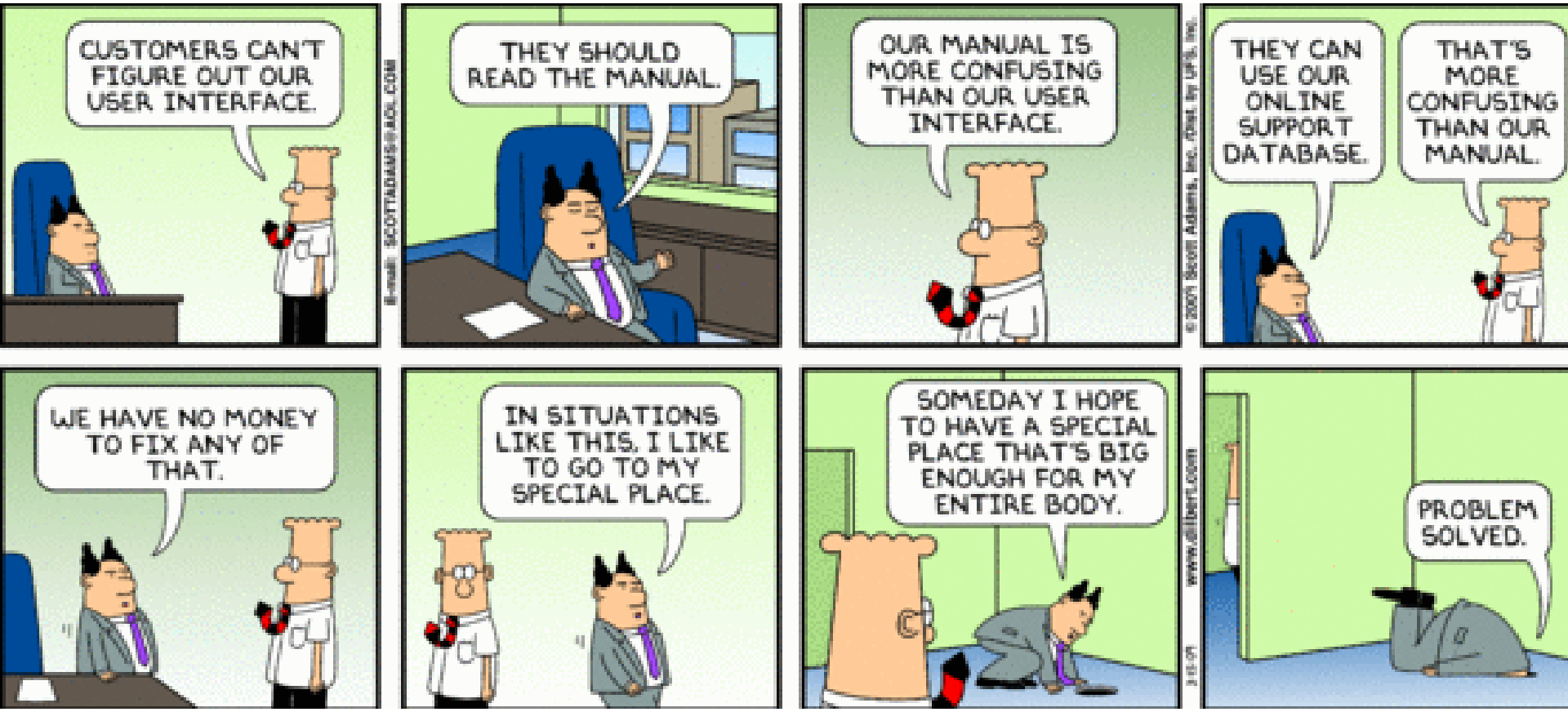
SANITATION
VALIDATION & VERIFICATION

ECOLAB®


CUSTOMERS CAN'T FIGURE OUT OUR USER INTERFACE.
THEY SHOULD READ THE MANUAL.
OUR MANUAL IS MORE CONFUSING THAN OUR USER INTERFACE.
THEY CAN USE OUR ONLINE SUPPORT DATABASE.
THAT'S MORE CONFUSING THAN OUR MANUAL.
WE HAVE NO MONEY TO FIX ANY OF THAT.
IN SITUATIONS LIKE THIS, I LIKE TO GO TO MY SPECIAL PLACE.
SOMEDAY I HOPE TO HAVE A SPECIAL PLACE THAT'S BIG ENOUGH FOR MY ENTIRE BODY.
PROBLEM SOLVED.
E-mail: SCOTTADAMS@AOL.COM
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Grandbabies!!

ACRONYMS FOR THIS YEAR!

- SOC
  - Self Opening Container
- MOAS
  - Mother Of All Spoilages
- KSP
  - Kinda Sterile Product
- SMOO
  - Somewhat Moving Organic Object

VALIDATION & VERIFICATION

- Food Safety Modernization Act (FSMA)
  - If C&S is a Preventive Control, have to validate & verify it

- Regardless:
  - Recognized and expected practice in the food industry
  - GFSI-recognized programs (SQF, BRC, FSSC 22000, IFS…) require:
    - Proof cleaning and sanitizing program is effective and carried out consistently and safely while minimizing risk to raw materials/ingredients/product and personnel

GLOBAL FOOD SAFETY INITIATIVE (GFSI)

Industry-driven Evolution of Food Safety Requirements

- Regulatory requirements and their enforcement vary around the globe
- Major international brand owners have historically gone above and beyond regulation for Food Safety & Quality as a condition of doing business
- GFSI formed as a way to benchmark & recognize food safety programs
- GFSI-recognized programs are the next evolution
  - Adopted by major manufacturers, retailers, foodservice, distributors and service providers
  - Impacts through the supply chain include:

Retail/Foodservice:

- Due diligence
- Supplier management
- Improve confidence

Suppliers:

- Condition of doing business with retail/foodservice
- Improve operations
- Due diligence
- Supplier management
- Improve confidence

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GFSI-RECOGNIZED PROGRAMS

Many Options, Most Popular in North America

Safe Quality Food Program (U.S.-based)	British Retail Consortium (UK-based)
Integrated Food Safety and Quality Management System covering entire farm to fork	Food Safety and Management System for food manufacturing only
Only GFSI-recognized program with multiple levels of implementation and certification (3 levels)	Focus is legality, food safety and customer requirements
Provides enhanced control over quality with implementation of HACCP-based food quality plan	Quality is integrated throughout the program

GFSI-RECOGNIZED PROGRAMS

Many Options, Most Popular in North America

FSSC 22000
Food Safety System Certification 22000
(EU-based)

- Food Safety and Management System for food manufacturing only
- Combines ISO 22000 and ISO 22002-1 (prerequisites for manufacturers)
- Can be combined with ISO 9001 to cover quality management
- Appeals to facilities with ISO based systems

IFS – International Featured Standard for Food (EU-based)

- Food Safety and Management System for food manufacturing only

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DEFINITIONS

	Validation	Verification
Definition	Determining if the intervention, when properly applied, will effectively control the hazards	Demonstrating that the system is operating as designed
Simplified	Will the control measures work?	Are the control measures being followed?
For C&S	Scientific proof your C&S program is effective in your plant: *Chemicals, tools process, personnel are suitable to control hazard*	Proof your C&S program is being carried out in your plant as designed: *Proof it's being done consistently*

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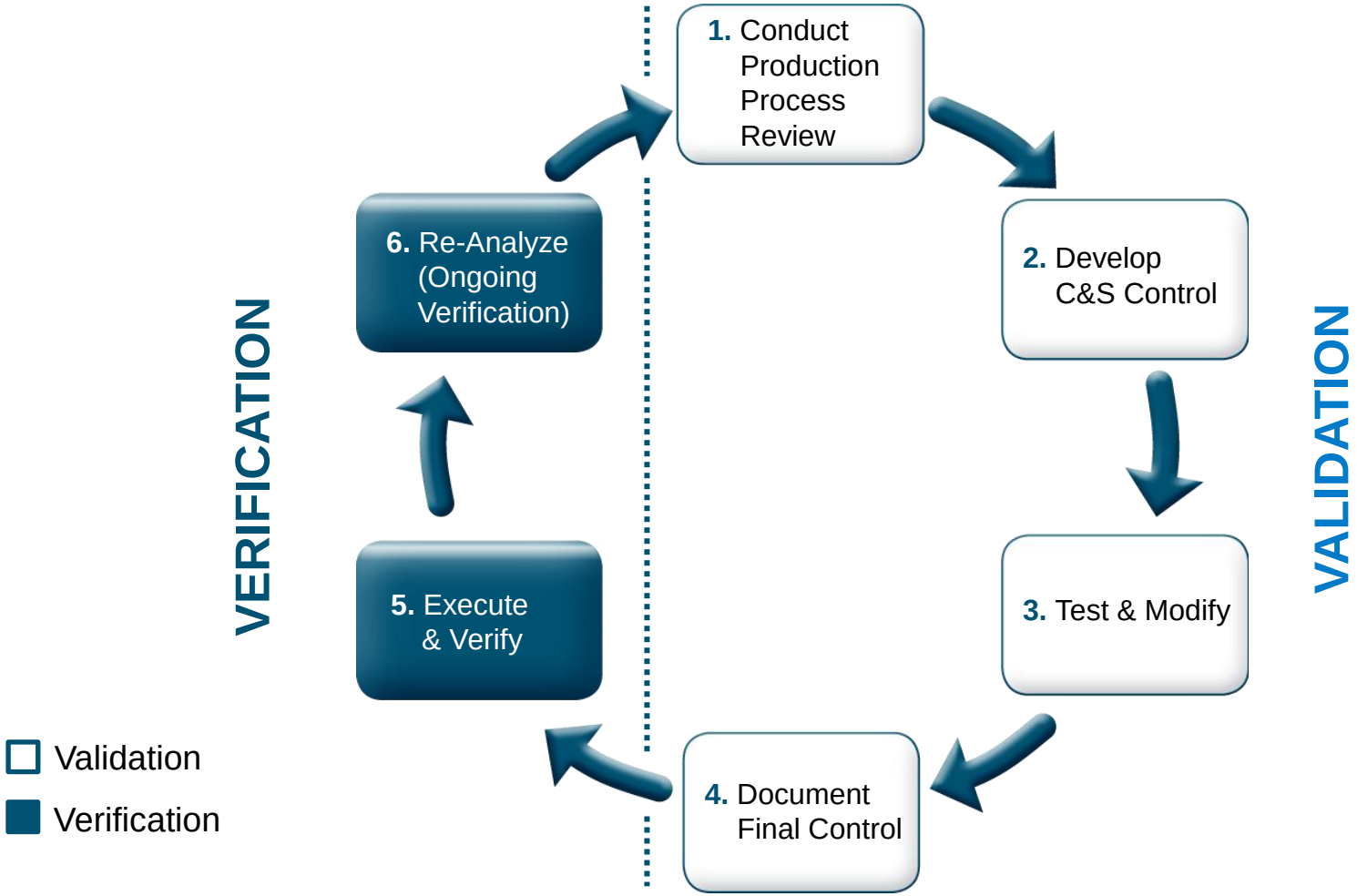
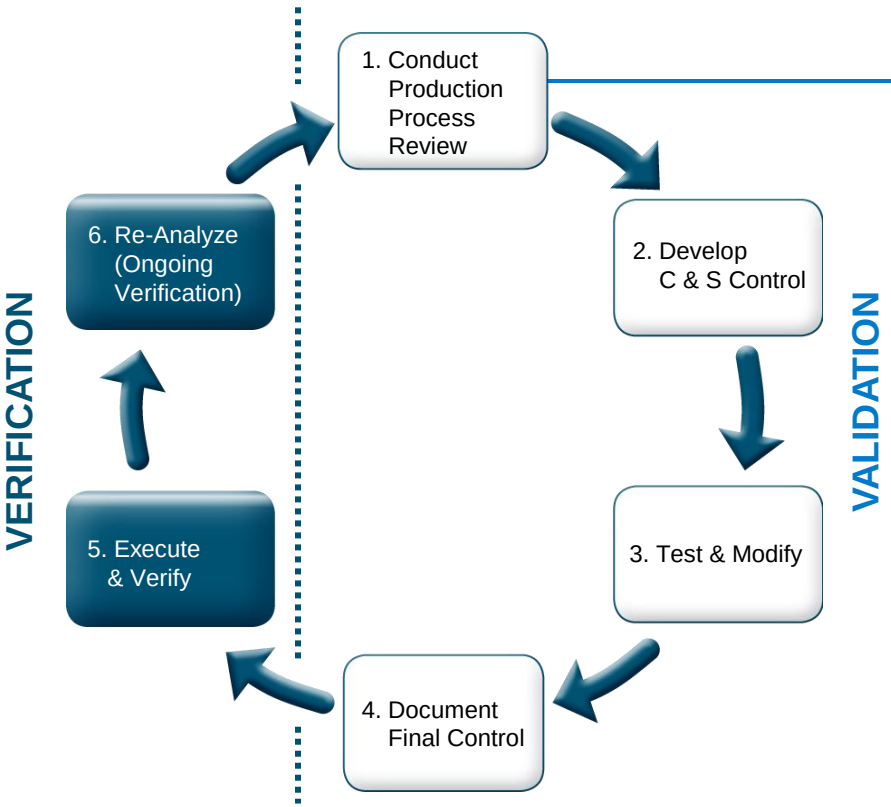
VALIDATION & VERIFICATION PROCESS



VALIDATION & VERIFICATION PROCESS



1. Conduct Production Process Review

- Process flow – Drawing Cutouts and Physical System Walkthru.
- Process parameters:
  - Food Composition
  - Temperature
  - Run Time
  - Down Time Before C&S
- Equipment Review
- Environment Review
- Chemistry Review

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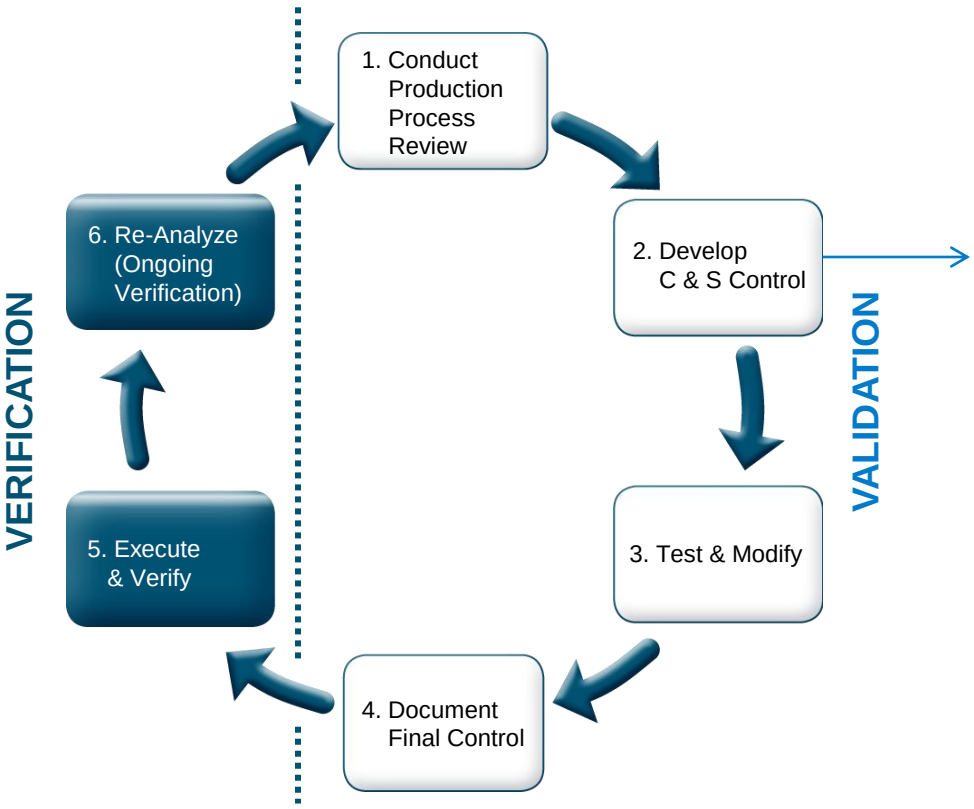
VALIDATION & VERIFICATION PROCESS



2. Develop Cleaning & Sanitizing Control

- Determine Scope of Control
  - Specific piece of equipment
  - Line
  - Process
- Determine End Goal: Level of Clean

  (E.g., Equipment cleaned to food production standards, allergen clean, microbial clean, visually clean)
- Design & Justify C&S Control for Specific Equipment & Environment:
  - Design: Establish Master Sanitation Plan, SSOPs/specific cleaning procedures (who, what, where, when, how, how often?)
  - Justify: Is the Control theoretically sound?
    - Existing literature, studies, advice
    - Facility-specific data
- Determine Acceptance Criteria
- Determine How to Measure Results

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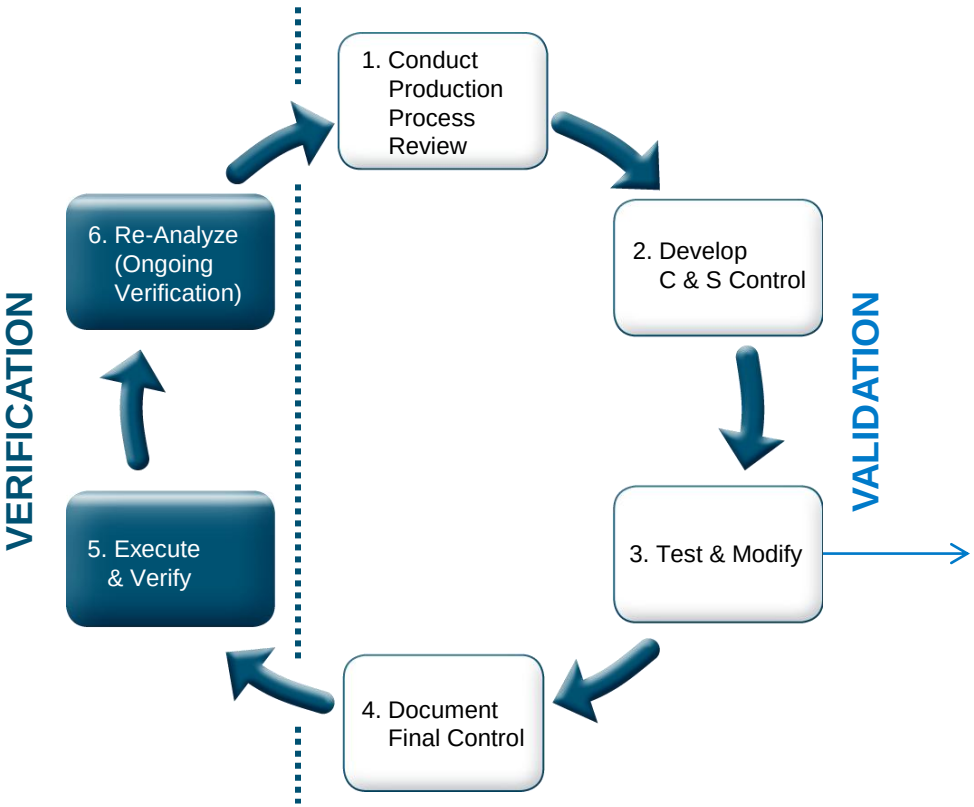
SANITIZER REGISTRATION

Initial Validation

- Use of an EPA-registered sanitizer provides initial validation that the product is effective when used according to label directions for use
- EPA testing allows comparison of different sanitizers, but may not duplicate operating conditions

VALIDATION & VERIFICATION PROCESS



3. Test & Modify

- Initial in-plant validation that Control measures can be implemented per plan to achieve intended result
- Perform the Control per plan
- Evaluate Results
  - Need 3 consecutive passes vs. acceptance criteria or a single confirmation (minimum) of established CIP performance requirement
- Confirm Control is:
  - Feasible
  - Comprehensive
  - Understandable
- Modify Control and procedures as needed and retest

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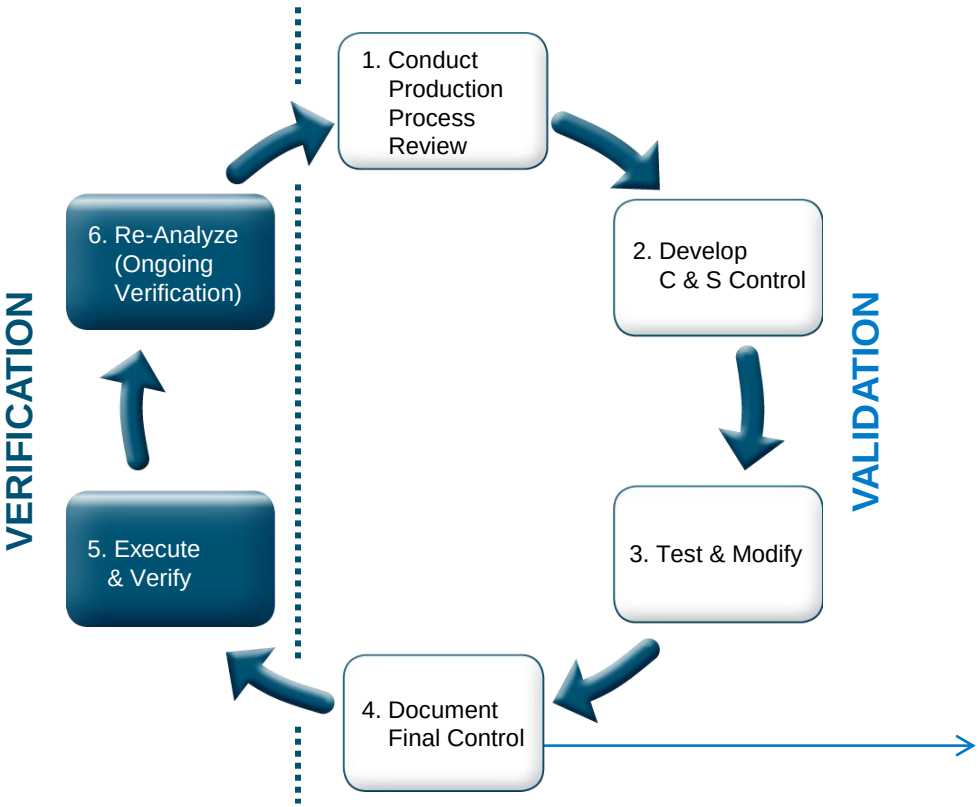
VALIDATION & VERIFICATION PROCESS



4. Document Final Control Protocol

- Now Control is VALIDATED!
- Train staff; document training

VALIDATION RESOURCES
AVAILABLE FROM ECOLAB

- Cleaning procedures
- Catalog sheets
- Labels
- Case studies, sell sheets, brochures
- Letters of Guaranty (LOG)
- Safety Data Sheets (SDS) – available on Ecolab.com site
- Sanitation Validation & Verification Evaluation & Action Plan
- Training Classes:
  - Sanitation Food Safety Workshop
  - Ecolab Food Safety Institute

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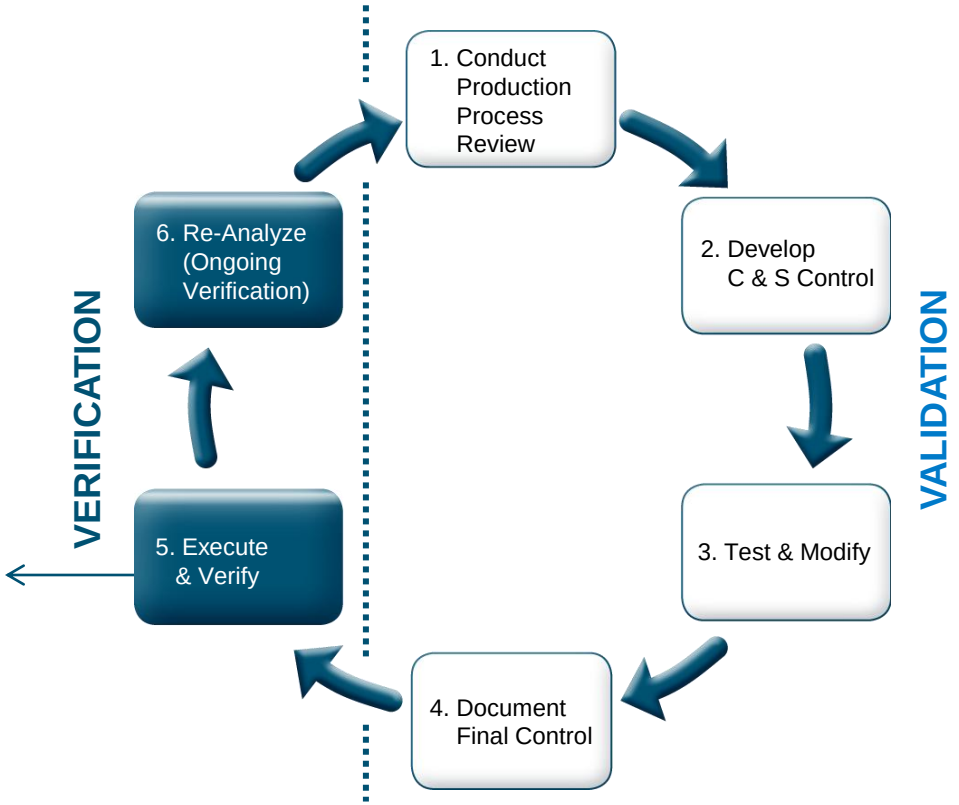
VALIDATION & **VERIFICATION** PROCESS

5. Execute & Verify

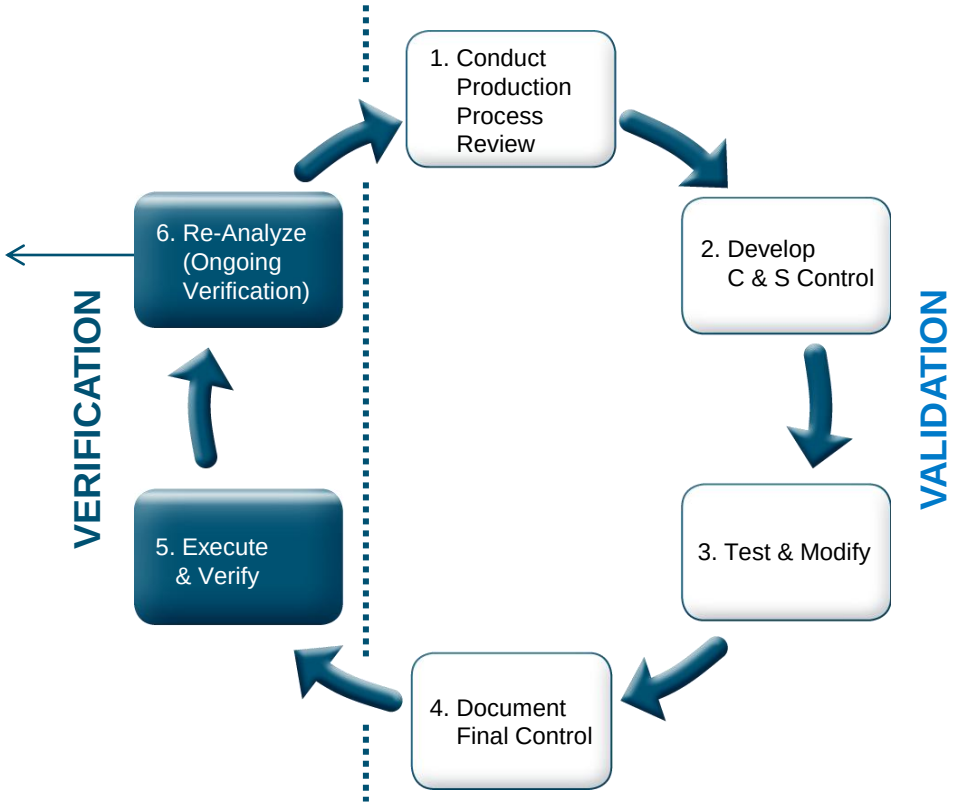
- Execute & Verify Control
- Ensure consistency in:
  - Implementation of Validated Control per Design & Schedule
  - Implementation of Sampling & Analytical Procedures
  - Delivery of Acceptance Criteria



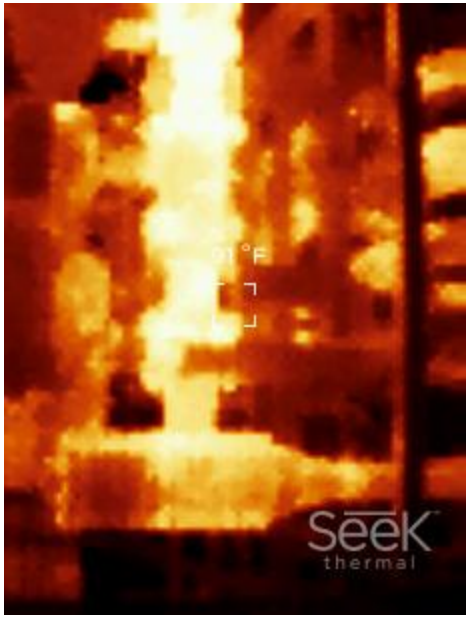
VALIDATION & **VERIFICATION** PROCESS

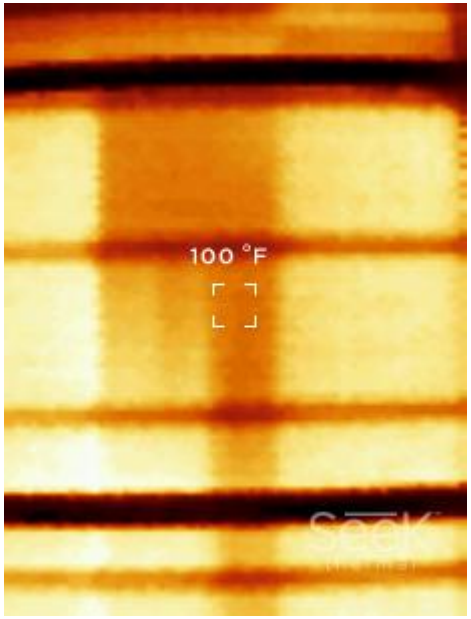
6. Re-analyze (Ongoing Verification)

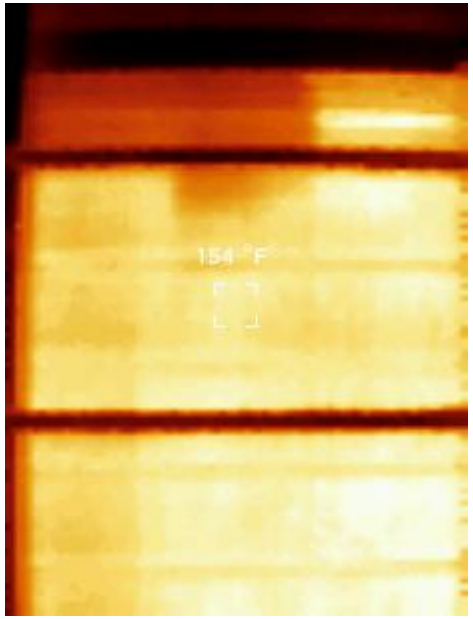
- Continuous monitoring for ANY issues/changes that may affect validated C&S Control:
  - Formulation
  - Production Process
  - Equipment
  - Scientific Information
  - Staffing
  - Water (source or season)
- Validation begins again if change OR periodically



OTHER VERIFICATION TOOLS:







IR Camera Photos – In process and gaps found

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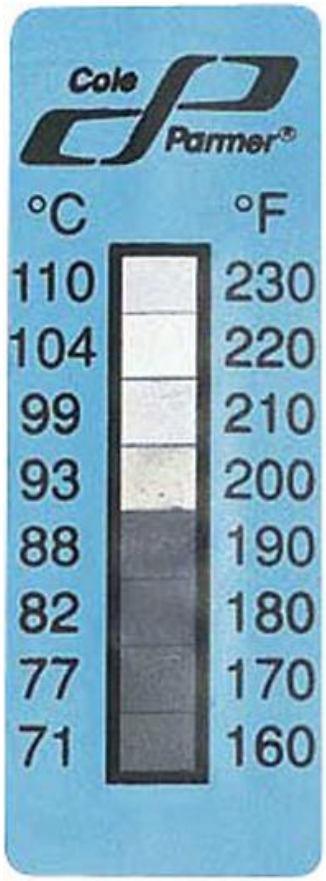
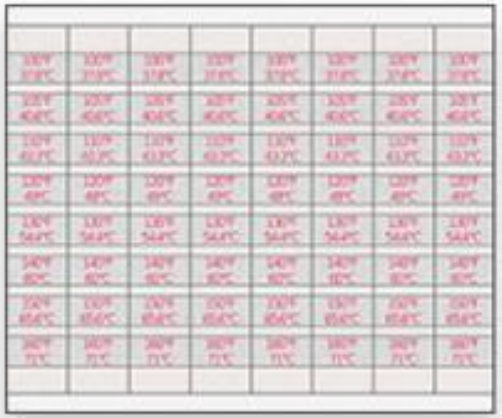
TEMPERATURE VERIFICATION





VERIFICATION RESOURCES

- ServiceChexx™ Reporting
  - Service Activity Focus and Service Activity Details
    - General audit, hygiene audit, third party audit prep
    - CIP Performance Check
    - ATP Program Analysis
- Titration Log Sheets
- Pest Log Sheets

ECOLAB HYGIENE MONITORING PROGRAM

Responsive to Food Safety Changes

- Increase in environmental micro sampling due to pending FSMA regulations
- Increase in micro testing due to customer demands
- Export needs – increased shelf life
- Extended runs – cleaning time reduced

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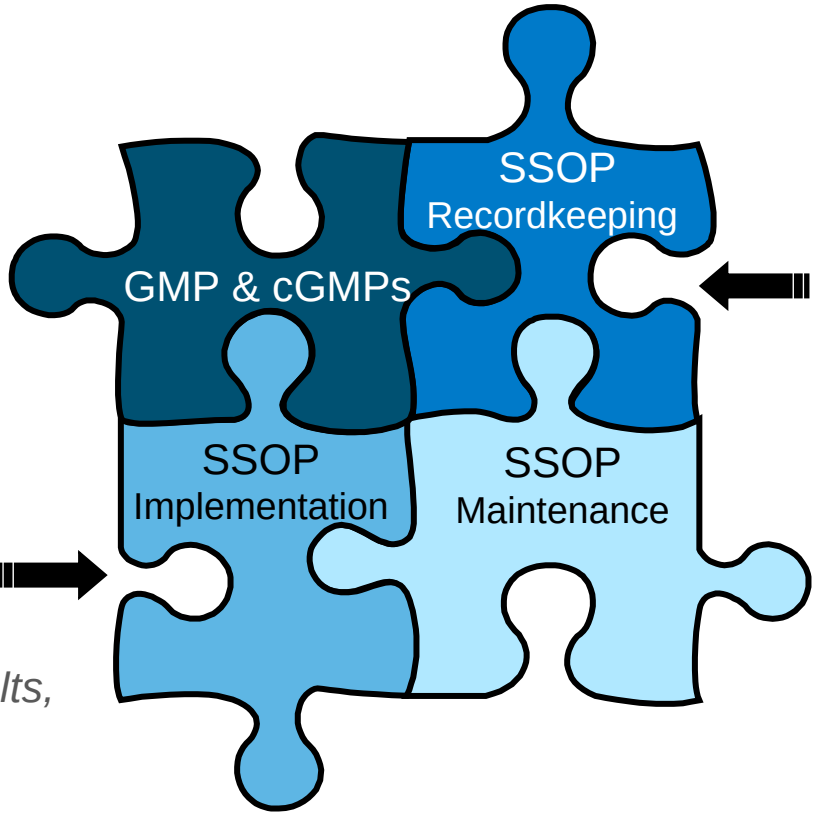
HYGIENE MONITORING PROGRAM

Provides Validation & Verification of Control Procedures

Measures and records cleaning results –
Proof that a C&S program is effective with ATP testing



PocketSwab® Test

PocketSwab® Test
Validation of RLU limits compared to micro results, product quality

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MAKE SURE YOUR INTEGRATOR DOES NOT “DUMP” AND “RUN”

VALIDATION & VERIFICATION OF CLEAN-IN-PLACE (CIP) SYSTEMS

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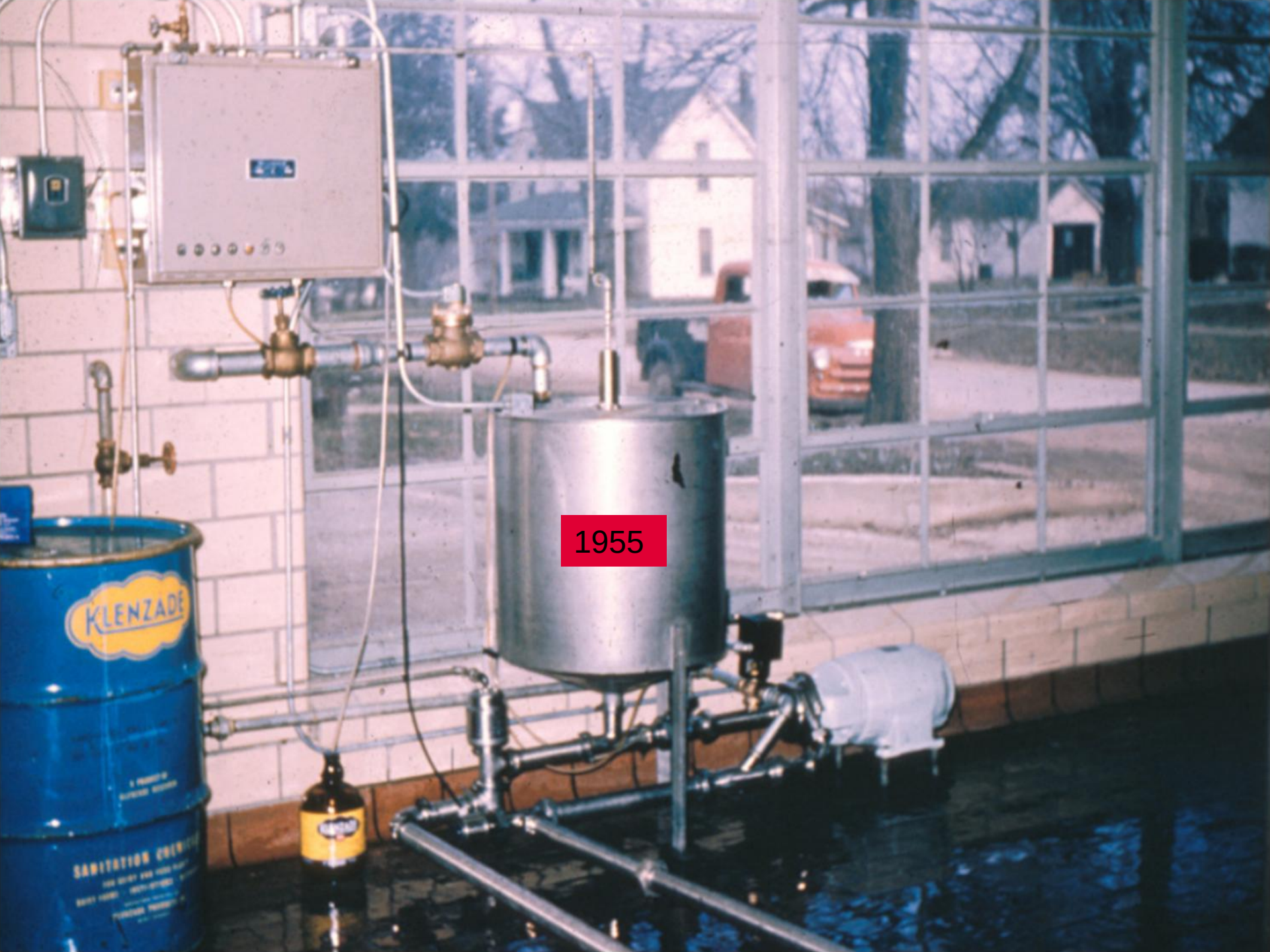
CIP

- Why
  - Farmers in Ohio were tired of taking down pipe lines on the dairy farms.
- Who
  - Dr. Harper (RIP) and Dale Seiberling (grad student)
- Where
  - The OHIO STATE UNIVERSITY!!
- How
  - Milk and radioactive isotopes were circulated in existing pipelines and after cleaning and dumping the solution to the drain….a Geiger counter was used to confirm cleanliness.


1955
KLENZADE

REQUIRED DOCUMENTATION

As Built!!

- Instrument Calibration
  - Resistance Temp Devices
  - Flow
  - Conductivity
  - Level
  - Pressure
- Sequence Performance Checks
  - Titration
  - Inspection
  - Microbial
- Titration Logs
- Microbial Logs
- Exception Logs
- CIP/Process P&ID
  - Circuit Drawings
- Sequence Performance Documentation
  - Monitor
  - Record
- Documented CIP Logic
  - PLC programming with descriptors
  - PIN charts
  - Sequence steps with set points
  - Change log
  - Mix Proof Valve Pulsing
- Preventative Maintenance
  - PM schedule
  - Work Order log
  - Aseptic Valve Repair/Activity Logs

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VALIDATION OF CIP SYSTEMS

Part 1. Scientific proof it should be effective

- E.g., published peer-reviewed scientific studies, reference tables (e.g., USDA, ICMFS), chemical labels (& supporting EPA/FDA registration)

Part 2. Proof it actually works in a specific facility:

- Initial Validation (establish the baseline)
- Match the validation of the process to the running process parameters.
- On-going Validation

EACH FACTORY PLANT **MUST** OWN THIS!!

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VALIDATION OF CIP SYSTEMS: **INITIAL**

- Establish a baseline (chemicals, preparation steps, skid & circuit results)

- Establish a baseline for the chemicals:
  - Are you using the right chemicals for your soils?
  - Are you using the recommended concentrations for your operation?
  - Is the cleaning frequency appropriate for your needs?

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VALIDATION OF CIP SYSTEMS: **INITIAL**

Establish a baseline:

- ❑ Chemicals
- ❑ Preparation Steps
- ❑ Skid
- ❑ Circuit Results

Establish a baseline for the chemicals:

- ❑ Are you using the right chemicals for your soils?
- ❑ Are you using the recommended concentrations for your operation?
- ❑ Is the cleaning frequency appropriate for your needs?

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VALIDATION OF CIP SYSTEMS: **INITIAL**

Establish a baseline for the preparation steps to run CIP (manual cleaning & preparation):

- Visually check vessel
  manual rinse if necessary
- Disassemble
  clean all surfaces not cleaned by CIP
- Brush-wash dead areas
  like under man-way door
- CIP Charts

VALIDATION OF CIP SYSTEMS: **INITIAL**

Establish a baseline for the skid (the equipment)

- Know your CIP system and circuits
  - Maximum pipe size in the skid, program, line drawings of CIP system and valves

- CIP performance check – the skid:
  - Visual check – are wet surfaces shiny?
  - Check flow meter against calibrated meter if possible (e.g., Doppler)
  - Check probes against solution of known concentration
  - Are you getting the right flow?
  - Are there leaks?
  - What about the valves, gaskets & supply pump?

VALIDATION OF CIP SYSTEMS: **INITIAL**

Establish a baseline for the circuit (program) - CIP performance check:

- Check each circuit
- Are the valves actuating/pulsing?
- Is the CIP actually performing as per program:
  - Flow rate (established by line size)
  - Time
  - Temperature
  - Concentrations
  - Rinses
    - Are water rinses (pre & post) water free of detectable soils and detergent prior to sanitizing?
  - Visual Inspection

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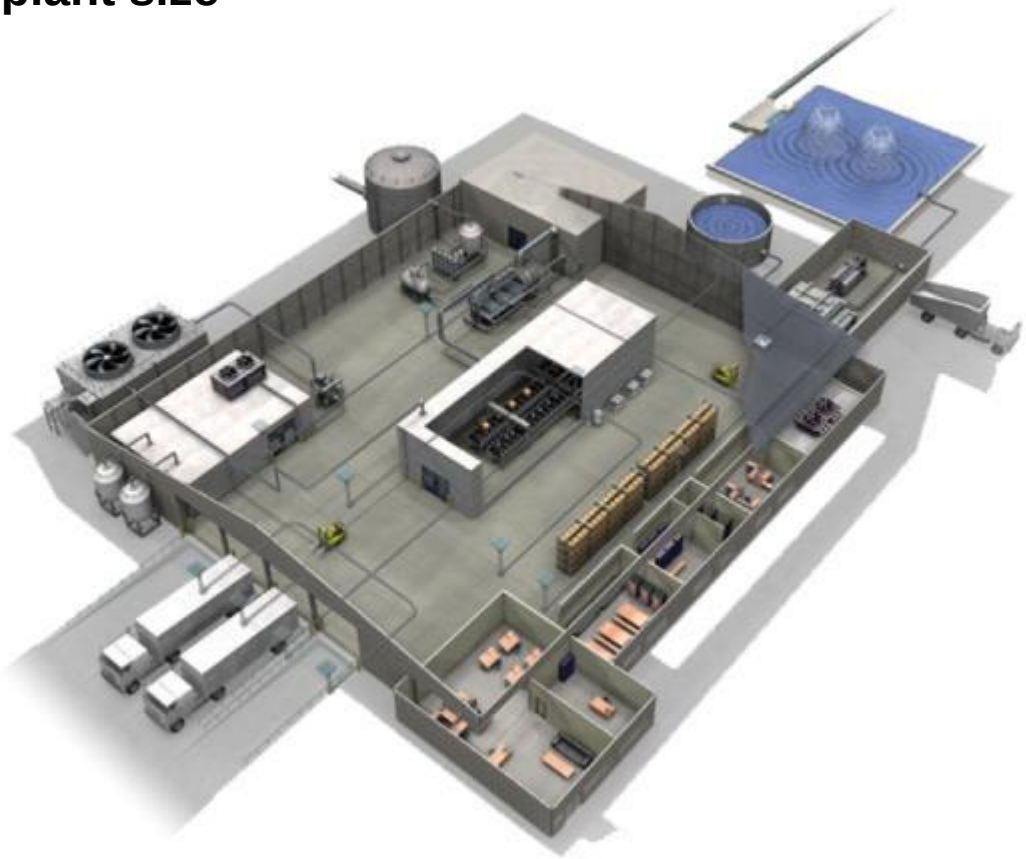
VALIDATION OF CIP SYSTEMS: **INITIAL**

Establish a baseline for results - did it work and is it repeatable?

- Visual inspections
- Microbiological results
- Allergen residues (if applicable)
- Collect enough data until you feel comfortable (e.g., rule of 3)

VALIDATION OF CIP SYSTEMS: **ONGOING**

- Minimum annually or when significant changes to product/process/equipment
- **Establish a cycle – consider plant size**



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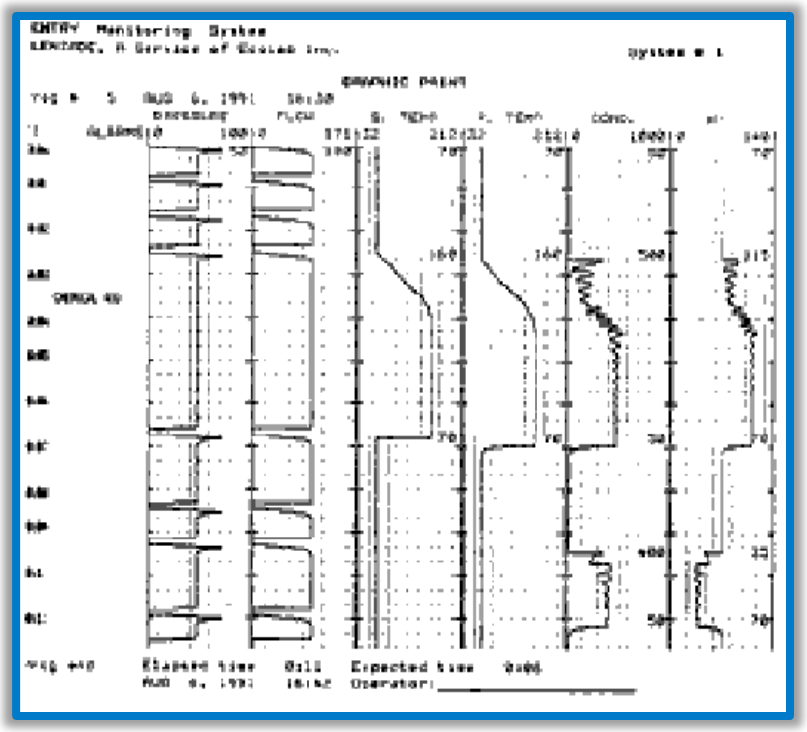
VERIFICATION OF CIP SYSTEMS

- Check the charts
- Periodic review of results and corrective actions



RESOURCES & NEXT STEPS

Review the Sanitation Validation & Verification Evaluation & Action Plan:

- Hands-on tool that includes questions you need to consider
- Create an action plan based on responses to those questions
- Includes tips to follow and suggestions.

THANK YOU!

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