Recommendation of the Quality Task Group (123)

Quality assurance in the RUMED through well-targeted process monitoring

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TARGETED PERSONNEL QUALIFICATION serves to ensure quality in the RUMED.
OTHER FACTORS can imperceptibly influence process quality.

PROCESS MONITORING helps to regognize discrepancies.

The focus of the first part of "Quality assurance in the RUMED" is on the structured and well-targeted development and maintenance of **PERSONNEL QUALIFICATIONS**.

In the second part we would like to draw attention to the myriad **OTHER FACTORS** that in some cases can imperceptibly influence the process quality and jeopardise the outcome quality.

In an efficient quality management system processes must be monitored. The **PROCESS MONITORING** measures must be planned and the outcomes documented. In that way discrepancies can be recognized at an early stage and remedial action taken (as per the PDCA cycle [1]).

The following quality assurance measures must be planned, implemented and monitored:

1. Maintenance plan

Maintenance includes servicing, inspection, repair and improvement and must be specified as such in a maintenance plan (Figure 1).

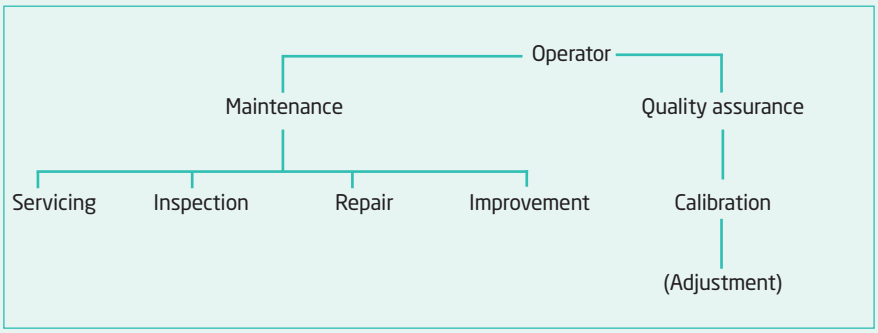

Fig. 1: Elements of the maintenance plan (Source: Washer-disinfector (WD) Guideline [2])

THE MAINTENANCE PLAN can be implemented with the help of external service providers.

One way to **IMPLEMENT THE MAINTENANCE PLAN** is to enter into contractual agreements with external service providers (inspection contract, servicing contract, maintenance contract, etc.).

The following targets should be achieved:

- Avoidance of disruptions and system breakdowns
- Minimization of operating and maintenance costs
- Value retention
- Improvement of operating safety
- Optimization of operating processes
- Cost planning reliability.

2. Validation

Validation involves verification and evidence-based documentation of the process effectiveness. In addition, a process must always function as specified and in compliance with the normative requirements (reproducibility), e.g. as per DIN 58341 [3]. Any discrepancies must be quickly analysed, remedied and this must be documented. Repairs impacting the WD control system may warrant **REQUALIFICATION** for a particular reason. This is the case e.g. when switching to other process chemicals or in the event of deviation of process parameters requiring system repairs that result in a change to the process.

REQUALIFICATION may be necessary after repairs.

A WORST CASE SCENARIO must be considered during validation.

Meticulous preparations should be made by the RUMED and its teams for conduct of process validation. Plans should be made for the **WORST CASE SCENARIO**

of having to decontaminate medical devices that are difficult to reprocess, while paying attention to the actual contamination load and the time lapses until the devices are reprocessed.

3. Routine tests

Each process step (e.g. cleaning and disinfection process, sealing seam process, etc.) is subject to routine tests to monitor each day, before equipment is placed in operation, whether the process is functioning as specified.

Furthermore, other **ROUTINE TESTS** are carried out at specified intervals to verify compliance with defined quality targets. One such example is verification of the cleaning results in accordance with DIN EN ISO 15883-1 [4]; the applicable intervals are specified at the time of validation.

ROUTINE TESTS are carried out to verify compliance with defined quality targets.

Routine tests are a core element of quality assurance since they help to quickly identify any discrepancy in the process quality, paving the way for timely and well-targeted improvement measures.

For example, equipment with faulty process sequences can be quickly shut down and remedial action taken. This helps to avoid more extensive **DAMAGE** and minimize downtimes and costs.

DAMAGE can be avoided by regular routine checks and downtimes and costs can be minimized.

The operator is responsible for deciding how often routine tests are carried out (daily, weekly, periodically).

For equipment-based processes, the nature of the tests and their intervals will depend on the equipment features (WD manufacturer's instructions, e.g. flow checks, conductivity test, temperature sensors, etc.) as well as on the process itself.

These tests ensure that

- The validated process continues to function fault-free and faults are detected early on
- The operating performance of equipment (WD, sterilizer, etc.) is demonstrated to be within specified limited values,
- The media supply (demineralized water, process chemicals, etc.) complies with the specifications.

In the case of manual process steps (e.g. packing instructions, device assembly, packaging, loading patterns, etc.), **SPOT CHECKS** can help to ensure that these manual steps, too, are always carried out to assure the specified quality (in accordance with the in-house standard operating procedures [SOPs]).

SPOT CHECKS of manual process steps also help to ensure quality.

All routine tests are set out in a plan and are an integral part of the quality management system. Documentation of the conduct and results of these tests serves as proof of compliance with all legal requirements, demonstrating that the processes continue to function as specified.

4. Complaints management

Complaints are not only an indicator of customer satisfaction but are also a key indicator of process quality. **DAILY EVALUATION** is recommended for timely identification and elimination of any discrepancies. This helps to avoid similar problems or escalation of customer dissatisfaction. Admittedly, the cause of an error does not always lie with the RUMED. The RUMED has many interfaces which should also be considered in error analysis.

DAILY EVALUATION of complaints is recommended.

Therefore, when carrying out fault analysis the cause, nature, incidence and responsible parties should always be identified and documented on the basis of the agreements in place with the various interfaces. Constructive collaboration between the RUMED and its clients helps to take well-targeted and timely **MEASURES** to avoid repeating such errors.

APPROPRIATE MEASURES can be taken to avoid repetition of errors.

The effectiveness of the measures taken must be checked and the process adapted accordingly if necessary. The input of staff should be sought and members given regular training in all partial processes. Staff must always be **BRIEFED** again following any process adjustment.

STAFF BRIEFING is required again after process correction.

Grading of complaints in terms of severity (e.g. minor, moderate, major, near incident, patient damage) gives insights into the nature of the errors. Personnel should be given regular **FEEDBACK** on individual mistakes as a learning exercise.

FEEDBACK to employees on individual errors is useful.

A digital complaints' management system contributes to transparent communication between the RUMED and user.

5. Feedback management

It is recommended to get feedback from the team and evaluate this to gain a better understanding of one's own processes and potential problems:

- Team meetings
- Staff meetings
- Shift management meetings
- Suggestion boxes
- Ideas management.

References

1 PDCA cycle: Plan – Do – Check – Act
2 Guideline compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices, status 2017, page 63, Information 9
3 DIN 58341:2020-07 Requirements for validation of cleaning and disinfection processes
4 DIN EN ISO 15883-1:2014-10 Washer-disinfectors – Part 1: General requirements, definitions and test methods