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3 Years Experience With Certification of Reprocessing Based on the German RKI/BfArM Recommendation - A Field Report



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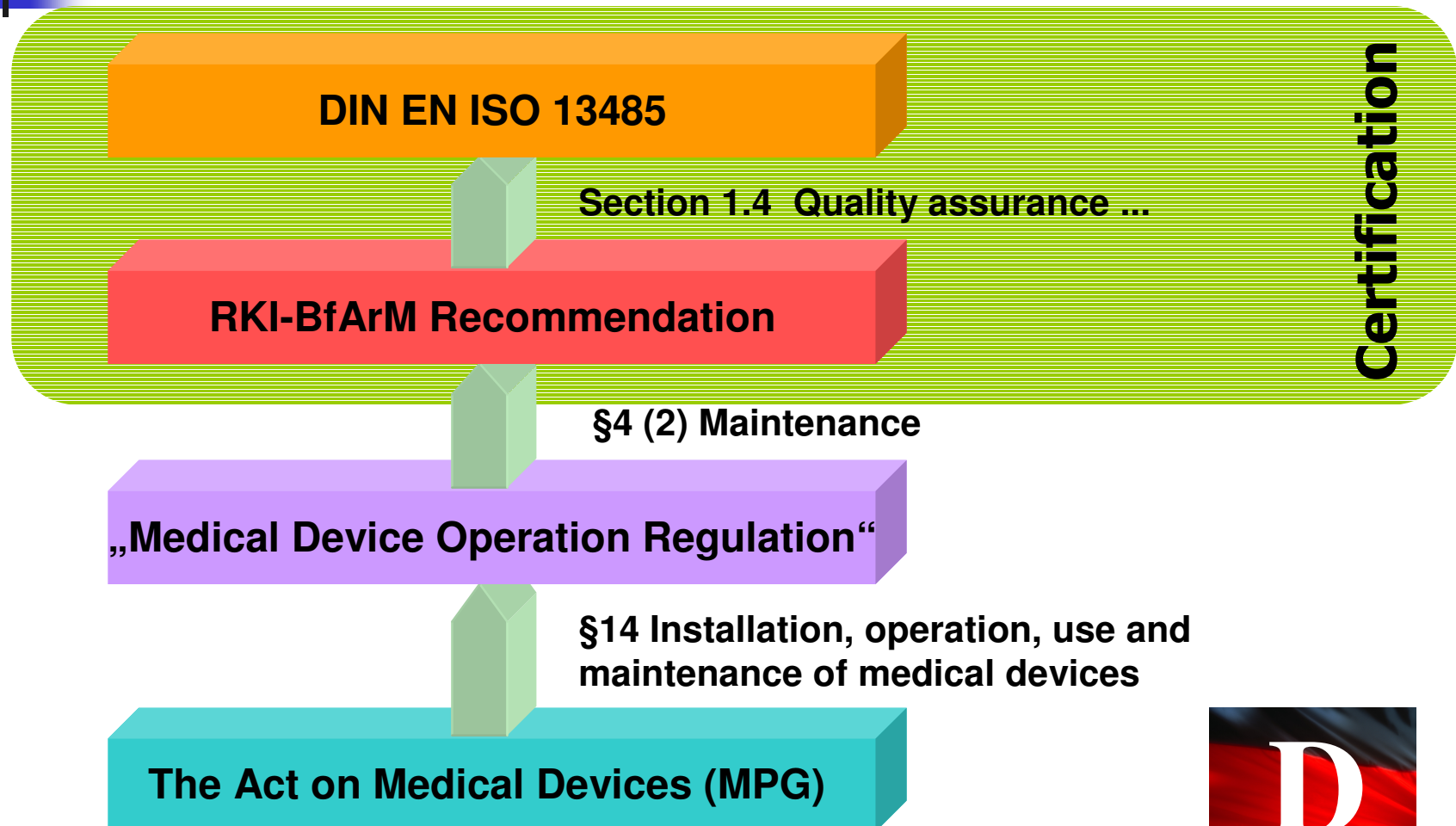
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Legal Basis in Germany



Classification (RKI/BfArM-Recommendation)

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



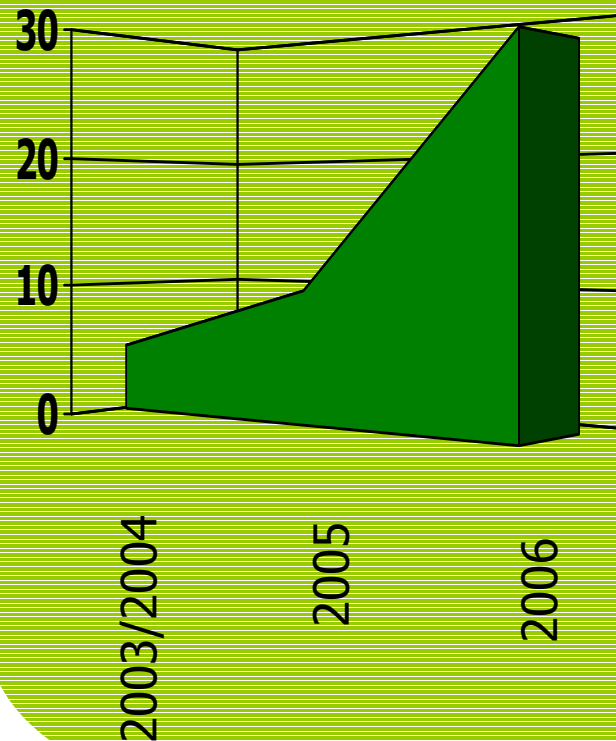
Accreditation of the Certification Body

- Certification according to DIN EN ISO 13485 combined with the RKI/BfArM Recommendation in Germany only allowed for accredited Certification Bodies
- Accreditation performed by the Central Authority of the German Federal States for Health Protection (ZLG)
- Intention: professional competence
 - for products and their reprocessing requirements
 - for reprocessing processes
- First accreditation 3 years ago
- Currently are three Certification Bodies accredited:
 - 2 for medical devices up to and including „critical C“
 - 1 for medical devices up to and including „critical B“

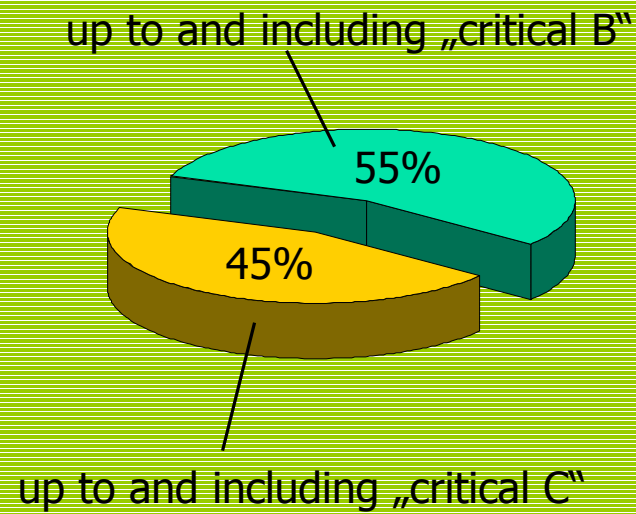


Considered Certification Projects

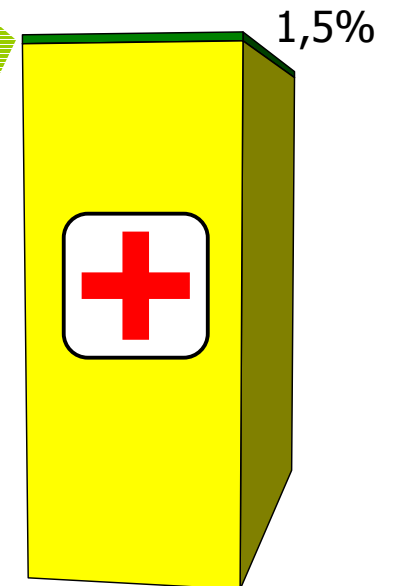
Number of Audits



Risk evaluation



Percentage of hospitals





Strengths of the QA Systems (1/3)



- Documents of the QA systems in general in good condition
 - A few systems were set up completely independently by the hospital
 - Often assistance by external consultants
 - Rarely adjustment needed
- In all cases a risk evaluation according to the RKI/BfArM Recommendation was performed, but different proceedings:
 - Individual evaluation of each medical device
 - evaluation based on groups
 - Overall evaluation
 - Use of the „decision tree“ compiled by the German Society for Sterile Supply (DGSV)
 - Results reported in charts (printout) or electronically in a database

Strengths of the QA Systems (2/3)

- Requirements for reprocessing of particular medical devices were defined in
 - Documents of the QA system (e.g. work instructions)
 - Packing lists / object lists (for sets of medical devices)
 - Usually a combination of both
- For personnel qualification in all cases the training programme of the DGSV (EFHSS) was taken into consideration:
 - Staff (level I training)
 - Supervisor (level II training)
 - 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 of the QA Systems (3/3)

- In many cases the work flow was supported by a specific IT system
 - Control of packing lists / object lists (for sets of medical devices)
 - Labelling
 - Assignment of the medical devices to sterilization batches
 - Traceability
 - Recording of process data

- Validation of steam sterilization (EN 554)
 - Hardly any discrepancies, hardly any observations
 - Performed by manufacturer, more and more by independent test laboratory
 - Very differing extent and quality of the validation reports





Weaknesses of the QA Systems (1/3)



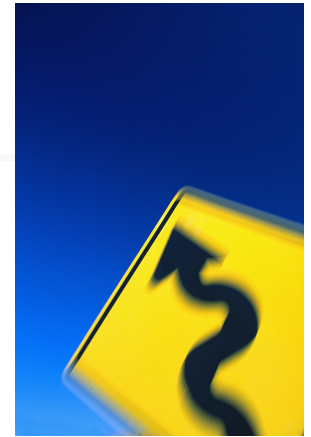
- Validation of processes, routine control
 - Washer-disinfectors (EN ISO 15883)
(tendency: much better quality during the last 6 months)
 - Low temperature sterilization processes, especially H_2O_2 plasma process (EN ISO 14937, EN 15424, EN 550)
 - Sealing process (EN ISO 11607-2)
 - Often caused by a lack of experience (validation lab, manufacturer and operator) how to realize the requirements from standards

- Expertise of the validation lab
 - Many times an interpretation of results is missing
 - Partially validation reports are incomplete (missing test results, missing checkpoints, missing entries and signatures)
 - Partially test results were misinterpreted



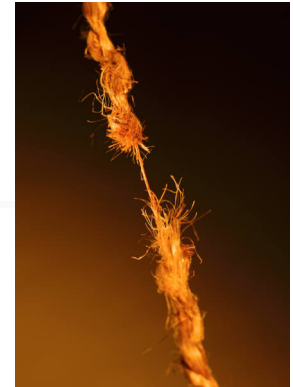
Weaknesses of the QA Systems (2/3)

- Manufacturers' instructions
 - For complex medical devices often the needed manufacturers' instructions are not available
 - Some manufacturers' instructions do not include utilizable information
 - When the proceeding differs from manufacturers' instructions often a documented rationale is missing, including a risk evaluation and information on evaluation date and members of the evaluation team
- Risk analysis, risk management
 - Typically a risk analysis beyond the classification according to the RKI/BfArM Recommendation is not performed, even though several estimations are done (e.g. for manual cleaning and disinfection of containers for sterile products)





Weaknesses of the QA Systems (3/3)



- Hygiene
 - Rarely severe deficiencies, most observations are related to details (only one case with a severe lack of hygiene: reliable disinfection was not ensured, re-contamination was not prevented)
- Reliable function or use of IT systems, traceability
 - No proof of evidence for the correct function of the specific IT systems by software validation (complete and correct recording of process data, reproduction of data during long term archiving)
 - Insufficient adjustment of the IT systems and the working process results in a lack of documentation: several sterile devices were not assigned to any sterilization batch but delivered for use

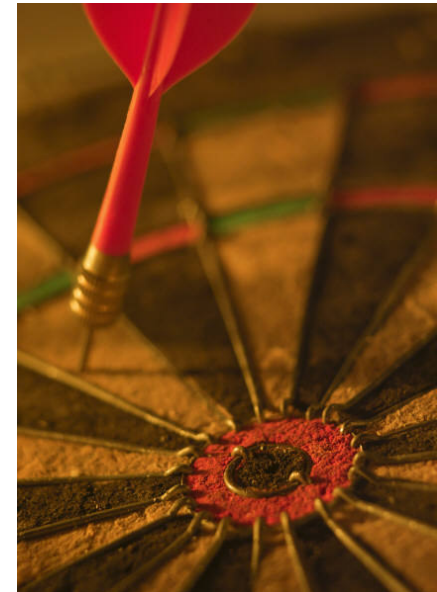
Reprocessing of Single Use Devices

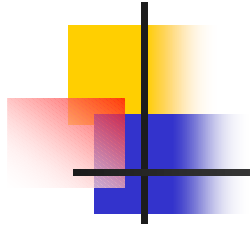


- RKI/BfArM Recommendation does not differentiate whether the manufacturer intended a single or a multiple use
- Single use devices are typically classified to be „critical C“
 - Certificate needed issued by an accredited Certification Body
- Manufacturers´ instructions for reprocessing are missing
 - Design and development of the complete reprocessing process must be done
 - 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 manufacturers´ lot number
- In Germany only a very limited number of companies fulfil these criteria

Summary

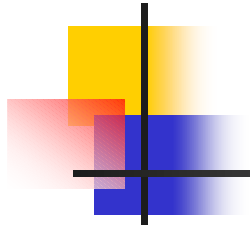
- In Germany certification according to DIN EN ISO 13485:2003 combined with the RKI/BfArM Recommendation demonstrate a high level for the reprocessing processes
- Room for improvement exist at:
 - Validation of particular processes
 - Manufacturers` instruction
 - Risk management
 - Software validation





End of Presentation

**Thank you
for your attention!**



I am looking forward to your questions





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