Validation of sterilisation methods in practice

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The term „practice“ comes from the Greek language and means „Performance“ and „Act“. It characterises the actual performance of an act.

In contrary to theory.
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Order from the management

Budget

Interface- management

What do we need?

Effective:
- laws
- notification
- standards
- guidelines

Team:
- Validating hygienist
- Hygiene experts
- Employees of the processing unit
- IT (information technology)
- Technicians (service, maintenance)
- TÜV (technical observation association)

Trained and motivated employees
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Tasks of the team

- Process description „target status“
- „Analysis of the current status“
- Define procedure and goal of the project
- Follow the effective laws, notifications, standards and guidelines
- Inspection and evaluation of the premises
- Clarification of the technical presets
- Education evaluation and creation of education plans
- Plans for Maintainence, Routine control (for all technical equipment used in the process)
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Tasks of the team

- Instruction of the employees with regard to the employee protective act
- Demand manufacturers’ instructions
- Creation of instructions in collaboration with the quality manager
- Creation of a packing list
- Division of the medical devices in groups of higher and lower risk (guideline Robert Koch institute)
- Steriliser load (definition of the worst case load)
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Guidelines from the quality management

Clarify responsibility and
Clarify competence
(organisation chart)

Documents
(written specification and
documented evidence)

specify:
• Control of Documents
• Archiving

Error management

To make use of documentation for the
traceability of the process
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Examples for problems, which occur while preparing the validation:

- Amount of medical devices insufficient
- Interface
  - Reprocessing unit / User
  - Reprocessing unit / Procurement
- Water analysis does not fulfill claimed values
- Manufacturers’ instructions for the processing are missing or deficient
- Problematic medical devices
  - (long tubes with large diameter)
  - (medical devices with excess length)
- Premises don’t meet the requirements
- Steriliser is too old
  - (doesn’t meet the requirements of the standard)
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The day of validation

- Prepare enough MDs for process qualification
- Prepare the worst case configuration
- Arrange technician: Technical problems during testing can be solved on site

After successful completion of the validation
CELEBRATE!
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- The patient can’t decide whether the medical device, he/she is going to be treated with is prepared well.
- The operator and the employees who take part in the processing process have to make this decision.
- Every employee, every operator and every director of a health care facility should be aware of this fact!
Thank you for your attention!