



Decommissioning a WFI loop

Last update: 2018-02-28

1 INTRODUCTION

WFI (Water For Injection) loops are used in pharmaceutical industry to distribute high quality water in process area.

When the installation is for example too aged, it may be needed to replace it, the current must be then decommissioned.

2 DECOMMISSIONING STRATEGY

As the WFI loop is used during daily production, the removal can only be performed during shutdown. This period is often short, so the decommissioning activities can be divided in two parts:

- The activities that have a potential impact on routine,
- The rest of the activities.

The first type of activities will be performed during the shutdown and their results will be summed up in an intermediate report to allow the restart of production at the end of the shutdown. Once the other activities are performed, a final report with all results will be released.

The activities without quality impact will be performed in a concurrent way.

3 DECOMMISSIONING TESTING

3.1 PREREQUISITES

Before starting the decommissioning activities, the environmental monitoring must be checked. The purpose of this test is only to verify that all samples have been sampled according to the sampling plan. The samples that are out of specifications are managed through the routine deviation process.

The second point to check before the beginning of the physical decommissioning is the calibration of all measurement equipment on the loop.

3.2 MECHANICAL AND ELECTRICAL PART

After the two previous verifications (see paragraph 3.1) and after emptying the loop, the physical removal of the loop begins. It can be divided into two parts:

- The physical removal during shutdown, which concerns all parts of the WFI loop inside the production area. The holes left by the removal must be filled with materials resistant to the cleaning agent(s) and compliant to the GMP condition. At this step, the loop must be also disconnected from the main water collector and the hole must be sealed with a cap.
- The physical removal after shutdown, which concerns all parts of the loop located in the technical area. At this step, the loop will also be disconnected from the black utilities.

Concerning the electrical part of the loop, all the I/O (Input/output) must be disconnected and removed from the electrical cabinet.

3.3 AUTOMATION PART

Before making any modifications, the backup availability of each impacted system must be checked. Once this verification has been made, the following modifications can be performed:

- Removal of the tags from impacted servers (alarm server, ...),
- Stop recording the data in the data server (they must be always available in the system),
- Stop of the audit trail,
- Overviews update and injection in all impacted HMI,
- Loop functions removed from the PLC (Circulation, Sanitization, ...).

A verification that the tags are not used anymore in the PLC can be performed thanks to a cross-reference check.

After the implementation of all changes, backup of all modified systems must be done.

3.4 DOCUMENTATION PART

With the removal of the WFI loop, there are a lot of documents and databases to update, hereafter is a non-exhaustive list:

- The calibration and maintenance follow-up system,
- The WFI loop spare parts must be deleted from the general list,
- The plans (P&ID, Electrical and pneumatic drawings),
- All procedure mention the WFI loop or one of its part,
- Logbooks,
- IT Specifications (ITS).
- ...

4 CONCLUSION

During the decommissioning of a WFI loop, there are several aspects to consider:

- The mechanical part of the loop,
- The electrical connection of the loop,
- The automated functions of the loop,
- The “documentation” mentioning the loop.

Depending on the time available during the shutdown, it is possible to divide the decommissioning activities into two parts.

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