Annual EFHSS and NfS Conference 2006
Jack van Asten memorial Lecture

Standards and norms under continuous development

Research leads to clear norms

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Manager Validation & Monitoring, Bureau Veritas
Jack A.A.M. van Asten
1956 - 2002
Jack

- Motivating and enthusiastic colleague in the field of decontamination
- Broad interests and new ideas
  - Innovation
  - Norm contribution
  - Source for inspiration
  - Pragmatic
  - Critical
- Thinking in solutions
Contents

• Introduction
• History
• Steam sterilization
• Decontamination
• Conclusion
Brief history sterilization

- Fundamental research about 1850 to 1960
  [Pasteur; Bigolow, 1921; Arrhenius, 1922; Rahn, 1943; Precht, 1955]
- In the period 1958 to 1963
  [MRC, NASA]
- Development of the F-value theory and the L-value theory
  [Asten van J.A.A.M. and Dorpema J.W., 1983]
- New sterilization methods
New sterilization methods

• Most of the sterilization methods applied are more or less known, but improved:
  - High pressure
  - Ultra sound
  - Pulsed light treatment
  - Oscillating magnetic fields

[David Hurrell, DSc-EFHSS conference, London 2005]

• Comply with ISO14937
ISO 14937

• Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937: 2000)

• About 50 pages
Examples unclear norms

Cleaning disinfection (ISO15883):
Why do we have over 10 test to prove clean?

Steam sterilization (EN554 - ISO17665)
Why are there differences in criteria for steam sterilizers?

New sterilizing methods (ISO14937)
Does not every claim made by the manufacturer be proved?
Standards and norms under continuous development

Research leads to clear norms and standards
Steam sterilization

- World wide most applied sterilization method
- Norms (national, international)
- Discrepancies
- Literature and research
Steam sterilization conditions

• Principle mechanism is coagulation: Water and energy is needed
  [Savage, 1937; Rahn, 1945; Precht, 1955; Sykes, 1965; ...]

• Experimental data, death rate: natural logarithm
  [Biolow, 1921; Rahn, 1943; Perkins, 1956, ...]
Perkins [1955]

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100% saturated steam
Medical Research Council (1959, MRC)

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Rational MRC: Steam quality
### Medical Research Council (1959, MRC)

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**Rational MRC: Steam quality**

May 20, 2006

EFHSS, Lillehammer
$F$- value definition

- The $F$- value is the time in minutes required to kill all the spores in suspension when at a temperature of 121 °C or 250 °F.

[Block, 1983]

Often used: $F = F_{\text{ref}} 10^{(T_{\text{ref}} - T)/z}$
## F-value

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## Differences

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<td>0</td>
<td>+5.5</td>
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Time discrepancies
MRC - $F$-value

- $D$-value In literature approached as linear logarithm (straight line on log axis).
Mathematical approach

• More exact calculation show that the $z$-value is not logarithm dependent on the temperature or the $D$-value.
z value
Suggestion

- Stick to the values of the MRC:
  - At least until new prove is giving
  - Technically it is possible
  - Proven to be safe

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Accuracy

• Available information based on water like liquid sterilization
  - Savage (1937) at 105 °C, maximum 1 °C overheated
  - MRC definition

• Steam sterilisation 100% saturated steam is necessary for ‘Perkins’ times
Saturated steam

- Saturation not direct measured
  - Accuracy
  - Responds time sensor
  - (Costs)
- p-T relation, calculation of the theoretical temperature: $T_{th} = f(p)$
- Relation only for 100 % saturated steam
p-T relation in graph
Steam sterilization process

Phase I

Phase II

Phase III

Pressure

Time
Temperature bands

• 3 °C - band
  - Protection

• 2 °C - band
  - Overheated steam
    • 100% saturated steam: 134 °C for 3 min
    • Dry heat: 134 °C over 12 hours
Graph

- $T_{hot}$ curve
- $T_{Theoretical}$
- $T_{cold}$ curve

2 °C - band

Temperature °C

Time (s)
Discrepancies to norms

Pressure

Time

Phase I

Phase II

Phase III

Cause
discrepantcy
Possible solution

Pressure

Overshoot

Phase I

Phase II

Phase III

Time
Possible solution

Pressure

Phase I

Time
Contradiction

• Duration steam sterilizing process
• Process time versus on production
  - Temperature overshoot
  - Steam penetration of narrow lumen
Accuracies p and T

Chamber temperature (°C)

Theoretical temperature (°C)

Aimed sterilization temperature

Aimed sterilization temperature - 0.5 °C
Temperatures

Theoretical temperature (°C)

Chamber temperature (°C)

134 136 138 140

136.5

134 136 138 140
Overheated / NC gasses
Result specification

• Research show that p and T criteria are realistic
  
  [IGZ, 1996 and 2000: van Doornmalen Dankert, 2005]

• Narrow lumen
Narrow lumen, worst case

• First approach:
  - Infinitely thin wall
  - No condensation
• At start 100 % saturated steam at L(0)
• Calculation gas composition c(x)
No condensation

\[ r = 1\,\text{mm} \]
\[ L = 1\,\text{m} \]

Pressure vs. Time graph:

- Start
Animation (dry)

c(x,t)

L (m)
Variations in L and r

\[ c(L,t) \]

\[ L(m) \]

\[ r(mm) \]
Lumen

- So far, no condensation
- What about condensation
- System more complex
Tube configuration

- Configuration $d = 1$ mm, $r = 1$ mm, $L = 1$ m
- Tube material:
  - teflon ($\rho = 2.2 \times 10^3$ kg/m$^3$, $c = 10 \times 10^2$ J/kg$^{-1}$ K$^{-1}$)
- Heat transfer
- Mass transfer
- Condensation form (film, droplets)
First approach with condensation

c(x,t)

Condensation

L (m)
Comparison
Although, theory not complete

- Because of:
  - Heat transfer model
  - Mass transfer model
  - Condensation form
  - Configuration of device
  - Experimental data not available
  - But general applicable
  - Further research is necessary
Criteria for steam sterilization of lumen

• With 100 % saturated at the entrance of the lumen

• Criteria for steam sterilisation appear not to be too strict for strict
Weakest link

- Without cleaning no disinfection no sterilization

Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model

X. Chaufour, MD; K. Vickery, PhD; Sydney, Australia; J Vasc Surg 1999; 30: 277-282.
Angio scope

Contaminate

Cut into pieces

Process pieces in different way

Use (/ contaminate) 231 duck

Results
Methods of decontamination

Contamination N = 231

**Unproper cleaning**
Flushing of angioscope onc with 5 ml of sterile water

N = 105

**Proper cleaning**
Submerging in clean tap water, brushing and flushing. Submerging in enzymatic detergent and flushing with detergent mix. Brushing and soaking in detergent mix (10 min) before flushing and rinsing with tap water

N = 88

Disinfection 2% Glutarald. 5 min 10 min 20 min EO

N = 10 10 35 10 10 35 10 10 33

Surgery in 1 day old ducklings
**Microbiological Results**

**Unproper cleaning**
- Disinfection 2% Glutarald. 5 min: 1 Positive, 14 Negative, 38 Total
- Disinfection 2% Glutarald. 10 min: 1 Positive, 14 Negative, 38 Total
- Disinfection 2% Glutarald. 20 min: 3 Positive, 7 Negative, 38 Total

**Proper cleaning**
- Disinfection 2% Glutarald. 5 min: 2 Positive, 33 Negative, 35 Total
- Disinfection 2% Glutarald. 10 min: 2 Positive, 33 Negative, 35 Total
- Disinfection 2% Glutarald. 20 min: 10 Positive, 10 Negative, 30 Total

**Control**
- Flushed: 100% Negative

**Conclusion**

- Disinfection 2% Glutarald. for 20 minutes shows the highest clearance rate.
- Proper cleaning methods are more effective than unproper cleaning.

**References**

- EFHSS, Lillehammer
- May 20, 2006
Cleaning / disinfection

- Conclusion (Chaufour et al.)
  Cleaning/disinfection before sterilisation is necessary

- Cleaning/disinfection challenges
  Scopes
Example scopes

Hollow Scope / Scope with Channel

Scope with small diameter

Camera unit

Diameter scope 1.5 mm

Front scope

Fiber Raster
Dirty scope
Cleaning a scope

Hollow Scope / Scope with Channel
Inside the scope
Summarized scopes

- Scopes can be dirty
- Definitions for cleaning and disinfection should be defined (perhaps depending on use)
- Cleaning method could be a point of attention
In general

• (Steam) sterilization and cleaning/disinfection procedures and processes need
  - (more) scientific prove
  - research (to optimise processes)
Challenges

• Not proven methods may lead to a false sense of safety
• Education
• Scientific prove, ends discussions/interpretations
• Norms and standards should be scientifically based
• Commercial interest
Conclusion

Due to ongoing science, norms and standards will, and should be changing continuously
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*Takker De for Deres oppmerksomhet*

Thank you, for your attention