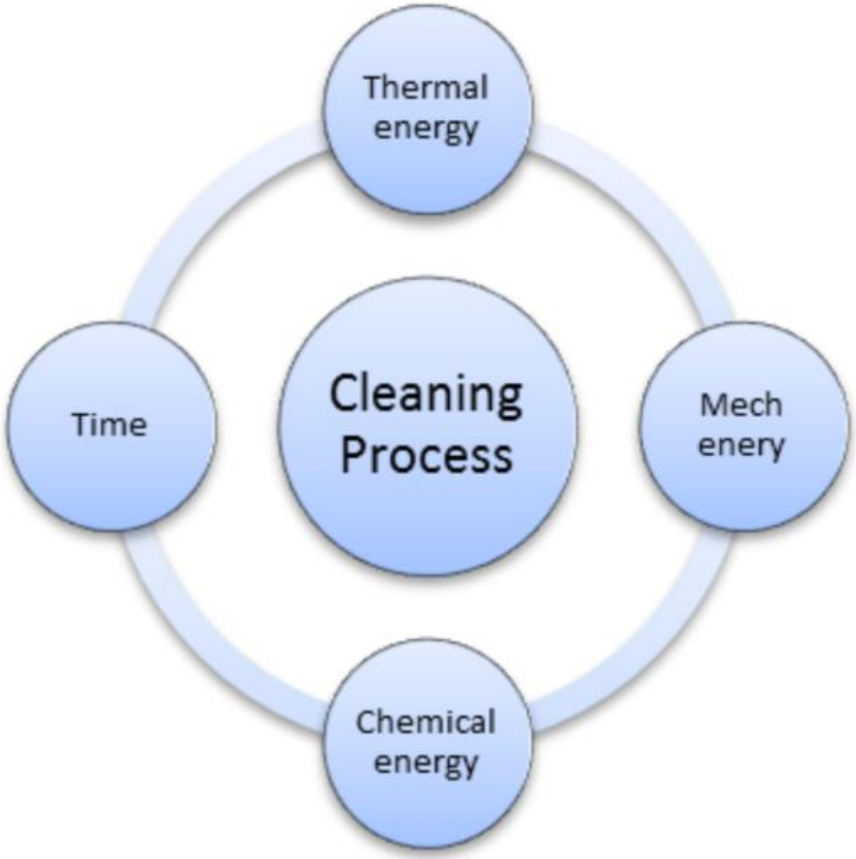
Validation of Cleaning Programs with a Focus on Allergens

George Howlett, CEO

What is Cleaning?

- Cleaning is a physio-chemical process involving a number of factors

What is Cleaning?



What is Cleaning?

- Objective – prevent contamination and cross-contamination
- Elimination or reduction - hazards
- Variety of hazards to be considered
- Biological, Physical, Chemical and Allergens
- Residuals remaining from detergents

Hazards

- Biological
  - Bacteria, yeasts, moulds, viruses, etc
- Physical
  - Wood, metal, plastic, etc
- Chemical
  - Enviornmental, process, ingredients, etc
- Allergens

Cleaning and Compliance

- Legal
  - Global regulatory agencies
  - National governments
- Commerical
  - GFSI – BRC, SQF, IFS, FSSC 22000
  - Retailer standards

Reference and Guides

- http://www.qsd.ie/wp-content/uploads/2013/06/Best-Practices-with-Alle...-Food-Safety-Magazine.pdf
- http://www.sqfi.com/wp-content/uploads/Allergen-Guidance-Document.pdf
- http://www.charm.com/resource/file/218
- http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074922.htm
- http://safefood360.com/resources/Cleaning.pdf

Risk Assessment

- Significance of hazards
- Conducted as part of HACCP or models
- List of target hazards and controls required

What is Cleaning Validation?

Verification

- Proof that cleaning has been conducted according to the approved procedure

Validation

- Proof that approved cleaning procedure is capable of producing safe food

When is Cleaning Validation Required ?

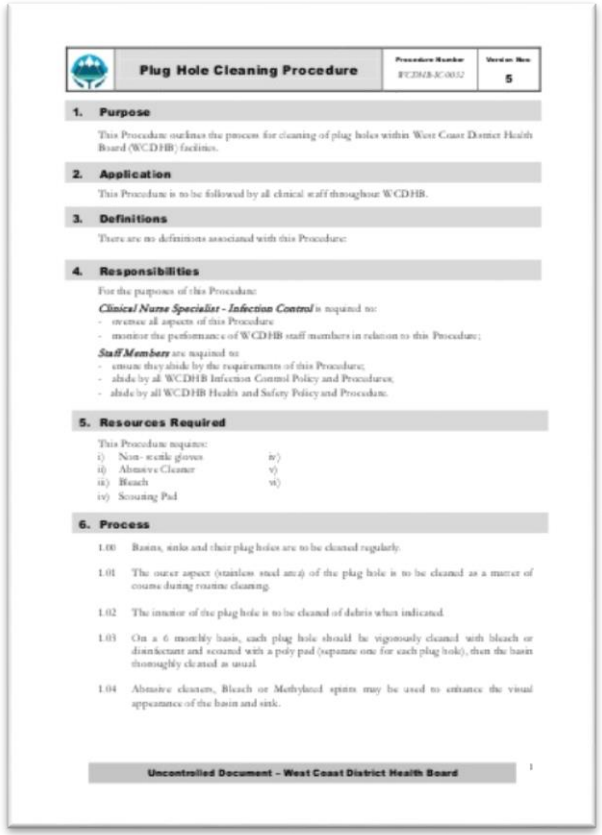
- When risk assessment or legislation requires it
- Critical cleaning, e.g. between manufacturing of one product and another or specific contact surfaces
- Not necessarily for non-critical cleaning, e.g. between batches of the same product or of floors, walls, the outside of vessels

Cleaning Validation Pre-requisites

- Cleaning SOPs for cleaning processes in place
- Cleaning schedules should also be in place
- **Cleaning Validation Procedure** required:
  - contact surfaces
  - cleaning after product changeover
  - between batches in campaigns
  - categorizing products for cleaning validation and
  - periodic evaluation and revalidation of the number of batches manufactured between cleaning validations.

Cleaning Validation Procedure

- Objectives & responsible people
- Cleaning SOP's
- Cleaning chemicals, concentration, solution volume, water quality
- Time and temperature
- Flow rate, pressure and rinsing
- Number of cleaning cycles



Plug Hole Cleaning Procedure	Procedure Number: WCDHB-IC-0032	Version No: 5

1. Purpose

This Procedure outlines the process for cleaning of plug holes within West Coast District Health Board (WCDHB) facilities.

2. Application

This Procedure is to be followed by all clinical staff throughout WCDHB.

3. Definitions

There are no definitions associated with this Procedure.

4. Responsibilities

For the purposes of this Procedure:

Clinical Nurse Specialist - Infection Control is required to:
- oversee all aspects of this Procedure
- monitor the performance of WCDHB staff members in relation to this Procedure;

Staff Members are required to:
- ensure they abide by the requirements of this Procedure;
- abide by all WCDHB Infection Control Policy and Procedures;
- abide by all WCDHB Health and Safety Policy and Procedure.

5. Resources Required

This Procedure requires:

i) Non- sterile gloves
ii) Abrasive Cleaner
iii) Bleach
iv) Scouring Pad
v)
vi)

6. Process

1.00 Basins, sinks and their plug holes are to be cleaned regularly.

1.01 The outer aspect (stainless steel area) of the plug hole is to be cleaned as a matter of course during routine cleaning.

1.02 The interior of the plug hole is to be cleaned of debris when indicated.

1.03 On a 6 monthly basis, each plug hole should be vigorously cleaned with bleach or disinfectant and scoured with a poly pad (separate one for each plug hole), then the basin thoroughly cleaned as usual.

1.04 Abrasive cleansers, Bleach or Methylated spirits may be used to enhance the visual appearance of the basin and sink.

Uncontrolled Document – West Coast District Health Board

Cleaning Validation Procedure

- Description of the equipment - make, model, complexity of design
- Training of operators
- Equipment used for monitoring (e.g. conductivity meters, pH meters)
- Sampling procedures (e.g. direct sampling, rinse sampling, in process monitoring and sampling locations) and the rationale for their use
- Analytical methods

Cleaning Validation Procedure

- Analytical methods
- Acceptance criteria (with rationale for setting the specific limits)
- Revalidation requirements

Cleaning Chemicals

- Solubility of the materials to be removed
- Design and construction of the equipment and surface materials to be cleaned
- Minimum temperature and volume of cleaning agent and rinse solution
- Manufacturer's recommendations

Cleaning Chemicals

- Released by quality control and meet food standards or regulations
- Composition known
- Easily removed with rinsing - demonstrated - with acceptable limits defined
- If persistent residues - avoided
- Consider also detergent breakdown

Categorizing

- Very similar cleaning procedures for products and processes - no need for individual validation.
- “Worst case” may be acceptable and should be justified.

Categorizing

- Representative product - most difficult to clean.
- Equipment - only when it is similar or the same equipment in different sizes (e.g. 300 l, 500 l and 1000 l tanks).

Cleaning Validation Reports

- The relevant cleaning records – (signed by the operator, checked by production and reviewed by quality assurance) – and source data (original results) should be kept.
- The results of the cleaning validation should be presented in cleaning validation reports stating the outcome and conclusion.

Equipment

- Cleaning of contact surfaces to be validated
- Critical areas should be identified.
- Dedicated equipment for:
  - products which are difficult to clean,
  - equipment which is difficult to clean,
  - products with a high safety risk

Equipment

- The design of equipment may influence the effectiveness of the cleaning process.
- Which are the critical areas for sampling?
- What would be considered an appropriate approach for cleaning validation for this piece of equipment?

Equipment

- What is important about cleaning validation for components/ parts of equipment?
- Consider also the different materials, e.g. stainless steel contact surfaces, silicon seals and others

Sampling

Two methods of sampling:

- direct surface sampling and
- rinse samples
- Combination of the two - most desirable

Resampling

- May indicate residue presence and poor cleaning procedure

Direct Surface Sampling (direct method)

- Most commonly used method
- Use “swabs” - type of sampling material should not interfere with the test
- Factors to be considered include:
  - supplier of the swab,
  - area swabbed, number of swabs used, whether they are wet or dry swabs,
  - swab handling and swabbing technique

Direct Surface Sampling (direct method)

- Other factors include:
  - location from which the sample is taken (including worst case locations)
  - composition of the equipment (e.g. glass or steel)
- Critical areas (hardest to clean)
  - e.g. in semi-automatic/fully automatic clean-in-place systems
- Use appropriate sampling medium and solvent

Rinse Samples (indirect method)

- Allows sampling of:
  - a large surface
  - areas that are inaccessible or that cannot be routinely disassembled
- Provides an "overall picture"
- Useful for checking for residues of cleaning agents
- In combination with other sampling methods such as surface sampling

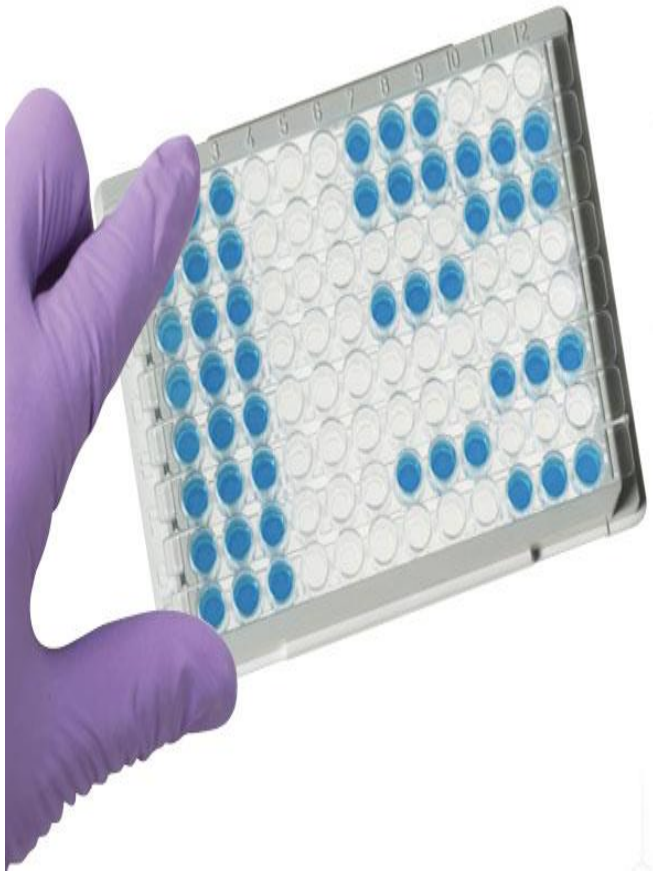
Analytical Methods

Validated analytical methods – able to detect residuals or contaminants:

- specific for the substance(s) being assayed
- at an appropriate level of cleanliness (sensitivity)

Sensitive and specific - may include:

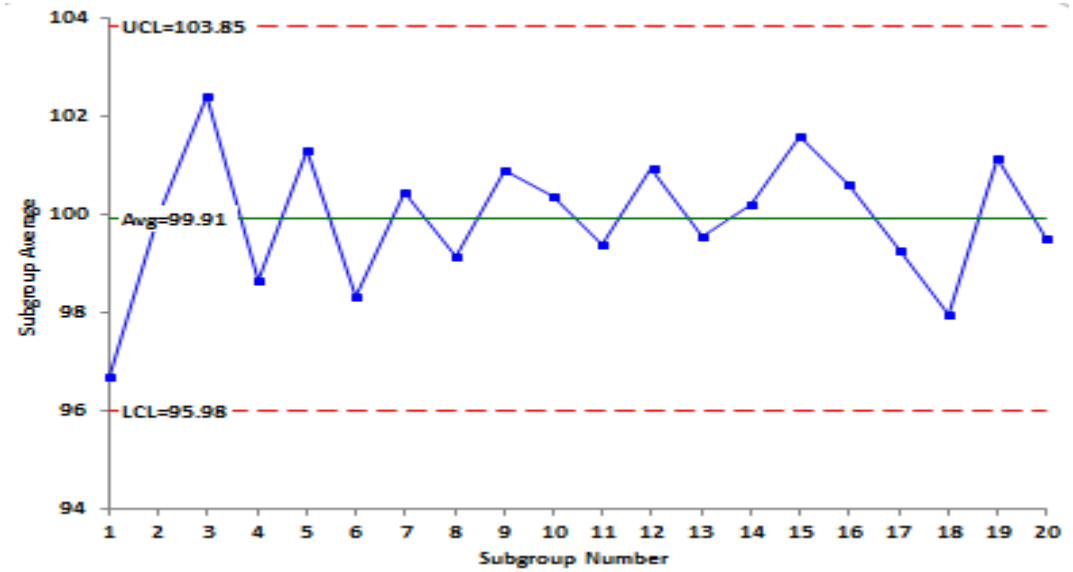
- ELISA
- Specific Allergen Testing
- Non Specific Testing



Analytical Methods

- Validation of the analytical method should include, e.g.
  - limit of detection (LOD)
  - Reproducibility

Establishing Acceptable Limits



- Limits: Practical, achievable and verifiable
- Rationale: Logical, based on knowledge of materials
- Each situation assessed individually

Establishing Acceptable Limits

There should be no residue from:

- Previous product
- Reaction by-products and detergents
- Cleaning process itself (e.g. detergents or solvents)
- Remember: Uniform distribution of contaminants is not guaranteed

Establishing Acceptable Limits

The limit-setting approach:

- be product-specific
- group products into families and choose a worst case product
- group products into group s according to risk

Establishing Acceptable Limits

- Limits may be expressed as:
  - a concentration in a subsequent product (ppm),
  - limit per surface area (cfu/cm2), or
  - in rinse water as ppm.
  - Visual

Establishing Acceptable Limits

- Certain allergenic ingredients and highly potent material should be undetectable by the best available analytical methods

Cleaning Validation Sample Procedure

- No absolute or correct way to do validation
- The following is a good generic example of a validation may be conducted

1. Pre-validation Tasks

- Hazard(s): List of hazards / contaminants
- Risk Assessment: Determine significance
- SOP’s: Documented, approved and used for cleaning
- Schedules: Documented and approved
- Validation Procedure: Written and approved
- Training: conducted for relevant staff

2. Approach: Collection of scientific data.

- Data on hazards and risks
- Legislation
- Chemicals to be used
- Analytical methods

3. Parameters and Decision Criteria

- Define microbiological, allergen and other relevant criteria necessary to consider SOPs to be validated

4. Conduct Validation Activity

- Implement the relevant SOP's for a specified period of time and number of cleans e.g. 3-4 weeks / 10 cleaning activities
- Conduct microbiological / allergen testing of food contact surfaces after cleaning and disinfection have been completed using approved SOP's

5. Analyze the results

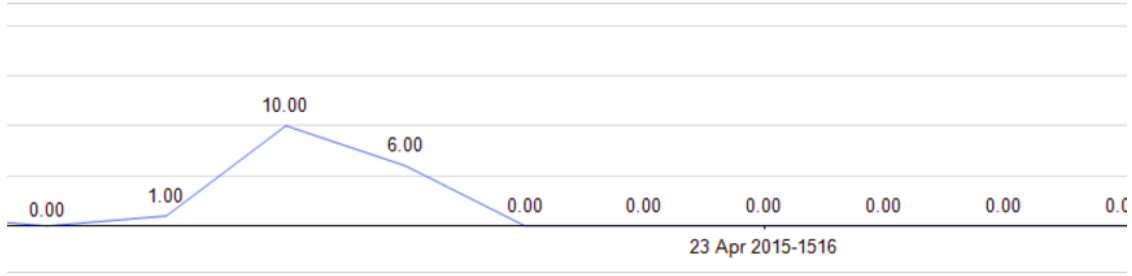
- Collate the results obtained over the validation period
- Conduct appropriate statistical analyses to determine the variability in efficacy of the cleaning SOP's e.g. capability studies

Example of Statistical Analysis

Report (Microbiological Control)

From: 14/01/2015 To: 14/01/2016 Show: TVC@37oC For: All Products

1 of 1 Find | Next

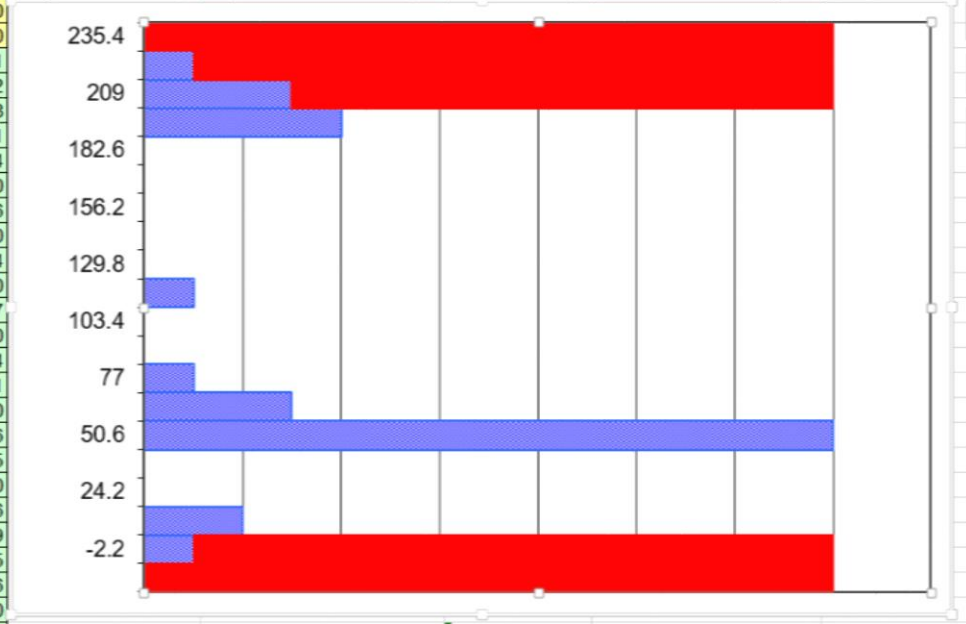


					30 Apr 2015-1523	01 May 2015-1524	02 May 2015-1525	03 May 2015-1526
Microorganism								
.00TVC@37oC	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00

Example of Statistical Analysis

Line Number:	Vemag 1	**Supplier:**	n'a	**Cleaning SOP:**	SSOP 1.2
Product name:	Mince	**Incoming RM Count:**	n/a	**Cleaning Time Interval:**	14 hours
Microorganism	TVC	**Product Temp:**	7oC	**Room Temp:**	10oC

Micro Criteria Maximum:	200
Micro Criteria Minimum:	0
Date 1	11
Date 2	52
Date 3	68
Date 4	121
Date 5	74
Date 6	210
Date 7	56
Date 8	50
Date 9	54
Date 10	190
Date 11	67
Date 12	210
Date 13	4
Date 14	11
Date 15	50
Date 16	56
Date 17	55
Date 18	220
Date 19	56
Date 20	49
Date 21	55
Date 22	56
Date 23	210
Date 24	55
Date 25	59
Date 26	191
Date 27	48
Date 28	195
Date 29	56
Date 30	190



Average:	92.63333333		
Standard Deviation:	70.22794578		
Upper 3 Sigma Value:	303.3171707	"# of Sigmas Capability":	1.3
Lower 3 Sigma Value:	-118.050504	2-tail PPM "Traditional":	187156.3889
Cp Index:	0.474644858	1-tail PPM "Traditional":	93578.19443
Cpk:	0.439679353	PPM "w/1.5 Sigma Shift":	571801.275

6. Document and review the validation

- Document the data in a validation report
- Clear presentation of scientific basis, materials, methodology, results and findings

7. Conclusion

- If results indicate that the SSOPs are capable of consistently delivering results that comply with the established criteria during the period, then the cleaning SOP's can be considered effective and validated.

- If results indicate that the SOPs are incapable of consistently delivering results that comply with the established criteria during the period, then the cleaning SOP's can be considered ineffective and not validated.

8. Recommendations

- Recommendations should be made to redesign the SOP and repeat the validation procedure