Food & Beverage – CIP/SIP Cleaning Procedure for Production Lines			
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Reviewed by	Michael Douglas (Production Supervisor)	**Approved by**	Christian Jones (Manufacturing Manager)
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1. Purpose

To define the standardized procedure for **Cleaning-In-Place (CIP)** and Sterilization-In-Place (SIP) in food and beverage production lines.

2. Scope

This procedure applies to **all automated production lines requiring CIP/SIP cleaning** in the food and beverage facility XXXX**..**

3. Objectives

- Ensure hygienic conditions for food safety compliance.
- Minimize downtime during cleaning cycles.
- Standardize cleaning steps across all lines.

4. Tools and Materials

- CIP/SIP system
- Sanitizing agents
- PPE: gloves, goggles, aprons
- Flow meters
- Temperature sensors

5. Applicable Regulations

- FDA 21 CFR Part 117
- 3-A Sanitary Standards
- Internal hygiene protocols

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6. Procedure

6.1 Preparation

a. **Notify QA and maintenance teams**: Inform the Quality Assurance and Maintenance departments prior to initiating the cleaning cycle. This ensures proper coordination, availability for verification, and readiness for any required maintenance interventions during or after cleaning.

b. **Verify cleaning schedule and cleaning agents availability**: Confirm that the cleaning cycle aligns with the approved cleaning schedule. Check that all cleaning agents (detergents, caustic solutions, acids, sanitizers) are available, properly labeled, and within their expiration dates. Ensure chemical concentrations are prepared according to the manufacturer's specifications.

C. **Ensure all valves and sensors are functional**: Inspect flow control valves, temperature and conductivity sensors, and pressure gauges to confirm correct operation. Verify that automated valves respond to control commands and that the system's monitoring instruments are calibrated and operational.

6.2 System Shutdown

a. **Stop production and drain product from lines**: Safely stop the production process following standard shutdown procedures. Drain any remaining product from tanks, piping, and filler heads to prevent contamination and ensure efficient cleaning. Dispose of residual product according to waste management guidelines.

b. **Initiate lockout/tagout procedures:** Apply lockout/tagout (LOTO) controls to isolate electrical, steam, and pneumatic energy sources. Confirm that all system components are de-energized and clearly tagged to prevent accidental startup during cleaning operations.

6.3 CIP Cycle

a. **Start pre-rinse with warm wate**r: Begin the cleaning process with a pre-rinse using warm potable water to remove loose residues and product remnants. Verify that rinse water drains clear before proceeding to the detergent phase.

b. **Circulate detergent solution at specified temperature and time**: Prepare and circulate the designated cleaning solution (alkaline or acidic, depending on soil type) through the system at the defined temperature, flow rate, and contact time. Monitor conductivity and temperature to ensure the solution remains within the validated range. The purpose of this step is to dissolve fats, proteins, sugars, and other deposits.

c. **Rinse with potable water**: Flush the system with potable water until the rinse water meets established conductivity or pH criteria, confirming that all detergent residues are removed. Continue rinsing until verification parameters are stable.

6.4 SIP Cycle

a. **Inject steam to reach sterilization temperature**: After CIP completion, introduce clean, dry steam into the system to achieve sterilization temperature (typically 121°C / 250°F or as validated for the process). Monitor steam pressure and temperature throughout the system to ensure uniform distribution.

b. **Maintain temperature for required duration**: Sustain the sterilization temperature for the validated hold time to ensure effective microbial inactivation. Use calibrated temperature sensors to confirm that critical points maintain target conditions throughout the cycle.

c. **Cool down system before restart**: After sterilization, allow the system to cool gradually to a safe operating temperature using sterile air or filtered water. Verify that all condensate has been drained, and confirm that the system is dry and ready for production startup. Record cycle data for QA review before resuming operations.

7. Documentation

a. **Log cleaning parameters and results**: Record all relevant process data and cleaning parameters for each CIP/SIP cycle on the MES system. This includes start and end times, temperatures, flow rates, chemical concentrations, contact durations, and conductivity readings. Ensure that system-generated data (from the CIP control unit or SCADA) is properly archived and traceable on the Smart Factory MES. Any deviations or anomalies observed during the cycle must be documented with corresponding corrective actions taken.

b. **QA to verify and sign off:** The Quality Assurance (QA) department shall review the recorded data and visually inspect the cleaned equipment and line sections, confirming that all cleanliness and sterilization requirements have been met. QA personnel must sign off the cleaning record before authorizing the line for production restart. If verification results are unsatisfactory, additional cleaning cycles or swab tests shall be conducted as required.

8. Multimedia Aids

1. Flow diagrams of CIP/SIP system
2. Video tutorial of cleaning process
3. Audio safety instructions

9. Quality Controls

1. **Verification of temperature and flow rates**: During the CIP and SIP cycles, continuously monitor and record temperature and flow rate data to confirm compliance with validated parameters. Temperature must reach and be maintained at the target sterilization level during SIP, while flow rates must ensure adequate turbulence and contact throughout the system. Any deviations from the established limits shall trigger an alarm, requiring corrective action and QA notification.

2. **Swab tests post-cleaning:** After completion of the CIP/SIP cycle and prior to production restart, conduct microbiological and ATP (adenosine triphosphate) swab tests at designated critical points, such as tank outlets, filler nozzles, and transfer lines. Results must demonstrate the absence of product residue and microbial contamination. Failed test results necessitate re-cleaning and re-testing until acceptable hygiene levels are achieved.

3. **Cleaning log review by QA:** QA personnel must review all cleaning and sterilization records, including temperature, flow, and chemical concentration logs, as well as results of visual inspections and swab tests. Only after QA verification and documented approval may the equipment or production line be released for manufacturing. Records should be retained in accordance with the company's document control and traceability policy.

10. Problem Resolution

1) **If temperature not reached, repeat SIP cycle**: In the event that the sterilization temperature fails to reach or maintain the validated threshold during the SIP cycle, immediately halt the process and investigate potential causes (e.g., steam supply failure,

valve malfunction, or temperature sensor error). Once the issue is corrected and verified, repeat the full SIP cycle to ensure proper sterilization before resuming operations.

2) **If contamination detected, initiate corrective cleaning:** Should microbiological or ATP test results indicate contamination after cleaning, initiate a full corrective cleaning cycle following the CIP/SIP procedure. Identify and document the root cause of contamination (e.g., dead legs, faulty valves, or ineffective detergent concentration). QA must verify the effectiveness of the corrective cleaning before production restart.

3) **Report deviations to QA and maintenance**: Any deviations, abnormalities, or system malfunctions observed during the CIP/SIP process must be reported immediately to the Quality Assurance and Maintenance departments. Both teams are responsible for evaluating the deviation, implementing corrective and preventive actions (CAPA), and recording the event in the deviation log for traceability and continuous improvement.