# Validation and Verification Supporting Information

Validation requires scientific proof that a process should and does work. Related to non-CIP cleaning and sanitation programs, the following are examples of validation documentation typically maintained by facilities and accepted by food safety auditors (Tables 1 and 2). They are classified into "theoretical" and "practical". Table 3 addresses verification. Tables 4 and 5 discuss the same type of information for CIP systems.

If there are changes to the process which may significantly impact the efficacy of the control measure such as a change in equipment, the introduction of a new ingredient/product (new soil) or a change in the chemicals used, the process may need to be re-validated.

**TABLE 1. Examples of Information Supporting Validation: Theoretical Proof Supporting Efficacy of Control Measures.**

| Source | Item |
|---|---|
| Scientific Community | Challenge studies conducted by Corporate entity/service provider in a well-controlled environment<br>Peer-reviewed publications<br>White papers |
| Regulatory Authority | Reference tables<br>Safe harbor documents |
| Cleaning & Sanitation Product Provider | Product Labels (e.g, EPA Registration information)<br>Catalog sheets<br>Case studies<br>Sell sheets, brochures<br>Letters of Guaranty (LOG)<br>Safety Data Sheets (SDS) |

**TABLE 2. Examples of Information Supporting Validation: Scientific Practical Proof of the Efficacy of the Control Measures within a Specific Facility.**

| Source | Item |
|---|---|
| Manufacturing Facility | Justification that chemistry and chemical concentrations are appropriate for the soils in the application |
| | Documented Cleaning & Sanitation Program<br>Cleaning procedures/ Instructions/Sanitation Standard Operating Procedures (SSOPs)<br>Master Sanitation Schedule (MSS)<br>Results and Analysis of Hygiene Monitoring Program:<br>• Microbiological data (applicable indicators - Total Plate Count, Coliform Count, Yeast & Mold, *Escherichia coli*, *Salmonella* spp., *Listeria* spp*., etc.),* collect enough data until you feel comfortable (e.g., suggest that 3 consecutive passes vs. acceptance criteria or a single confirmation (minimum) of established CIP performance requirement are achieved<br>Records of chemical concentrations and proper use of test kits |

Verification requires scientific proof that the control measures have been implemented as designed. In other words, that they are in place, are being followed according to plan and they are being carried out consistently. This follows validation and needs to be done at a consistent frequency. Related to cleaning and sanitation programs, the following are examples of verification documentation typically maintained by facilities and accepted by food safety auditors (Table 3).

**TABLE 3. Examples of Information Supporting Verification.**

| Source | Item |
|---|---|
| Cleaning & Sanitation Product Provider | External reporting (e.g., Ecolab's ServiceChexx™):<br>• General audit, hygiene audit, third party audit preparation<br>• CIP Performance Check<br>• ATP Program Analysis |
| Manufacturing Facility | Titration Log Sheets<br>Master Sanitation records showing activity was carried out<br>Pre-operational checks<br>Microbiological swab results<br>ATP testing results<br>GMP/hygiene audit results<br>Internal Audit Reports<br>System Walks |
| Corporate Entity | Internal Audit Reports<br>System Audit Reports |

# Validation & Verification of Clean in Place (CIP) Systems

The same principles apply when validating and verifying CIP Systems. Validation should be carried out initially to establish a baseline for all inputs and then a long-term on-going validation process should be planned and executed by the manufacturing facility. The initial validation process requires establishing a baseline for the chemicals, preparation steps, the skid and the circuit results. See Table 4 for details.

**Table 4. Steps Needed to Conduct Initial Validation for CIP Systems.**

| Baseline to be Established | Requirements |
|---|---|
| Chemicals | Justification that chemistry is appropriate for the soils in the application<br>Justification that the chemical concentrations are appropriate to the application<br>Justification that the cleaning frequency is appropriate to the operation (consider run times, nature of product, etc.) |
| Preparation steps to run CIP (manual cleaning & preparation) | Visually check vessel, execute manual rinse if necessary<br><br>Disassemble the equipment and clean all surfaces not cleaned by CIP<br>Brush-wash dead areas (e.g., *under man-way door)*<br>Review CIP charts |
| The skid (the equipment) | Know your CIP system and circuits:<br>• Maximum pipe size in the skid<br>• Program<br>• Line drawings of CIP system and valves<br>Conduct a CIP performance check:<br>• Visual check to confirm wet surfaces are shiny<br>• Check flow meter against calibrated meter if possible (e.g., Doppler).<br>• Check conductivity probes against solution of known concentration<br>• Check if flow is appropriate (e.g., using calibrated flow meter, using time v. volume check with stopwatch)<br>• Check for leaks<br>• Assurance that valves (drain, circulation, water, steam) are functioning, gaskets are functional and supply pump is large enough (right flow) |
| The circuit (program) | Conduct a CIP performance check:<br>Check each circuit<br>• Assurance that valves are actuating/pulsing<br>• Assurance that CIP is actually performing as per program:<br>– Flow rate (established by line size)<br>– Time<br>– Temperature<br>– Concentrations |

| Baseline to be Established | Requirements |
|---|---|
| | – Rinses<br>– Confirmation rinse water (pre & post) water free of detectable soils and detergent prior to sanitizing<br>Visual Inspection |
| Results of the CIP process | Confirmation the process is effective and repeatable:<br>• Visual inspections<br>• Microbiological results<br>• Allergen residues (if applicable)<br>• Collect enough data until you feel comfortable (e.g., suggest that 3 consecutive passes vs. acceptance criteria or a single confirmation (minimum) of established CIP performance requirement are achieved |

Ongoing validation should be conducted annually as a minimum or when a significant change(s) is (are) made to the product, the process (including the chemistry) or equipment. As the cycle is established, the size of the plant should be considered.

Table 5 lists the typical records the facility should have in place to support the validation and verification of CIP systems.

**TABLE 5. Typical Records Supporting Validation and Verification of CIP systems.**

| Type | Item |
|---|---|
| Instrument Calibration | • Resistance Temp Devices<br>• Flow<br>• Conductivity<br>• Level<br>• Pressure |
| Sequence Performance Checks | • Titration<br>• Inspection<br>• Microbial |
| Logs | • Titration Logs<br>• Microbial Logs<br>• Exception Logs<br>• Corrective Action Logs |
| CIP/Process P&ID | • Circuit Drawings |
| Sequence Performance Documentation | • Monitor<br>• Record |
| Documented CIP Logic | • PLC programming with descriptors<br>• PIN charts<br>• Sequence steps with set points<br>• Change log |
| Preventative Maintenance | • Preventive Maintenance schedule<br>• Work Order log |