RECOMMENDATIONS BY THE QUALITY TASK GROUP (105)

Risk assessment and release of new medical devices before investment and new procurement

Authors: T. Appel, M. Bertram, D. Diedrich, C. Diekmann, S. Eberhardt, A. Forster, T. Gerasch, J. Graf, A. Jones, M. Kamer, S. Krüger, R. Otzmann, M. Schreiner, K. Wiese, U. Zimmermann

qualitaet@dgsv-ev.de

Introduction

Reprocessing Units for Medical Devices (RUMEDs) face continual challenges related to the risk assessment and subsequent purchase and release of new medical devices (MDs). As part of the decision-making process, in addition to the manufacturer's instructions, the reprocessing demands arising from assignment of the respective medical device(s) to a risk category as per the KRINKO/BfArM Recommendation* must also be taken into account. Compliance between these two sets of demands is not always assured and it is not unusual for the manufacturer's instructions to stipulate processes not available or feasible in the respective RUMED. This means that the medical device(s) cannot be reprocessed using the available reprocessing process.

If problems arise in relation to reprocessing of the MDs, it should be established prior to purchase whether alternative MDs can be procured from another manufacturer.

AN MD PROCUREMENT DECISION MAKING PROCESS should be set out in the quality management system.

The **MD PROCUREMENT DECISION-MAKING PROCESS** should be set out in the quality management (QM) system. Business management aspects will not be discussed in this present Recommendation.

Structured approach

1. Risk assessment and classification of MDs in accordance with the provisions of the KRINKO/BfArM Recommendation

Factors such as medical device compatibility with the available reprocessing process, or the effectiveness of the latter, cannot necessarily be guaranteed. Accordingly, in addition to the functional requirements the MD manufacturer's reprocessing instructions must also be evaluated (in accordance with DIN EN ISO 17664).

RISK ASSESSMENT AND CLASSIFICATION is effected in line with the provisions of the KRINKO/BfArM Recommendation.

Pursuant to the provisions of the KRINKO/BfArM Recommendation (Item 1.2.1.), **RISK ASSESSMENT AND CLASSIFICATION** of the MDs as "Non-critical", "Semi-critical" or "Critical" is effected in line with the nature of their previous and subsequent use. The aim here is to ascertain the burden and nature of the pathogens anticipated in the area used as well as their resistance to the intended process.

A REPROCESSING PROCESS must be set out in writing for each MD based on the assigned risk group.

Based on the assigned risk group, the designated **REPROCESSING PROCESS** must then be set out in writing for each MD, stating also whether a limit has been imposed on the permitted number of reprocessing cycles. To that effect, the constructional, material and functional characteristics of the MD which could be impacted by reprocessing must also be taken into consideration.

Accordingly, semi-critical and critical MDs are further divided into groups: MD groups not subject to any particular reprocessing requirements (group A); MD groups subject to more exacting requirements (group B). Among the critical MDs there are additionally MDs calling for particularly stringent reprocessing requirements (group C).

Graphical representation of these classification criteria as well as the reprocessing specifications based on the risk category can be viewed on the website of the German Society of Sterile Supply (DGSV). For a practical guide, please consult Recommendation 77, 2013, "DGSV flow chart for classification of MDs".

It may also be useful to form MD groups in terms of their suitability for the available process(s) so as to categorize the reprocessing problems associated with particular MDs. That task is made easier if equivalence to available, already evaluated MDs can be established.

* KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

Grouping on the basis of MD design or geometry could be done as follows:

- Group 1: – Smooth surfaces, no joints or lumens
- Group 2: – Jointed instruments
- Group 3: – Sliding-shaft instruments
- Group 4: – Tubular-shaft instruments
- Group 5: – Complex instruments
- Group 6: – Flexible instruments
- Group 7: – Utensils (bowls/containers)
- Group 8: – Anaesthesia/synthetics
- Group 9: – Robotic instruments

To meet the specifications an MD must be clearly identifiable, featuring at least its article number and, for MDs of limited reprocessability, the lot/serial number.

Once reprocessing has been completed, the new MD must be **VISUALLY INSPECTED, UNDERPINNED BY A PROTEIN TEST**, if necessary, to ensure it is of the expected cleanliness standard and undamaged. This inspection/test does not obviate the need for performance requalification if the reprocessing requirements are more stringent than those applicable to the already available MDs

VISUAL INSPECTION, UNDERPINNED BY A PROTEIN TEST, IF NECESSARY ensure that the MD is of the expected cleanliness standard and undamaged.

2. Evaluation of the manufacturer's instructions

Once the new MD has been assigned to a risk category, the **MANUFACTURER'S INSTRUCTIONS** must be compared with the specifications applicable to the respective risk class (risk category). Next, the specifications are evaluated in terms of their compatibility with the processes available in the respective RUMED.
The provisions of the KRINKO/ BfArM Recommendation embody the legal framework and must in principle be observed. If they do not concord with the manufacturer's instructions, the manufacturer must be contacted and a written statement requested. Examples of the potential deviations are listed in Table 1.

THE SPECIFICATIONS FROM THE MANUFACTURER'S INSTRUCTIONS must be compared with the specifications applicable to the respective risk class.

Table 1: Examples of potential deviations between manufacturer's and KRINKO BfArM stipulations

Manufacturer's stipulation	KRINKO BfArM stipulation
Rinse the MD under running water	Preferentially, automated processes for critical A and critical C In principle, automated processes for critical B
Reprocess with pH-neutral detergent	Preferentially, alkaline detergent
Unusual designations of chemicals (e.g. multi-purpose cleaner) or specification of chemical disinfectants whose efficacy has not been demonstrated or which are not available in the EU	German Association for Control of Viral Diseases (DVV) Robert Koch Institute (RKI)
No, or incorrect, specifications for disinfection parameters, e.g. for disinfection A_0 value 600	Bactericidal (including mycobactericidal), fungicidal and virucidal
Specification: 4 minutes at 132 °C holding time in sterilization process (saturated steam)	Steam sterilization 134 °C
No reprocessing instructions	The manufacturer's instructions must be available

3. Expert assessment of reprocessability from the RUMED management's perspective

THE RUMED MANAGEMENT must analyse the amenability of the MD and its accessories to reprocessing in terms of their design.

Prior to procurement of new MDs, in addition to risk classification and evaluation of the manufacturer's instructions, the **RUMED MANAGEMENT'S** specialist knowledge is also called upon in analysing the amenability of the MD and its accessories to reprocessing in terms of their design. This also includes establishing whether additional measures (e.g. supplementary process validation, accessories, etc.) are needed.

1. Is it ensured that all inner and outer surfaces of the MD can be accessed by the media? For example, through:
   - The use of suitable adapters for lumens
   - Dismantable MDs
2. Are the MDs possibly placed on trays that could cause spray shadowing? Can these be removed or replaced with more suitable support aids? Must support aids be purchased/ used?
3. Do MDs of limited reprocessability have their own identifiable serial number?
4. Is there a validated reprocessing process available in the RUMED to which the new MD can be assigned or must performance requalification for a specific reason be carried out?
5. Must staff training be provided?
6. Are additional aids, e.g. brushes, needed?
7. Must a dedicated standard operating procedure be compiled?

DOCUMENTATION of the results of this classification and evaluation is necessary.

The results of this classification and evaluation procedure must be **DOCUMENTED** using a suitable from/checklist.

The flow chart in Fig. 1 depicts an exemplary process sequence.

Fig. 1: Flow chart exemplary process sequence