



World Federation for  
Hospital Sterilization Sciences

**DGSV**

Deutsche Gesellschaft für  
Sterilgutversorgung e.V.

WORLD CONFERENCE  
CENTER FOR

**International Best Practices –**

**Do Bacteria know Country Borders?**

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## Thesis:

**There should be a gold standard about best reprocessing**

- Internationally accepted
- Evidence based

**but there is not !**

- **Current reprocessing in many aspects are based on history !**
  - Different from Country to Country
  - Variety of philosophies behind.
  - Different Focus-Points



Moving Target !

Where to spend the efforts?

We want to get better !

How much efforts to spend??

- Laws and Government Regulations (Have to do..)

- Guidelines ( You better do..)

Different from country to country

- Official (RKI, Institut Pasteur, HTM)
- Associations ( DGSV, AKI ...)

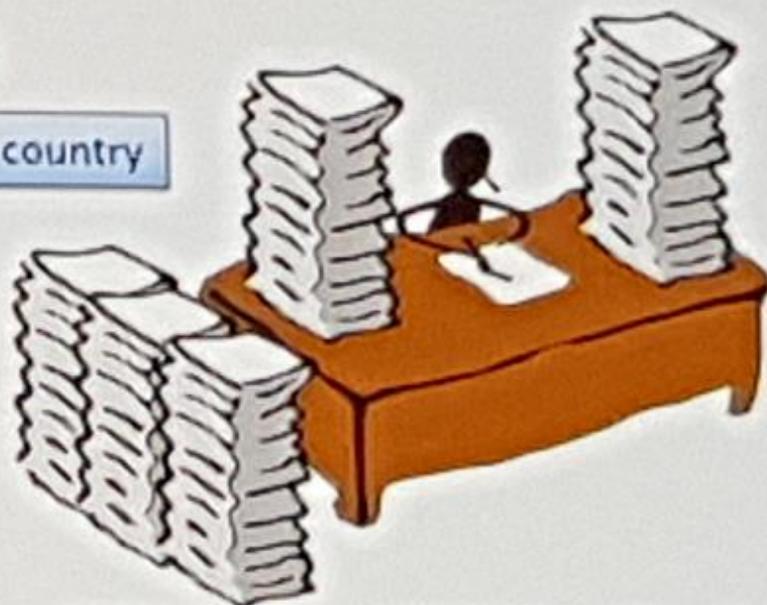
- Standards (Do at least as good as..)

- ISO 13485 QM In Medical Devices
- ISO 15883 Machine Cleaning
- ISO 868, EN285 Sterilization
- ISO 11607 Packaging
- AAMI ST79 and other...

- Manufacturer IFU (Follow... / Consider...)

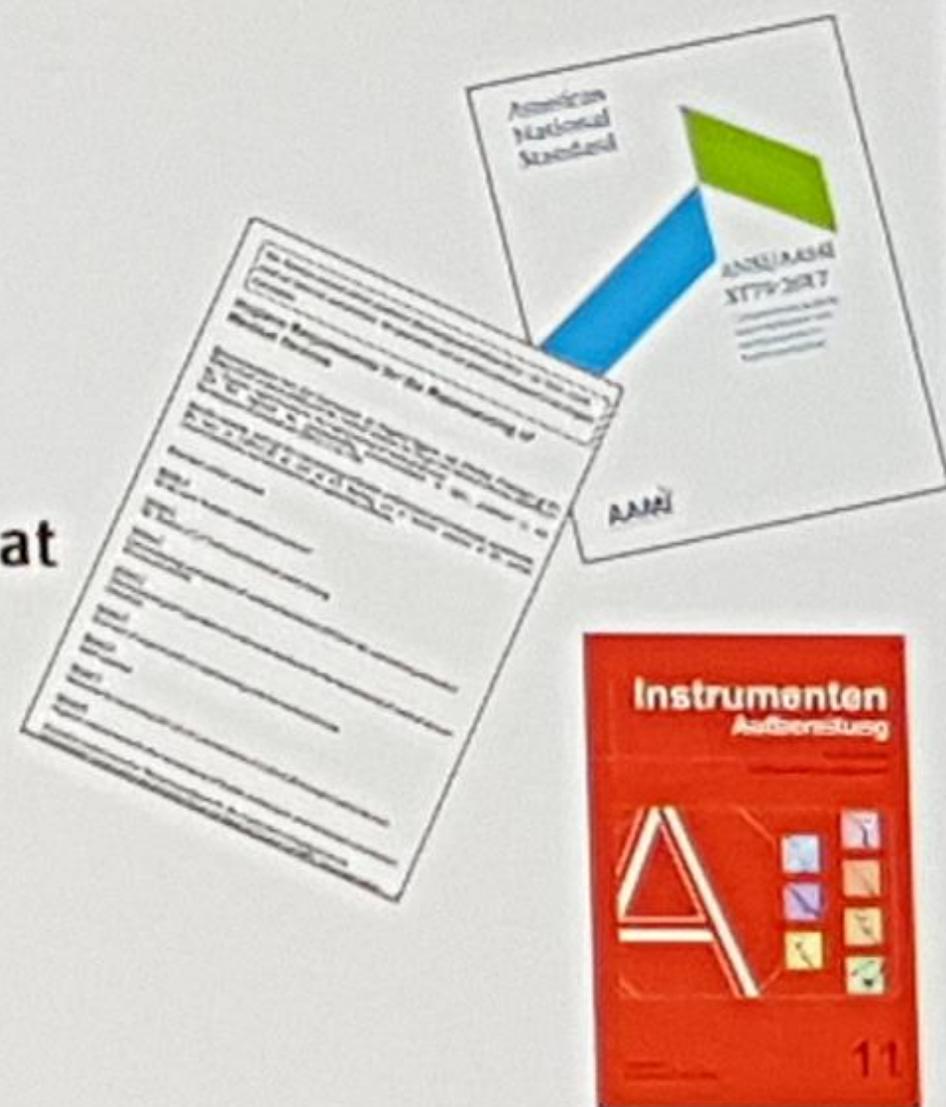
- Health Protection Laws (Have to do..)

- Audits (Notified Bodies / JC / Authorities) (Have to do..)

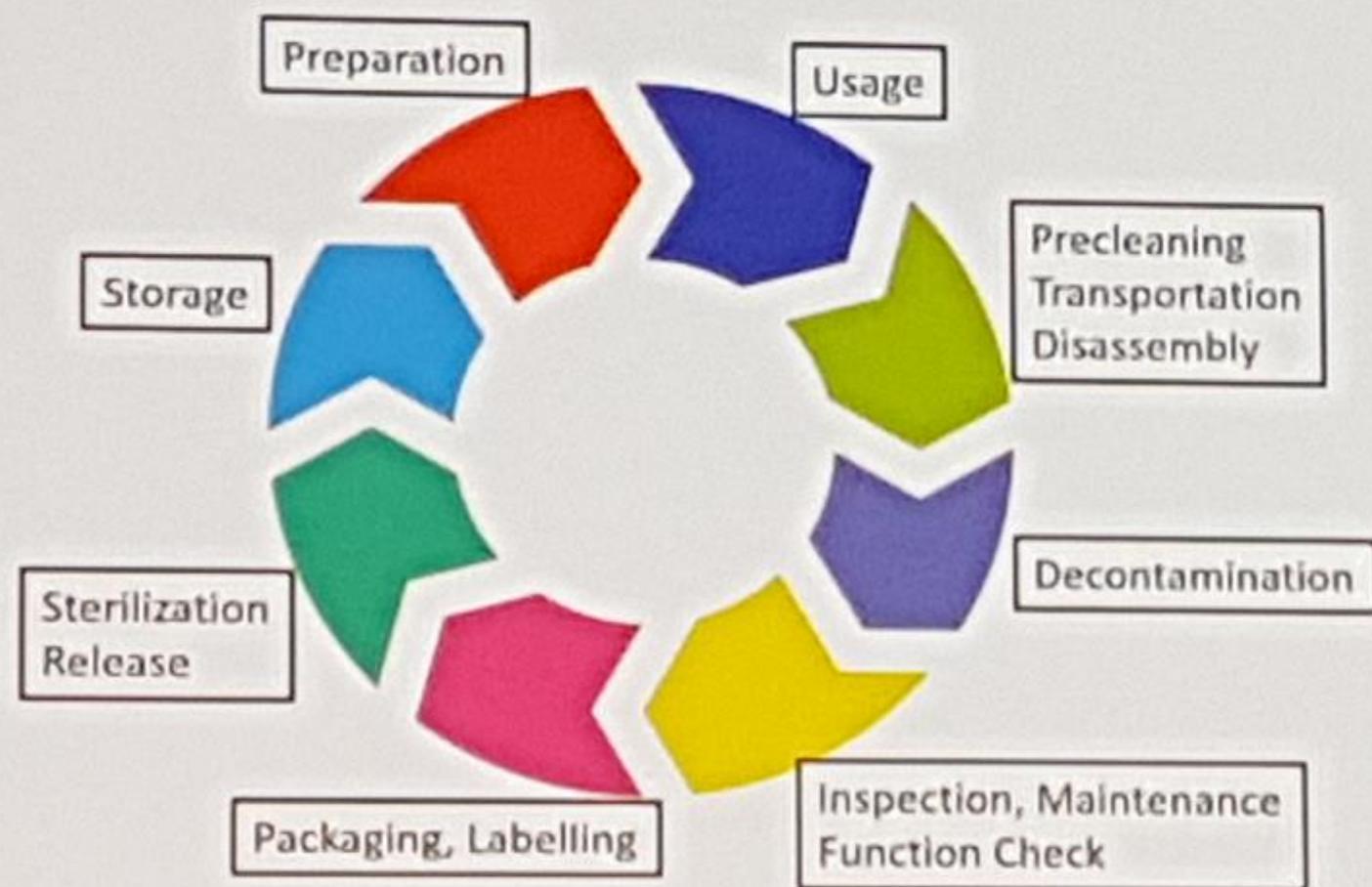


## Three Examples for User Guidelines

- **AAMI ST79 (USA, since 2010 (1970s))**
  - 1st Focus: Practical Guidebook for CSSD
- **Reprocessing of Medical Devices (KRINKO at RKI) (Germany, since 2002)**
  - 1st Focus: Hygienic Safety, Requirements
- **„Red Book“ (Germany, since 1976)**
  - 1st Focus: Value Preservation of Instruments



# Many Aspects – High Complexity Database 65 Aspects



## Side Aspects

- Sterile barriers
- Single Instruments
- Special Items
- Low Temperature Sterilization
- Water Requirements
- Room Requirements
- Reprocessing of Containers
- Special Requirements Implants
- CJD precautions
- Education of Personnel
- Tracking
- Quality Control / Management
- ..

## Selected (controversy) Aspects

- Treatment of Instruments after Use,
- Cleaning of Instruments
- Quality Control in Steam Sterilization
- Air Quality in Packing
- Water Quality

### What do Guidelines say?

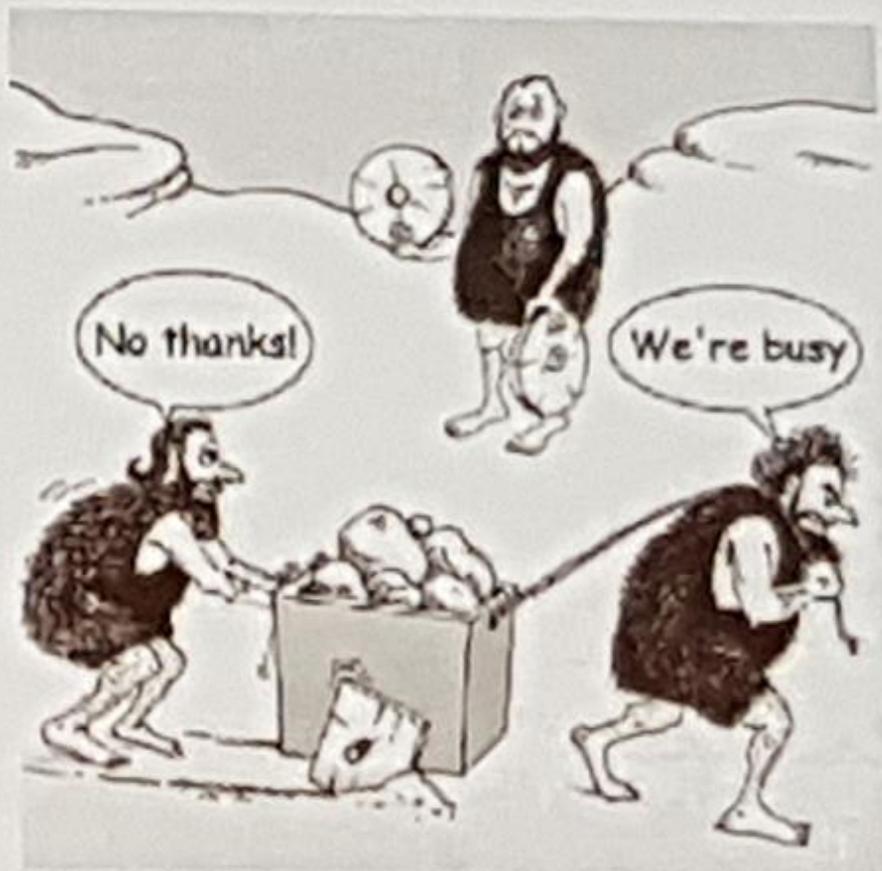
Is there a clear goal of the process?

Is there a reference to international standards?

Is there a reference to scientific evidence?

Can a best practice be proven?

**Do we have a gold standard ?**



## Treatment of Instruments after Use

- **Goal**

- Standardized and efficient workflow
- Support proper cleaning
- Avoid damage, corrosion and surface changes

⇒ **Evaluation only together with cleaning**

- Point-of-Use Pre-Cleaning
- Disassembly
- **Dry / Moist / Immersed Transportation**
- Transportation Protection
- Maximum Transportation time



	AAMI	KRINKO	Red Book
On-site Pre-Cleaning	Wipe off gross dirt	Wipe/ rinse off dirt	Wipe off gross dirt etc
Disassembly	In CSSD	-	In OR
Mode of Transportation	Moist (moist towel, spray...)	-	Dry Disposal recommended
Protection	In closed container, marked as contaminated	Avoid damage	Gentle handling, special racks for delicate instruments
Maximum Transportation Time	Immediately, as quickly as possible	Avoid delays	As quickly as possible, maximum 6h



„... use adequate / appropriate methods....“

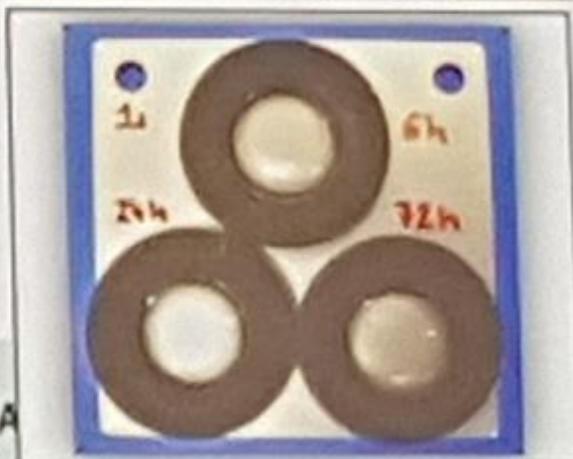
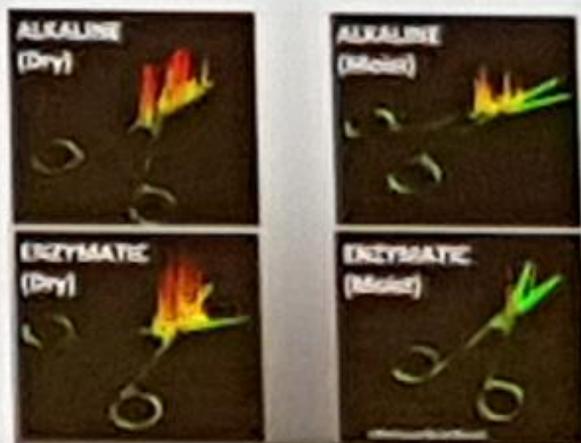
## Evidence

- **D. Perrett, London (WFHSS 2016, ..)**
  - keep moist with low amounts of water
  - cleaning possible, if kept moist, after 48h
  - best: clean within 1h
  - foam agents leave residue
- **I. P. Lipscomb.. (Journal of Hospital Infection, 2007)**
  - protein dried on after 1h
- **H. Biering ..(Central Service, 2010): Sprays**
  - partially Gel-formation, difficult to remove
  - few effects on material

### Rational:

- longer waiting makes cleaning more difficult
  - depending on soil?
  - depending on geometry?
- aggressive liquids may cause corrosion

(picture:  
D. Perrett)



## Daily Practice (from Consulting Experience)

	Germany	France	USA
On-site Pre-Cleaning	partly	Yes, including disinfection	rarely
Disassembly / Opening	partly	partly	partly
Mode of Transportation	Dry	Moist / Immersed	Dry / Moist
Protection	Containers / Mats	-	Stringers
Maximum Transportation Time	Over night / weekend	Over night / weekend	Over night / weekend

### Challenges:

- Organization, shift times
- Motivation of OR-Personnel



# THE BIG QUESTION

What is most painful ?



What is achievable?



## Washer / Disinfector - Process

- **Goal**
  - Hygienic Safety for Personnel in Packing
  - Hygienic Safety for subsequent Patients
    - especially CJD
  - Avoid Corrosion and Surface Changes
- **Acceptable condition after process / process performance**
- **Process Design**
- **Quality Control / Validation / Verification**



	AAMI	KRINKO	Red Book
Cleaning	Follow IFU (FDA: 2 parameters...)	End Condition <100µg protein / Instrument	Reference to ISO15883
Disinfection	Thermal or Chemical	A* 3000, thermal disinfection 5 log	Thermal, Chemical or Thermo-Chemical
Process	Manual cleaning and / or machine cleaning	Machine cleaning mandatory for complex designs	Machine Cleaning recommended
Process Design	Use detergent and enzymatic	Alcaline cleaning, tested performance (pH10 recommended)	(Only material compatibility related)
Quality	Routine Tests and regular Maintenance	Annual Validation (ISO 15883 + Guideline) Individual Routine Controls	-

... use an effective cleaning method....



## Evidence

(too much to mention)

- **What is a safe condition?**
  - 100µg Protein; based on vCJD (EOR<sub>4</sub>, UK)
  - Mikrobiology: Reduction by 5 log (like EN 13727)  
2-3 log ASTM E2314-03)
  - (Biocompatibility ISO10993)
- **What is achievable?**
  - 20-100µg, 2-3,75µg/cm<sup>2</sup> Protein (German Guideline)
  - 6,4µg/cm<sup>2</sup> Protein, 2,2µg/cm<sup>2</sup> Hemoglobin, 1,8µg/cm<sup>2</sup> Carbohydrate, 12µg/cm<sup>2</sup> TOC, 2,2 EU/cm<sup>2</sup> Endotoxin (M. Alfa)
  - 20µg Protein per Instrument (Austrian Guideline)
  - 5-10µg per side (British Guideline)

### Rational:

- More extensive cleaning processes give better results
  - depending on soil?
  - depending on geometry?
- Not every Instrument to be checked => process
- Biological effects ???
- Visual Inspection limited: Crevices / Lumen
- Depending on Test Method
- Indicator Substance (Protein,...), more than one



< 100µg before Cleaning



Inspection does not replace proper cleaning processes  
Visible contamination is the tip of the Iceberg !!!

=> Process is Crucial !



Cleaning



Residue I  
=> post cleaning



Inside



Visually o.k.  
=> sterilization



Inside

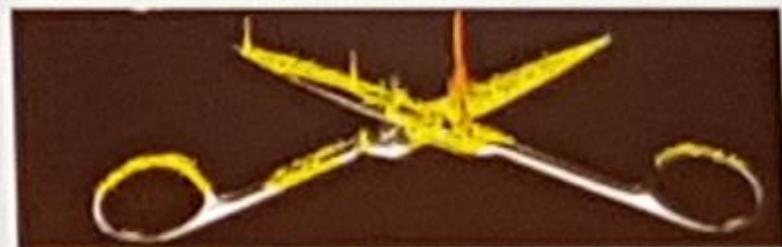


## Daily Practice

	Germany	UK (end 2017)	USA
Cleaning	100µg or lower	5 /10 µg per side (Luminizenz)	No tests in hospitals, manufacturer 6,4µg/cm <sup>2</sup>
Disinfection	A* 3000	A* 600 - 3000	Most A* 600
Process	Machine Cleaning, evtl. manual pre clean	Machine Cleaning, evtl. manual pre clean	Manual Cleaning plus Machine Cleaning
Process Design	Alcaline cleaning, 10-20min Total process 45-75min	Neutral cleaning 5-10min Total process 40-60min	Neutral cleaning 3-6min, Total process 30-50min
Quality	Annual Validation Individual Routine Controls	Validation (Authorized Engineer), Ongoing Tests	Maintenance Individual Routine Controls

## Challenges

- Instrument Mix requires universal Processes
- Worst Case difficult to cover (Load, Soil, Waiting ...)
- Test Methods still under discussion



(picture: D. Perrett)

# THE BIG QUESTION

What is good enough?

How to achieve easiest?  
Process Design

What is safe enough?  
(Process Variations / Outliers)

How to check ?



# Quality Control in Steam Sterilization

- **Goal**

- Detect non-sterile Products
  - Process Failures
  - before use (Immediately)



Pictures  
S. Winter  
Belimed

- **Sterilization Parameters**
- **Steam Penetration**
- **Moisture**
- **Handling Errors**
- **Load / (Sterile Barrier)**

Standards:

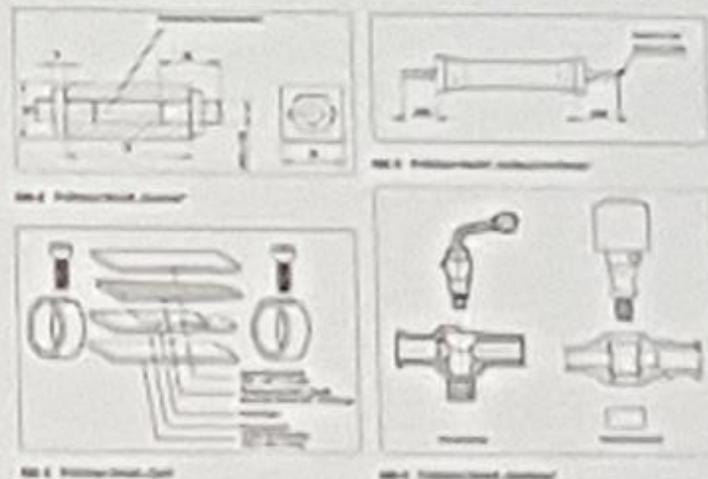
- EN 285 Large Steam Sterilizers
- EN 556 Sterilization of Medical Devices
- ISO 17665 Steam Sterilization Healthcare
- ISO11607 Sterile Barrier System
- ISO 11138 Biological Indicators
- ISO 11140 Chemical Indicators
- ...

	AAMI	KRINKO	Red Book
Process Indicator (outside)	yes	Yes (reference to EN556 )	
Chemical Indicator per Set	yes	No (reference to ISO17665)	
Chemical Indicator per Load	Yes	No (reference to ISO17665)	
PCD (chemical) per load	Recommended	No (reference to ISO 11140-4)	
Biological Indicator	Daily, each implant load	No	
Bowie-Dick-Test	Daily	Daily (reference to ISO 11140-3)	
Vacuum/ Leakage-Test	Daily	According to IFU (reference to ISO 17665-2)	-
Non condensable Gas Test	„regular“	Annually (reference to ISO 17665-1)	-
Parametric Release	Check all data	Yes	-
Double Sensor Systems	no	Yes (reference to EN285 )	-
Verification	yes	-	-
Validation	-	Annual Validation (reference to ISO 17665)	



## Evidence

- **ISO Standards (ISO 11138/40): tolerances of indicators**
  - Chemical Class 6: Time +0%/ - 6% Temperature: +0°C, -1°C
  - Biological: +/-20%, limited spore population, survival time e.g. 1min
- **Sensitivity of BD-Test (ISO 11140 -3)**
  - e. g injection of 0,02% air (ca 70ml in ca 6 STU) => 6-7mbar
  - compare to Vacuum Test (EN285)
- **Worst case geometry (Haas, Henn et al, 2004)**
  - Efficiency in worst case geometries
  - Various Cycles
- **(more difficult: Package integrity)**



## Daily Practice

- **Tests done precisely per guideline**

- Traditional Focus in CSSDs

- **Most common issues**

- Load configurations
- Drying issues
- Cool down protocols
- Steam Quality
- Sterile Packaging damages
- Recontamination

- Biological Indicators versus Chemical Indicators
- BD versus Helix Tests
- ...



# THE BIG QUESTION

What is worst case?

How can risks  
be reduced ?



How much effort to spend on double and triple checks?  
Use it elsewhere?

## Water Quality

- Corrosion and Surface Changes
- Recontamination
- Bioburden (Endotoxins...)

## Which Water Quality to be used where?

- Final Rinse
- Steam Quality
- Steam Feed Water
- (other cleaning steps)
- Final Rinse manual clean
- Final Rinse w/o thermal Disinfection



	AAMI	KRINKO	Red Book
Water for Final Rinse „Critical Water“	TIR 34 Conductivity: max 10 $\mu$ S Hardness: <0,1mmol/l Chloride: <1mg/l Silicate: -	- 	EN285 <i>but</i> Conductivity: < 15 $\mu$ S Hardness: <0,02mmol/l Chloride: <0,5mg/l Silicate: <1mg/l
Microbiological	-	Minimum Drinking Water	Minimum Drinking Water
Steam Quality Steam Feed Water	only • Dryness • Superheat • Non Condensable	EN285	EN285, Feed Water; see above Condensate: Conductivity: < 4,3 $\mu$ S Hardness: <0,02mmol/l Chloride: <0,1mg/l Silicate: <0,1mg/l
Endotoxin	Not Regulated in all; Regulation in Australian Guideline 0,25EU/ml		
Other Water Qualities	-	-	PreClean: <100mg/l Chloride

## Evidence

- **Staining: Presentation Dr. Tschoerner**

- Under which circumstances does it appear?
  - Systematic Comparison of Hospital Processes
  - Test Sterilizer (defined Steam Quality)

- **Corrosion: Boiling test (DGSV 2015)**



### Execution

- Degrease
- Dry
- Boil 30 min in Demineralized Water (EN 285)
- Cool 60 min in Water
- Dry 120 min (Air)
- Inspection



by Standard  
max. 2mg/l Chlorid



4mg/l Chlorid  
(Test phys. NaCl 0.1)



20mg/l Chlorid

at room temperature



20mg/l Chlorid, 1h



100mg/l Chlorid, 1h



100mg/l Chlorid  
Boiling Test



NaCl 0.3%, 1h

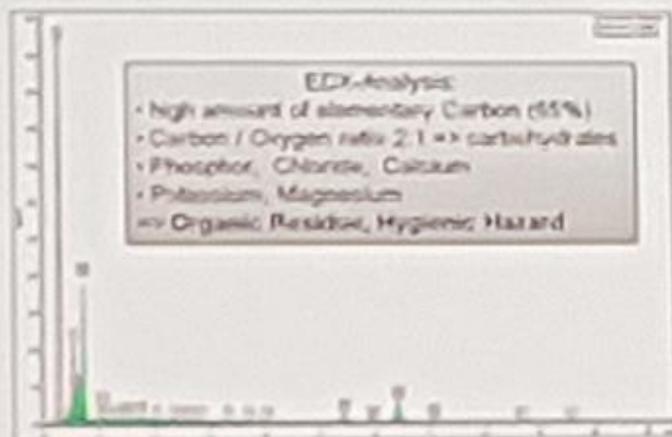
# Risks WFHSS 2015

## Laboratory Analysis of Surface Changes

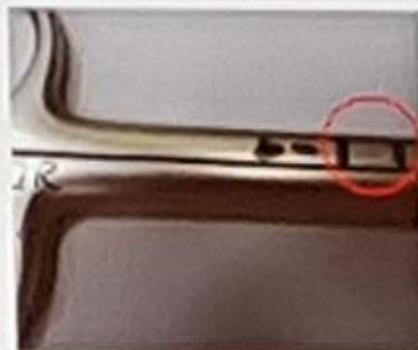
- REM-Picture: Structure / Dimension
- EDX Analysis



Instruments picked from working sets  
primary Assessment: Corrosion



REM Picture => Structure, Volume  
here: about 10% of Protein



Example  
Old Pitting Corrosion  
here 60ug Protein



REM-Picture  
deep Pitting  
Corrosion



Example:  
12% Carbon  
no link between carbon  
and visual appearance



REM-Picture:  
Residue on  
Surface

### Results:

- In 24 of 34 analyzed instruments, the elementary carbon content of residue was more than 10%
- Co-Elements like Nitrogen, Sulfur, Potassium frequently point towards organic / patient residue

## Daily Practice (from Consulting Experience)

	Germany	Australia (new)	USA
Final Rinse Water	Osmosis evtl + Ion Exchange / EDI	Osmosis evtl + Ion Exchange / EDI	Mainly Ion Exchange
Microbiological	Partly UV-light	<b>Thermal or Chemical</b>	Rarely
Steam Quality Steam Feed Water	Clean Steam Generators	Partly clean steam, partly black steam	Black Steam + Filters
Endotoxin	-	New limit	-
Other Water Qualities	Partly only Osmosis	-	Soft water

### Observation

- Incidence of corrosion related to water quality
- Staining seems more related to steam

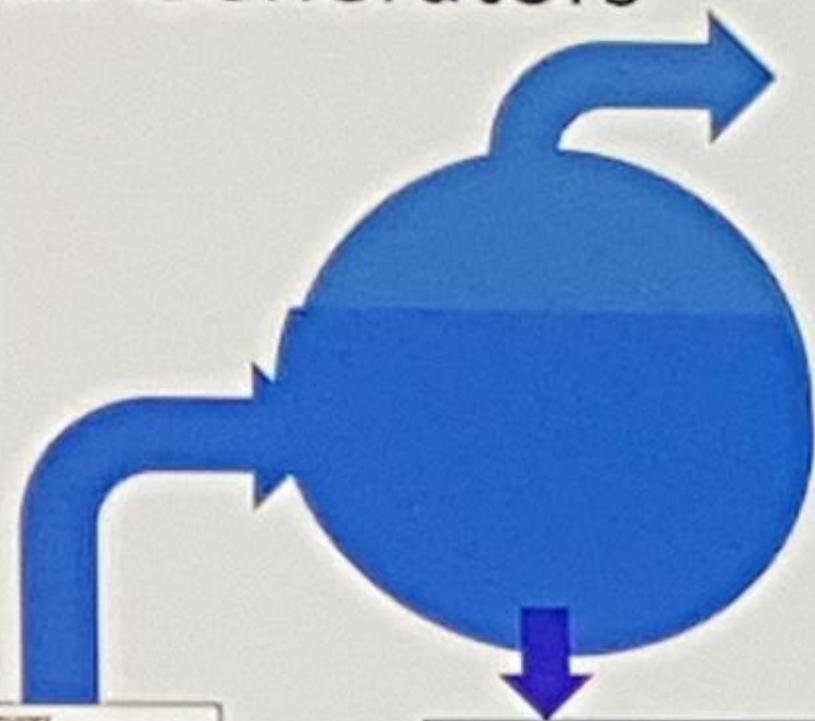


- **Germany: Major Issue Steam Quality**
- **Australia: most recent Guideline => addressing Microbiologics**

# Function of Steam Generators



Black Steam –  
Pure Steam



Bestimmungen im Zusammenhang mit dem Wasserversorgungsnetz für eine geeignete Dampfqualität

Substanz/Parameter	Maximalwert
Tabelle (DIN)	≤ 0.1 mg/l
Eisen	≤ 0.1 mg/l
Calcium	≤ 0.001 mg/l
Magnesium	≤ 0.001 mg/l
Schwammrückstände außer Eisen, Kalium, Blei	≤ 0.1 mg/l
Chloride (Cl <sup>-</sup> )	≤ 2 mg/l
Phosphate (P <sup>3+</sup> )	≤ 0.5 mg/l
Leitfähigkeit bei 25 °C	≤ 3 µS/cm
pH-Wert (nach der Amdt)	5 bis 7
Aussehen	klar, ohne Ablagerungen
Merke! (bei Entkalkung)	≤ 0.02 mmol/l



Bestimmungen im Zusammenhang mit dem Wasserversorgungsnetz für eine geeignete Dampfqualität

Substanz/Parameter	Maximalwert
Abbauhilfsstoffe	≤ 10 mg/l
Tabelle (DIN)	≤ 1 mg/l
Eisen	≤ 0.1 mg/l
Calcium	≤ 0.001 mg/l
Magnesium	≤ 0.001 mg/l
Schwammrückstände außer Eisen, Kalium, Blei	≤ 0.1 mg/l
Chloride (Cl <sup>-</sup> )	≤ 2 mg/l
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**Improvement Boiler Water**

- Salt Disposal: Conductivity Sensor, irrigation at max conductivity
- Mud Disposal: by time (important for silicate)

# THE BIG QUESTION

How much hygienic impact  
does it have?



What is the best standard ?

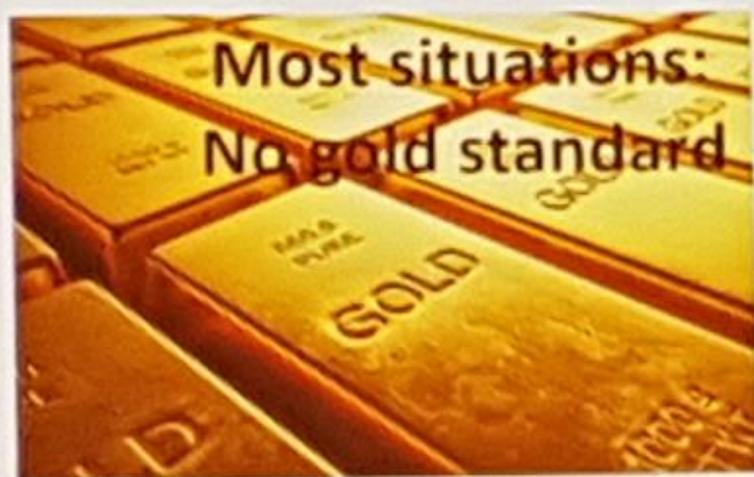


Is it worth the investment for value preservation?

## Conclusion

We are seriously lacking evidence and studies (Comparison of Methods)

We do not even have a common agreement about the evaluation of processes (minimization / acceptable limit or risk)



## Air Quality in Packing Room

- **Goal: Avoid Recontamination after Disinfection**

	AAMI	KRINKO
Temperature	20-23°C	?
Humidity	30-60%	-
Air Exchanges	10/ hour	-
Pressure Difference	Overpressure	-
Air Quality	Particel minimized	-
Bacteria Load	?	-

- **KRINKO: No Evidence for effects**

- Major financial impact for Ambulatory Centers and Private Practice
- Reality (most hospitals): Air conditioning for temperature control, according to DIN1946-4

### Influence Factors:

- Packing Table (Disinfection)
- Hand Hygiene / Gloves (Japan)
- Clothing
- Hair Cover / Beard Cover (France)
- Mouth Cover (UK)

### Acceptance Criteria:

None available

- xx CFU per Instruments / Which ?
- xx µg Protein
- Total Organic Carbon
- Particles

## Potential Study

- Condition of Instruments after WD compared to
- Condition before closing sterile pack
- depending on
  - Ventilation
  - ....

### ⇒ Improvement by

- Microbiological Load
- Protein
- ....

(Study by Dubuisson et al, Central Service 04/2017)

- **Improvement for Patient Outcome ?**
- **Acceptable Condition ?**



Be open minded, challenge daily Practices

Take Home Messages



**We should ask ourselves:**

- Where do we still see failures / issues?
- Which test always come sout the same?
- Risk management



If you want to travel fast,

- travel on your own

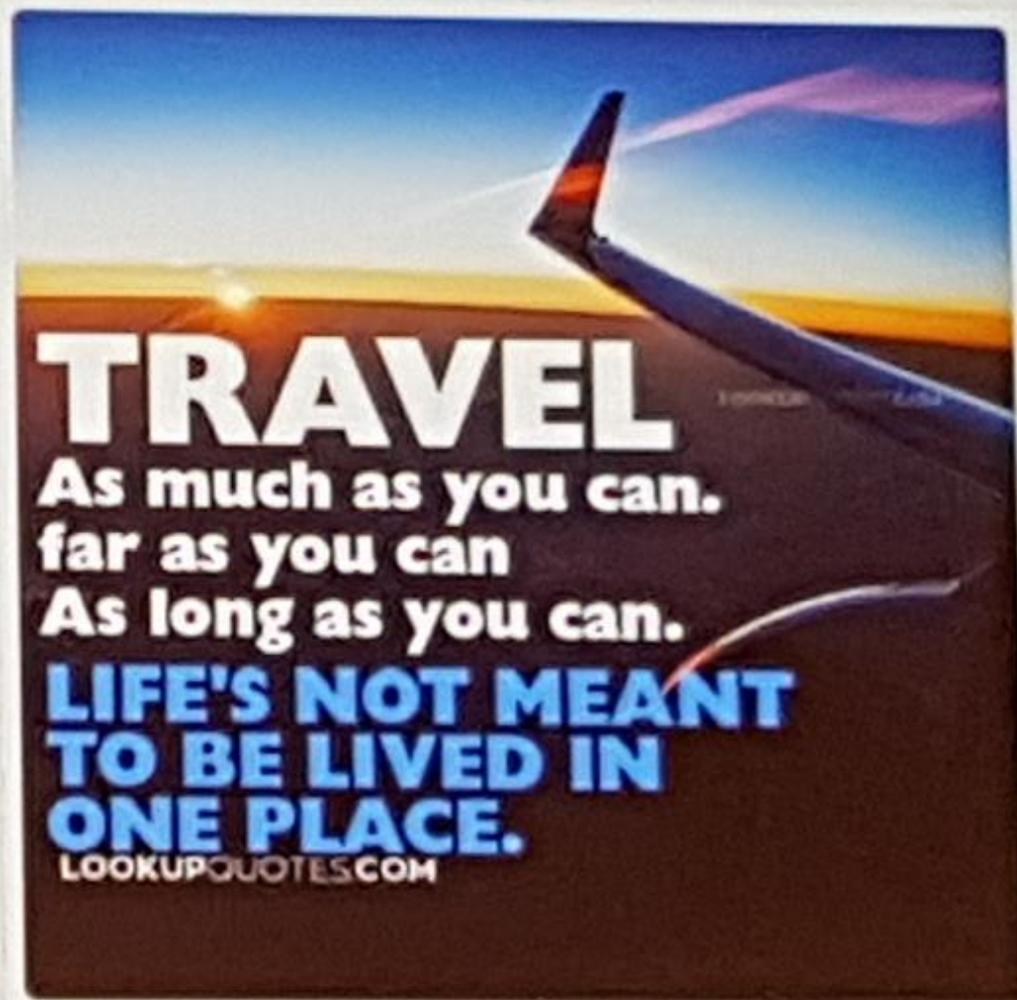
If you want to travel far,

- go in a group

How much effort to spend

Where to spend?

- Equipment
- Instruments
- Education
- Validation





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**Thank You !**

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