

# Recommendations by the Quality Task Group (53): Verification of Completeness of Validation Protocols for WD Processes

**H**ave the cleaning and disinfection processes in your washer-disinfectors (WDs) been validated? Was validation conducted as per the standard DIN EN ISO 15883 or according to the Guideline drafted by the DGKH, DGSV and AKI?

Despite the fact that the questions posed above have received an affirmative response, inspection of the validation folder (s), unfortunately, reveals that while it features several measured curves with thermologgers, other important tests have not been, or not in their entirety, performed. Often, parts of process validation have not been carried out or not documented, e.g.

- The photo documentation for the reference loads and positioning of loggers and test instruments
- Visual inspection of instruments contaminated under everyday-use conditions for cleanliness
- Measurement of any residual protein using the biuret method or a comparable method
- Measurement of residual chemicals in the final rinse water

The CSSD management is responsible for carrying out medical device decontamination in line with the dictates of quality assurance and must therefore be able to check whether all tests needed for process validation have been performed and the results documented.

Below is a guide to help overcome these shortcomings:

## **Content of a validation folder**

### **1. Cover page:**

Information on the:

- Operator, location
- WD manufacturer, WD make, serial number and year of manufacture
- Validation firm and person/team conducting validation
- Validation results and routine checks prescribed
- Information on any deviations and shortcomings in respect of the WD, operating materials, operation and results of previous validation.

**Note: the operator and validation inspector must sign the validation folder.**

### **2. Information:**

- Information on standards and legislative acts while specifying the sources
- Proof of qualification of the person/team conducting validation
- Details of the measuring instruments used, together with calibration protocols
- Details of the process chemicals used
- Manufacturer's information on processing as per EN ISO 17664
- Risk assessment and classification for all medical devices that will be processed in the WD

### **3. Validation preparation:**

The minutes of validation preliminary meetings while taking account of the content of the Guideline drafted by the DGKH, DGSV and AKI, as of November 2006 (Checklist 7)

- Definition of the reference load(s).
- Standard operating procedures for manual preparatory tasks.
- Qualification of WDs that do not conform with the standard EN ISO 15883

- Information on:
  - Constructional and organisation prerequisites. (Checklist 1 and 2)
  - Information for the operator. (Checklist 3)

**4. Installation qualification:**

Information on:

- Scope of delivery, WD fittings, accessories
- Operating materials supplied, waste water and exhaust air

**5. Operational qualification:**

Information on:

- Correct media connections
- Correct connections for waste water and exhaust air
- Functional check of WD and accessories
- WD non-leakage tests
- Functional test of central dosage facilities

**6. Performance qualification:**

- Description of process sequences of the programmes to be validated
- Information on:
  - Positioning of test instruments
  - Positioning of temperature sensors, also in contact with the walls
  - Description of cleaning pressure tests
  - Process challenge devices
    - Visual inspection
    - Protein test
  - Everyday (real) instruments:
    - Visual inspection
    - Protein test
  - Measurement of water level
  - Documentation of conductivity of final supply and waste water used in cleaning programme (residual quantities of process chemicals)