



Cleaning Validation of Cleaning Tools

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Cleaning Validation of Cleaning Tools

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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

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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

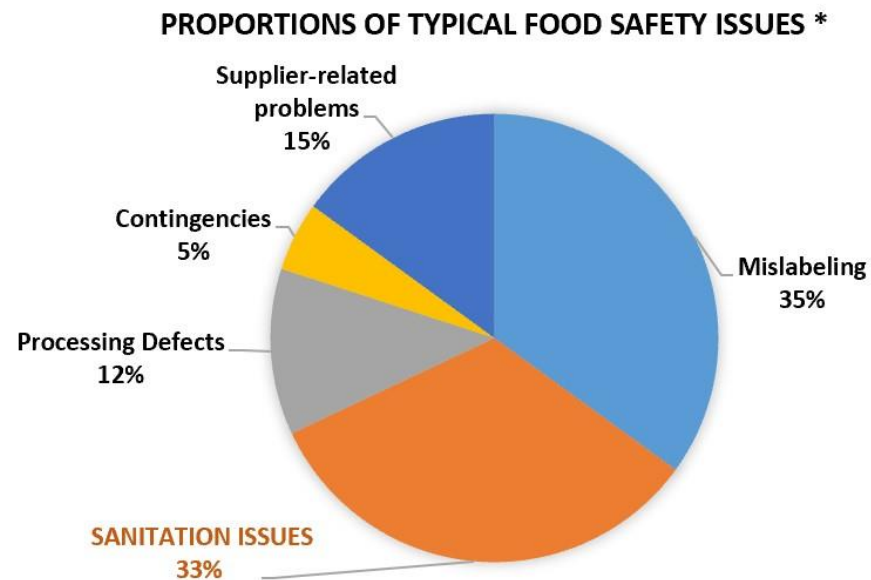
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- **Food Hygiene and Sanitation PDG Mission:**

- *"To provide information on the developments in hygiene and sanitation in the food industry"*



1 in 3 food recalls may be related to hygiene and sanitation issues

Cleaning as a Value-Added Operation

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Unclean tools that clean complex equipment are at unmarked locations!

Can we justify the cleaning of a cleaning tool?



Brushes



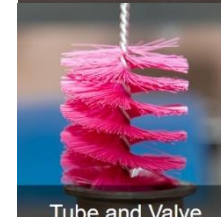
Brooms



Scrapers



Deck Scrubs



Tube and Valve Brushes



Squeegees

Cleaning tools must be properly cleaned before and after use!

Cleaning Tools, Vectors for Contamination

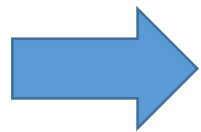
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- Unlike facility environments and equipment, cleaning tools are rarely considered as influencing food safety.¹

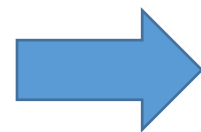
U.K. Government
Funded Study (1990)²



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:

1. Smith, D. (2018). Raising Awareness of Global Food Safety Scheme Audit Requirements with Regard to Cleaning Tool and Utensil Selection and Use. In *IAFP European Symposium on Food Safety*. IAFP April, 2018.
2. Holah, J.T. (1990). Effective microbiological sampling of food processing areas. Guideline No. 20, Campden & Chorleywood Food Research Association.
3. Schäfer, D., Steffens, J., Barbosa, J., Jamile Z., Rogério L. C. (2017). Monitoring of contamination sources of *Listeria monocytogenes* in a poultry slaughterhouse. *LWT – Food Science & Technology*. Dec 2017, Vol. 86, p. 393-398.

Perspectives of Regulations and Global Standards

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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*

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DEFINITIONS ¹	The Context	
VALIDATION: “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.”	<i>Development of a consistently effective and appropriate method of cleaning tool decontamination</i>	 Designing/ Planning/ Parameterization
MONITORING: “The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is working.”	<i>Use of methods to determine if validated tool cleaning protocols have been conducted effectively in a timeframe that allows for rapid detection & correction of any shortfall in the decontamination achieved</i>	 Real-Time “Check” & Path Correction
VERIFICATION: “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.”	<i>Use of methods, in addition to monitoring, that determine whether the validated tool cleaning protocols chosen have been conducted effectively or are still effective</i>	 Periodic Review

Reference:

Codex Alimentarius Commission. 2008. Guidelines for the validation of food safety control measures, CAC/GL69-2008. Geneva, Switzerland

Understanding the Challenges and Prerequisites of Cleaning Validation

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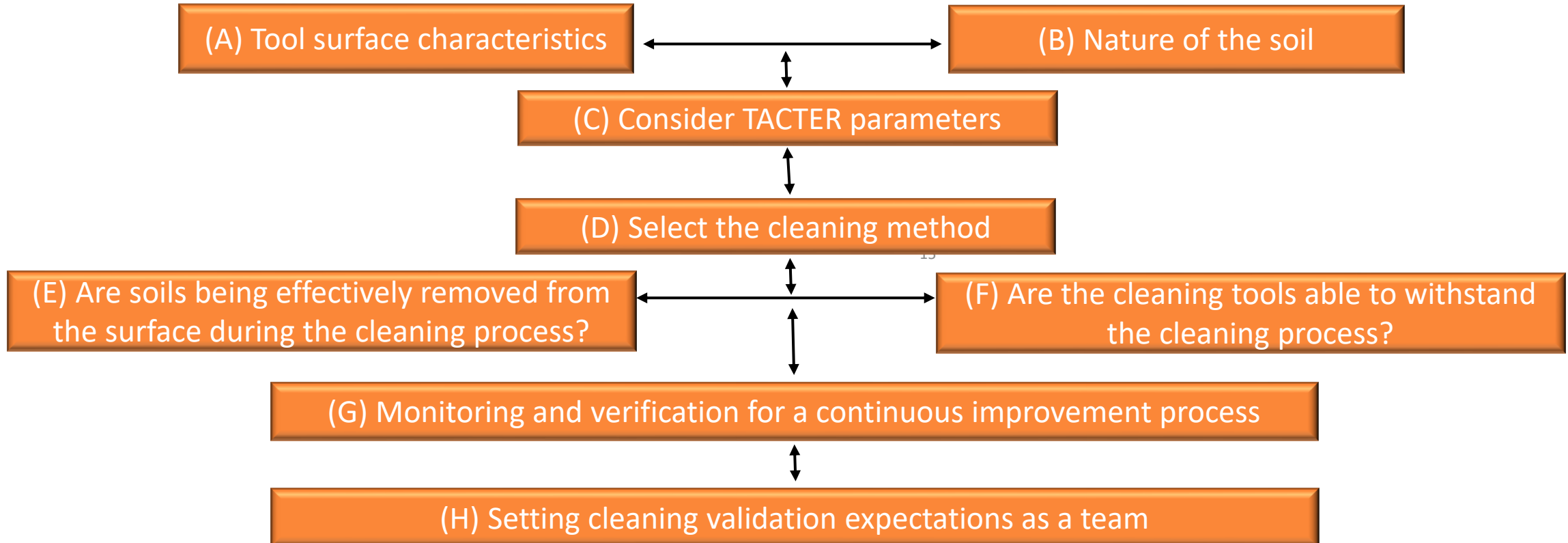
- Validation of cleaning protocols, even for equipment, is still newer for the industry, and still not a regulatory requirement.
- Absent the basic foundation of food safety practices, the GMPs, any such detailed activity would likely fall short in its effectiveness.
- Cleaning validation, monitoring and verification are protocols that are carried out objectively by different individuals or groups.

Simple Model Parameterization: Cleaning Validation of Cleaning Tools

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(A) Tool Surface Characteristics

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Features:

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

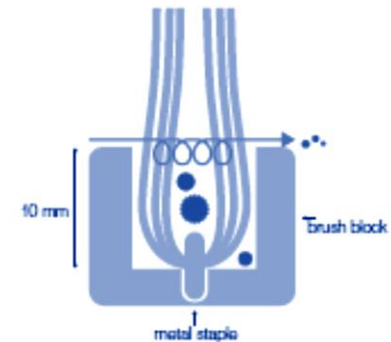


Deck scrub tool

dismantle



Look out for the “nooks and crannies”



Cleaning Tools as “High-Touch” Surfaces

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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>
Follow manufacturer’s instructions.

(B) Nature of the Soil

Soils that may adhere to a tool surface can be classified broadly into three types:

1. *"Visible" soils*



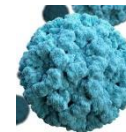
2. *"Invisible" soils such as microorganisms, tiny particles of allergens or foreign material ...*



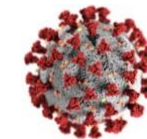
Listeria



Salmonella



Noroviruses



SARS-Cov-2

3. *Soils inadvertently introduced during the cleaning process*

(C) Consider TACTER Parameters

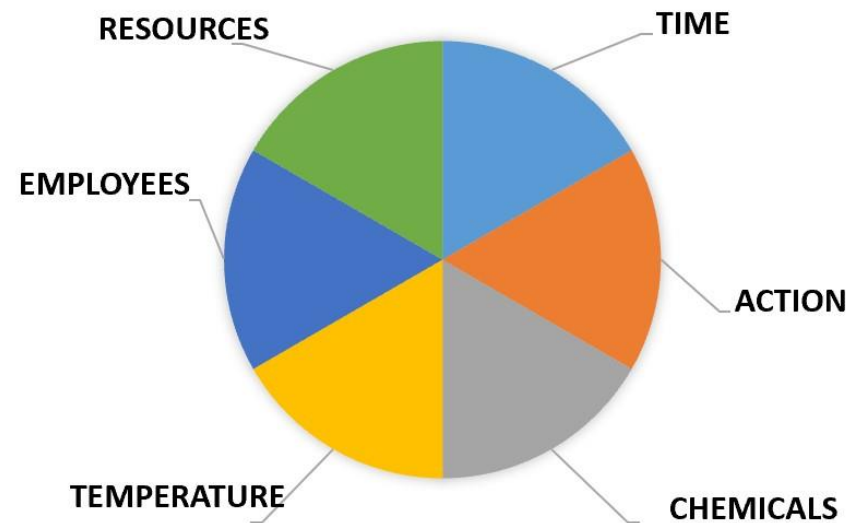
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Sinner's Circle (TACT) is an effective approach towards designing a tool decontamination process.

Employees and resources should also be part of this approach.



(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

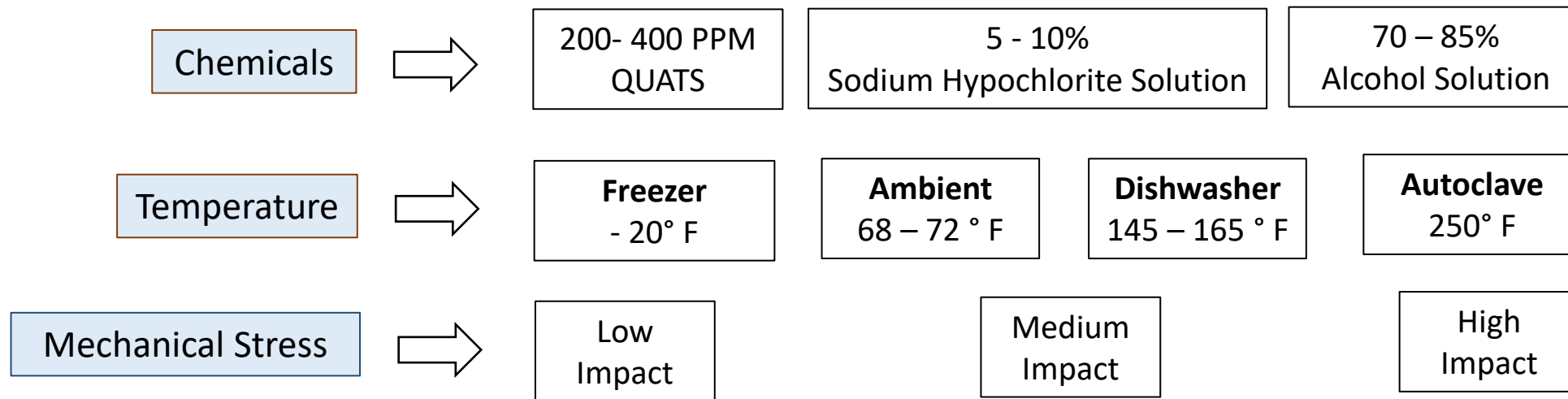


(E) Are 'Soils' Being Effectively Removed from the Tool During the Cleaning Process?

SOIL / CONTAMINANT	METHOD OF DETECTION	THRESHOLDS
Foreign material	Visual; metal detector (for metal fragments only); X-Ray, etc.	Absence (or) Maximum Acceptable Limit
Organic Matter	Visual; ATP kit	
Chemical Residues	Contaminant residue test; pH strip	
Spoilage Organisms	Microbiological analysis	
Allergens	Visual; Allergen-detection kit	Absence or "Zero Tolerance"
Pathogens	Microbiological analysis	
Biofilms	Fluorescent microscopic examination (not easy to detect mature biofilms)	
Viruses	PCR kit (not easy to detect viruses)	

(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:



Tip: Consider worst-case scenario combinations, and assess durability of the tool with continued use, under those conditions, **with time**.

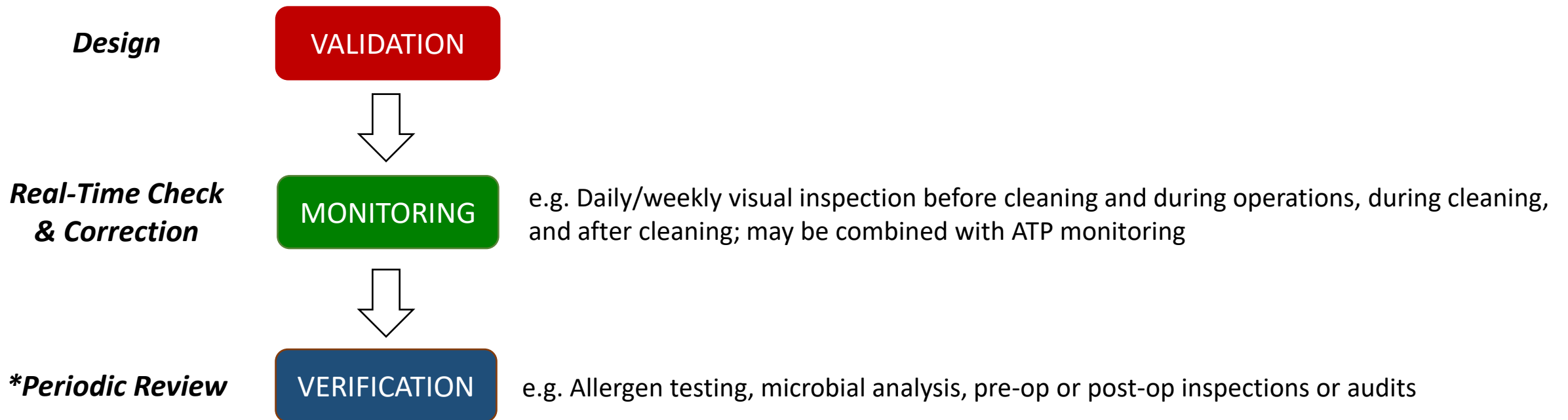
(G) Monitoring and Verification for a Continuous Improvement Process

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Validation is followed by monitoring and verification. These are interdependent activities:

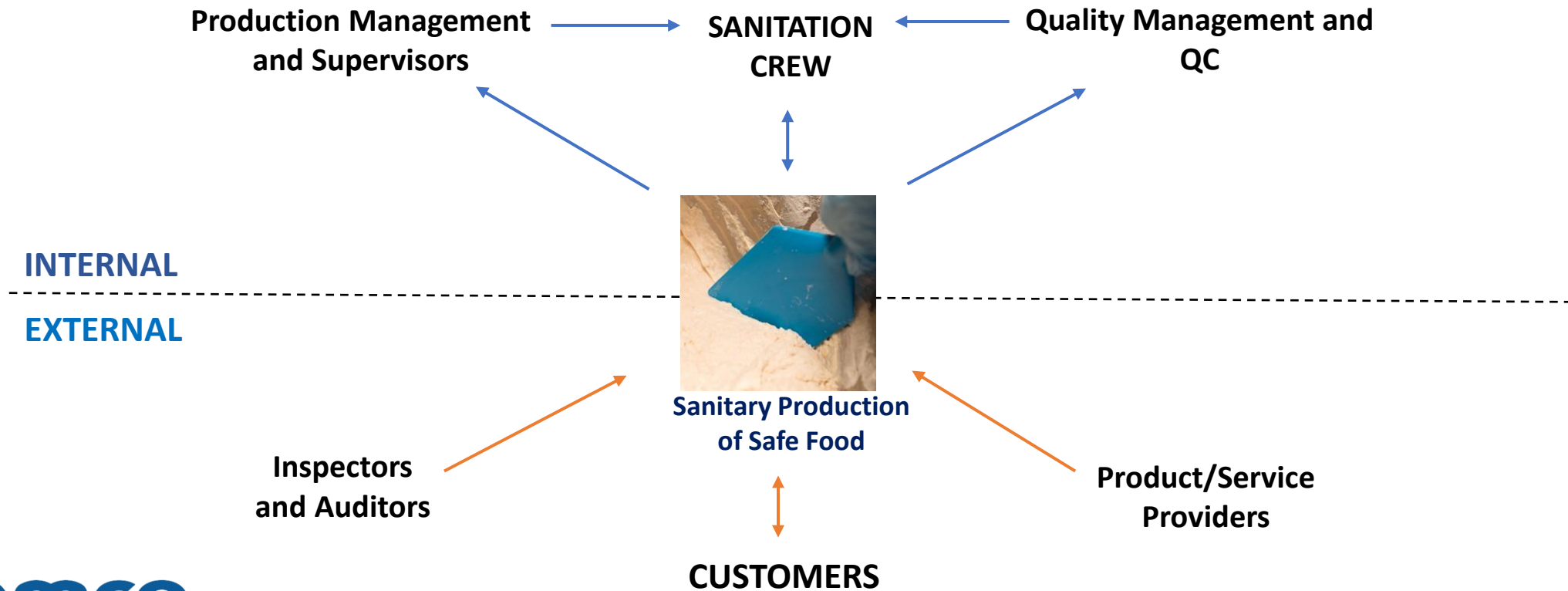


*If any of the cleaning parameters show a significant change, there may be a need to re-validate tool cleaning processes

(H) Setting Cleaning Validation Expectations as a Team

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- 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:



Other Important Considerations



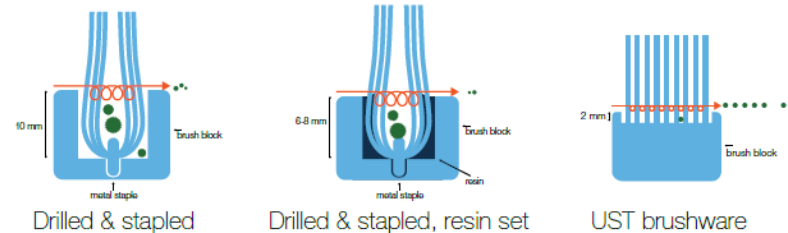
Proper storage, care, and maintenance



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

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- **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”**

Questions?

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Questions?

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