KRINKO/BfArM Recommendation

Requirements on

- validation and performance of the reprocessing steps and applied processes
- documentation and record keeping
- labelling

Prerequisites

- risk management
- classification

KRINKO/BfArM Classification

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BfArM

Properties of the medical device (design, material)	Type of use (prior, subsequent) Type of contact: noncritical	Semi-critical	critical
without particular requirements A			(WD) Steam sterilization QA
increased requirements B		(WD) QA	Qualification WD Steam sterilization QA
maximum requirements C	not definined		Qualification WD Low temperature sterilization QA Certification

- Quality Management System generally required
- Particular QM requirements for critical A/B/C and semi-critical B
- For critical C a certified ISO 13485 QM system is mandatory for some cases:
  - Applied reprocessing processes not qualified by manufacturer (IFU)
  - Single-use devices

Result:

- Most certifications done by choice, not mandatory by law

Accredited Certification Bodies, Recognized Bodies

DIN EN ISO 13485 certification in combination with the KRINKO/BfArM Recommendation in Germany is allowed

- For mandatory certification (dedicated "critical C" products) by ZLG Recognized Bodies
  ZLG = Central Authority of the Laender for Health Protection
- For voluntary certification by DAkkS accredited Certification Bodies

Recognition/Accreditation performed by the intention: professional competence

  - for products and their reprocessing requirements
  - for reprocessing processes
- First accreditation in year 2004 – 13 years ago

Currently just a few Certification Bodies recognized/accredited:

- 3 ZLG Recognized Bodies for "critical C"
- 4 DAkkS Accredited Bodies, 2 of them also ZLG Recognized

Certifications Since Year 2004

- Since 2004 regulatory background significantly changed
- Update of KRINKO/BfArM Recommendation in year 2012
- Several process related standards implemented or updated, e.g. for washer-disinfectors, moist heat sterilization, sterile barrier packaging
- Several guidance documents implemented, some describing best practice
- At the moment estimated in total 150 certificates are valid
- Certificates divided into
  - critical C about 60 %
  - up to critical B about 40 %

Background of Field Report

500 audits since year 2004

(Some) results are

- representative
  - for Hospitals/Service Providers with implemented and maintained Quality Management System for reprocessing of medical device
- not representative
  - for the overall situation in Germany, because during implementation of such a system various corrections and improvement took place

Strengths – Control of Document

Documents of DIN EN ISO 13485 QM system

- In general acceptable quality level
  - A few systems were set up completely independently by the hospital
  - Often assistance by external consultants
  - Rarely major adjustments needed
- Stand-alone QM system for reprocessing vs. Shared QM system
  - Documents from other existing QM system(s) are shared, typically ISO 9001 QMS
  - Redundant information can be avoided
  - Awareness about different requirements needed!
- Standard Operating Procedures (SOP) and Work Instructions (WI) mostly in compliance with requirements
  - Major revisions seldom needed

Strengths – Planning of Reprocessing

- At all audits risk classification as required by KRINKO/BfArM Recommendation could be identified, using different approaches:
  - Individual evaluation of each medical device
  - evaluation based on product families
  - Overall evaluation
  - Use of the „Flow Chart for Classification of Medical Devices“ compiled by the German Society for Sterile Supply (DGSV)
  - Results reported in charts (printout) or electronically in a database

- At all audits personnel qualification followed the education concept of the DGSV:
  - Staff (level I training)
  - Supervisor (level II training)
  - Department/Facility manager (level III training)
  - Staff member without any training courses were only allowed to work under supervision in a limited range of function

Strengths – Planning of Reprocessing

- Information about correct reprocessing of particular medical devices provided by:
  - Documents of the QA system (e.g. SOPs, WIs)
  - Packing lists / object lists (for sets of medical devices)
  - Usually a combination of both
- Sometimes combined with very detailed information about inspection and maintenance
- Often a CSSD specific IT system in use
  - Control of packing lists / object lists (for sets of medical devices)
  - Labelling
  - Assignment of the medical devices to sterilization batches
  - Traceability
  - Record keeping of process data

Strengths – Validation

- Moist heat sterilization
  - Validation well established
  - Often performed by manufacturer, more and more by independent test laboratory
  - No major inconsistencies, when performed by qualified labs
  - Very differing extent and quality of the validation reports
- Automated cleaning and disinfection using washer-disinfector
  - Validation well established
  - Often performed by manufacturer, more and more by independent test laboratory
  - Usually a reasonable compromise, often with minor deficits

    Background:
    - More complex compared to moist heat sterilization
    - Guideline established, not addressing all important requirements

Weak Points - Validation

- Low Temperature Sterilization
  - Used specimen are not representative for users products
  - No information about degassing
  - No detailed information about used Biological Indicators

- Automated cleaning and disinfection of fiberscopes using washer-disinfector
  - No information about disinfection effectiveness
  - No information about residuals

- Sterile barrier packaging
  - Complex validation program, anyway: not all material evaluated
  - No information about qualification of used material

Weak Points - Validation

Potential causes for the weak point at validation

- Unsuitable proceeding by the validation lab
  - Economic reasons
    - Standard proceeding without customizing and addressing the user's requirements
    - Competitive environment
  - Use of guidelines instead of related process standards
  - Staff not sufficiently qualified
- Obviously not sufficient qualified lab contracted by financial reasons
  - Neither established QM system, nor accreditation

Possible solution: Accreditation

- But not mandatory in Germany

Weak Points – Reprocessing Instructions

Improvement needed at management and evaluation of reprocessing instructions, to be provided by the manufacturers of the medical devices

- Required instructions
  - Not available
  - Not up-to-date
  - Poor contents, insufficient information
- Evaluation of existing instructions not comprehensible
  - Often this evaluation poorly documented with very common information, often no records available
  - Not documented means: not done!

Risk management

- Several measures for risk reduction implemented, but not (sufficiently) documented.

Weak Points – QM System

DIN EN ISO 13485 demands some important activities, not mentioned within KRINKO/BfArM Recommendation

- Root cause analysis as part of corrective actions during handling of
  - Customer feedback/complaints
  - Non-conformities
  - Audit findings

  not or insufficiently done

Weak Points – CSSD Specific IT Systems

CSSD specific IT systems meanwhile well established for years

Nevertheless

- Records of process parameters (e.g. from sterilizer, washer-disinfector) do not include complete information needed for the release of these processes (as required by related process standards)
- Recorded data differ from real data
- Some IT systems did not include long term archiving using an established data format

None of the IT system installation has been found validated BEFORE the first use

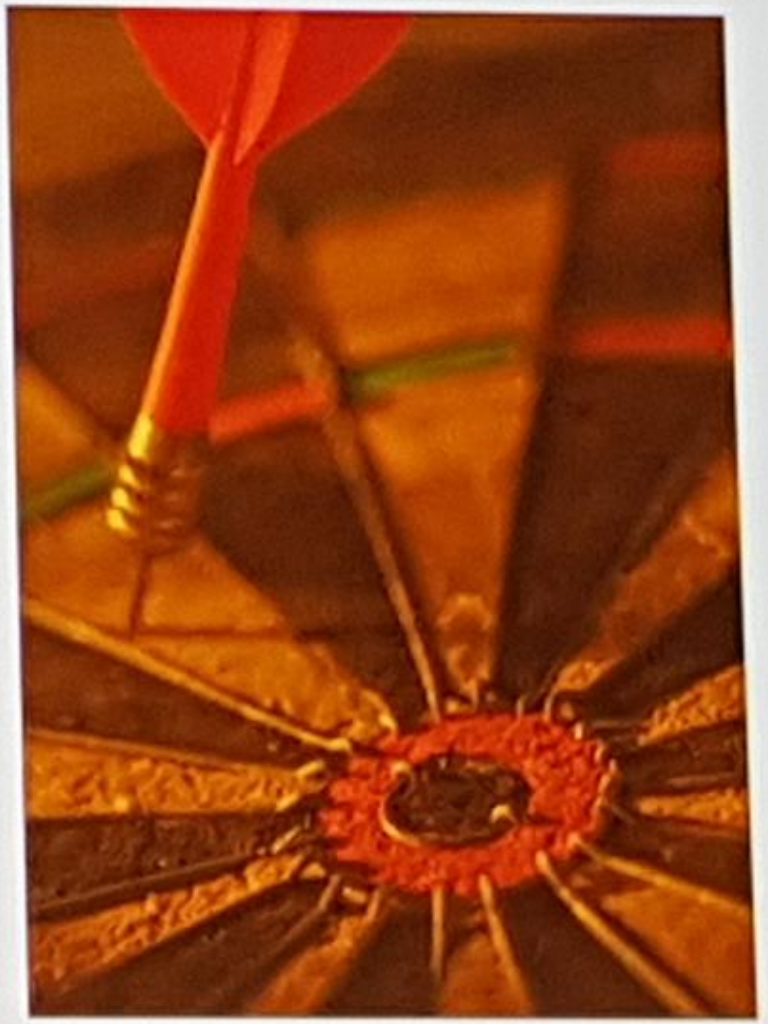
Reprocessing of Single Use Devices

- KRINKO/BfArM Recommendation does not differentiate reprocessing of medical devices intended to be re-used or single-use devices.
- Single use devices are typically classified to be „critical C“
  - Certificate needed issued by an Recognized Body
- Manufacturer’s instructions for reprocessing are not available
  - Design and development of the complete reprocessing process must be done under its own responsibility
  - Section 7.3 „Design and Development“ of DIN EN ISO 13485 must be covered within the QA system and is part of the certification process
  - Detailed evidence of suitability related to process qualification and safety of reprocessed devices is needed
  - High demands on traceability, amongst others back to manufacturer’s lot number
- In Germany only a very limited number of companies fulfil these criteria

Summary

1. In Germany certification according to DIN EN ISO 13485:2003 combined with the KRINKO/BfArM Recommendation demonstrates a high level for the reprocessing processes

2. Further improvement needed at:
   - Validation of particular processes
   - Reprocessing instructions from manufacturer in combination with risk management
   - CSSD specific software



End of Presentation

For Your Attention!