

**STANDARD OPERATING PROCEDURE  
STAN MAYFIELD PILOT PLANT**

**TITLE: Chemical Inactivation by CIP Cycle**

**AUTHOR: G.W. Luli**  
**APPROVALS: Process Change Committee**

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**A. Scope**

This SOP provides a method of verifying that the cleaning system used on vessels that contain genetically modified microorganisms is sufficient to inactivate the microorganisms.

**B. Safety and Training Requirements**

Refer to UF lab safety policies regarding equipment listed in section D below before starting any process work.

Refer to UF Biosafety guidelines and the NIH Guidelines whenever handling biological cultures/genetically modified organisms.

Review the location of fire extinguishers, fire blankets, safety showers, spill cleanup equipment and protective gear before beginning any process work.

During operations in the plant, the following safety gear will be utilized at all times:

- Safety Goggles
- Protective Gloves
- Hard Hat

**C. Related Documents and SOPs**

1. Primary Propagator 2A SOP-3210
2. Primary Propagator 2B SOP-3215
3. Secondary Propagator 3A SOP-3220
4. Secondary Propagator 3B SOP-3225
5. Fermentation Tank A SOP-3230
6. Fermentation Tank B SOP-3235
7. Fermentation Tank C SOP-3240
8. Sampling SOP-0511
9. Beer Well SOP-4600
10. Clean In Place (CIP) SOP-8205
11. Steam Supply System Operation SOP-9305
12. Potable Water SOP-9705
13. Air system SOP-9405

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**D. Preparation/Materials/Equipment**

**E. Detailed Procedure**

1. For each vessel, refer to the CIP section of the respective SOP and Clean In Place (CIP) SOP-8205.
2. Ensure the beer well is ready to receive the initial rinse water according to the Beer Well SOP-4600.
3. Ensure the steam system is ready according to Steam Supply System Operation SOP-9305.
4. Set valves to return rinse water to the beer well by:
  - a. Close valve 3205-V-41 and open valve 3205-V-42 for Primary Propagators 2A and 2B and Secondary Propagator 3A and 3B and Fermentor A.
  - b. Close valve 3206-V-41 and open valve 3206-V-42 for Fermentor B.
  - c. Close valve 3207-V-41 and open valve 3207-V-42 for Fermentor C.
5. Start the rinse cycle as described in the respective SOP, but returning to the Beer Well.
6. During the initial rinse cycle of the CIP process, collect samples of the rinse water for each vessel by:
  - a. Using Sampling SOP-0511, collect 50 mL of rinse water at the beginning of the initial rinse cycle using the drain just before the pump being used, *and* as the water flows towards the Beer Well.
  - b. Using Sampling SOP-0511, collect 50 mL of rinse water during the last minute of the initial rinse cycle using the drain just before the pump being used, *and* as the water flows towards the Beer Well.
  - c. Take each sample immediately to the lab and process for differential plating count according to Differential Plating SOP-0522 without dilution of the sample.
7. Proceed with the CIP procedure according to the respective tank SOP .

**F. Evaluation of Samples**

1. The differential plating results should be negative:
  - a. If the results are negative, then release the tank for normal operation and dispose of the rinse water contained in the Beer Well.
  - b. If the results are positive, add bleach to the Beer Well to a final concentration of ~1% and dispose of the rinse solution.