

Visual Residue Assessment (VRA) Study and Visual Inspection (VI) Training

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PROJECT DESCRIPTION

It is an agency expectation that staff are trained to visually inspect equipment for residues following cleaning. This training must be formal and include a detailed SOP. If visual inspection is leveraged as a sampling method, particularly in cases where parts cannot be removed or accessed for swab sampling, small-scale VRA studies should be performed to characterize the appearance of soil residues and confirm residues of concern are visible at the carryover limit.

The Hyde Analytical Laboratory was contracted to perform a small-scale VRA study for multiple soils. The VRA study characterized the visual aspects of the soils through an appearance assessment and a detectability assessment. The appearance assessment captured and documented the appearance of the soils after exposure to cleaning agent, which provides knowledge of what can be expected on equipment surfaces after an ineffective cleaning cycle. The collected images were used to aid the training of client operators for full-scale VI activities. The detectability assessment portion of the VRA study determined if the soils would be visible if they remained on the equipment surface after a cleaning cycle. This was accomplished by spiking each soil onto small-scale surfaces, simulating viewing conditions present at full scale, and having multiple analysts view the surface to indicate if they could see the soil.

The results of the small-scale VRA study were leveraged as inputs to full-scale visual inspection training and procedures. A visual inspection SOP was drafted, and Hyde personnel trained client personnel on performing visual inspections. The training included classroom training on VI background/theory and viewing pictures of client-specific soil residues gathered during the preceding VRA studies. Additionally, the procedural steps in the VI SOP were reviewed with the trainees, which included discussions of when to use visual aid tools (e.g., flashlight), what to do if a failure occurs, etc. The training also included confirming each client operator was capable of accurately and repeatably detecting a soil residue that was expected to be visible.

STUDY OVERVIEW

The laboratory conducted a small-scale VRA study to provide examples of soil residue appearance on equipment surfaces and assess whether the soil is detectable by visual inspection at the limit of concern under simulated full-scale viewing conditions. Additionally, Hyde drafted a visual inspection (VI) SOP and traveled to the client site to train operators on performing visual inspection of full-scale equipment.

SCOPE AND DELIVERABLES

Assess and Document Soil Appearance:

- Gather images of process soil residue unexposed and partially exposed to representative cleaning cycle parameters. These images serve as training aids and SOP guidance for inspecting full-scale equipment that may be inspected after an ineffective cleaning cycle, i.e., soil remains on the surface.

Evaluate the Detectability of Soil Residue:

- Determine if soil residue at the limit of concern can be visually detected under viewing conditions representative of those present in full-scale equipment.
- Identify Required Visual Aid Tools:
- Determine if alterations to full-scale viewing parameters are required to visually detect soil residue (e.g., is a flashlight required).
- Provide VI SOP:
- Provide instructions for client operators performing visual inspection of full-scale equipment, including how to tell if visible residue is soil or cleaning agent, if a flashlight is required, what to do if there is a visual failure, etc.

Train Client Operators:

- Perform training activities at the client site to assess the operators' ability to accurately and repeatably detect residue in full-scale equipment. Additionally, perform train-the-trainer activities so the client can fully own the program once the Hyde trainers leave the site.

SOLUTIONS, RESULTS AND ACCOMPLISHMENTS

- ✓ **Determined some residues are visible at the limit of concern under full-scale viewing conditions.** Certain soils were confirmed to be accurately and repeatably detected at the limit of concern, which indicates visual inspection can be relied upon as a sampling method for these soils.
- ✓ **Identified the need for a visual aid tool when performing visual inspections.** Some soil residues were not visible at the limit of concern unless a flashlight is used. This indicates these certain soils cannot be detected on equipment surfaces unless the visual inspection activities include the use of a flashlight. It was recommended that the client write the use of a flashlight into the VI SOP so operators have the viewing conditions required to visually detect the soil.
- ✓ **Determined some residues are not visible at the limit of concern. Some soils evaluated in this study could not be detected at the limit of concern, even with the use of a visual aid such as a flashlight.** This indicates visual inspection cannot be used as a sampling method for these soils and other methods such as swabbing or rinsing must be used.
- ✓ **Established a client-owned training program for VI.** Initial training of client operators was performed by Hyde. During the training activities, client personnel were also trained as trainers so they could train future client operators. This allowed the client to own the newly established training program and have a standardized approach for ensuring all operators are able to accurately and repeatably detect visual failures while inspecting full-scale equipment.

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