

Validated procedures in CSSD – Basic knowledge and requirements



Validated procedures in CSSD –

Basic knowledge and requirements



- What is validation?
- Why do we need validated procedures?
- Which procedures should be validated?
- Which procedures can be validated?
- How is validation performed in CSSD?
- Preparation of validation in CSSD
- Re-qualification
- What is needed to make it work?
- Who is responsible for validation?
- Who can validate?

Validated procedures in CSSD –

What is validation?



Validation is a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications (prEN ISO 14937:2008)

Validated procedures in CSSD



What is validation?

Validation consists of:

- Installation qualification (**IQ**)
 - Operational qualification (**OQ**)
 - Performance qualification (**PQ**)
-
- Re-qualification (performance)

Validated procedures in CSSD



Why do we need validated procedures?

i.e. Germany:

- Required by law >> Medical Device Directive
- RKI/BfArM Guideline >> Hygienic processing of medical devices

European Union:

- **M**edical **D**evice **D**irective 93/42 EEC, amended by Directive 2007/47 EC

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Why do we need validated procedures?

Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007

amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

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Why do we need validated procedures?

The goals in validation of procedures according to the medical device directive are to achieve a

- ✓ high safety in reprocessing of medical devices (cleaning, disinfection, packaging, sterilisation),
- ✓ to protect the patient's health and safety
- ✓ To protect the staff

All steps of reprocessing must be carried out properly and documented

Validated procedures of CSSD

Which procedures should be validated?



All procedures (processes) where the end product can't be checked for Quality (because it would be destroyed by doing so) should be validated

>> Sterile Medical Devices <<

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Which procedures should be validated?

According to RKI/BfArM-Guideline all steps of the reprocessing cycle must be validated

- Validated cleaning and disinfection
- Validated inspection and function control
- Validated packing
- Validated sterilization

Validated procedures in CSSD



Which procedures can be validated?

At present the following automated procedures can be validated

- Steam sterilization (EN ISO 17665)
- Cleaning and disinfection (EN ISO 15883)
- Sealing of pouches (EN ISO 11607)
- Formaldehyde sterilization (EN 14180)
- Etylenoxide sterilization (EN 1422)

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How is validation performed in CSSD?



Installation qualification (IQ)

process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2001, definition 2.20]

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How is validation performed in CSSD?



Operational qualification (OQ)

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO/TS 11139:2001, definition 2.24]

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How is validation performed in CSSD?



Performance qualification (PQ)

process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[ISO/TS 11139:2001, definition 2.26]

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How is validation performed in CSSD?



After all tests have been carried out the validating person evaluates the results and writes a

Validation Report

Validated procedures in CSSD

How is validation performed in CSSD?



Re-qualification (performance)

repeat of part or all of the validation test requirements for the purpose of confirming process reliability

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How is validation performed in CSSD?



CSSD is mainly involved in the preparation of the performance qualification (PQ) and re-qualification

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Preparation for Validation in CSSD



- ✓ Set up Quality management
 - ✓ Writing a Quality manual
 - ✓ Recording and documentation of all procedures carried out to reprocess Medical Devices
 - ✓ Recording and documentation of all supporting procedures
 - ✓ Developpe and write SOPs (Standard Operating Procedures) for all steps of the cycle

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Preparation for Validation in CSSD



CSSD Managers and Staff need to know more about validation

In recent years Guidelines for validation have been written by experts to enable CSSD to prepare for the validation procedures

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Preparation for Validation in CSSD



Guidelines available on WFHSS Website

- Guideline for the Validation of processes in Washer/Desinfectors (WD) build according to EN ISO 15883-1 (3. issue 2008)
 - Including guideline for processes in older WD
- Guideline for validation of the sealing process (1. issue 2008)
- Guideline for validation of processes in a steam sterilizer (DGKH revised in 2008, only in German)

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Preparation for Validation in CSSD

CSSD Managers and Staff can prepare with according to those Guidelines

Performance Qualification cannot be done correctly without the CSSD Staff

- They know the worst case loads for cleaning/disinfection
- They know the worst case loads for sterilization
- They have to make sure that all measures mentioned in the QM-Manual are followed to the point

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Intervalls for re-Qualification



The defined interval may be determined by

- European Standards
- Regulatory Authorities
- risk analysis.

Normal practice would be for re-qualification to be carried out annually or for specified reasons

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Re-qualification (performance)

shall be carried out:

- ✓ if changes or engineering work has been carried out on the equipment and installation that could affect the performance
- ✓ if review of records of routine tests of WD performance indicate unacceptable deviation(s) from data determined during the initial validation
- ✓ if performance is unacceptable
- ✓ if process conditions are changed

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What is needed to make it work?



To validate procedures good cooperation between manufactures, CSSD and Technical department is **compulsory**
Validation is very complex and depending on correct preparation of everyone involved

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Who is responsible for validation?



The Hospital or the Central Service provider are responsible for validation

- There has to be profound knowledge of the procedure of validation in CSSD
- Validation has to be a part of the education for CSSD Managers

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Who can validate?



Everyone who has

- The needed knowledge
- The needed equipment

So far there are no **legal** requirements for a „Validator“

- The guideline for validation of WD processes has an Annex which states requirements

Validated procedures in CSSD



„What about manual procedures?“

- Manual cleaning and disinfection
- Visual control
- Functional control
- Lubrication
- Packaging

Quality management

is the key to standardization and validation of manual procedures



**Thank you for your
Attention!**

Any questions?