Clean-In-Place: Best Practices to Improve Operations

Caitlin Lucia
Sr. Process Engineer, Global Engineering
Campbell Soup Company
- **Dynamic** community of Manufacturing, Engineering & Operations professionals

- Over 250 companies **collaborate** on solving common operational challenges

- Develop best practices and protocols for **free** industry adoption

PMMI FOUNDED OpX LEADERSHIP NETWORK in 2011
AN ENGAGED INDUSTRY
BY INDUSTRY, FOR INDUSTRY - IDEATION TO ADOPTION

PMMI Forums (vision 2020 & top 2 top)

OpX exec council

Solution Groups

Work Products

Pilots

Experiences & Metrics

Adoption

PMMI Leadership Network Moving Operational Excellence Forward
GOAL:

*Clear, common language document* for CPGs and OEMs outlining generic definitions, equipment considerations, best practices, and protocols for CIP that can be *leveraged across food plants* to drive improved operational, food safety, and sustainability results.
This document is the result of collaboration between:
SCOPE AND DELIVERABLES

Key Deliverables

1. Definition of Key CIP Parameters
2. Tools for Managing CIP
Leadership Guidance

1. OVERVIEW
2. CONTRIBUTORS
3. CLEANING
   3.1 Definition
   3.2 Reasons to Clean
   3.3 Business Goals
   3.4 Determining Cleaning Approach
**Cleaning** is the process of removing soils from a product contact surface.

<table>
<thead>
<tr>
<th>SOILS</th>
<th>METHODS</th>
<th>FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product liquids, solids, and particulates</td>
<td>(Fully Automated, Partially Automated, Manual)</td>
<td>Time</td>
</tr>
<tr>
<td>(Fats, Sugars, Proteins)</td>
<td>Clean in Place (CIP)</td>
<td>Temperature</td>
</tr>
<tr>
<td>Denatured Product</td>
<td>Clean out of Place (COP) (Wash Tunnel, Tub, Cabinet,)</td>
<td>Mechanical Action or Force</td>
</tr>
<tr>
<td>Viscous and semi-viscous product</td>
<td>Hand or Manual (Dry Clean or Wet Clean)</td>
<td>Chemical Action</td>
</tr>
<tr>
<td>Allergens</td>
<td>Assisted Circulation System (ACS)</td>
<td>Procedures</td>
</tr>
<tr>
<td>Scales and Films</td>
<td></td>
<td>Equipment design &amp; Materials of Construction</td>
</tr>
<tr>
<td>Mineral deposits (Water hardness, Calcium,</td>
<td></td>
<td>Equipment Installation</td>
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<tr>
<td>Titanium dioxide)</td>
<td></td>
<td>Water Chemistry</td>
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<tr>
<td>Corrosion</td>
<td></td>
<td>Internal/external cleaning methods</td>
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<tr>
<td>Biological and biological films</td>
<td></td>
<td></td>
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<tr>
<td>Physical hazards (Metal shavings, plastics,</td>
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<td></td>
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<tr>
<td>plastics, wood, and lubricants)</td>
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**Sanitizing** is the process of reducing the number of microorganisms present on a clean surface to an acceptable level.

<table>
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<tr>
<th>METHODS</th>
<th>FACTORS</th>
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<tbody>
<tr>
<td>Heat (Steam, Hot water, or Hot air)</td>
<td>Concentration</td>
</tr>
<tr>
<td>Radiation (Ultraviolet)</td>
<td>Temperature</td>
</tr>
<tr>
<td>Chemicals (Chlorine, Iodine, Quaternary ammonium, alcohol etc.)</td>
<td>Contact time</td>
</tr>
<tr>
<td></td>
<td>Equipment design (sanitary design)</td>
</tr>
<tr>
<td></td>
<td>Residual soils after cleaning</td>
</tr>
<tr>
<td></td>
<td>Equipment Installation</td>
</tr>
</tbody>
</table>
3.2 REASONS TO CLEAN

Cleaning is necessary to eliminate food hazards, meet regulatory requirements, and assure product quality attributes resulting in safe, high quality food. These hazards include:

**CHEMICAL**
- Allergens
- Gluten
- Residual cleaning or sanitation chemicals
- Lubricating chemicals

**DIETARY COMPLIANCE**
- Organic
- Kosher
- Halal
- “Free of” claims
- GMO/Non-GMO

**PHYSICAL**
- Foreign material

**PRODUCT QUALITY**
- Product sensory characteristics
- Housekeeping

**BIOLOGICAL**
- Pathogens
- Spoilage organisms
- Pests

**OPERATIONAL**
- Product build up that affects equipment functionality/reliability
- Human safety

**REGULATORY**
- PMO
- USDA
3.4 DETERMINING CLEANING APPROACH

What am I trying to remove?
Protein | Allergens | Carbohydrates | Fats/Oils | Minerals

What is the physical state of residue?
Viscous | Solids | Fouling | Scale

What do I want to accomplish?
Cleaning | Sanitizing
What is my chemistry?
Water Only | Alkali | Acid | Sanitizer

How can I accomplish?
CIP (Automated) | ACS (Assisted) | COP | Manual
4. **CLEANING-IN-PLACE (CIP)**
   
   Overview
   4.1 Preparation
   4.2 Pre-rinse
   4.3 Wash
     - 4.3.1 Alkaline Wash
     - 4.3.2 Intermediate Rinse
     - 4.3.3 Acid Wash
     - 4.3.4 Final Rinse
   4.4 Cleaning Solutions
   4.5 Fluid Characteristics
     - 4.5.1 Time
     - 4.5.2 Temperature
     - 4.5.3 Turbulent flow
     - 4.5.4 Flow Rate
     - 4.5.5 Chemical Concentration
     - 4.5.6 Pressure
   4.6 Sanitization
   4.7 Final Rinse
   4.8 Inspections and Testing for Efficiency and Residuals
For a system to truly be cleanable in place it must abide by 5 rules:

1. The unit operations and equipment components used in the system have been designed for CIP and have been verified to clean in place, by 3A-SSI, EHEDG, or an acceptable alternative method.
The system must have been installed so that it **maintains** its’ clean in place **integrity**. This includes not only the materials and craftsmanship but also the **proper fluid dynamics** for the CIP solution supply and return to the process equipment.

3A-SSI accepted practice 605 is a good guideline.
The process piping and equipment must be able to receive the prescribed flow, temperature, time, chemical concentration and pressure of cleaning solution required. Active monitoring and adjustment of these critical process parameters throughout the cleaning cycle is important.

Often the process lines are not capable of delivering the CIP flow required of the equipment and additional design considerations should be made.
Once a CIP process has been validated, proper change control procedures should be in place to maintain an accurate record of the critical process parameters. Routine visual inspection, chemical residual verification, and microbial verification are common safeguards to ensure system performance.

The validation plan is developed and maintained by the consumer product manufacturer.
For a system to truly be cleanable in place it must abide by 5 rules:

5. A preventative maintenance and instrument calibration program must be in place to ensure the equipment and process is maintained as designed. Periodic inspection of in-line filters and magnetic traps is required to mitigate potential threats from foreign materials.

Worn elastomers, leaking seals, corrosion of stainless steel and mechanical damage to equipment can all create concerns for cleaning.
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   4.7 Final Rinse
   4.8 Inspections and Testing for Efficiency and Residuals
“Time required to clean is directly proportional to degree of difficulty to remove the soil load.”

“Time spent within acceptable ranges for chemical concentration, temperature, and flow is a critical parameter of each step in the cleaning sequence.”

“The actual time required to clean any circuit... can only be truly determined once the system is in place and in use.”
“Excessively high or low temperature can be detrimental to chemical performance.”

“For proper measurement of CIP fluid temperature, the CIP system should have **two temperature indicators** – one on the supply, one on the return line.

“The return line indicator should be used for recording and validation as it indicates the **minimum temperature** experienced by the entire system.”
“Turbulent flow is critical to provide the mechanical action necessary for the removal of soils.”

“A fluid velocity of 5 ft/sec is the minimum recommended velocity to achieve turbulent flow of aqueous solutions in sanitary process piping systems.”
4.5 FLUID CHARACTERISTICS & TIME

4.5.4 FLOW RATE

“Flow rate is a critical parameter and cannot be replaced by pressure measurement. It is recommended to measure flow rate at the supply and return of the CIP system.”

“Sequential pulsing of valves and flow diversions can cause the measured flow to fluctuate below the nominal flow. These fluctuations must be accounted into the validated duration of a cleaning cycle.”
4.5 FLUID CHARACTERISTICS & TIME

4.5.5 CHEMICAL CONCENTRATION

“The chemical concentration required to achieve effective cleaning depends on the characteristics of the particular soil.”

“Chemical concentration is typically measure in-line with a conductivity or pH meter. When a conductivity meter is used, a correlation of titration data must be used to calibrate and routinely maintain meter accuracy.”
“Pressure, when used in conjunction with flow measurement, is a good indicator of performance consistency.”

“A change in pressure from baseline may indicate a mechanical change, such as a system leak, spray device not in place, or strainer blockage, that may affect the cleaning performance.”
5. CIP EQUIPMENT AND SANITARY DESIGN ......................................................... 00

Related 3-A standards
5.1 CIP Equipment
   5.1.1 Single Tank, Multi-Tank Systems
   5.1.2 Spray Balls, Nozzles, Accessories
   5.1.3 Controls and Automation, Documentation
5.2 CIP Systems
   5.2.1 Single-Use CIP Systems (Single Use of Water, Chemicals, Solutions)
   5.2.2 Re-use CIP Systems (Multiple-Use of Water, Chemicals, Solutions)
The advantages of single-use systems include:

- Operational flexibility
- Multiple detergents and chemical concentrations
- Fresh wash solutions
- Multiple operating temperatures
- Lower initial capital cost

The disadvantages of single-use systems include:

- Higher water use
- Higher detergent use
- Time delay to reach operating temperature
The advantages of a reuse system include:

- Cleaning solutions and rinse water are recovered
- Lower water, heat, and chemical usage
- Faster overall wash cycle time due to less heating especially in winter months
- Recovered cleaning solution are heated and charged with chemical

The disadvantages of a reuse system include:

- Allergen and micro contamination risk
- Single concentration for all cleaning circuits
- Common cleaning solutions will be used for all product soils
- Larger floor space required (multiple tanks require significant space)
- Higher initial capital cost
- Rinse water recovery tank may harbor micro-organism
- Intermittent cleaning of the caustic, acid and recovery tank required
6. VALIDATION ACTIVITIES
   6.1 Overview
   6.2 Validation
   6.3 Verification
   6.4 Monitoring

7. GLOSSARY (DEFINITIONS)

8. REFERENCES

9. CIP TOOLS AND RESOURCES
   9.1 Examples Of CIP Systems
      1 Tank CIP System
      2 Tank CIP System
      Multi-Tank CIP System
      Dual Operating/Multi-Circuit CIP System
   9.2 Checklist For CIP
   9.3 FAQ’s
   9.4 OpX Leadership Network Toolbox
**Glossary**

**API Standards**
American Petroleum Institute Standards for oils and gas
www.api.org/Standards

**ASME (U&S)**
American Society of Mechanical Engineers; U Code Symbol and U Stamp for pressure vessels.
www.asme.org

**Assisted Circulation System (ACS)**
A closed system pipe manual (CPM) with little to no automation in comparison to a fully automated CIP system.
Common terms: Pot-in-Pot: in-place cleaning using existing processing equipment (i.e., no CIP tank).
Flash system: Pot-in-Pump cleaning in place without re-circulation (i.e., one pass cleaning).
Thorsen

**JA-SSI**
J-A SSI is an independent, not for profit corporation dedicated to advancing hygiene equipment design for the food, beverage, and pharmaceutical industries.

**Biofilm**
A thin usually resistant layer of microorganisms (such as bacteria) that form on and coat various surfaces.
www.merriam-webster.com/dictionary

**ASME/BIPE**
ASME BIPE (American Society of Mechanical Engineers Bioprocessing Equipment) is an international standard developed as an aid for the design and construction of equipment intended for use in the manufacturing of biopharmaceuticals.
Wikipedia

**Cabinet**
A case (wardrobe) usually having shelves and a door.
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**Clean in Place (CIP)**
(1) "CIP" means cleaned in place by the circulation of flowing by mechanical means through a piping system of a Desinfectant solution, water rinse, and sanitizing solution or over equipment surfaces that require cleaning, such as the method used, in part, to clean (Clean) and Sanitize a fresh or frozen dessert machine.
(2) "CIP" does not include the cleaning of equipment such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of circulation.

**Clean Out of Place (COP)**
Systems designed for cleaning out of place (COP) require cleaning by disassembly and/or removal from the normal location into CIP tanks where they are cleaned using water movement, which removes Soil from the Components. Fluid flow is utilized in the application of force for cleaning. When this method of cleaning is required, the equipment design shall provide for easy disassembly with the use of simple hand tools commonly available to plant production or sanitation employees.

**Denature**
To modify the molecular structure of (something, such as a protein or DNA) especially by heat, acid, alkali, or ultraviolet radiation or so as to destroy or diminish some of the original properties and especially the biological activity.

**Dry Clean**
Also, Dry Sanitation involves 7 Steps of Effective Dry Sanitation:

- Step 1: Prepare the area
- Step 2: Secure, Disassemble
- Step 3: Dry Clean
- Step 4: Detail Clean
- Step 5: Self Inspect & Pre-Op Preparation, Re-assembly
- Step 6: Final Inspection
- Step 7: Final Sanitizing

**European Hygiene Engineering and Design Group (EHEDG)**
European Hygiene Engineering and Design Group is an NGO devoted to the advancement of hygienic design and food engineering.
FDA
US Food and Drug Administration

**Foreign Material**
A material substance of a particular kind or for a particular purpose that is foreign to the product.

** Fouling**
Fouling is the process of accumulation, clogging, or blocking of a substance or foreign substance.

**FSMA**
Food Safety Modernization Act of 2015

**GMP also cGMP**
(1) GMP means the requirements found in the regulations, and administrative provisions for methods to be used, and the facilities and controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to ensure such drug moves through the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or represents to possess.
(2) GMPs are that of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subset, GMPs include, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization product authorization or brand holder or applicant and ensures the product is made in compliance with its specifications qualified person certification in the EC.

**HACCP**
Hazard Analysis Critical Control Point. A food safety system required by FDA for poultry and seafood and by USDA for meat and poultry.
www.fda.gov/food/guidance regulation/haccp
www.fsis.usda.gov/wps/portal/fsis/topics/regulatory/compliance/haccp

**Hand Clean (aka Manual Clean)**
Use of buckets and brushes/rolls/sponge to wash, swab, rub-down, and dry the product that need to be disassembled to component level.

**Potable Water**
Raw or treated water that is considered safe to drink.

**Product Contact Surface**
Any surface that contacts a product component or dietary supplement, and those surfaces from which drainage onto the product component or dietary supplement, or onto surfaces that contact the product component or dietary supplement, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging.

**Sanitation Lexicon, GMA Sanitary Design Workgroup, 2013**

**Proteinaceous Soils**
Soil that is in protein material.

**Sani-trize**
To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

**PSMA, Final Rules For Fed Reg 80, Sept 17, 2015**

**Wash In Place (WIP)**
A closed system pipe manual (CPM) with little to no automation in comparison to a fully automated CIP system.
Common terms: Pot-in-Pot: in-place cleaning using existing processing equipment (i.e., no CIP tank).
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### ITEM OR ACTIVITY – TASKS TO BE ACCOMPLISHED

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<thead>
<tr>
<th>3. PRE-RINSE</th>
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<tr>
<td>Water is a detergent and can remove soluble soils and under pressure many insoluble soils. Remove residual product and loose soils from the system within SOP criteria.</td>
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<tr>
<td>3.1 Verify temperature of potable water: warm for fat/soil solubility, but not too hot for equipment thermal shock</td>
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<tr>
<td>3.2 Verify flowrate requirements for spray balls or other equipment; (e.g. lines- flowrate required to achieve turbulent flow and Hover option for velocities)</td>
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<tr>
<td>3.3 Conduct a visual and/or use analytical methods to check after rinse to get most of soil removed in initial step</td>
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<tr>
<td>3.4 Verify level of visual inspection on every clean (e.g. tanks, pipe switching, assure that all steps and physical connections are in place to begin the CIP wash cycle). Have regulatory document at hand.</td>
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9. Validation, Verification and Monitoring
To ensure efficient, effective, and repeatable sanitation procedures are being executed the following should be addressed in the program

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<tr>
<td>9.1</td>
<td>Develop and document a comprehensive “Initial Validation and Verification” report summarizing protocols followed and results collected for each specific line/system to properly manage the hazards of concern.</td>
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<tr>
<td>9.2</td>
<td>Collect and reference appropriate documentation to validate the effectiveness of the chemistry and/or cleaning method. Obtain product label directions and training for cleaning and sanitizing processes from the chemical and equipment suppliers.</td>
</tr>
<tr>
<td>9.3</td>
<td>Identify the verification processes to ensure proper execution of sanitation such as visual inspection, assessment of employee execution of the SSOP(s), e.g. measuring chemical concentrations, ATP swabs, microbial swabbing, record review, etc. Choose</td>
</tr>
<tr>
<td>9.4</td>
<td>Verify monitoring activities that include overseeing, measuring and recording results to ensure that control measures are operating as intended. Critical elements of sanitation include time, temperature, flow, pressure, concentration/conductivity.</td>
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VALUE TO CPGS AND OEMS

- **Value to CPGs**
  - Foundational educational for those new to food industry; new to CIP
  - Design guidelines and probes for consideration
  - Comprehensive checklist to jog and refresh

- **Value to OEMs**
  - Customers more educated and invested in design
  - Resource to give to CPGs to help answer fundamentals questions
  - Jump start reference on cleaning methodology

- **Value for collaboration**
  - Speaking in one voice, one vocabulary
  - Definitions of common parameters
  - Guidance on how existing practices can be applied
NEXT STEPS

- Currently Out for Peer Review

- Final work product published and placed on OpX website available for free download at:

  www.opxleadershipnetwork.org