

Decontamination Sciences Congress 2005



Closing Ceremony

Decontamination Sciences Congress 2005



DSc 2005

**Jack van Asten Memorial
Lecture**

David J Hurrell MSc FIHEEM AP(S)

Managing Director, Healthcare Science Ltd.

Jack van Asten,



who was a good colleague and friend, passed away at the age of 45 on Sunday, 24th February 2002.

Jack's major pre-occupation was the practice of "sterilization" in the healthcare field.

He was committed to the development of greater understanding of sterilization and sterile services and opened new horizons for many practitioners both in the Netherlands and in many other countries throughout the world.

His commitment to our profession should be an inspiration to us all.

The changing emphasis

From 'Sterile supply'

To

'Decontamination Science'

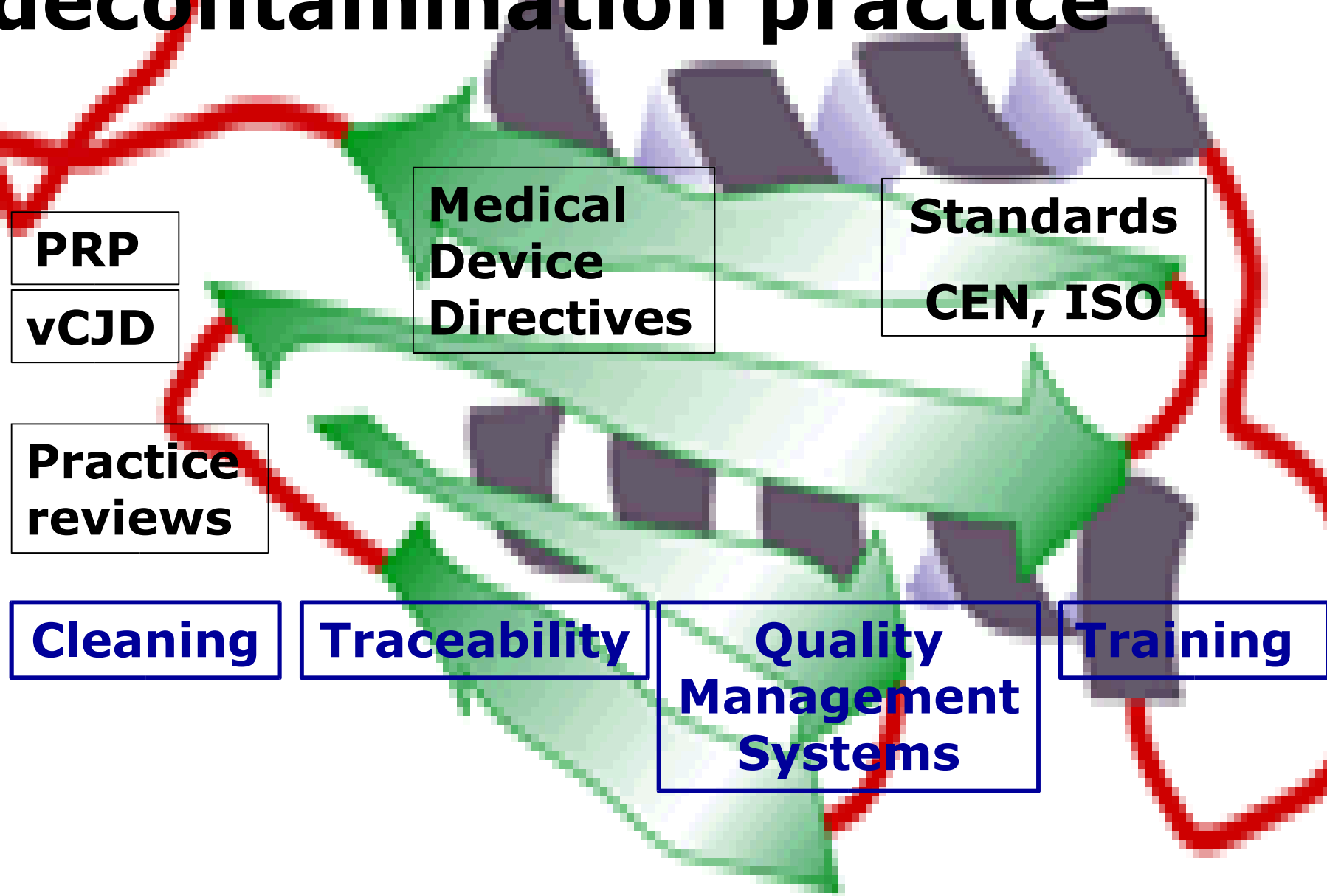
What are the signs that there is a change?

Decontamination Science

- World Congress
- ISSM becomes IDS
- First higher degree programme in Medical Device Decontamination begins September 2005

Why has this change of emphasis occurred?

Triggers for change in decontamination practice



An evidence based, risk management approach.

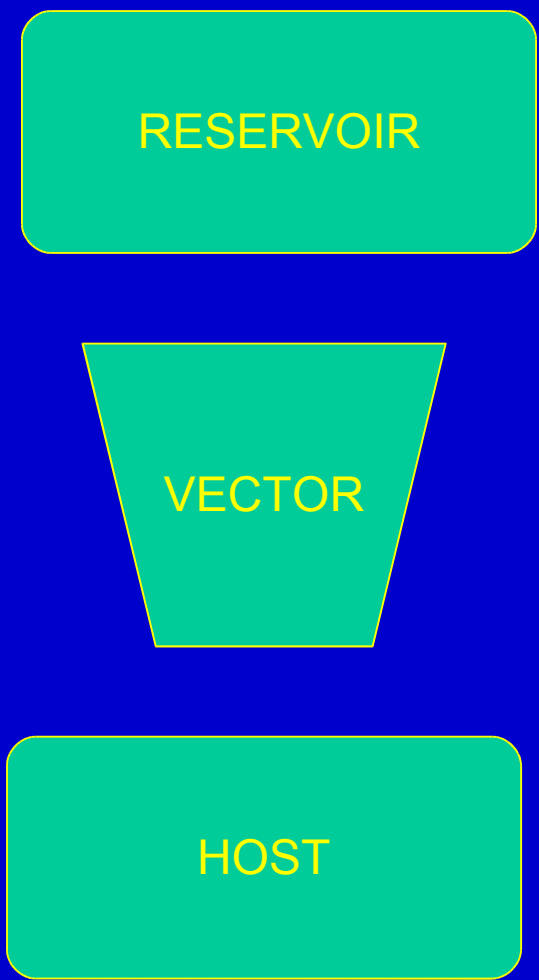
HACCP

- Hazard Analysis – Critical Control Points
- Pierson, M. D. and Corlett, D. A. J. 1992.
- HACCP principles and applications.
- Van Nostrand Reinhold Publishing. New York.

A risk management approach; where are the major risks?

- Acute sector
- Primary care
- HAI
 - Role of decontamination

Routes of infection



RESERVOIR

The diagram illustrates the routes of infection through three vertically stacked components. At the top is a light blue rounded rectangle labeled 'RESERVOIR'. Below it is a light blue trapezoid labeled 'VECTOR'. At the bottom is a light blue rounded rectangle labeled 'HOST'. A vertical line with downward-pointing arrows connects the three components, indicating the direction of infection transmission.

VECTOR

HOST

Reservoirs, vectors and hosts

Reservoirs

– Passive

- Contamination diminishes with time
 - eg Contaminated work surfaces

– Active

- Contamination increases with time
 - Eg Contaminated water, infected host

Reservoirs, vectors and hosts

Vectors

– Direct

- Mechanical transfer on
 - Instruments
 - Hands

– Indirect

- Airborne
- waterborne

Reservoirs, vectors and hosts

Hosts

- Susceptibility
 - Immune system
 - Antibiotics
- Inoculum
 - Size
 - Virulence
- Route of introduction
 - Inhalation, ingestion, injection, in-contact

Eliminating infection

H

OST RESISTANCE

A

BOLISH RESERVOIR

I

NTERRUPT TRANSFER

Decontamination is about:

- Abolishing the reservoir
- Interrupting the transfer

Areas of current concern

- Cleaning
- Control of steam sterilization
- Design of instruments
- Manufacturers' reprocessing instructions
- Transport of dangerous goods
- Environmental impact

Cleaning

- Definition of what is required
- Means of
 - Validating cleaning processes
 - Monitoring attainment of required standard of cleanliness

Why is cleaning necessary

- Device function and longevity
- Clinical procedures
- Patient
- Subsequent processing (disinfection, sterilization)
- Legal requirements

Why do we need to clean?

- If debris or organic matter is not removed it will interfere with microbial inactivation and may compromise the disinfection or sterilization process

(Favero, 2001; Parker, 1995; Alfa, 1998; Rutala, 1998; Sehulster, 2002; CDC, IC Practice for Dentistry, 2003)

What do we mean by clean?

- prEN 15883-1 Washer-disinfectors defines cleaning as:
- Removal of contamination from an item to the extent necessary for its further processing and intended use

Standards of cleanliness

- Attainment of 'clean' status judged by:-
- Visual inspection
 - Unaided vision
 - With illumination & magnification
- Chemical test
 - Quantitative
 - Qualitative
- Microbiological test
 - Enumeration
 - Speciation

Chemical tests

- Protein residue tests
 - Orthophthlaldehyde (OPA)
 - Ninhydrin
 - Biuret
- Sensitivity approx 100 micromole protein determined as HSA
- ATP activity

Tests for cleanliness

- There is no simple, accurate, in-process test for cleanliness.
- When the output from a process cannot be checked for compliance with the specification before use the only available control method is:-
- **VALIDATION + PROCESS MONITORING**

Validation

- Documented procedure for obtaining, recording and interpreting the data required to show that a process will comply consistently with pre-determined specifications
- This requires an understanding of the factors that affect the cleaning process



A miscellany of cleaning methods



Cleaning

- We currently have
 - No firm information on the effects of most contaminants on subsequent processes or patients
 - No definition of maximum permissible limits for residual contaminants
 - No relevant, standardised test methods for determining the efficacy of cleaning processes either
 - for validation or
 - routine monitoring

Control of steam sterilization

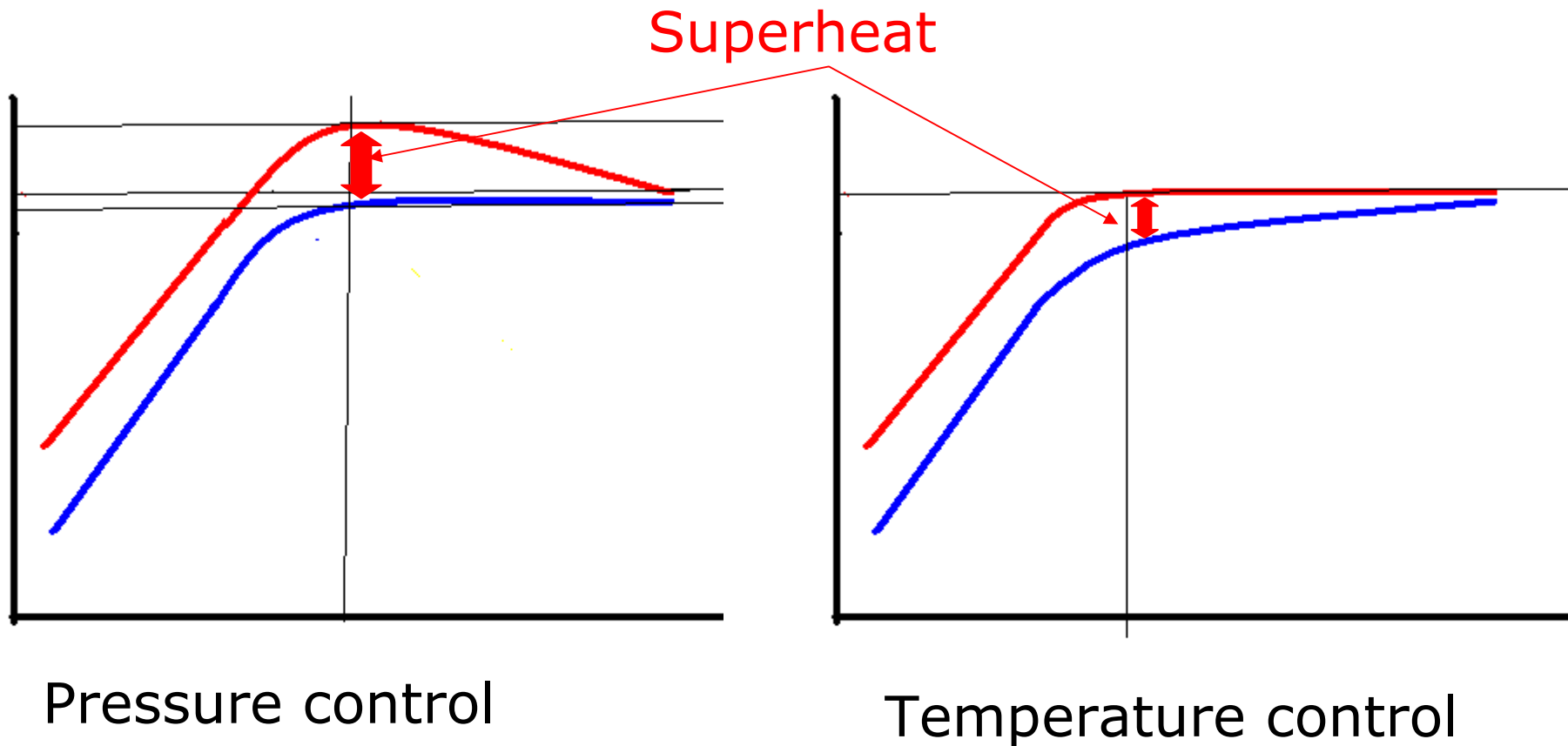
- Moist heat *versus* Dry heat

$$134^{\circ}\text{C} / 3 \text{ mins} = 134^{\circ}\text{C} / 30 \text{ hours}$$

- Therefore important to
 - ensure **moist heat** present throughout load on every cycle and
 - eliminate
 - Superheat
 - Air retention/ingress

Superheat:

Ease of detection depends on control method



Measuring presence of air

- Bowie Dick test
 - Physical
 - Chemical
 - Tape / test sheet
 - Single / multi-layer
- Alternative Bowie Dick test
 - Chemical
 - Electronic
- Air detector
 - External to chamber
 - Sensitivity

Design of instruments

- Decontamination needs to be considered as an equal priority to clinical use and marketability



For example:

Dental handpieces

Suckers

TOEs

Flexible reamers

Manufacturers' reprocessing instructions

- Need to be
 - Based on validated processes
 - Relevant to national practice
 - Comprehensive
 - Generic
- AVAILABLE before PURCHASE

Transport of dangerous goods Regulations

- Covers used medical devices
- When transported on public roads
- UN approved sealed, leak proof containers
- Over 300 litres/kgs needs
 - Trained driver
 - Identification on vehicle
 - Load records

Environmental impact

- Single use devices
- Power usage
- Water usage
- Discharge to drain
 - Contaminated water
 - Detergents
 - Disinfectants

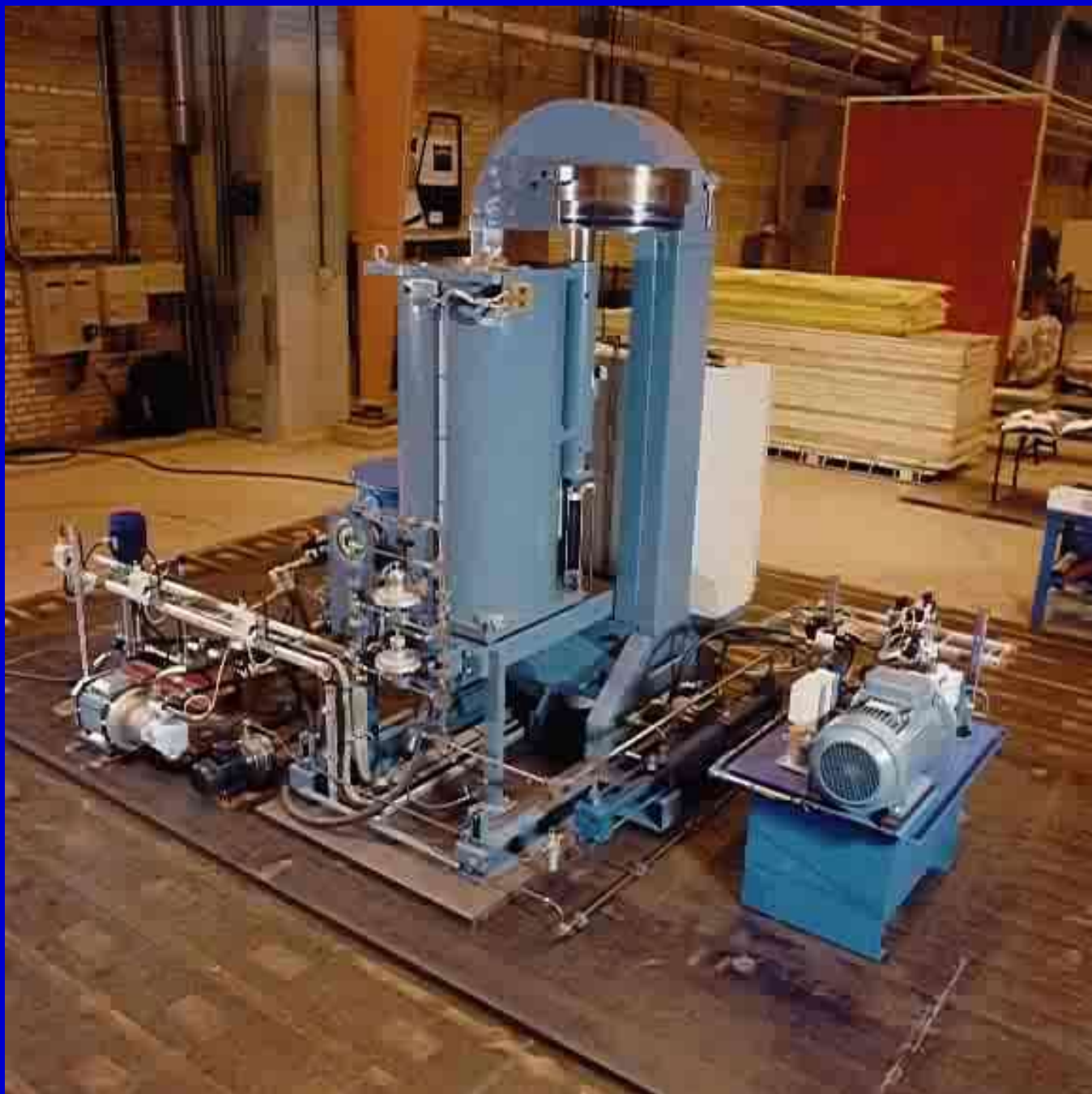
New decontamination processes

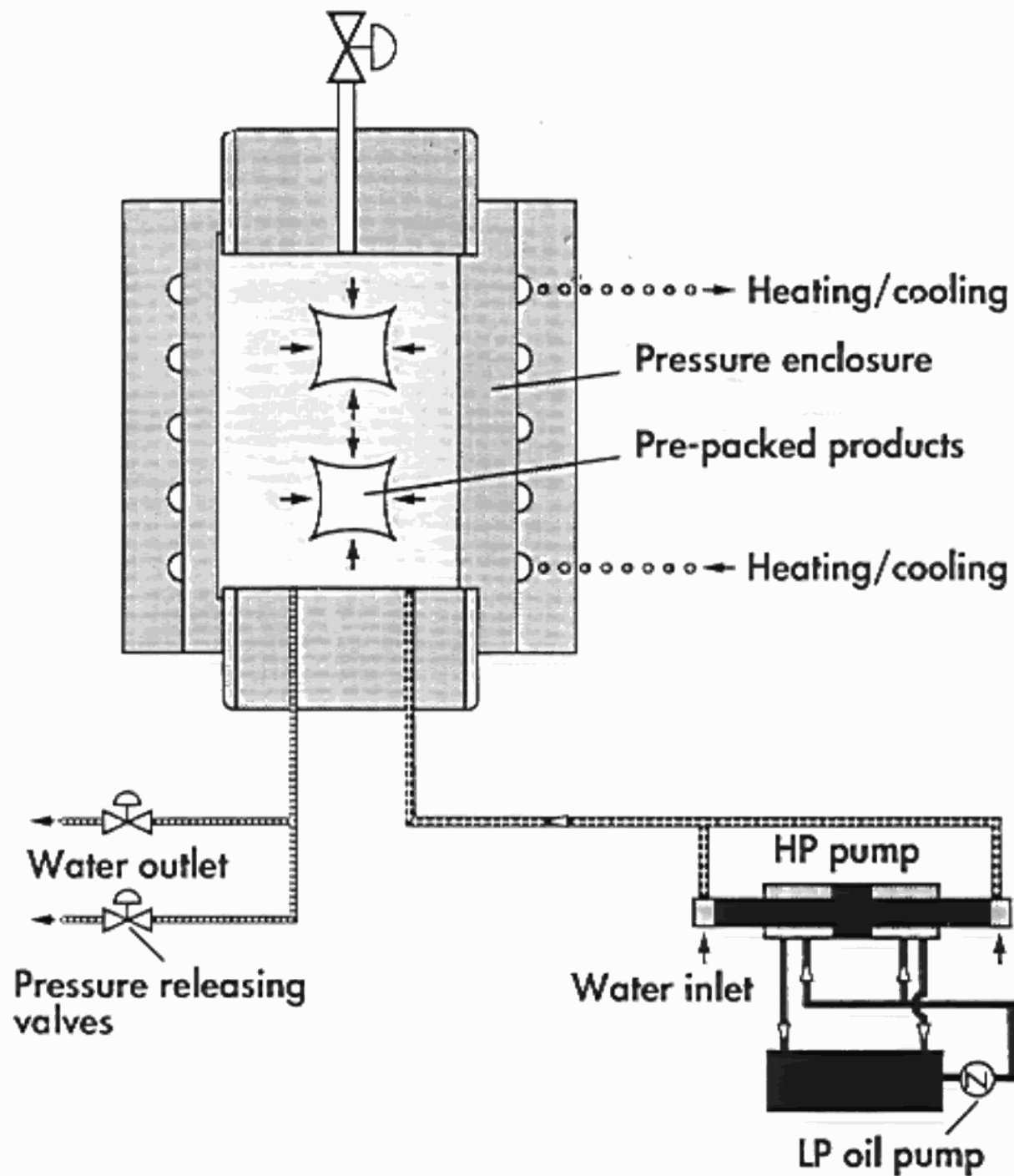
Sterilization / disinfection methods of tomorrow ?

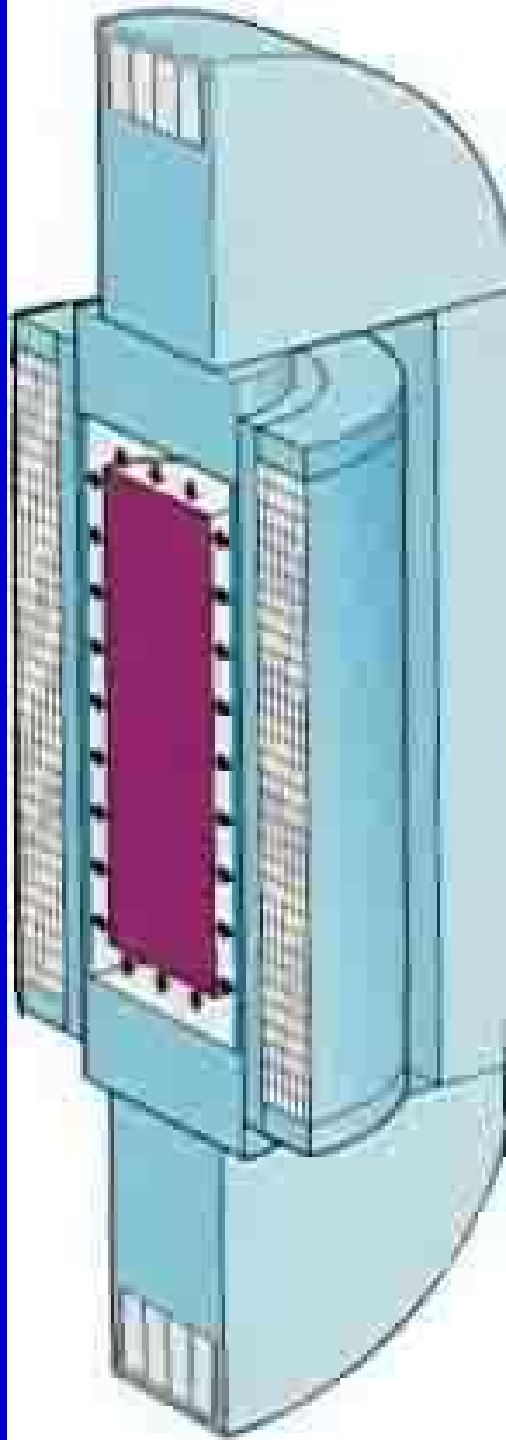
- High pressure processing
- Ultrasonic
- PEF
- Electroporation + bactericide
- OMF
- Pulsed light

High pressure processing

- Pressures in the MPa to GPa range
- Temperature ambient and above
- Exposure time < 30 minutes
- Cycle time < 90 minutes
- Applicability?
 - Food
 - Liquid pharmaceuticals
 - Thermolabile devices







High-pressure processing

- Inert gases or water are the most commonly used pressure media.
- The relative incompressibility of water makes it the preferred pressure medium in many applications.
- The decrease in volume of water is about 5 percent when its pressure is increased from 0 to 4 000 kg/cm² at 22° C.
- This volume reduction is much smaller compared with inert gases, where high volume reductions can make operations more hazardous.
- Typically, small amounts of oil may be added into the water for anticorrosive and lubricant purposes.

High pressure processing

- The time required to pressurize the vessel is influenced by the compressibility of the pressure medium and the nature of the processed material.
- The presence of air in the load increases the pressurization time, since air is considerably more compressible than water.
- After pressurization, the load is kept under high pressure for the required process time, which may be for several minutes.
- Upon completion of the pressure exposure, depressurization can be done quite rapidly.
- Reduced process times at high pressures are obtained when used in combination with higher temperatures

High Pressure Processing

REFERENCES

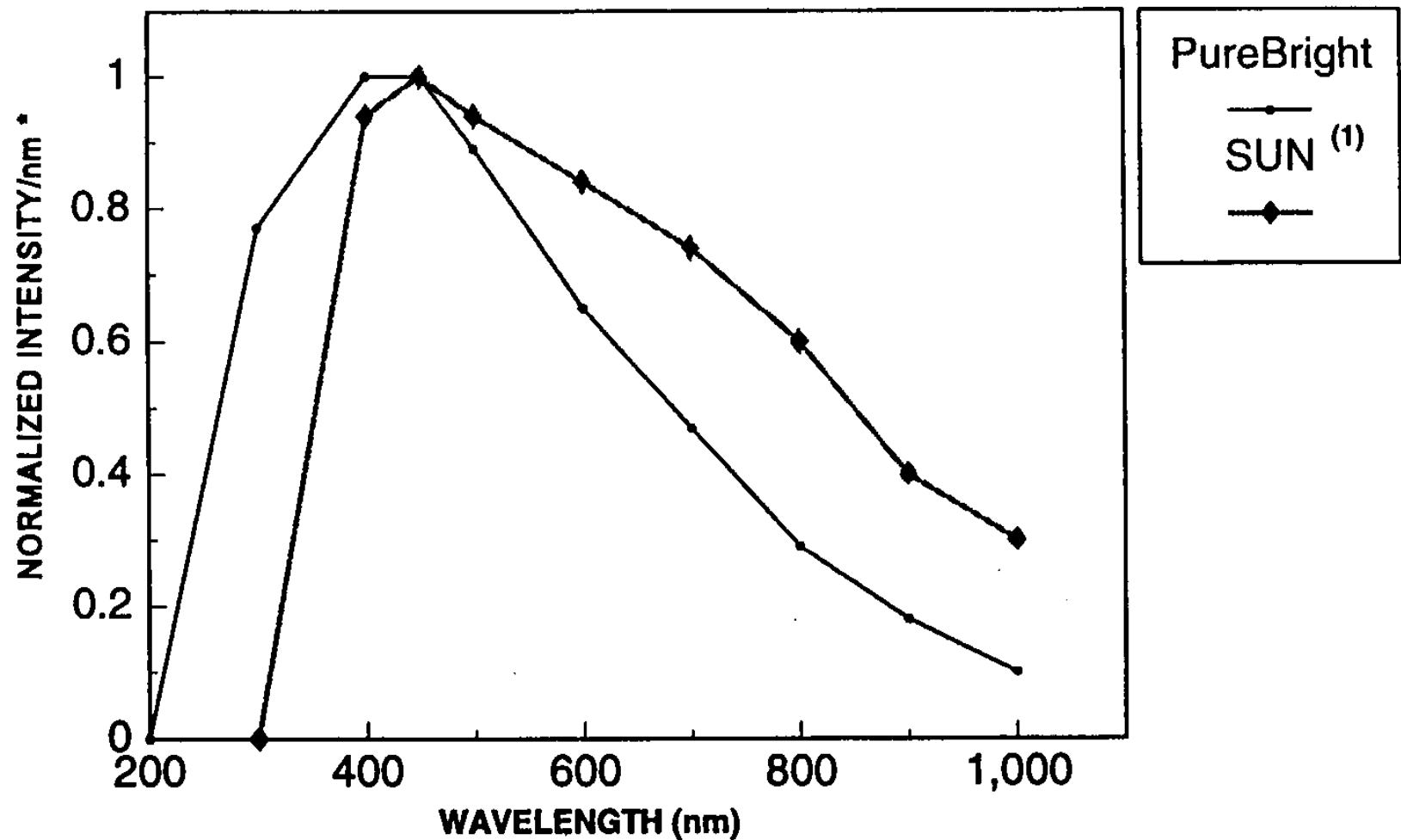
- Dring, G. J. 1976. Some aspects of the effects of hydrostatic pressure on microorganisms. S. A. Skinner and V. Hugo(eds.). Inhibition and inactivation of vegetative microbes. New York. Academic Press Inc.
- Kim, J. 1983. Disinfection by increased hydrostatic pressure. Dev. Ind. Microbiol. 24: 519-525.
- Butz, P., Trangott, V., Ludwig, H., Ries, J. and Weber, H. 1990. The high pressure inactivation of bacteria and bacterial spores. Die Pharm Ind. 52:487-491
- Smelt, J. P. P. M., Rijke, A. G. F. and Hayhurst, A. 1994. Possible mechanism of high pressure inactivation of microorganisms. High Press Res. 12:199-203
- Enomoto, A., Nakamura, K., Hakoda, M. and Amaya, N. 1997. Lethal effect of high-pressure carbon dioxide on a bacterial spore. J Ferment Bioeng. 83(3): 305-307

Ultrasound

- Raso, J., Pagan, R., Condon, S. and Sala, F. J. 1998. Influence of temperature and pressure on the lethality of ultrasound. Appl Environ Microbiol. 64(2):465-471
- Raso, J., Palop, A., Pagan, R. and Condon, S. 1998. Inactivation of *Bacillus subtilis* spores by combining ultrasonic waves under pressure and mild heat treatment. J Applied Microbiol. 85:849-854

PULSED-LIGHT TREATMENT

- Flashes of high-intensity light for killing microorganisms on surfaces.
- This procedure (trade name PureBright) uses a light spectrum ranging from ultraviolet to near-infrared.
- The spectrum is similar to that of sunlight
- The peak of intensity is in the blue-violet region
- The PureBright spectrum contains wavelengths in the 200 to 300 nm region, which are not present in sunlight reaching the earth's surface.
- Sunlight, on the other hand, has more radiation in the infrared region than does PureBright.
- The intensity of PureBright is 20 000 times that of sunlight measured at the earth's surface.
- The intense flashes of light produced by the PureBright system are used in the destruction of microorganisms.



(1) SUNLIGHT SPECTRUM AT SEA LEVEL

*** PureBright APPROX. 20,000 TIMES THE INTENSITY OF SUNLIGHT
AT SEA LEVEL**

PULSED-LIGHT TREATMENT

- The PureBright system involves illuminating the desired treatment area with 0.1 to 3 J/cm² per flash, with total accumulated fluences of 0.1 to 12 J/cm².
- Flashes are, in general, applied at a rate of 0.5 to 10 Hertz, for duration of several hundred microseconds.

PULSED-LIGHT TREATMENT

- The application of pulsed light can reduce up to 9 logs of vegetative microorganisms and more than 7 logs of bacterial spores on smooth, nonporous surfaces such as those of packaging materials.
- When the surfaces are more complex and porous, such as in case of food materials, microbial reduction is of the order of only 2 to 3 log cycles.
- The pulsed light systems affect only the surface of the product being treated.
- PureBright. Pure Pulse Technologies, Inc., San Diego, CA, USA.
Dunn, J., Ott, T. and Clark, R.W. 1995. Pulsed-light treatment of food packaging. *In J. Food Technol.* 49: 95-98.

OSCILLATING MAGNETIC FIELDS

- Published studies show contradicting results on microbial inactivation in oscillating magnetic fields (OMF).
- Studies indicate
 - an inhibitory effect,
 - no effect, or
 - a stimulating effect on microbial populations
- Mechanisms describing these observations are under scientific inquiry.
- In one study, foods with high electrical resistivity were placed within a magnetic coil in an apparatus and subjected to one or more pulses of OMF with an intensity of 2 to about 100 Tesla and a frequency of 5 to 500 kHz (27).
- It was observed that a single pulse of magnetic field generally decreased the microbial population by at least two orders of magnitude. OMF involves little thermal energy input.

Decontamination Science

- All scientific disciplines have their own 'laws' governing physical behaviour within the discipline.

What are the laws of 'decontamination' ?

Laws of decontamination

- Any decontamination process will
 - Take three times longer than the clinician is prepared to allow
 - Be more difficult and more expensive than the manufacturer claimed
 - Only work on a limited range of items

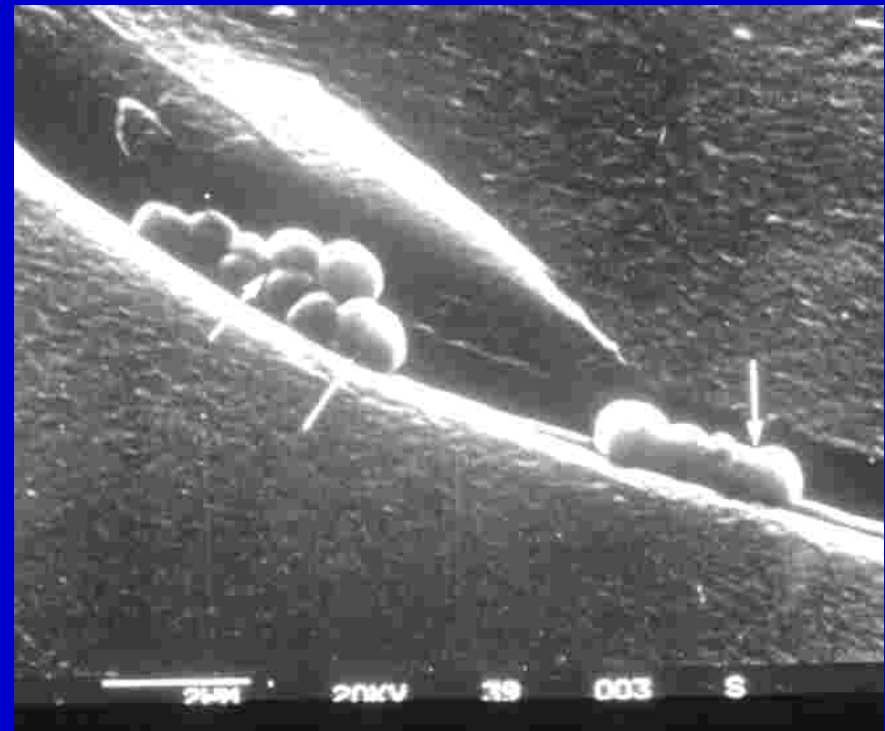
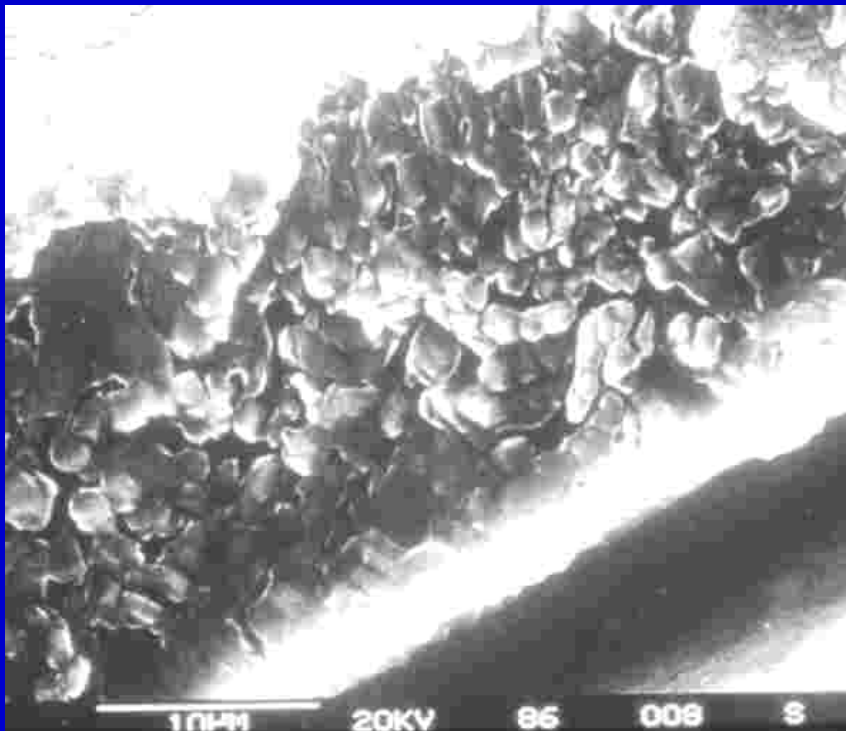
Laws of Decontamination

- If you cannot visually inspect a surface you cannot provide reliable assurance that it is clean.

If you can visually inspect a surface you still cannot provide reliable assurance that it is clean.

Laws of Decontamination

- If cleaning was 100% effective sterilization would be unnecessary!



Laws of Decontamination

- The preferred test method will be the one that
 - Is easiest to do
 - Usually gives the desired result
 - Costs the least
 - Provides the manufacturer with the biggest profit

Proper definition of performance requirements will permit the development and use of relevant test methods.

Laws of Decontamination

- If a clean sterile functional instrument is not available the instant it is required by the surgeon the fault lies with the sterile service provider.

Cooperative working between user and provider will resolve most of the supply problems.

Laws of Decontamination

- Our pursuit of an optimum solution should not stop us employing the best methods that are currently available.

Laws of Decontamination

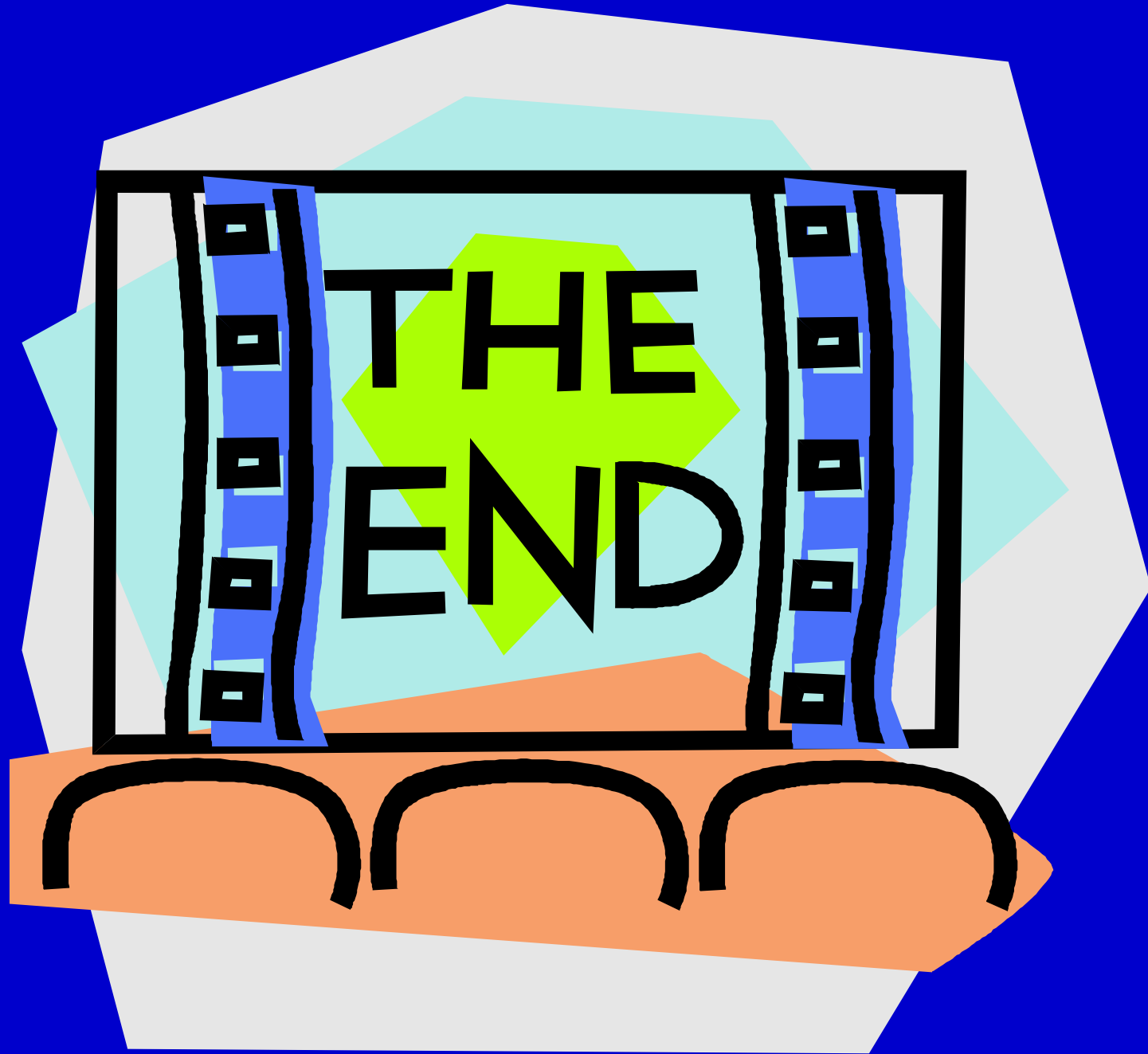
- If you search the literature carefully any 'new' sterilization method is 50 to 100 years old.

Laws of Decontamination

- Any new project will have 6 key stages:
 - Enthusiasm
 - Disillusionment
 - Panic
 - Search for the guilty
 - Blame of the innocent
 - Honour and praise for those who were not involved.

Laws of decontamination

- I welcome your suggestions (with documented experimental evidence) for additional laws.



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