Cleaning Validation of Cleaning Tools

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Presenter: Amit Kheradia  Remco, Indiana, USA

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Cleaning Validation of Cleaning Tools

- This forum will help participants learn about:
  - Why cleaning tools should have validated cleaning procedures and be regularly monitored and verified;
  - Methods of validation, monitoring, and verification for cleaning tools; and
  - Specific cleaning, sanitizing, and disinfection protocols for different tools.
Cleaning Validation of Cleaning Tools

• INTRODUCTION OF THE SPEAKER:
  • Amit M. Kheradia
  • Education and Technical Support Manager, Remco, IN, USA

• Amit M. Kheradia has over 15 years of experience in food safety, quality, and processing technology. He holds qualifications in Food Safety and Quality Assurance from the University of Guelph, Canada (MSc), and Food Science and Technology from University of Nairobi, Kenya (BSc). Besides being a member of the IAFP Food Hygiene and Sanitation PDG, he is also conversant with HACCP, GFSI benchmarked standards, U.S. FDA FSMA, and Canadian and global food regulations.
Cleaning Validation of Cleaning Tools

**Presenter:** Amit M. Kheradia, *Remco, IN, USA*
Webinar Outline

1. Why is it essential to validate, regularly monitor, and verify the cleanability of cleaning tools?

2. Key elements to consider before and during the process of validating the cleaning protocols for cleaning tools.

3. Importance of taking into account other considerations, e.g. tool selection, replacement, storage, care, and maintenance procedures.
Sharing IAFP’s Vision of Protecting the Food Supply

• **Food Hygiene and Sanitation PDG Mission:**
  
  “To provide information on the developments in hygiene and sanitation in the food industry”

**PROPORTIONS OF TYPICAL FOOD SAFETY ISSUES**

- Supplier-related problems: 15%
- Contingencies: 5%
- Processing Defects: 12%
- Mislabeled: 35%
- Sanitation Issues: 33%

*General percentages. May vary from plant to plant depending on situation or scenario*

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1 in 3 food recalls may be related to hygiene and sanitation issues
Cleaning as a Value-Added Operation

Unclean tools that clean complex equipment are at unmarked locations!

Can we justify the cleaning of a cleaning tool?

Cleaning tools must be properly cleaned before and after use!
Cleaning Tools, Vectors for Contamination

• Unlike facility environments and equipment, cleaning tools are rarely considered as influencing food safety.  

U.K. Government Funded Study (1990)²

47% of cleaning tools tested were positive for *Listeria monocytogenes*

Schäfer et al. (2017)³

67% of equipment and utensils used in a poultry processing plant were contaminated with *L. mono*, even after cleaning

References:
FDA FSMA Regulations, 21 CFR 117.60: Unlike the process preventive controls, it is not mandatory to validate sanitation preventive controls. However, cleaning and sanitation control measures must still be monitored and verified.

SQF Code for Food Manufacturing, Edition 8 – Clause 11.2.13: Cleaning and Sanitation: No explicit mention of cleaning validation of cleaning tools. However, according to 11.2.13.2: “Provisions shall be made for the effective cleaning of processing equipment, utensils & clothing.”

Issue 8 – Clause 4.11.3 as part of ‘Housekeeping and Hygiene Requirements’: “Where cleaning procedures are part of a defined prerequisite plan to control the risk of a specific hazard, the cleaning and disinfection procedures and their frequency shall be validated and records maintained.”

ISO 22000-1:2009: PRPs on Food Safety, Clause 11.3: “Cleaning and sanitizing programs shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.”
### Cleaning Validation of Cleaning Tools

**– setting the context**

<table>
<thead>
<tr>
<th>Definitions</th>
<th>The Context</th>
</tr>
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<tbody>
<tr>
<td><strong>VALIDATION:</strong> “Obtaining evidence that a control measure or a combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.”</td>
<td>Development of a consistently effective and appropriate method of cleaning tool decontamination</td>
</tr>
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<td><strong>MONITORING:</strong> “The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is working.”</td>
<td>Use of methods to determine if validated tool cleaning protocols have been conducted effectively in a timeframe that allows for rapid detection &amp; correction of any shortfall in the decontamination achieved</td>
</tr>
<tr>
<td><strong>VERIFICATION:</strong> “The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.”</td>
<td>Use of methods, in addition to monitoring, that determine whether the validated tool cleaning protocols chosen have been conducted effectively or are still effective</td>
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</table>

**Reference:**
Validation of cleaning protocols, even for equipment, is still newer for the industry, and still not a regulatory requirement.

Absent the basic foundation of food safety practices, the GMPs, any such detailed activity would likely fall short in its effectiveness.

Cleaning validation, monitoring and verification are protocols that are carried out objectively by different individuals or groups.
Simple Model Parameterization:
Cleaning Validation of Cleaning Tools

(A) Tool surface characteristics

(B) Nature of the soil

(C) Consider TACTER parameters

(D) Select the cleaning method

(E) Are soils being effectively removed from the surface during the cleaning process?

(F) Are the cleaning tools able to withstand the cleaning process?

(G) Monitoring and verification for a continuous improvement process

(H) Setting cleaning validation expectations as a team
(A) Tool Surface Characteristics

Features:

- Compliant?
- Fit-for-use?
- Accessible?
-Inspectable?
- Cleanable?
- Maintainable?
- Easily replaceable?

Deck scrub tool

Look out for the “nooks and crannies”
Cleaning Tools as “High-Touch” Surfaces

Tool Cleaning Protocol

- Cleaned and sanitized before and after use
- Cleaned on a risk-based frequency
- Cleaned routinely, and disinfected* frequently and between employee uses

* EPA-approved disinfectants for use against SARS-CoV-2: [https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2)
Follow manufacturer’s instructions.
Soils that may adhere to a tool surface can be classified broadly into three types:

1. **“Visible” soils**

2. **“Invisible” soils** such as microorganisms, tiny particles of allergens or foreign material...

3. **Soils inadvertently introduced during the cleaning process**

- Listeria
- Salmonella
- Noroviruses
- SARS-Cov-2
Sinner’s Circle (TACT) is an effective approach towards designing a tool decontamination process. 

* Employees and resources should also be part of this approach.*

* Follow appropriate supplier’s instructions on chemical usage and any regulatory or safe industrial requirements.*
(D) Select the Tool Cleaning Method

- While there are various cleaning techniques (CIP, COP, Manual etc.), **Cleaning methods** range from **DRY** to **WET**:

![Decontaminating Tools in a Soapy Bath](image)

**Generalized process decision tree for brush tool cleaning**

- **Dry and wet cleaning**
  - **Brush, shake or bang the brush to remove gross debris**
  - **Wet cleaning**
    - **Wash in soapy water**
    - **Rinse in clean water**
    - **High risk**
      - **Dry**
      - **High risk end**
    - **Low risk**
      - **Dry**
      - **Low risk end**
  - **Wet cleaning**
    - **Low risk**
    - **Sanitize & dry**
    - **Dry cleaning end**

*Reduce the level of microbes to an acceptable level*

**Kill all microbes**
(E) Are ‘Soils’ Being Effectively Removed from the Tool During the Cleaning Process?

<table>
<thead>
<tr>
<th>SOIL / CONTAMINANT</th>
<th>METHOD OF DETECTION</th>
<th>THRESHOLDS</th>
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<tbody>
<tr>
<td>Foreign material</td>
<td>Visual; metal detector (for metal fragments only); X-Ray, etc.</td>
<td>Absence (or) Maximum Acceptable Limit</td>
</tr>
<tr>
<td>Organic Matter</td>
<td>Visual; ATP kit</td>
<td></td>
</tr>
<tr>
<td>Chemical Residues</td>
<td>Contaminant residue test; pH strip</td>
<td></td>
</tr>
<tr>
<td>Spoilage Organisms</td>
<td>Microbiological analysis</td>
<td></td>
</tr>
<tr>
<td>Allergens</td>
<td>Visual; Allergen-detection kit</td>
<td></td>
</tr>
<tr>
<td>Pathogens</td>
<td>Microbiological analysis</td>
<td>Absence or “Zero Tolerance”</td>
</tr>
<tr>
<td>Biofilms</td>
<td>Fluorescent microscopic examination (not easy to detect mature biofilms)</td>
<td></td>
</tr>
<tr>
<td>Viruses</td>
<td>PCR kit (not easy to detect viruses)</td>
<td></td>
</tr>
</tbody>
</table>
(F) Are Cleaning Tools Able to Withstand the Cleaning Process?

As part of the validation process, it may be important to test the tool under different simulated operating conditions, and then see whether the surfaces remain intact and functional. This could involve some form of an experimentation process. For example:

- **Chemicals**
  - 200-400 PPM QUATS
  - 5-10% Sodium Hypochlorite Solution
  - 70–85% Alcohol Solution

- **Temperature**
  - Freezer -20°F
  - Ambient 68–72°F
  - Dishwasher 145–165°F
  - Autoclave 250°F

- **Mechanical Stress**
  - Low Impact
  - Medium Impact
  - High Impact

**Tip:** Consider worst-case scenario combinations, and assess durability of the tool with continued use, under those conditions, with time.
Validation is followed by monitoring and verification. These are interdependent activities:

**Design**
- **VALIDATION**

**Real-Time Check & Correction**
- **MONITORING**
  - e.g. Daily/weekly visual inspection before cleaning and during operations, during cleaning, and after cleaning; may be combined with ATP monitoring

**Periodic Review**
- **VERIFICATION**
  - e.g. Allergen testing, microbial analysis, pre-op or post-op inspections or audits

*If any of the cleaning parameters show a significant change, there may be a need to re-validate tool cleaning processes
(H) Setting Cleaning Validation Expectations as a Team

- Cleaning validation is about designing a systematic cleaning process even if it is for a simple tool. It is a team effort. The ultimate aim is the production of safe and hygienic food products for the consumer:

**Sanitary Production of Safe Food**

- **EXTERNAL**
  - Inspectors and Auditors
  - Product/Service Providers
- **INTERNAL**
  - Production Management and Supervisors
  - Quality Management and QC

**CUSTOMERS**

**SANITATION CREW**
Other Important Considerations

- Proper storage, care, and maintenance

- Take worn out, damaged, or unhygienically-constructed tools out of service and replace them immediately.

**Tool selection can be critical:** Hygienically designed tools are preferred
IAFP 2020 Conference

- 2-Day Advanced Sanitation and Hygienic Design Workshop

- Food Hygiene and Sanitation PDG 2020 Meeting

- Symposium S32 – “Allergen Control – Challenges, Perspectives & Solutions”

- Symposium S66 – “They Get By With a Little Help From Their Friends”

October 25-28, 2020
300 Lakeside Ave, Cleveland, OH 44113
foodprotection.org
Questions?

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Questions?

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