EN ISO 15883 – A Milestone?

ÖGSV

WFHSS

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EN ISO 15883 = A Milestone?

- EN ISO 15883 has cast ist shadows before it
  - Manufacturer: Adjustment of WDs to the requirements of the standard
  - Inspectors: Adjustment of test methods, developing of guidelines
  - User: Taking account of the provisions of the standard in their calls for tenders.

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- CEN TC 102 /WG 8
  - Approx. 10 years of exhausting work on the standards
  - Interests of the member countries and their representatives respectively (WD-manufacturers, hygienists)
  - Critics: No users, not all countries represented
  - Parts 1,2,3 and 5: valid standard worldwide
  - Finished for more than one year but still not published (?)

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- **Part 1:** General requirements, definitions and tests
- **Part 2:** Requirements and tests for washer disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment hollowware, utensils, glassware etc. (= „WDs for instruments“)

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- **Part 3:** Requirements and tests for washerdisinfectors employing thermal disinfection for human waste containers (= „bedpan-washers“)
- **Part 4:** Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (= „WDs for Endoscopes“)

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- „Special case“ ISO/TS 15883-5: Test soils and methods for demonstrating cleaning efficacy
  - Task of CEN to work out uniform test methods could not be finished by now
  - (Nearly) every country has it´s own test method (AT, DE, FR, NL, SE, UK, US)

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- Scope
  - General requirements on WDs and accessories
  - Cleaning and disinfection of reusable medical devices used in the context of medical, dental, pharmaceutical and veterinary practice.
  - Not for laundry washing machines and dishwashers
  - (in Austria: A_0-concept for this purpose integrated as well)

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- Part 1:
  - Technical (safety-, electrical) requirements
  - Performance Requirements to be demonstrated in the course of
    - Type-and works test
    - Validation: IQ, OQ, PQ

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- Type test:
  - Different views concerning scope and contents
- ÖGSV- guideline on testing, validation and routine control of cleaning-disinfection processes for medical products – Annex 3: Procurement
  - Contents of the type test, which have to be available before IQ and OQ
  - Planned: List of WDs with corresponding type tests

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- General requirements
  - Cleaning efficacy shall be demonstrated by use of a test method given in ISO/TS 15883-5
  - Preference must be given to thermal disinfection.
  - The chamber shall be disinfected as well (single chamber devices)
  - Means shall be provided to verify and/or record the attainment of the specified process conditions.

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- General requirements (2)
  - The manufacturer shall give information about the **process chemicals** to be used and the **water quality**
  - **Prerinsing** should be carried out with water below 45 °C
  - The concentration of the **process chemicals** has to be lowered to a level, which was stated by the manufacturer to be safe

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- Process verification (depending on risk)
  1. Indication only (e.g. bedpan washers)
  2. Recording of disinfection parameters only
     - (e.g. WDs for instruments, if cleaning efficacy can be verified visually)
  3. Recording of Cleaning ***and*** disinfection parameters
     - MP, which are used withour further treatment (e.g. endoscopes)
     - or cleaning efficacy cannot be verified visually (e.g. MIS-instruments)

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- Thermal Disinfection
  - Meeting the specified temperatures and holding times – or -
  - Equivalent lethal effect (A_0 -concept)
  - Disinfection temperature band: Specified temperature – 0 /+5 °C

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- A_0 - concept
  - A_0-value = time in seconds at 80 °C to produce a given disinfection effect, when z= 10*
    - $A_0 = \Sigma\ 10^{(T-80/z)} * \Delta t$
    - $t = A_0/10^{(T-80/z)}$

.z= Temperature change, which is required to change the D-value by afactor of 1 log

.** D-value: Time in minutes at a given temperature to lower the germ count by a factor of 1 log

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- Which A_0-value has to be achieved depends on the expected species and count of microorganisms on the MP as well as further treatments and the intended use
- Proposed A_0 –values for:
  - „Critical" MP acc. to RKI (e.g. surgical Instr.: 3000
  - „Semicritical" MP (e.g. anesthetic equipment): 600
  - „None-critical" MP (e.g. bedpans): 60

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Process Temp (°C)	Holding time for A_0=3000 (critical MP)		Holding time for A_0=600 (semicritical MP)		Holding time for A_0=60 (uncritical MP)	
	sec	min	sec	min	sec	min
65	94868	1581,1	18974	316,2	1897	31,6
70	30000	500,0	6000	100,0	600	10,0
75	9487	158,1	1897	31,6	190	3,2
80	3000	50,0	600	10,0	60	1,0
85	949	15,8	190	3,2	19	0,3
87	599	10,0	120	2,0	12	0,2
90	300	5,0	60	1,0	6	0,1
93	150	2,5	30	0,5	3	0,1
95	95	1,6	19	0,3	2	0,03

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- Part 4: WDs for endoscopes
  - ÖGSV: Guideline for testing, validation and routine control of cleaning and disinfection processes for flexible endoscopes: Under construction
  - To be considered when purchasing a new machine:
    - Rinse step between cleaning and disinfection
    - Single channel cleaning (no pressurized chamber machines)
    - Single channel monitoring (?)
    - Traceability (documentation)

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YES!

Despite the barrage of criticism addressed to the various parts of the standard, this can on the whole be viewed as a milestone in the field of medical device decontamination, which will contribute to the standardisation, comparability and quality assurance in the field of medical devices' decontamination and thus to patient safety.

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Thank you for your attention!!!