Review paper
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A SYSTEMATIC APPROACH TO FOOD SAFETY

Anders Göransson[1*], Kristina Petersson[1]

[1]Tetra Pak Processing Systems, Ruben Rausings gata, SE-221 86 Lund, Sweden

[*]e-mail: anders.goransson@tetrapak.com

Abstract

To secure food safety there is a need for using a structured approach to validate CIP of the process equipment. It is important to consider the CIP operations as an integrated part of the production cycle. CIP validation is a tool for securing food safety.

The CIP validation tool offers a systematic way to control the CIP of the processing equipment. A prerequisite for managing CIP operations is the hygienic design. Badly designed equipment cannot be compensated for. The CIP validation tool also covers the entire process starting from design qualification through installation qualification and operational qualification to performance qualification. Monitoring and recording the critical CIP parameters such as cleaning time, pressure and temperature is a prerequisite for ensuring good hygienic processing.

There are two general types of sampling: indirect sampling with the use of rinse solutions and direct surface sampling with swab methods. A combination of the two methods may be used to confirm cleaning efficiency. Among the available techniques to verify the CIP there are microbiological as well as non-microbiological ones, e.g. visual surface inspection, UV light and ATP swabbing.

In order to reduce energy, water and chemicals it is important to clean according to need. When designing a CIP program it is important to consider type of product and production scenario. Following the CIP in real time makes it easier to design a CIP programme according to need and obtain a receipt on the status of the CIP.

Key words: *CIP validation, ATP, CIP design*.

1. Introduction

In the daily business within a food industry cleaning operations are frequently occurring phenomena. The CIP (cleaning-in-place) operations must be carried out in such a way that they do not hinder production more than necessary. This put high demands on the cleaning operations as well as on operations prior to production such as pre-sterilization and disinfection. These types of down-time operations must take as little time as possible but must not fail in order to secure food safety. It is therefore of importance to develop tools and solutions to secure the cleaning result and to minimize the down-time.

Tetra Pak has during recent years worked in a structured approach to focus on development and implementation of tools that can be used for securing cleaning results. One of these initiatives is a Cleaning Validation document.

2. Cleaning validation

The objective with a CIP validation tool is to verify the effectiveness of the cleaning procedure which is used to remove product residues, i.e. to obtain a systematic approach to food safety. Cleaning validation means establishing documented evidence that the cleaning process will remove soil to predetermined acceptable levels. The general process for qualification and validation is shown in Figure 1 (Nicolay and Schmitt [1]).

The cleaning validation as described in this paper has the starting point from the equipment manufacturer's point of view, i.e. to validate that the CIP operations work according to specifications. The cleaning validation tool covers the whole process ranging from white paper project to the daily maintenance and inspection of the CIP. In Figure 1 is shown the outline of the validation tool focusing on the four qualification steps: design qualification, installation qualification, operational qualification and performance qualification. In the following sections a more detailed description follows.

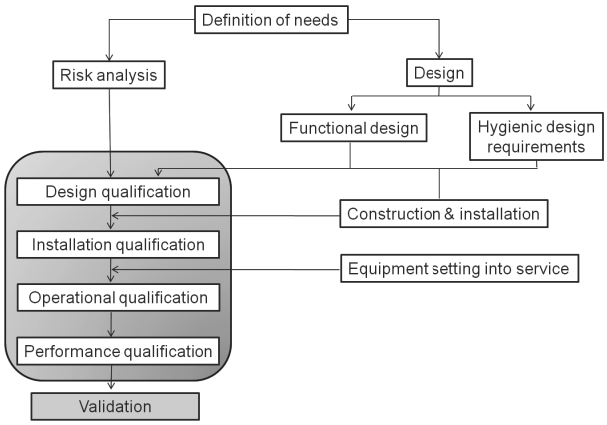

Figure 1. The general process for qualification and validation of equipment. From the equipment manufacturer's perspective focus is on the four qualification steps: design qualification, installation qualification, operational qualification and performance qualification

2.1 Design qualification

The hygienic design is a prerequisite for achieving a good cleaning result. If a bad design is built in the probability to get hygienic problems increases due to a non-satisfactory CIP. Typical risk design are e.g. dead-ends, which shall not be present but however, sometimes unavoidable. It shall also be ensured that the equipment is self draining. By following directives and standards such as the 2006/42/EC Machinery Directive [2] and EN 1672-2:2005 [3], food processing machinery it is guaranteed that the requirements are met in a satisfactorily way.

Questions to highlight before starting the work are e.g.:

- To which and for how many different food types will the equipment be utilised?
- To what extent and to what type of soil will the design be exposed?
- What are the cleaning, disinfection and pre-sterilization requirements?

2.2 Installation qualification

In this step a thorough mapping of the installed line/plant is carried out checking the flow charts ensuring all CIP circuits are mapped. By physically check the line to make sure that the installation is according to drawings and specifications. The aim with this step is to obtain a check that: all items are installed in the correct positions, the correct type and size of the component is used and that service media are connected to the corresponding process item.

2.3 Operational qualification

In the operational qualification step focus is set to ensure that the processing line operates correctly and that the CIP system works as planned. Main focus lies on the cleaning program and to see that the cleaning parameters in the Sinner's circle meet the requirements. To check that flow rate, temperature, detergent concentration/conductivity, pressure and circulation time are according to what has been stated. A requirement is that all the above mentioned parameters must be monitored and documented. One other important factor that is often forgotten is the water quality. At this point it is important to see that the values are according to specification.

2.4 Performance qualification

In the previous sections the purpose has been to secure that everything is functioning as defined. The purpose of the performance qualification is to demonstrate that the equipment is clean after completing the CIP program. One important issue to consider is when the acceptance criteria for cleanliness are met: how clean is clean?

When the performance qualification is carried out a worst case scenario shall be adopted, i.e. the piece of equipment that is to be cleaned will be exposed to the product most difficult to remove. It is also important to use production times that are relevant for the actual case. All relevant parameters must be monitored during the CIP: flow rate, cleaning temperatures, detergent concentrations and circulation times.

A relevant issue is to consider at this point is how to measure the cleaning result. When is the line clean enough and how to define "clean enough"? It is important to use methods with a detection limit sensitive enough to detect any soil residues. On the other hand a chosen method should not be too sensitive indicating a malfunctioning CIP procedure when it is actually performing well.

2.5 Cleaning validation techniques

There are two types of sampling: indirect sampling with the use of rinse solutions and direct surface sampling with the swab method. The advantage with rinse sampling is that a larger surface area may be sampled as well as areas that are inaccessible or cannot be routinely disassembled are covered. One disadvantage is that any soil still remaining on the surfaces are not detected. The combination of the two methods should be used to successfully validate the cleaning efficiency. However, the primary validation procedure for any cleaning program is visual inspection which can be refined by using UV light. This assessment of the cleanliness should be performed prior to sampling for any analytical cleaning evaluation methods just to

ensure that the cleaning result is visually acceptable. Another simple and straightforward method is to wipe the surface with a white tissue paper to investigate if any discolouration appears on the tissue.

Another classification shown in Figure 2 is to distinguish between microbiological and non-microbiological methods. In addition to the already mentioned visual methods the ATP swab methods belong to the non-microbiological methods. The ATP measurement techniques are used as a rapid hygiene monitoring tool, however being very sensitive it should be used with utmost care. It is important to establish a base line when using the ATP technique, one value at one position might not be the same as for another position, however still the CIP is fulfilled in a satisfactorily way. There are many manufacturers of ATP instruments and the suggested value for cleanliness might differ at a wide range.

Regarding microbiological methods there are the traditional swab method and direct agar contact plates method (ISO 18593:2004) [4]. Both are using general or selective media. Typical microbiological requirements that are used are according to Table 1 (Romney [5]).

Table 1. Acceptable microbiological requirements used in dairy applications

Parameter	Value [cfu/dm^2]
Total count	< 100
Enterobacteriaceae	< 1
Yeast and mould	< 10-100

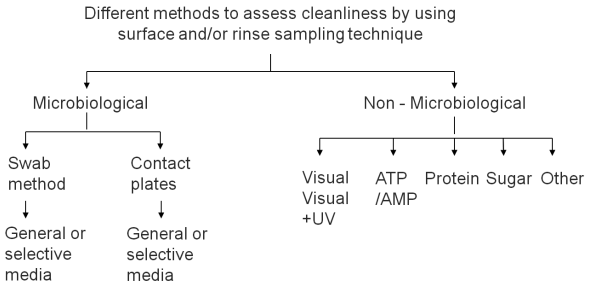

Figure 2. Methods to assess surface cleanliness (Lelieveld *et al*. [6])

2.6 Clean according to need

Cleaning validation is a tool when validating the performance of a CIP program but also a support tool to design new CIP sequences. The cleaning should be an integrated part of the production cycle, and the production strategy should be focused on fouling mitigation and strategies of CIP.

The trend is moving towards more diverse production, the very same module shall handle different types of products with more complex formulations. A wide range of food additives are used resulting in different fouling tendency of the products. It is important to consider issues like:

- When during the production cycle should CIP take place
- Design of CIP programs adjusted to type of product and production length.

Cleaning should deliver a value. There is a balance between production time and downtime, i.e. what is the price of product losses and cleaning cost including cost of detergents and utilities, compared to the value of continuation of production for another few hours. Long production times require more intense CIP programs with respect to both time and temperature compared to shorter production cycles. This must be taken into consideration when CIP programs are designed.

3. Conclusions

– New trends in food production put more pressure on the equipment manufacturers. The diversification of food products containing a wide spread range of food additives implicates that cleaning will be more challenging. To secure food safety it is therefore important to have tools to secure that cleaning is performed according to the specified needs.

– In this paper a systematic approach is described how to accomplish a validation of the CIP of a production line with starting point in design qualification followed by installation qualification, operational qualification and performance qualification.

4. References

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