of such a program first entails the determination of constraints imposed by equipment geometries and facility lighting. VRLs can then be determined for post-productions residues of concern, which, of course, carries its own specific challenges. Once VRLs have been determined, they cannot be immediately applied without considering certain strategic cleaning program approaches and potential sources of variability.

Many factors influence how visual inspection will be conducted in a manufacturing facility. Among the most critical are inspection conditions in the facility, the condition of existing equipment surfaces, and the physical characteristics of post-production residues deposited on product contact surfaces. While many in industry embrace the importance of visible residue limits (VRLs), few have a clear pathway to translate VRLs determined in the laboratory to the manufacturing floor. The intent of this paper is to provide the background and information that will allow industry to formulate a plan of attack to practically integrate VRLs into the visual inspection program. To begin, the best starting place is to determine the constraints imposed by the manufacturing floor.

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