Cleaning Validation

EHEDG Guideline Doc. 45 - Cleaning Validation, Monitoring and Verification (Sept. 2021)

Cleaning Validation – What & Why ?

- **Obtaining the documented evidence** that cleaning with or without disinfection processes, if **properly implemented**, is **consistently effective** at achieving a **predefined** level of hygiene on product contact surfaces identified during the hazard evaluation. *(EHEDG Glossary – V 2020/08.G04)*

- **It is a very important activity to ensure the foods products to meet consumer safety and product quality requirements.**
- **A mandatory activity in the quality management system of most food companies**

Which activities?

What is the difference?

- **Verification** - Confirmations that the control parameters have been implemented as intended
- **Monitoring** - Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.
- **Validation**

How? Cleaning Validation Master Plan

A structured approach to identify and explain the steps to complete the validation, containing:

The Validation Protocol

- Objective (why and what)
- Responsibilities (who)
- Scope (where - process or part to be validated)
- Number of repeat
- Identification of relevant contaminants
- Selection of worst-case conditions
- Sampling and testing (number of samples, locations/areas to be sampled, analytical methods)
- Acceptance criteria

Validation Input documents Required:

- Qualification evidence including P&IDs (Process and Instrumentation Diagrams) of the equipment to be cleaned (see EHEDG Doc. 34)
- Qualification evidence CIP installation including P&ID's (see EHEDG Doc. 50)
- Standard Operating Procedures (SOP) for the cleaning (and disinfection, if applicable)
- Calibration & Maintenance records
- Specification of water (e.g. hardness, micro data, pH etc..) & C&D chemicals
- Cleaning training records of staff

For revalidations: historical data of monitoring and verification activities (out-of-limits situations and the completion of corrective actions).

Validation Master Plan - **contaminants**

Identification of relevant contaminants, may include:

- Unwanted product residue
- Microbial contaminants
- Non-recipe chemicals, e.g. allergens, DNA, flavours, colours and/or proteins
- Cleaning-chemicals
- Foreign bodies
- GMO’s
- N.B. Religious laws, such as Kosher/Halal

Validation Master Plan - **Selection of worst-case conditions**

Worst-case conditions Selection, may include:

- ***Product:*** most difficult of the group, soil, high risk, vulnerable users, and highest levels of contaminants (allergens, microbial)
- ***Process conditions：*** e.g. high temperature, long holding time, longest run length
- ***Unhygienic Designed equipment and process parts***
- ***Sub-optimal Cleaning conditions:*** e.g. least optimal temperature, cleaning agent concentration, lower flow *or impact and cleaning shadow etc.. (large diameter pipeline, PHE, vessel lid, dead-ends etc..),*
- ***Maximum time between***
  - end production ~ start of the cleaning process;
  - completion of cleaning and the initiation of next production

Validation Master Plan - **Methods to confirm cleaning results**

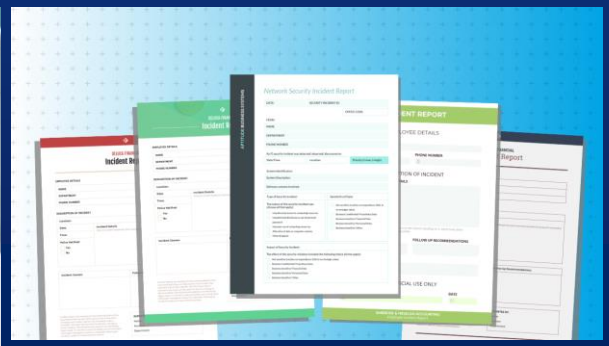
- **Visual & sensory inspection** (primary pass criteria, not recommend of further analysis if this fails)
- **Analytical Methods (**specified, sensitive, reproducible, quantification skilled people)

Contaminant detection	(Analytical) Method	Sampling	Advantages	Disadvantages
Product Residue	Visual Inspection (flashlight/ UV/Boroscope)	• Product contact surface	• Quick result • Easy to use • Cost effective	• Only applicable at (easily) accessible process line • Not applicable for invisible contaminants e.g. Micro, chemical, allerge etc..
Micro-organisms	Microbiological analysis	• Swab • Contact plate • Rinse medium • Finished product	• Semi-quantitative • Sensitive method • Can be specific	• No immediate results
Organic residues	Bioluminescence – ATP	• Swab • Rinse medium • Finished product (for aseptic)	• Quick result • Automatic trending possible • Easy to use	• Not selective, not suitable for all soils • Pass and fail levels must be defined for all sample locations
Allergen protein	ELISA	• Rinse medium • Surface swab • Finished product	• Specific and sensitive method • Quantitative method	• No immediate results • Costly • Poor reproducibility • Sensitive to false positive and false negative

Validation Master Plan - **Execution Validation**

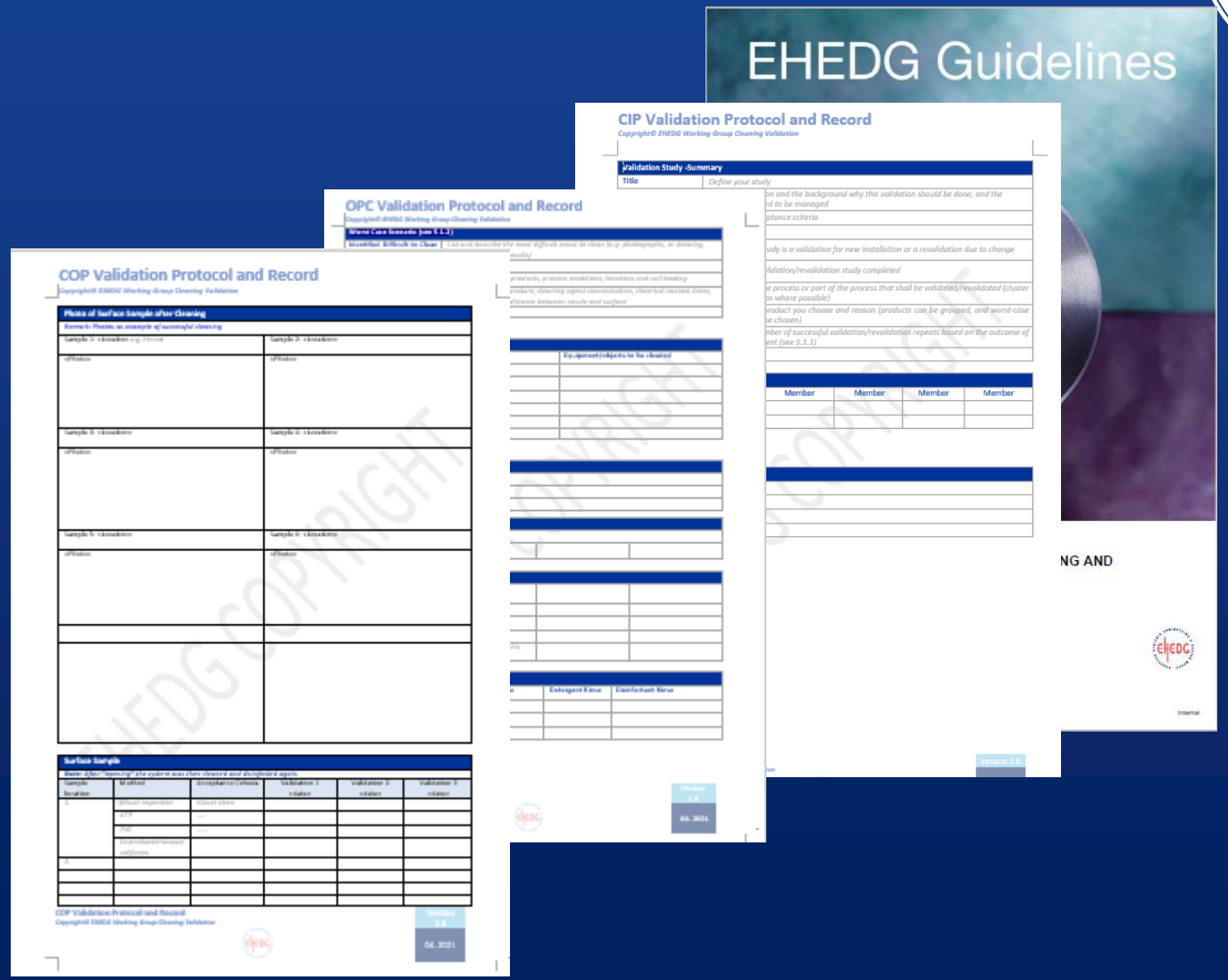
- **Review: process PFD, P&ID, C&D SOP's**
- Verify/monitoring Cleaning
  - Collect and analysis of CIP data

- **Visual Inspection, sampling for analysis:** May need partial or complete disassembling
- **Analysis, Reporting & Approval**
- **For all deviations, CAPA (corrective and preventive actions) defined**



EHEDG supporting Documents

- Guideline Doc. 45
- 3 Templates for CIP, OPC and COP
- With practical examples
- Webinar on 16 February 2022 (recording available on EHEDG website)



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Acknowledgement

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