Sterilizers and Sterilization Processes for Medical Devices: The Importance of Validation and Testing

Presented by:
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Sandvika, Oslo, Norway, May2025

1210 >1235

CONTENTS

EU Medical Device Regulation

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- **Chapter 1, General Requirements.**
- **11.5 Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.**

Post processing recontamination?

Get it wrong and you harm the patient !

Dancer et al, 2012

Post surgical site infection resulting from contaminated surgical orthopaedic and ophthalmology sets arising from incorrect control of the sterilization process resulting in post sterilization wetting of packs and microbial recontamination.

Conclusion;

Inspection of the sterilization plant highlighted inadequate maintenance of autoclave components and poor handling practices by staff. This was compounded by lapses in inspection of surgical sets by theatre staff

Journal of Hospital Infection 81 (2012) 231–238

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Surgical site infections linked to contaminated surgical instruments

S.J. Dancer [a,*], M. Stewart [a], C. Coulombe [a], A. Gregori [b], M. Virdi [c]

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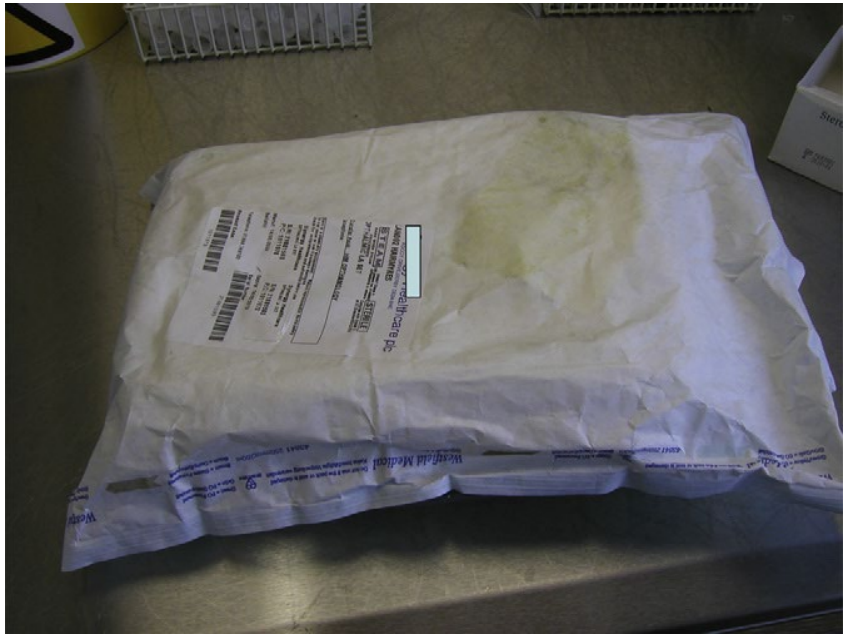

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Sterilization Processes

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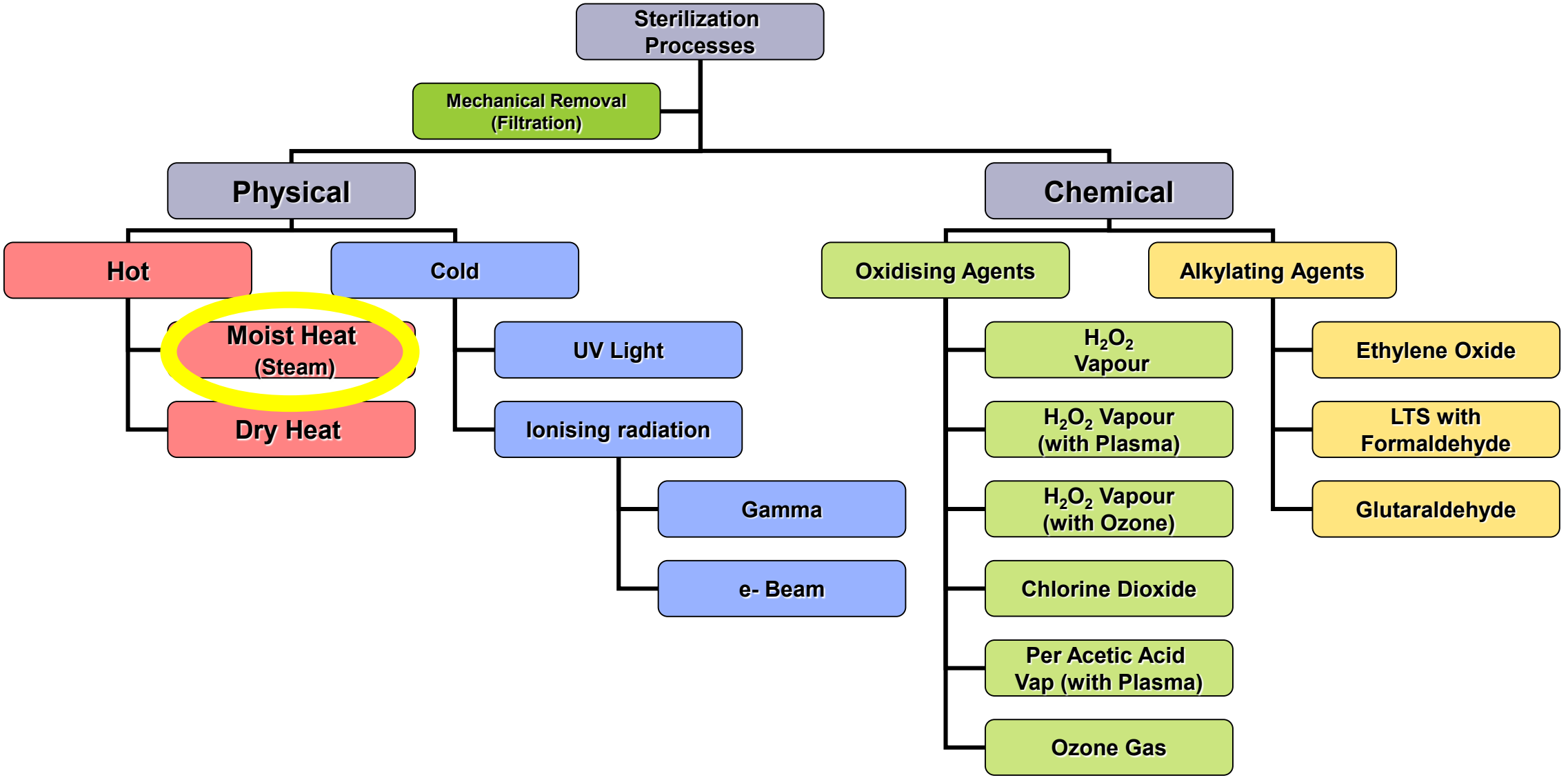
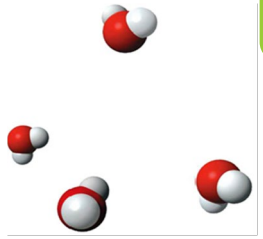
Sterilization Processes



Moist Heat Sterilization Process variables

Sterilizing Agent = Moist Heat – Thermal energy in the presence of moisture used as the sterilizing agent to achieve the specified requirements for sterility. (ISO 17665:2024)

Moist Heat Sterilization Process Variables



- Time
- Temperature
- Moisture

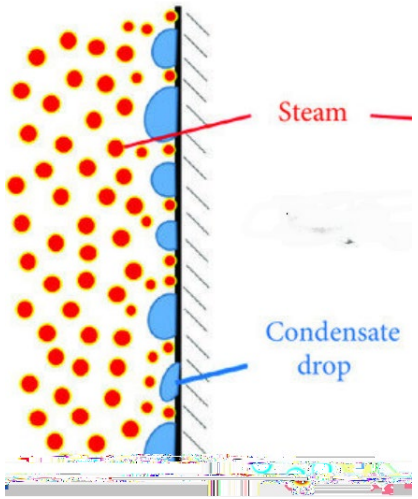
- Moisture
  - Saturated Steam
  - Liquid Water

Process Variables are those which contribute to <u>microbial kill</u> and <u>sterilization attainment.</u>

Two Types of Moist Heat Sterilization

Saturated Steam Sterilization: Validated process which involves the **direct contact** of **saturated steam** as the **sterilizing agent** on **product surfaces** to achieve the specified requirements for sterility

Contained Product Sterilization: Validated process where **indirect contact** of a **heating medium** on the **external surfaces** of **contained product** is used to create **moist heat internally** to achieve the specified requirements for sterility within the contained product



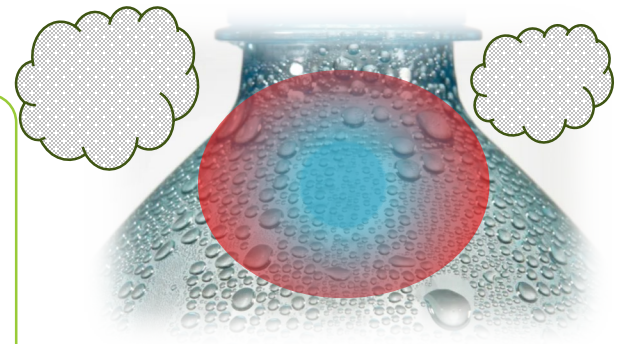
- SSS
- Passive Purging (Gravity Displacement)

SSS Ind | CPS Ind

SSS HC | CPS HC

- SSS
- Active Air Removal; (pre-vac)

eat Transfer by
SS
- SAM
- Water Sprays
- Water Immersion



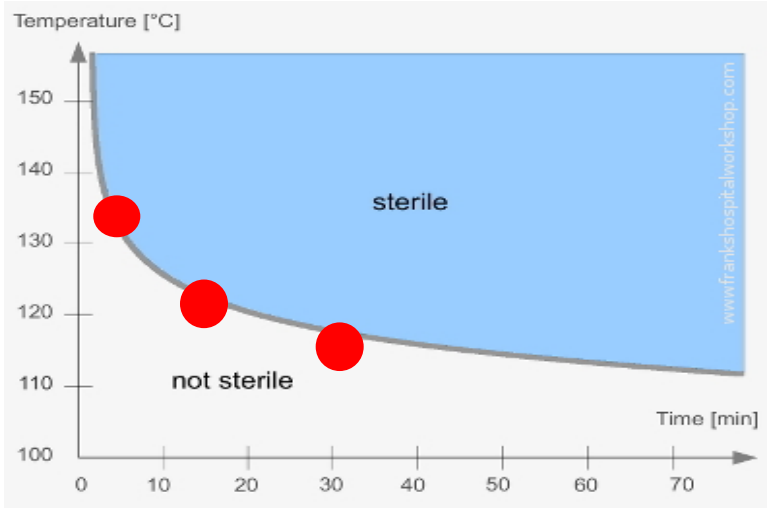
Moist Heat – thermal energy in the presence of moisture used as the sterilizing agent to achieve the specified requirements for sterility

The importance of Temperature and Time;

There are no magic numbers

- The rate at which micro-organisms are inactivated is dependent on the temperature.
- The higher the temperature the more quickly the micro-organisms are killed as shown in the diagram.
- The table shows the “D” values for G stearothermophilus at different temperatures.
- The relationship between D value (a function of time) and temperature is logarithmic so increasing the temperature by 10C increases the capacity of the process to kill microorganisms 10 fold.
  - Chemical reactions typically double for each 10C rise in T

The D value of spores of G stearothermophilus at different temperatures (min)	
110	76
115	16
121	2.5



Commonly Used Time Temperature Relationships for moist heat sterilization	
Temperature (º C)	**Time (mins)**
134	**3***
132	**4**
126	**10***
121	**15***
115	**30** *rarely used today*

***Medical Research Council ,Lancet. 1959 Feb 28;1(7070):425-35**

The importance of Moisture

- How long to boil or bake an egg ?

Moist Heat - 100 ° C – 4-7 minutes

People also ask

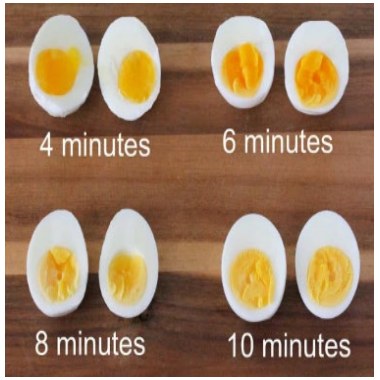
How long should you boil an egg for?

7 minutes

Place eggs in a large saucepan. Cover them with cool water by 1 inch. Cover pan with a lid and bring water to a rolling boil over high heat; when the water has reached a boil, set the timer for the desired time. Boil for 6 – **7 minutes** over medium-high heat for perfect hard boiled eggs.

How To Make Perfect Hard Boiled Eggs - How To Boil Eggs

https://www.deliciousmeetshealthy.com/how-to-make-perfect-hard-boiled-eggs/



- Dry Heat (<5% rh) 175 ° C – 30 minutes

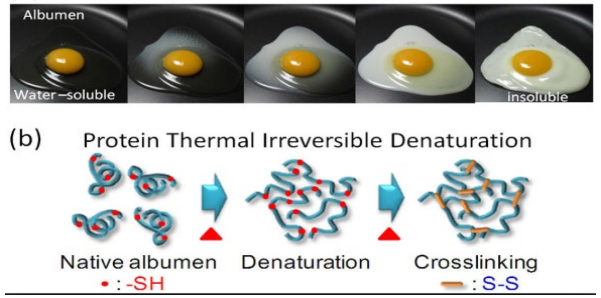
Directions

1. Preheat **oven** to 350 degrees F (175 degrees C).
2. Put 1 **egg** in each of 12 muffin cups.
3. **Bake** in preheated **oven** for 30 minutes.
4. Plunge **baked eggs** in a large bowl filled with ice water until cooled completely, about 10 minutes.

Hard Boiled Eggs in the Oven Recipe - Allrecipes.com

https://www.allrecipes.com/recipe/232024/hard-boiled-eggs-in-the-oven/

Microorganism	Moist Heat D value /Temp	Dry Heat D Value
G stearothermophilus	2 .5 minutes/121	
B coagulans	1.6 minutes/121	1000 mins / 110
B atrophaeus	0.44 minutes/121	

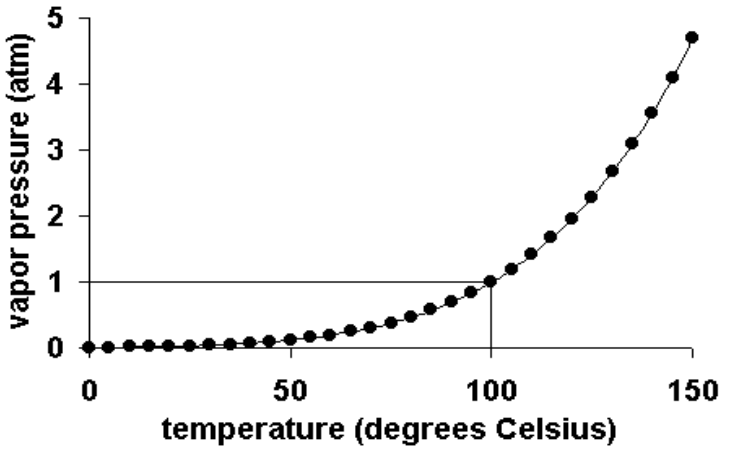


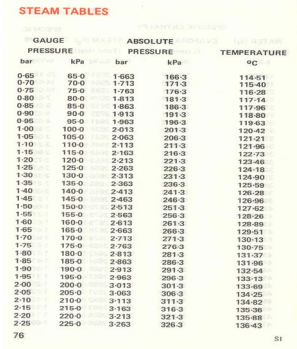
Water molecules “catalyse” these reactions.

Moist Heat Sterilization – the engineering

- At atmospheric pressure (1 bar) water / steam has T = 100 ^{o}C
- To get the high temperatures required to achieve rapid microbial inactivation steam needs to be pressurised
- The temperature of saturated steam is dependent on the pressure.
- As the pressure rises the temperature rises
  - the relationship is given in steam tables.
- In order to use pressurised steam we use a pressure vessel called an autoclave.
- In larger autoclaves steam is generated in a separate boiler and piped into the chamber

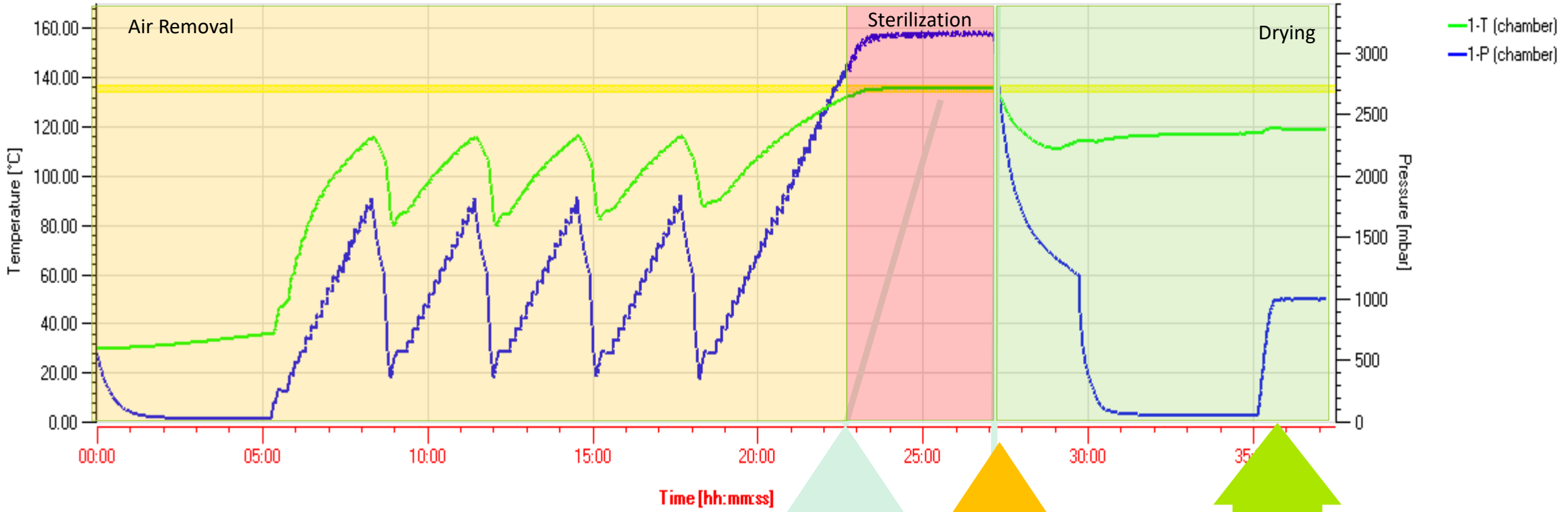
- ***Saturated steam is water vapour in equilibrium with liquid water.***
  - ***Describing bulk properties where some molecules condense and others vaporise***
  - ***Note at a given pressure***




STEAM TABLES

GAUGE PRESSURE		ABSOLUTE PRESSURE		TEMPERATURE
bar	kPa	bar	kPa	°C
0·65	65·0	1·663	166·3	114·61
0·70	70·0	1·713	171·3	115·40
0·75	75·0	1·763	176·3	116·28
0·80	80·0	1·813	181·3	117·14
0·85	85·0	1·863	186·3	117·96
0·90	90·0	1·913	191·3	118·80
0·95	95·0	1·963	196·3	119·63
1·00	100·0	2·013	201·3	120·42
1·05	105·0	2·063	206·3	121·21
1·10	110·0	2·113	211·3	121·96
1·15	115·0	2·163	216·3	122·73
1·20	120·0	2·213	221·3	123·46
1·25	125·0	2·263	226·3	124·18
1·30	130·0	2·313	231·3	124·90
1·35	135·0	2·363	236·3	125·59
1·40	140·0	2·413	241·3	126·28
1·45	145·0	2·463	246·3	126·96
1·50	150·0	2·513	251·3	127·62
1·55	155·0	2·563	256·3	128·26
1·60	160·0	2·613	261·3	128·89
1·65	165·0	2·663	266·3	129·51
1·70	170·0	2·713	271·3	130·13
1·75	175·0	2·763	276·3	130·75
1·80	180·0	2·813	281·3	131·37
1·85	185·0	2·863	286·3	131·96
1·90	190·0	2·913	291·3	132·54
1·95	195·0	2·963	296·3	133·13
2·00	200·0	3·013	301·3	133·69
2·05	205·0	3·063	306·3	134·25
2·10	210·0	3·113	311·3	134·82
2·15	215·0	3·163	316·3	135·36
2·20	220·0	3·213	321·3	135·88
2·25	225·0	3·263	326·3	136·43

What do we need to achieve in a saturated steam process?



At this point sufficient air removed from all load surfaces (external and internal) to ensure presence of moisture and load at sterilizing temperature.

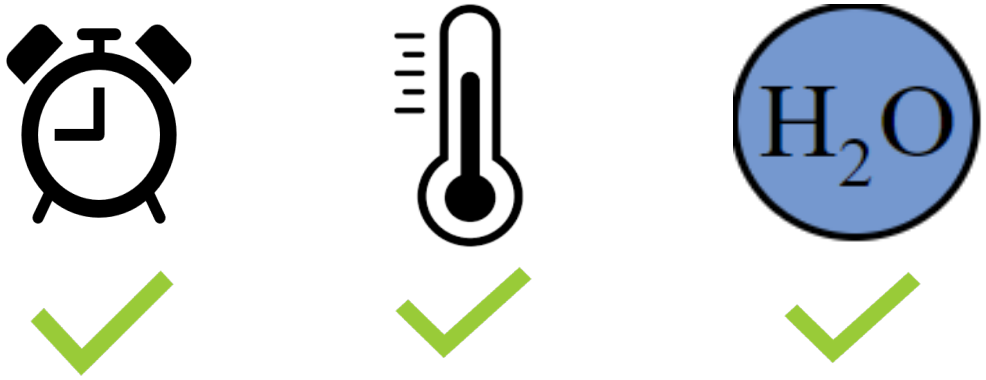
At this point sufficient time and temperature of exposure to ensure sterility (eg 134 to 137C for 3 mins)

At this point the load is sterile and dry

Monitoring Sterilization Processes using PI, CI & BI

Moist Heat Sterilization Process Variables

- Time
- Temperature
- Moisture



Process Variables are those which contribute to microbial kill and sterilization attainment.

INSIDE A PCD

Monitoring Sensors

Physical Indicators

Respond to the absence of air or detect presence of moisture

Chemical Indicators

Respond to defined process parameters

Biological Indicators

Respond to all process variables and demonstrate kill

Biological and Chemical Indicators and Lumened Process Challenge Devices -PCD

Home Made

EN ISO 17665 (10.5) states that
"*for saturated steam processes, the data shall include;*
d) ***the results obtained from a process challenge device."***

A PCD is an item designed to constitute a defined challenge to a sterilization process and is used to assess performance of every process.
PCD's come in many forms including customer made devices and those commercially manufactured.

- Commercially produced

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EU Medical Device Regulation

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- **Chapter 1, General Requirements.**
- **11.5 Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.**

Validation and Routine Testing

Proving what we want is what we get.

A sterile product

But who is responsible for what?

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Sterility Assurance is Achieved By;

Specifying;

Writing a detailed specification explaining what equipment is used, the process steps followed and how it is monitored

Reference to standards and regulatory requirement of great help in this process

Validating ;

Documenting and **carrying out** a procedure which provides data showing we get what we want; ie a sterile, safe, efficacious product.

Involves three steps – Installation Qualification, Operational Qualification and Performance Qualification

Routinely Monitoring;

Taking actions to ensure ongoing process efficacy.

STERILE PRODUCT

A sequence of actions which should be carried out. One step does not negate the need for the others.

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Validation is a three step process - IQ, OQ, PQ

Installation Qualification

Once the sterilizer has been installed by the supplier checks are made on such items as;

- Services –
- Electrical, Compressed Air, Steam quality, water supply, drainage,
- Fixtures and Fittings –
- The build of the sterilizer
- Safety Systems

Operational Qualification

The sterilizer is put through a series of tests, some of which are described in standards (eg EN 285) or local guidance documents to confirm that it provides basic performance requirements.

This can include suchs tests as BDT, Thermometric Small and Full Load tests etc

Performance Qualification

During this stage evidence is generated which demonstrates that the sterilizer can sterilize the loads which will be presented to it.

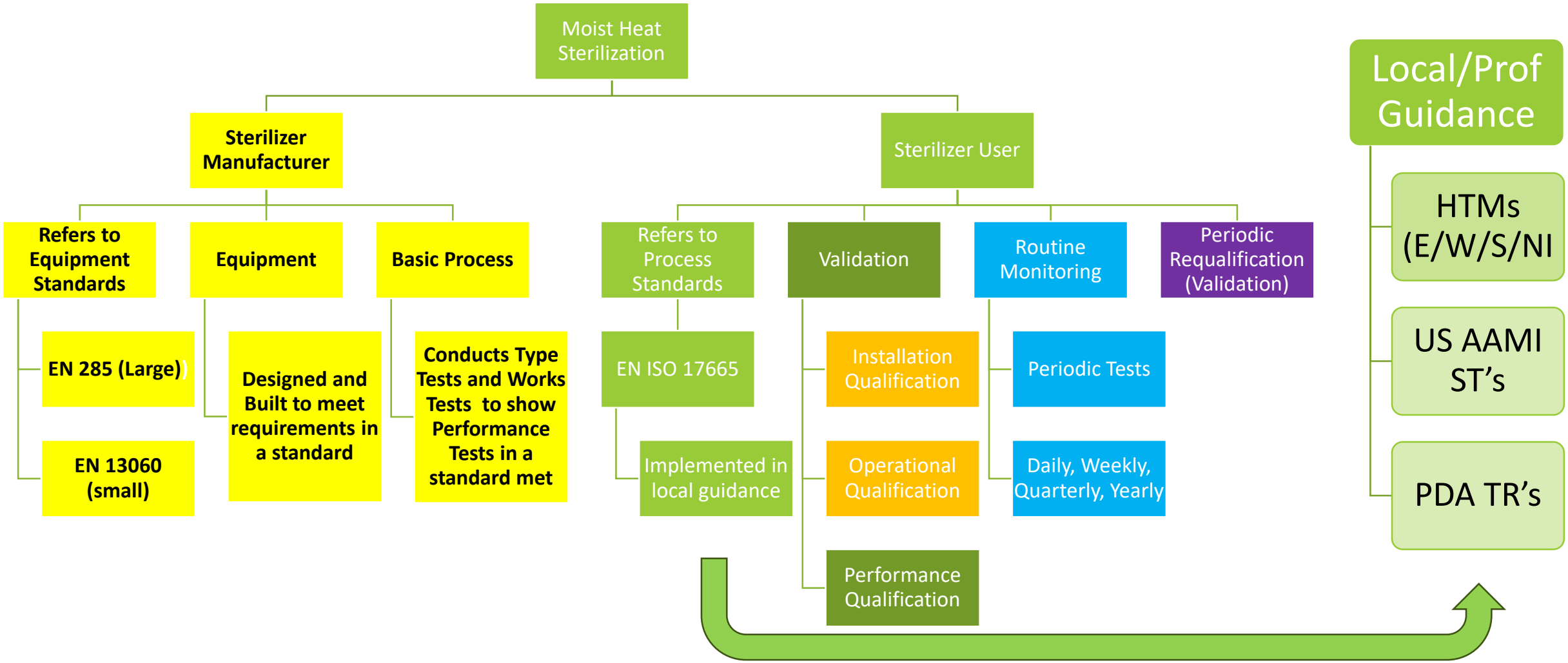
This is department specific since the loads will depend on what needs to be processed.

Products can be grouped into product families and processing categories to simplify PQ

Carried Out by User or Manufacturer/Supplier → Carried Out by the User

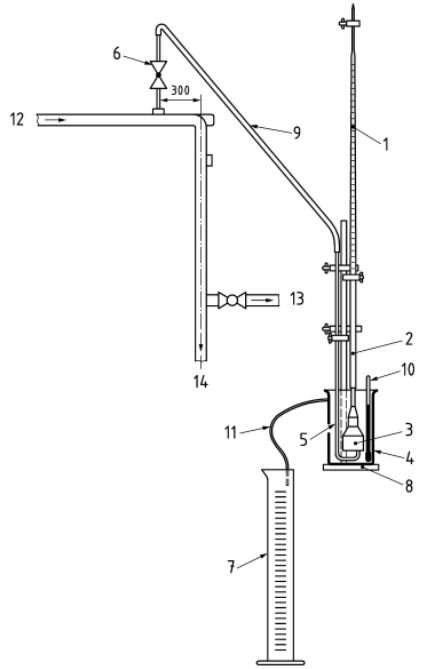
© 3

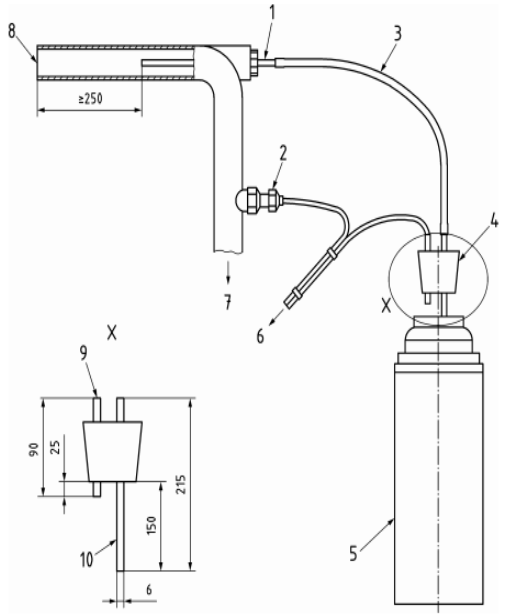
Responsibilities

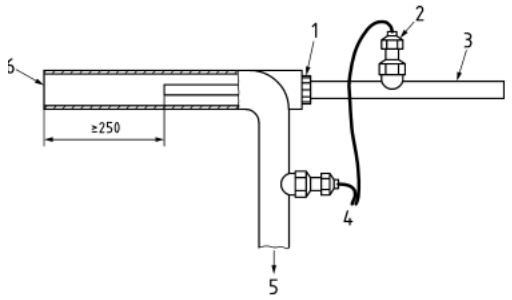


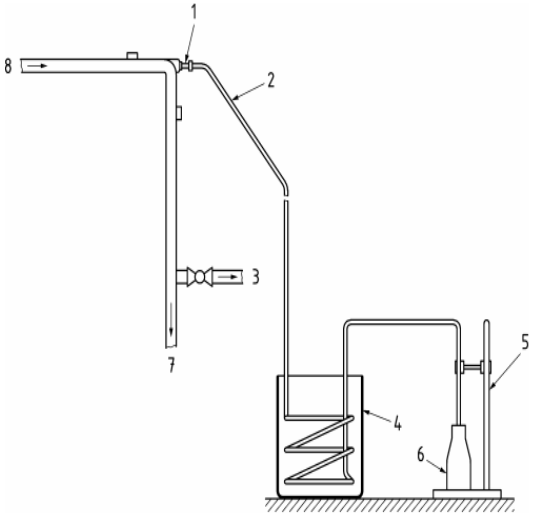
EXAMPLE OF IQ/OQ TESTS -STEAM QUALITY

NCG	DRYNESS VALUE	SUPERHEAT	CONTAMINANTS
• < 3.5 ml gas in 100ml condensate	• 0.95 • (5% liquid water)	• <25°C	• CHEMICAL • BIOCHEMICAL • PHYSICOCHEMICAL









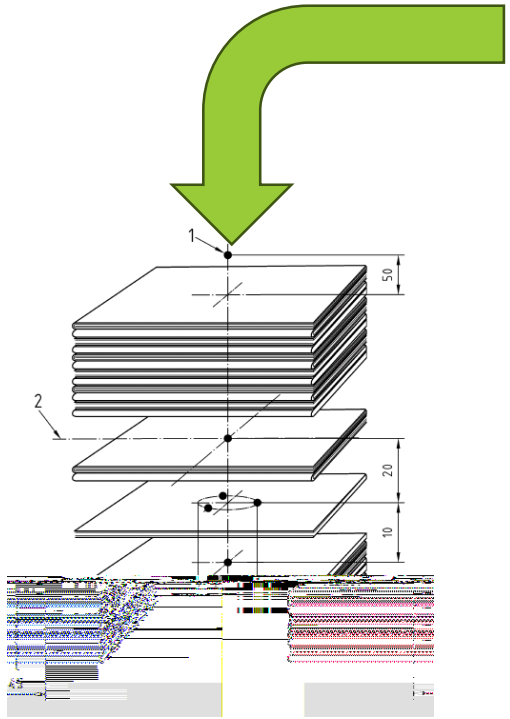
Examples of Operational Qualification Tests

- EN 285 and EN 13060 test methods and approaches which establish the air removal and steam penetration performance of the sterilizer based on the thermometric and chemical indicator performance of a stack of textiles and a coiled helix

- plus LRT, ADT, Load Dryness, Dynamic P test, ACT

Standard Test Pack Tests

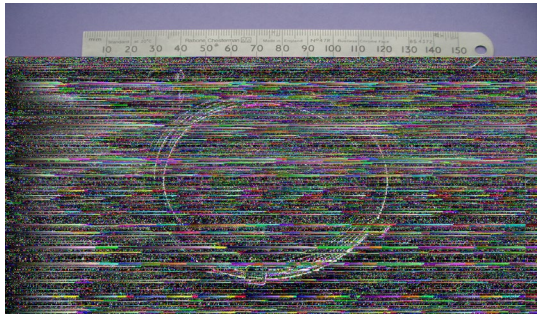
Small Load Thermometric



Full Load Thermometric

Bowie and Dick

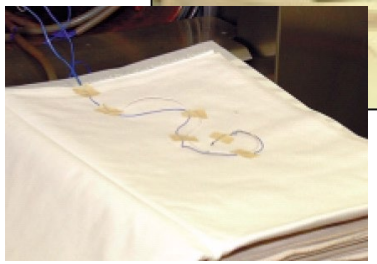
Hollow Load Test



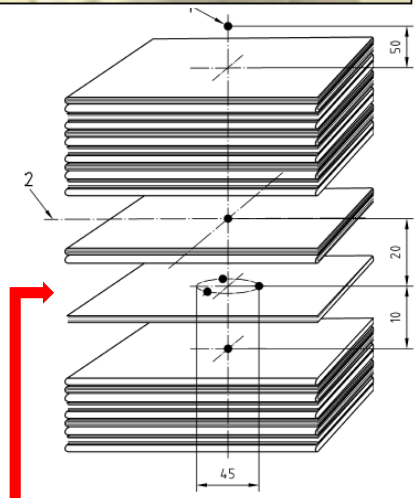
Expose Test PCD to a full cycle

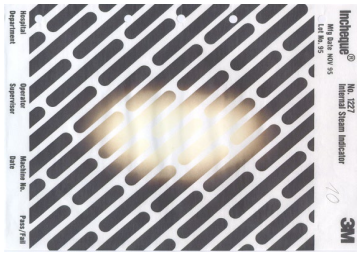
Accept Or Reject

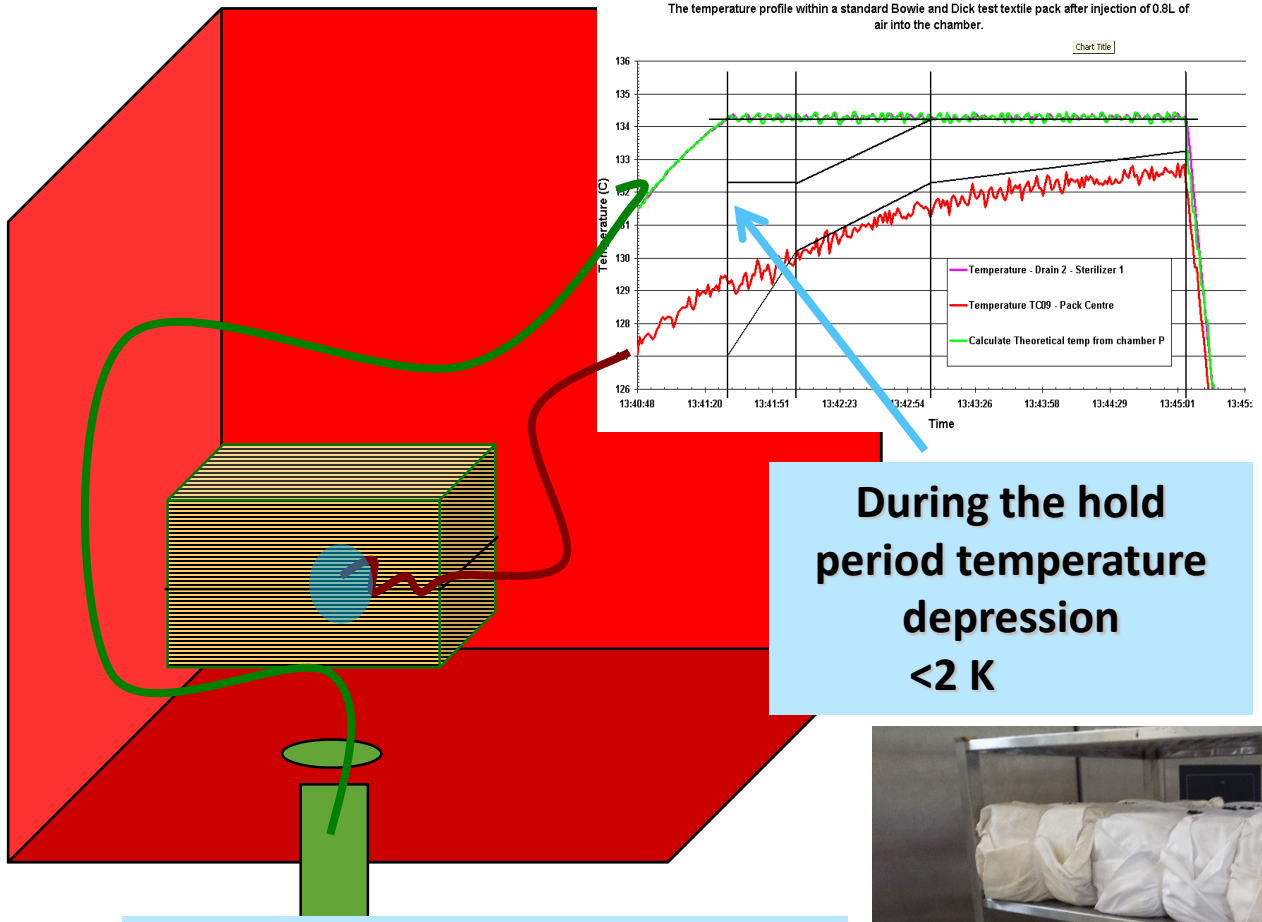
The Thermometric Test, Small & Full Load



Temperature Sensor Positions







During the hold period temperature depression <2 K

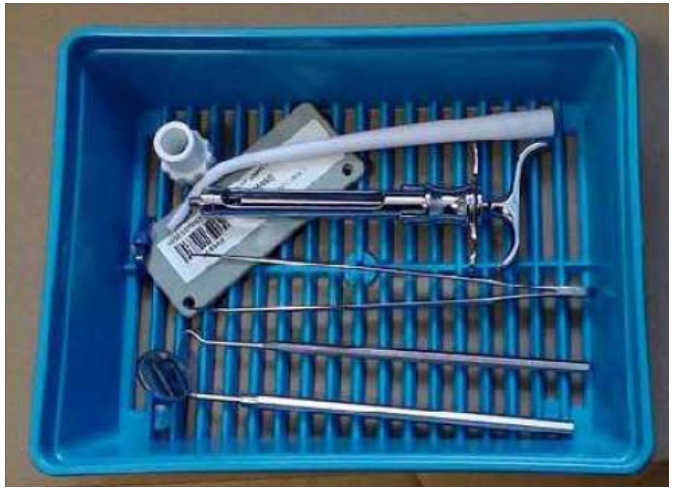
Full Load:
Same but fill empty space with additional textile packs

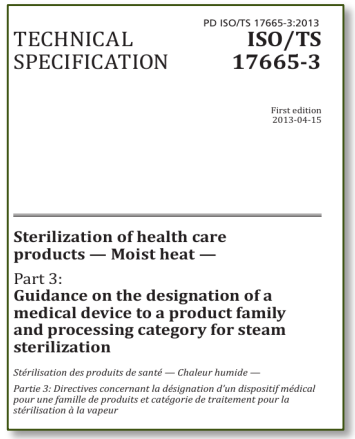
Examples of Performance Qualification

1. Loads categorised into **product families** and **processing categories i**n terms of sterilizability. Factors to consider;
   - Air removal / Steam Penetration
   - Weight (ease of drying)
   - SBS in use
   - Nature of the instrument;
   - Solid metal
   - Hollow instrument
   - Complex eg lumen surrounded by different materials eg Phaco

2. Select harder to sterilize loads for testing using thermometric measurement and CIs and BIs if appropriate

E3 – medium to low complexity, suction tip most challenging





PD ISO/TS 17665-3:2013

TECHNICAL SPECIFICATION

ISO/TS 17665-3

First edition
2013-04-15

Sterilization of health care products — Moist heat —

Part 3:
Guidance on the designation of a medical device to a product family and processing category for steam sterilization

Stérilisation des produits de santé — Chaleur humide —

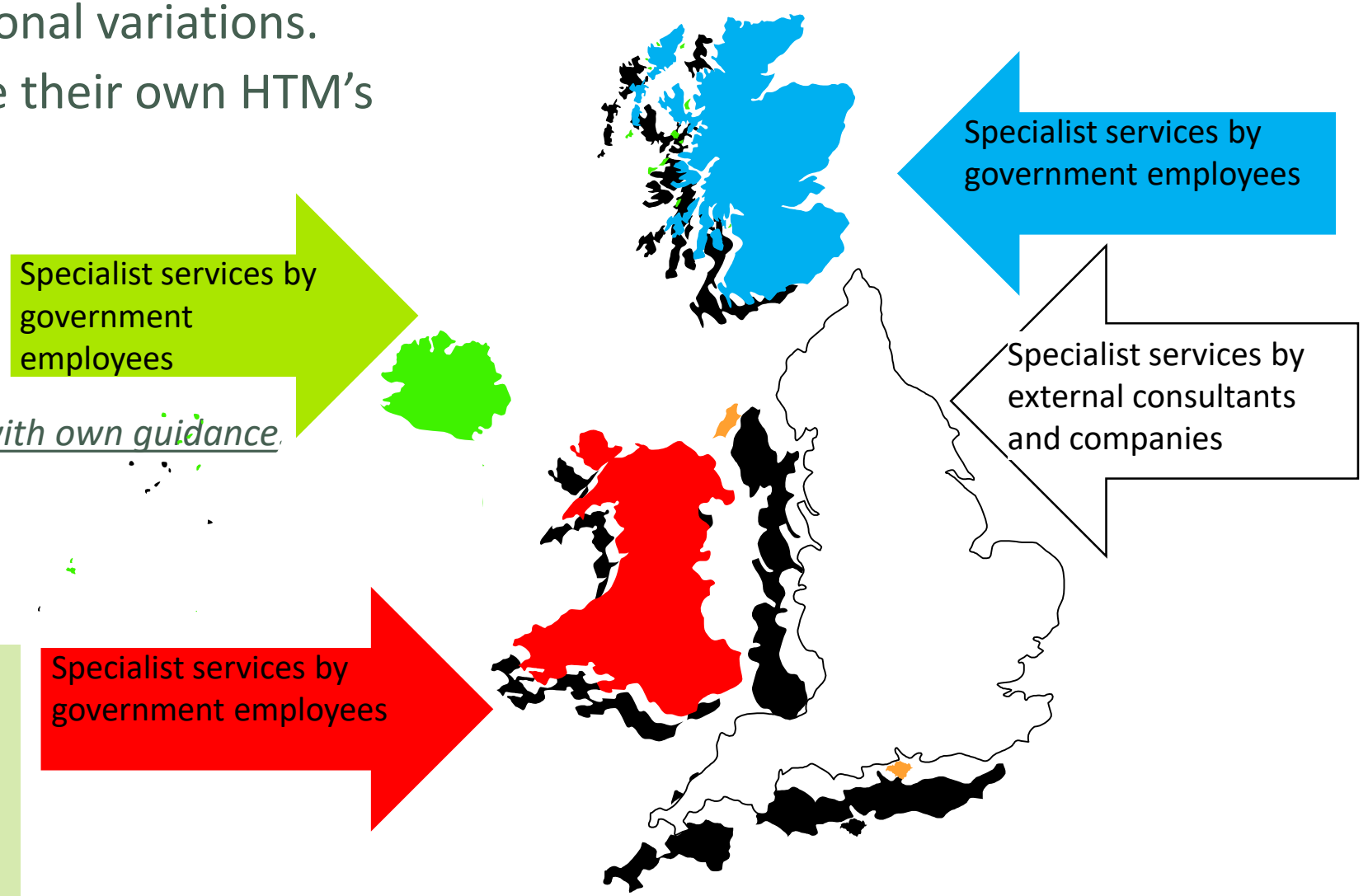
Partie 3: Directives concernant la désignation d'un dispositif médical pour une famille de produits et catégorie de traitement pour la stérilisation à la vapeur

E7+ - very complex set, heavy (10kg) with complex lumened devices

The UK approach to Validation and Routine Contro of steam sterilizers

The UK guidance

- Devolution has created regional variations.
- Scotland, NI and Wales have their own HTM's
  - England – HTMs
  - Wales – Welsh HTMs)
  - NI – Test Protocols
  - Scotland – SHTM's
  - *Note: Ireland is a separate state with own guidance*



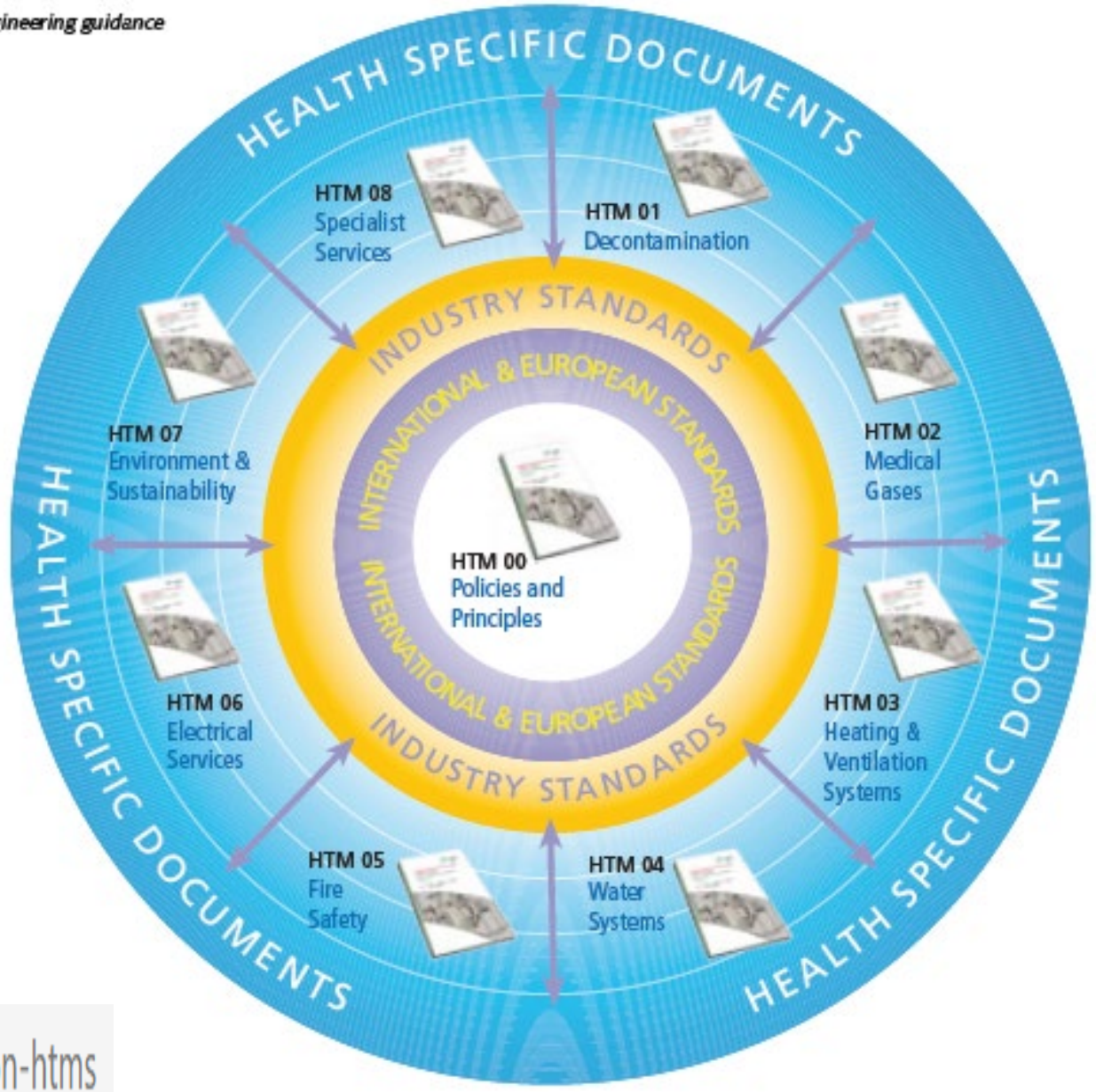
Specialist services are provided by suitably trained and experienced sterilization technologists either employed, independent or part of a manufacturers organization.

The Health Technical Memoranda Suite of Documents Published by UK Dept Health

Nine core documents

- 00 – Core Policy
- 01 – Decontamination
- 02 – Medical gases
- 03 – Ventilation
- 04 – Water
- 05 – Fire
- 06 – Electrical
- 07 – Environment
- 08 – Specialist

Figure 2 Engineering guidance

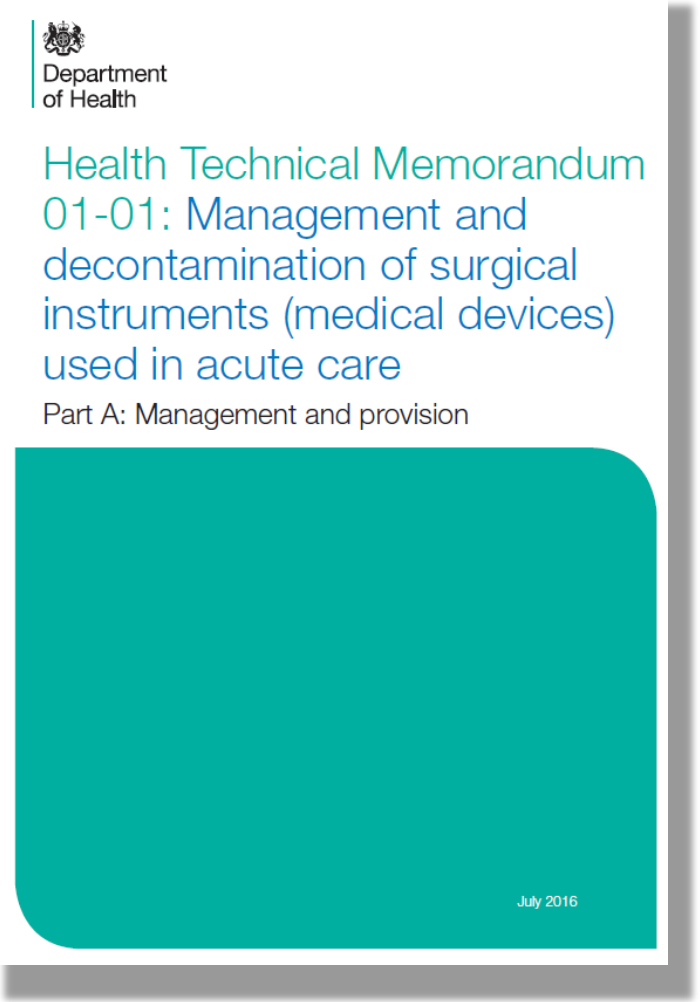


https://www.england.nhs.uk/estates/health-technical-memoranda/#decontamination-htms

Health Technical Memorandum - 01-01

Management and Decontamination of Surgical Instruments in Acute Care

- Part A – Management & Environment
  - Formulation of LOCAL policy based on risk control
- Part B – Common Elements
  - Instruments, engineering specification, responsibility, safe ops.
- Part C – Steam Sterilization
  - Validation and Routine Control and Testing
- Part D – Washer Disinfectors
  - Validation and Routine Control and Testing
- Part E – Alternatives to Steam
  - General discussion on Low Temperature Sterilization
  - Specifically on EO and vH2O2.



Validation and Periodic Tests according to UK Guidance and EN ISO 17665

Test	IQ	OQ	PQ	Annual	Quarterly	Weekly	Daily
Bowie and Dick Test		Yes		Yes	Yes	Yes	Yes
Safety Checks (weekly/ quarterly / annual)	Yes			Yes	Yes	Yes	
Automatic Control Test		Yes		Yes	Yes	Yes	
Air Leakage Test		Yes		Yes	Yes	Yes	
Air Detector Function Test		Yes		Yes	Yes	Yes	
Calibration Checks		Yes		Yes	Yes		
Thermometric Test – Small Load		Yes		Yes	Yes		
Non Condensable Gas in Steam		Yes		Yes			
Steam Dryness		Yes		Yes			
Steam Superheat		Yes		Yes			
Steam Chemical Contaminants		Yes		Yes			
Thermometric Test - Full Load		Yes		Yes			
Hollow Load Test		Yes		Yes			
Air Detector Performance Test – Small Load		Yes		Yes			
Air Detector Performance Test – Full Load		Yes		Yes			
Load Dryness – small load textiles		Yes					
Load Dryness – full load textiles		Yes					
Load Dryness – Metal Load		Yes		Yes			
Production Load Dryness			Yes	Yes			
Production Load cycle compatibility test			Yes	Yes			
Dynamic Pressure Test – as specified by manuf and InsCo							

Validation and Routine Tests in UK Guidance

Table 3 Schedule of testing for porous-load sterilizers

TEST	IQ	OQ	PQ
Weekly safety checks	X		
Non-condensable gas test		X	
Steam dryness test		X	
Steam superheat test		X	
Steam contaminants		X	
Automatic control test		X	
Thermometric test for a small load*		X	
Thermometric test for a full load		X	
Hollow load test		X	
Bowie-Dick test for steam penetration*		X	
Air leakage tests ×3		X	
Air detector performance test for a small load		X	
Air detector performance test for a full load		X	
Air detector function test		X	
Load dryness – small load textiles		X	
Load dryness – full load textiles		X	
Load dryness – metal (where required by the AE(D)) (see BS EN 285)		X	
Production load dryness test			X

* The automatic control test may be carried out at the same time as these tests.

Table 4 Periodic tests for porous-load sterilizers

Daily test – User

Bowie-Dick test for steam penetration

Weekly tests – CP(D)

1. Weekly safety checks
2. Air leakage test
3. Air detector function test
4. Automatic control test
5. Bowie-Dick test for steam penetration*

Quarterly tests – CP(D)

1. Weekly safety checks
2. Air leakage test
3. Air leakage test (temperature and pressure sensors connected)
4. Automatic control test
5. Verification of calibration of sterilizer instruments*
6. Thermometric test for a small load*
7. Air leakage test (sensors removed)
8. Air detector function test
9. Bowie-Dick test for steam penetration

Yearly and revalidation tests – CP(D)

1. Yearly safety checks
2. Non-condensable gas test
3. Steam superheat test
4. Steam dryness test
5. Steam chemical purity tests
6. Air leakage test
7. Air leakage test (temperature and pressure sensors connected)
8. Automatic control test
9. Verification of calibration of sterilizer instruments*
10. Air detector performance test for a small load
11. Air detector performance test for a full load
12. Thermometric test for a small load
13. Thermometric test for a full load
13a. Load dryness test for a metal load (see BS EN 285)
14. Test for PRQ as required by the user
15. Air leakage test (sensors removed)
16. Air detector function test
17. Bowie-Dick test for steam penetration
18. Hollow load test

At a frequency defined by the manufacturer

1. Dynamic pressure test

* May be carried out simultaneously with the preceding test

What can contribute to the Green Light ?

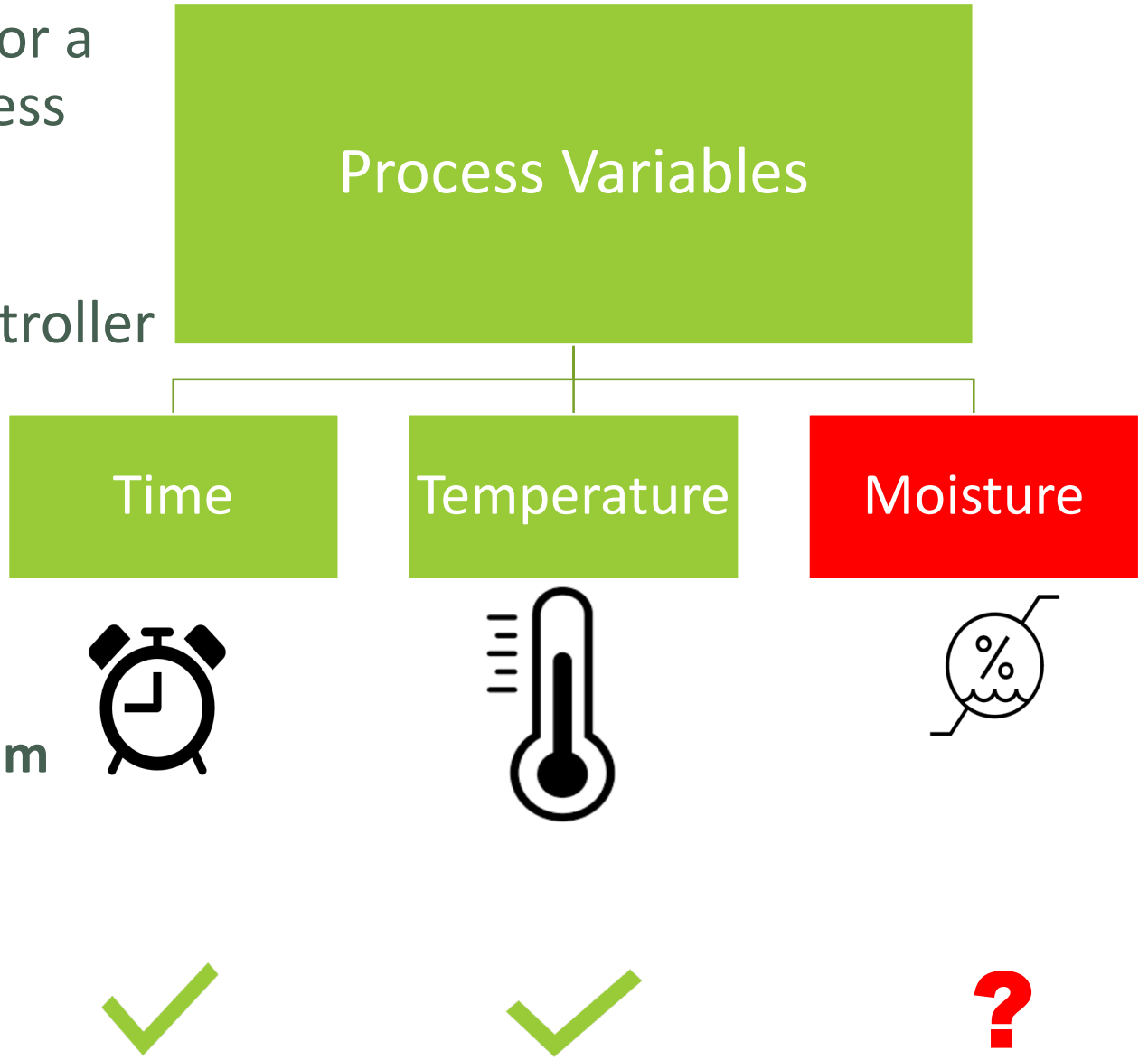
On-board sensor systems.

Routine Monitoring using “on-board” Physical Indicators

Physical Indicators are those which monitor a physical property of the sterilization process mounted on the sterilizer

Thus;

- **Time** - measured by the automatic controller
- **Temperature** - measured by sensors
  - Depends on location
- **Moisture**
  - How?
  - Moisture Sensors?
  - **Absence of air implies presence of steam hence moisture – air detectors?**
- Pressure measured by sensors
  - P is a cycle variable

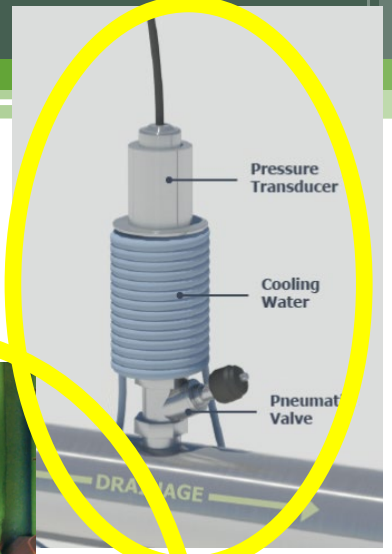


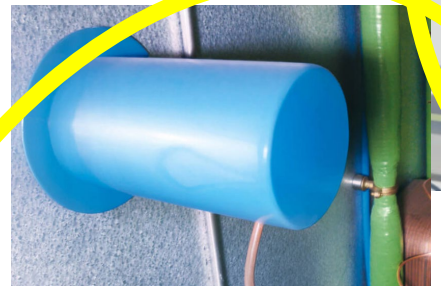
Air / Steam Detectors ?

- ***Every UK porous load sterilizer has an air detector fitted (an option in EN285)***

Principle of Operation:

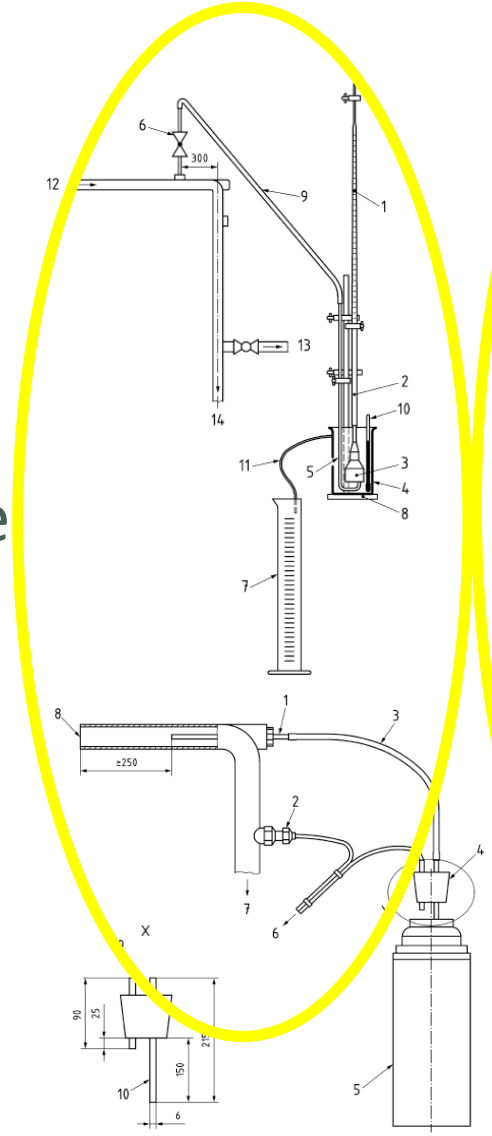
- Residual Pressure Based.
  - Capsule connected to the chamber drain sample content of chamber
  - Controller isolates the capsule, condenses the steam, measures residual pressure
  - If above a preprogrammed value – cycle aborted
- Temperature Based
  - Long thin tube attached to the chamber drain with vertical orientation.
  - Temp sensor located at the closed end of the tube.
  - Residual air reduces the temperature
  - Controller aborts the process is temp below a preset level
- Optical Based.
  - Long thin tube attached to chamber or drain with vertical orientation
  - Optical sensor mounted along the length differentiating air from steam.
  - If residual air forms a pocket in the tube, optical sensor detects and aborts cycle.

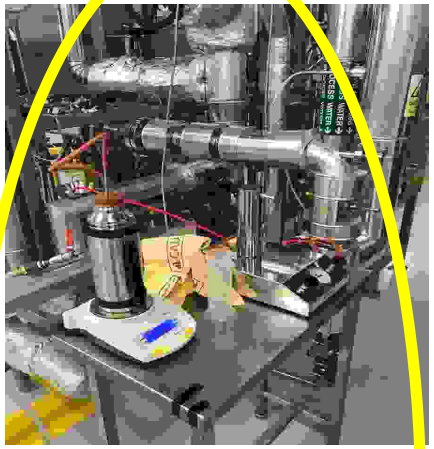


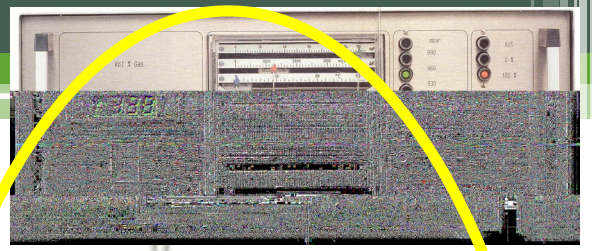


AUTOMATIC STEAM QUALITY TESTS

- Standard methods for determining NCG and Dryness fraction are found in ISO 17665 and EN 285.
- Easy to use kit forms are available
- In line devices are also available giving continuous readout but usually fitted up-stream of chamber







Conclusions:

The responsibility for producing a sterile product rests with the User.

> We cannot assume that upon delivery a sterilizer is working correctly.

Validation tests are needed to confirm (IQ/OQ)

> We cannot assume that a sterilizer will effectively process every load item and load configuration we throw at it

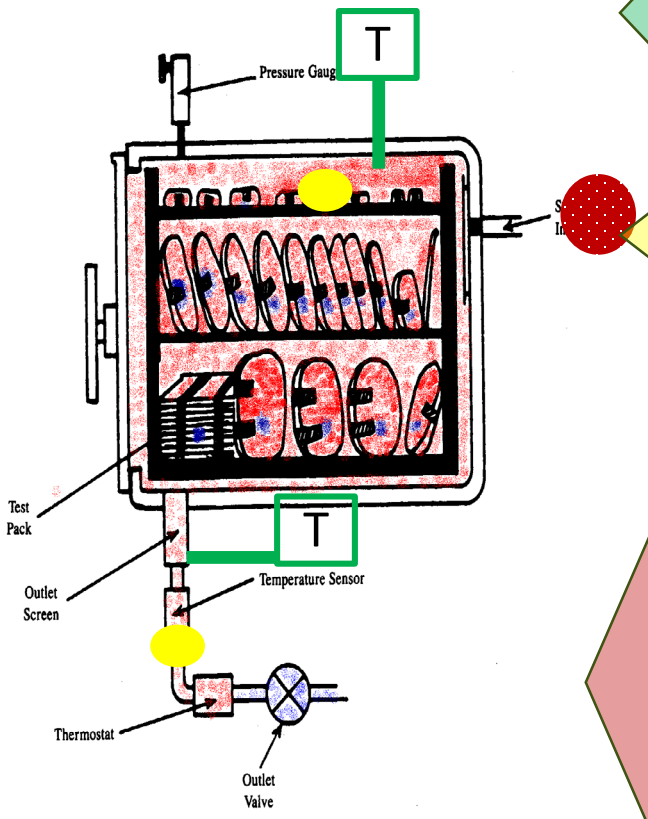
Validation tests are needed to confirm this (PQ).

> We cannot assume that a sterilizer will perform the same every time we use it.

Routine confirmatory tests are required on every load

THE END – QUESTIONS?

Detection of Pass/Failure by “on-board” sensors



Time/ Temperature Failures – No issue – control system deals with it

But Temperature depends on where temperature is measured from

Drain – close to chamber or deep within – thermal lag

Chamber temp – top or bottom

AR&SP

Monitored by Air / Steam Detectors

Depends where located eg drain, chamber

Steam Quality – All measured up stream from the supply pipe not the chamber

NCG

EN285 method > often infrequent eg quarterly, inherent bias eg solubility of CO_2 a major NCG. Method and operator dependent

Dryness Fraction

EN285 method very dependent on method and operator – crude calorimeter

Superheated steam

EN285 method crude and of uncertain provenance

Routinely T/P correlation possible by controller but again measurement point dependent and not all sterilizers do this.

What do you do if your control system does not have this level of sophistication?

Content

- Regulatory Requirements, Patient Safety
- Some definitions, Sterile, Sterilization, Validation
- Processes which can be used
- Sterilizer and Sterilization standards
- How to achieve a sterile product - Exposure to Process Variables
- As an example Moist Heat
- Process variables for Moist Heat
- How to demonstrate presence of PV's – PIs BIs CIs
- Examples of PI's including built in devices
- How to ensure a satisfactory Process – Use of a correctly designed and validated sterilizer and sterilization process and on going routine testing.
- The design and testing of a moist heat sterilizer – EN 285, 13060
- Approach for validation of a moist heat sterilizer – EN ISO 17665:2024
- What is Type Testing / Works Testing
- What is validation – IQ, OQ, PQ – model loads/product families
- Routine testing using HTM01 01 program of periodic testing.
- Does the inbuilt monitoring systems tell you what you need to know? Air detectors, steam quality testing, etc

What can contribute to the Green Light Syndrome

The green light says yes.

But what does this mean?

- Many will assume an efficacious sterilization process yielding a sterile load and may release the load based on this

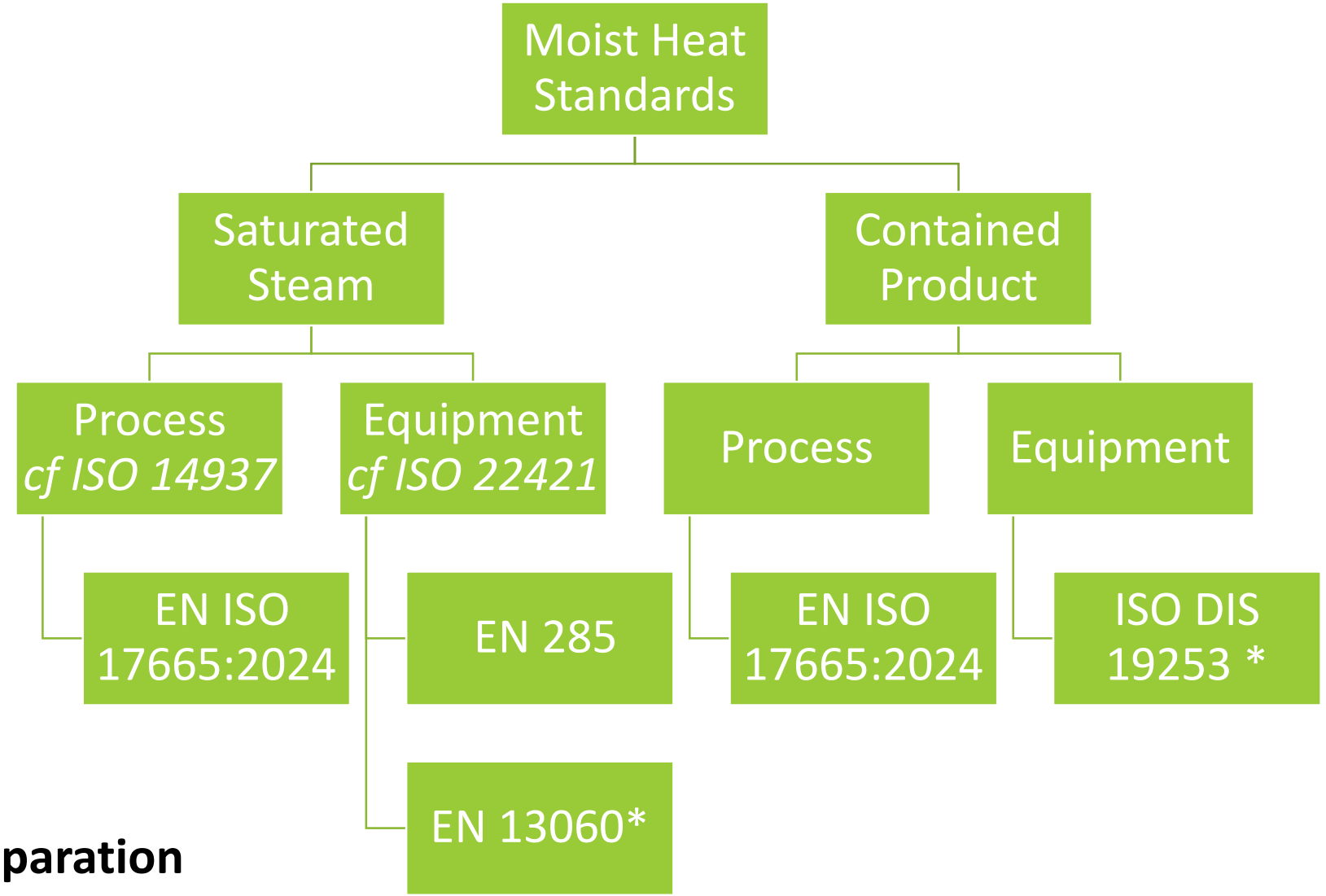
How true is this?

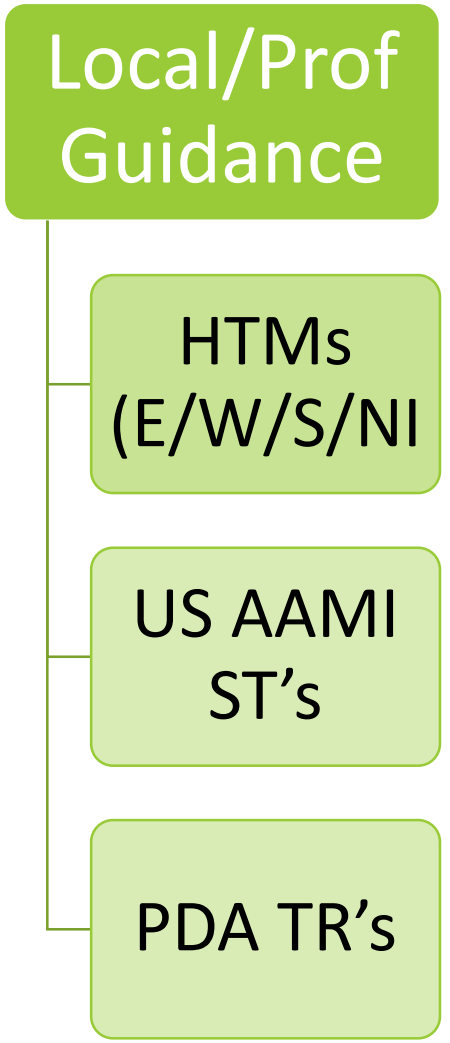
- This depends on the extent of process validation and the "on-board" monitoring systems which allow the controller to make a judgement against pre-set specification and settings.

But what if we are not monitoring all of the process variables which yield a sterile product?

- Lets examine what we need to monitor, how we can do it and what can go wrong.

Standards for Moist Heat Sterilization





- *** In preparation**

Some important definitions to consider in relation to MDR 11.5

- **Sterile / Sterility**
  - State of being free from viable microorganisms
- **Process/ processing**
  - Activity to prepare a new or used health care product for its intended use
- **Packaging (system)**
  - Combination of a sterile barrier system and protective packaging
- **Sterile Barrier System (SBS)**
  - Minimum package that minimises the risks of ingress of microorgansims and allows aseptic presentation of the sterile contents at the point of use
- **Sterilize / sterilization**
  - Validated process used to render product free from viable microorganisms (sterile)
- **Validation**
  - Confirmation process, through the provision of objective evidence, that the requiremensts for a specific intended use of application (a sterile product) have been fulfilled

- *From ISO 11139: 2018/Amd1:2025*

Consequences of non-sterile items being used

Basic requirements

Steam or Moist Heat sterilization is achieved by exposing surfaces which need to be sterilized (the medical device) to;

- Adequate temperature eg 121 ^{o}C or 134 ^{o}C
- Adequate time eg 15 mins or 3 mins
- In the presence of moisture ie water molecules which may be in vapour or liquid state.
- These are the “Process Variables” for a moist heat sterilization process (ISO 17665)
  - **Note pressure does not contribute to microbial kill. It is a cycle variable used to control the process.**

3.213
process variable
chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLE: Time, temperature, pressure, concentration, humidity, wavelength.
ISO 11139:2018 Sterilization of health care products - Vocabulary – Terms used in sterilization and related equipment and process standards (ISO11139:2018)

Commonly Used Time Temperature Relationships for moist heat sterilization

Temperature (^{o} C)	Time (mins)
134	3*
132	4
126	10*
121	15*
115	30 *rarely used today*

***Medical Research Council ,Lancet. 1959 Feb 28;1(7070):425-35**

Rates of Surgical Site Infection:

- The EU rates of Surgical Site Infection (SSI) range from 0.5 to 9%.
- This is extremely damaging to patient wellbeing causing morbidity and mortality.
- This also costs HC Systems many Millions of Dollars per annum and increases patient hospital (re) admission by many days.
  - $4000 to $22000 per patient incident
- SSI can be reduced by careful elimination of each link in the chain of infection.
- One such link which can be broken is to ensure the delivery of surgical instruments to the surgeons hands which are;
- **Clean, Sterile and Ready for use**
  - **(undamaged and functional)**

https://www.eloquesthealthcare.com/2018/07/11/financial-impact-of-surgical-site-infections-ssis/

https://www.onetogether.org.uk/downloads/OneTogether%20Surgical%20Environment%20Guide.pdf

Dirty Instruments, unprocessed surgical sets, stained packs - 2016

Improperly Sterilized Surgical Instruments Harming U.S. Patients

December 30, 2016 by Richard D. Fox

Issues with Sterilization in American Hospitals

In September 2016, state and federal regulators conducted a surprise inspection of the central sterile processing department at Detroit Medical Center after problems emerged suggesting improperly sterilized surgical instruments. The Detroit News reported that internal e-mails and reports indicated that surgeons and staff had been complaining for more than a decade about dirty, broken, and missing instruments. In early 2015, open-heart surgery on a seven-month-old baby had to be halted when a tube in the bypass machine was found to be clogged with blood from another patient.

In 2014, a number of surgical patients were put at risk of serious infection when the doctors and nurses at Abbott Northwestern Hospital in Minneapolis used non-sterilized equipment such as clamps and scissors during procedures. USA Today reported that the largest hospital in the Twin Cities area suffered a major breakdown in safety when 14 sets of unsterilized instruments were released for use.

Surgeries were put on hold at Adena Regional Medical Center in Chillicothe, Ohio, in 2014 when a staff member noticed rust-colored stains on surgical towels that were supposedly sterile. The Chillicothe Gazette reported that although the problem was fixed a few days later, the root cause was never identified.

DIRTY INSTRUMENTS

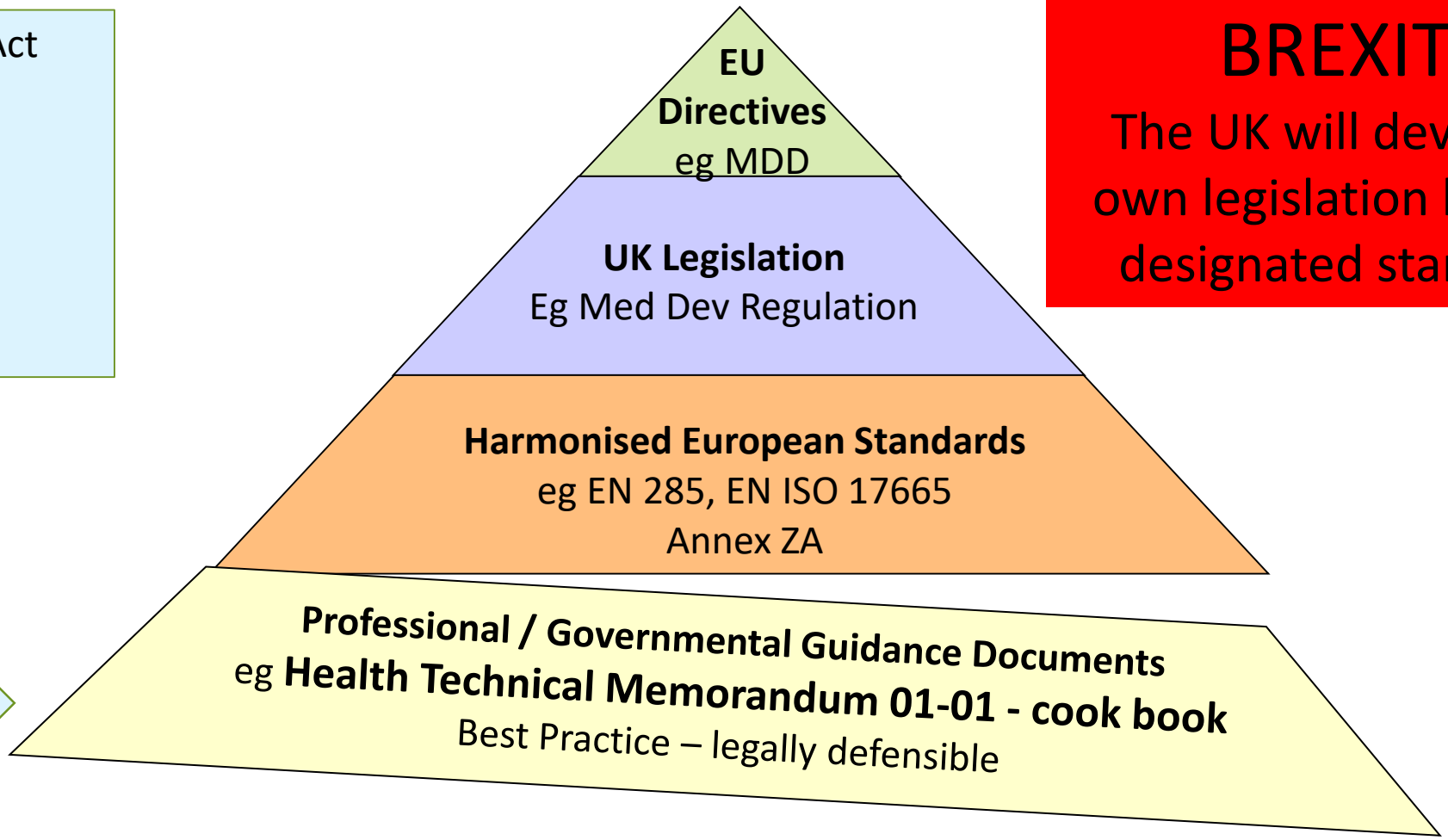
UNPROCESSED NON-STERILE SETS

RECONTAMINATED SETS

https://www.sommerspc.com/blog/2016/12/improperly-sterilized-surgical-instruments-harming-u-s-patients/

The relationship of standards & UK guidance to legislation

Health and Social Care Act
NICE
CQC
MHRA
Notified Bodies
HealthWatch
ACDP



BREXIT ?

The UK will develop its own legislation linked to designated standards.

ISO 17665 – medical devices Transition from three parts to one part

In 2017 revision begins to revise, update and combine


EN ISO 17665-1:2006

INTERNATIONAL STANDARD **ISO 17665-1**

First edition 2006-08-15

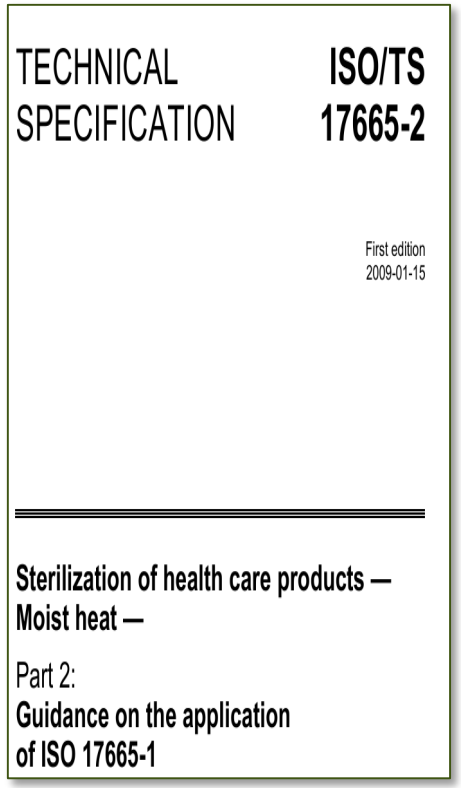
Sterilization of health care products — Moist heat —

Part 1:
Requirements for the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Chaleur humide —

Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux

2006
Core
requirements

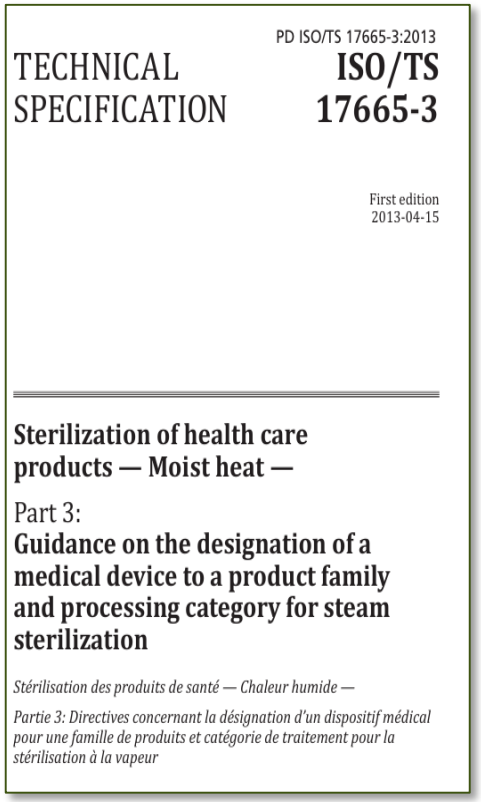

TECHNICAL SPECIFICATION **ISO/TS 17665-2**

First edition 2009-01-15

Sterilization of health care products — Moist heat —

Part 2:
Guidance on the application of ISO 17665-1

2009
Extensive
Guidance


PD ISO/TS 17665-3:2013

TECHNICAL SPECIFICATION **ISO/TS 17665-3**

First edition 2013-04-15

Sterilization of health care products — Moist heat —

Part 3:
Guidance on the designation of a medical device to a product family and processing category for steam sterilization

Stérilisation des produits de santé — Chaleur humide —

Partie 3: Directives concernant la désignation d'un dispositif médical pour une famille de produits et catégorie de traitement pour la stérilisation à la vapeur

2013
Product Families
designation aimed at
HC


ISO

International Standard

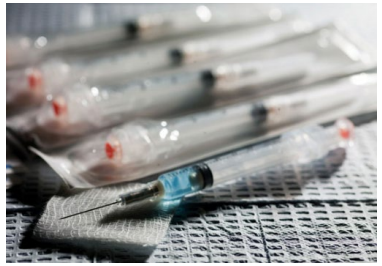
ISO 17665:2024

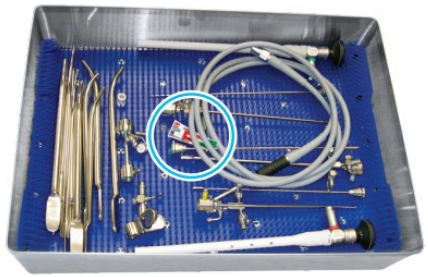
Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

Edition 1
2024-03

2024
Requirements + Guidance + PF
as informative annex

17665 – Moist Heat Sterilization HCP





- SSS
- Passive Purging (Gravity Displacement)

SSS Ind

CPS Ind

- Heat Transfer by
- SS
- SAM
- Water Sprays
- Water Immersion

SSS HC

- SSS
- Active Air Removal; (pre-vac)

CPS HC

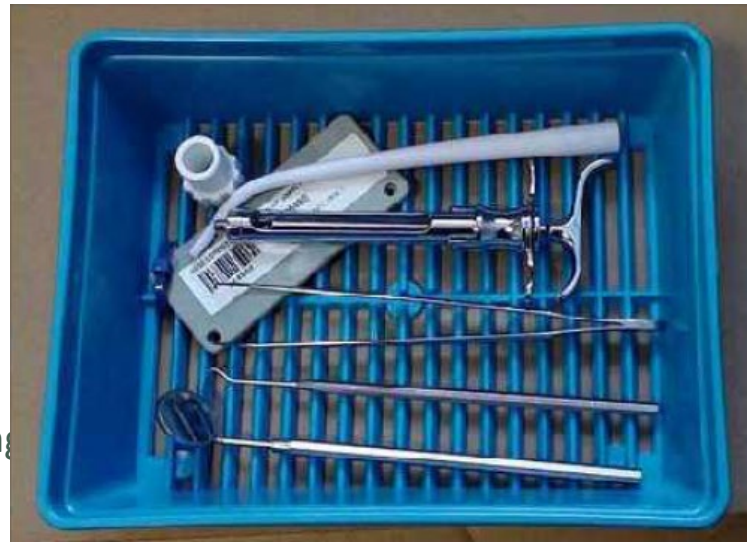
Although the scope of this document is limited to medical devices, it specifies requirements and provides guidance that can be applicable to other health care products and industrial applications

The Importance of Air removal and Steam penetration into loads- The Challenges

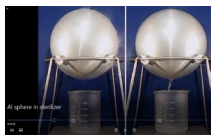
Typical load configurations (product families);

Simple – Solid instruments wrapped in permeable sterile barrier systems

- Challenges – air removal and steam penetration relatively easy
- BUT
- Heavy solid sets may create foci for barrier layers of NCG around the device impedin
- Heavy solid sets in containers which do not allow free drainage – video.



- Complex – complex instruments with cavities and lumen
- Challenges – air removal and steam penetration can be difficult
- Heavy porous masses – textile BDT
- Complex lumens – factors in Air removal and steam penetration
  - Bore and length and the ratio between them (literature evidence)
  - Surrounding mass and thermal conductivity (evidence)



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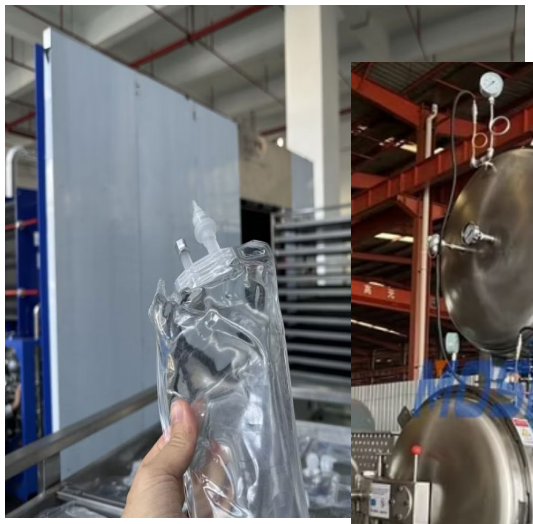
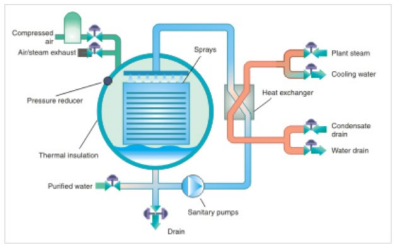
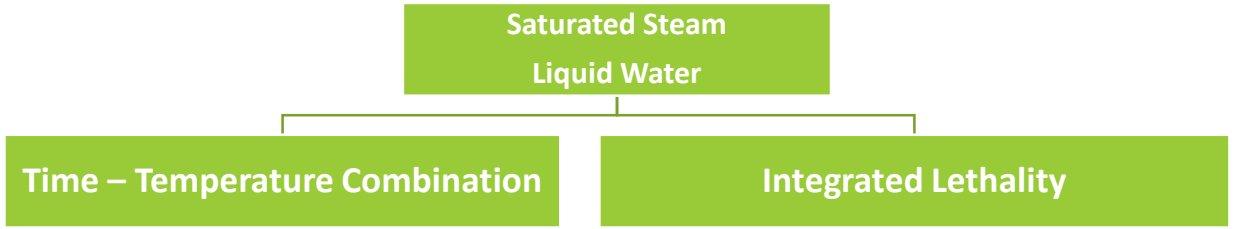
Moist Heat Sterilization - Sterilizers





Moist Heat Sterilization Processes



Commonly Used Time Temperature Relationships for moist heat sterilization	
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126	10*($F_0$31)
121	15*($F_0$15)
115	30($F_0$7.5) *rarely used today*

*Medical Research Council Lancet. 1959 Feb 28;1(7070):425-35
Perkins, 1956
Underwood, 1934

ANNEX B

Establishment and evaluation of a sterilization process primarily based on microbiological inactivation

Developed by Industry Experts for Industrial Moist Heat Sterilization based on four approaches;

B2 Bioburden

- Least conservative approach with a sterilization process specifically designed for a specified product which will have limited heat tolerance.
- Must know BB

B3 BB/BI

- Sterilization process designed on the basis of a knowledge of the resistance of bioburden but also inactivation of a biological indicator with greater resistance

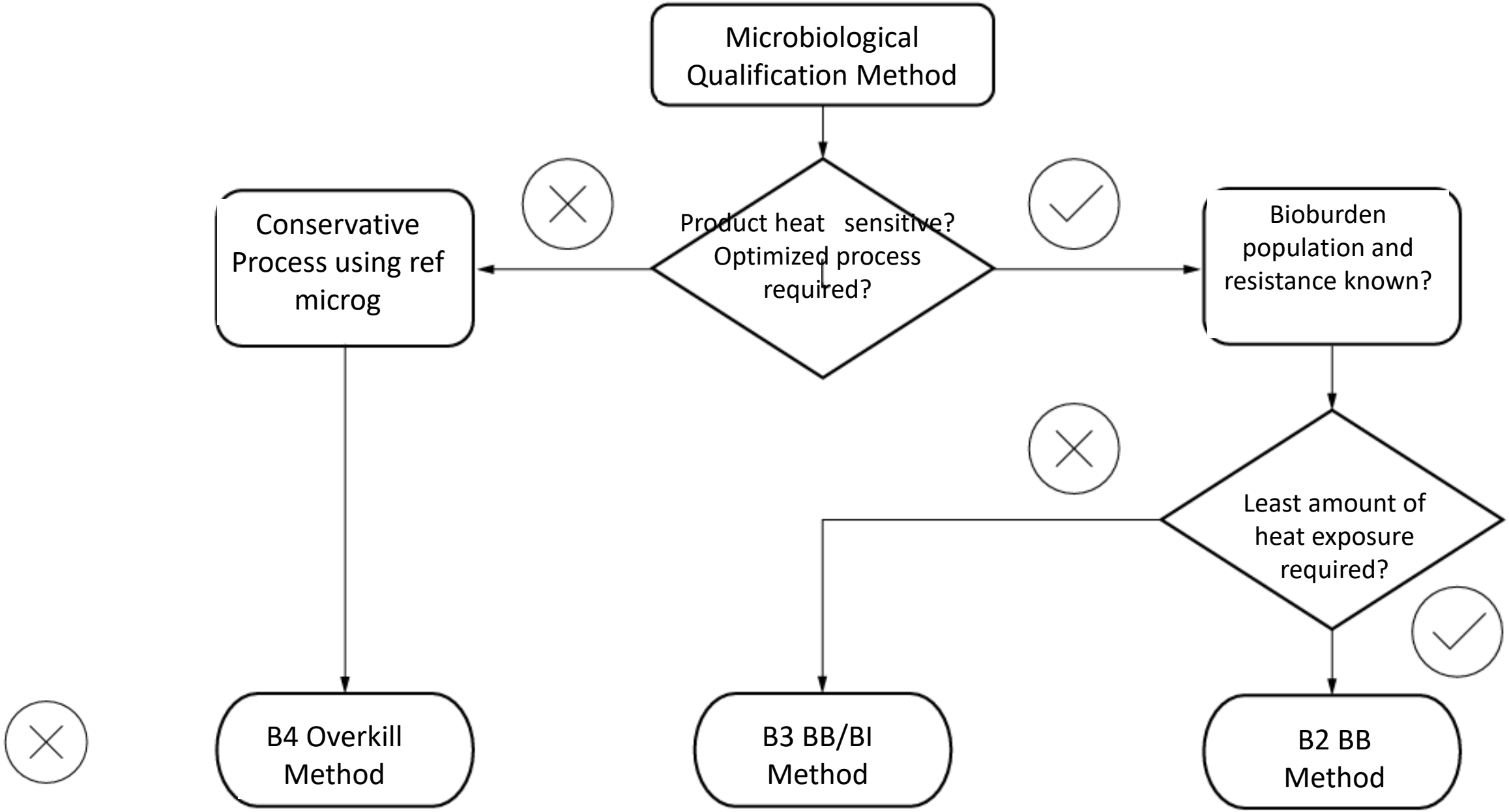
B4 Overkill

- Sterilization process designed to achieve a 12 log reduction in a microorganism with an assumed D_{121} of 1 min.
- SAL => 10^{-6}
- $F_{BIOLOGICAL}$ 12’

Pharmacopeial

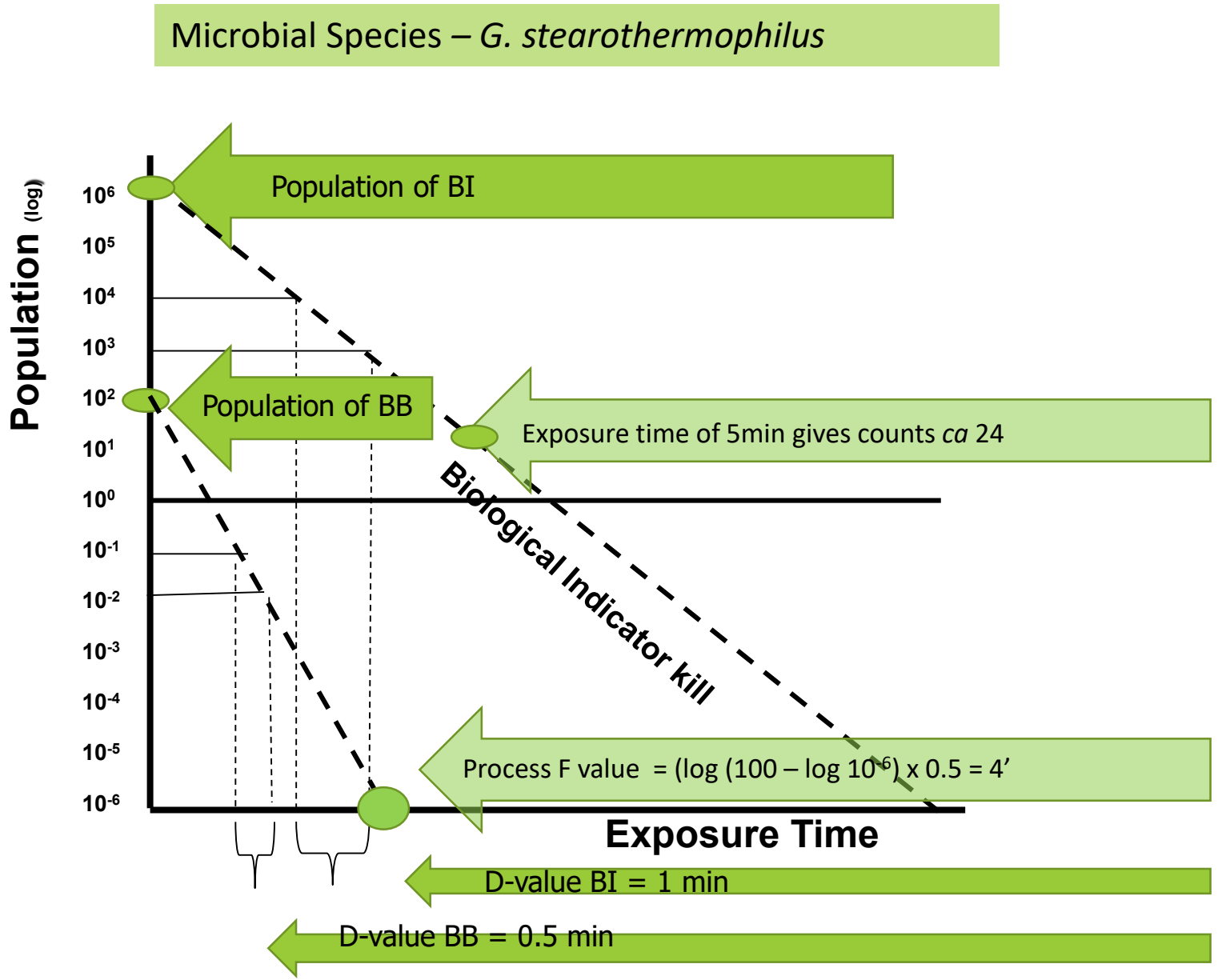
- Not in annex B but is used by industry. A standard pharmacopeial cycle is employed delivering very large overkill
- 121oC/15’
- 134oC/3’
- SLR >10^{35}

Annex B – Choice of microbiological approach



Annex B – B3 Combined BB and BI microbiological approach graphical

- Use of a BI meeting ISO 11138-3 with D_{121} > 1.5min
- Test for thermophilic microorganisms should be carried out.
  - Heat at 80 to 100oC for 10 to 15 mins
  - Survivors should be isolated (genus and species), identified and resistance assessed.
  - If no survivors then D value can be assumed <0.5min so less resistant than BI
- **Process development;**
- Determine most difficult to sterilize location in product (assessment /thermometric/ CI)
- Place BI's in most difficult to sterilize location (PCD can be used)
- Use SBS equivalent to that to be used in production.
- Place packaged BI/PCD in most difficult to sterilize location in load
- Expose to sub lethal treatment and recover BI survivors by plate count or MPN.
- Calculate rate of inactivation of BI. Then use this result to determine the F value needed to reduce BB to the required SAL



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- Expose to sub lethal treatment and recover BI survivors by plate count or MPN.
- Calculate rate of inactivation of BI. Then use this result to determine the F value needed to reduce BB to the required SAL

Bioburden characteristics

D_{121} = 0.5', Pop = 100 CFU action level, SAL = 10^{-6}

F value required = D_{121} x (logN0 – Log N)

F value required = 0.5 x (log 100 – log 10^{-6}) = 4'

Biological Indicator characteristics

D_{121} = 1.0', Pop = 10^6 CFU

The log reduction for the BI is;

LR = F value / D_{121}

LR = 4 / 1 = 4

5 BI's located in load, exposed for 5 mins to process

Survivor counts gave 23, 22, 24, 19, 17

Using the highest value of 24

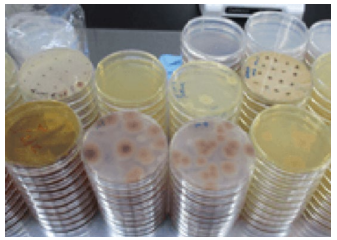
LR = Log N_0 – Log N

LR = log 10^6 – log 24

LR = 6 – 1.4 = 4.6

Since 4.6 > the required 4.0, the product SAL is achieved

BS 2646-Autoclaves for Sterilization in Labs



Liquid Sterilization Performance Test

Temperature distribution within the load

Model load of 500ml bottles (full load 9 to 50)
121oC / 15min cycle
During cycle all containers reach sterilization T for holding time
All bottle T within 2oC of each other
Thermal door interlock tested

Make Safe Mixed Load

Rapid and even temperature equilibration and hold T at t

Discard containers lined with a bag
Petri dishes with agar, stacked vertically to fill a discard container
50 ml bottles with 20ml water
Holding t at T but also equilibration time very important. Simulator

Equipment and Glassware

Thermal performance of an agreed challenge load

T and t maintained according to specification
Load dryness
Clean dry uncapped 500 or 50 ml glass bottles – orientation ?
Air removal acceptable
All T reach sterilization T and held for specified time
No condensate in bottles

Fabric and Glassware Disinfection

Temp distribution within the load

T at t
Load dryness
Tested using an EN285 or 13060 test pack
Successful air removal
Equilibration and holding time at a specified sterilization T
Test pack sensibly dry

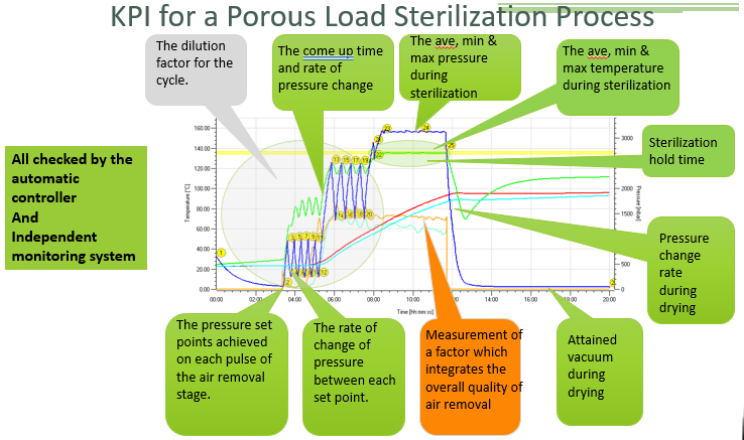
A vision of the future – AI – No more testing?

STERILIZER

LOAD

PROCESS

KPI for a Porous Load Sterilization Process



All checked by the automatic controller And Independent monitoring system

KPI's

AI

PASS

Hmm?

FAIL

Complex Adaptive Systems
-Mike

KPI for a Porous Load Sterilization Process

All checked by the automatic controller And Independent monitoring system

The dilution factor for the cycle.

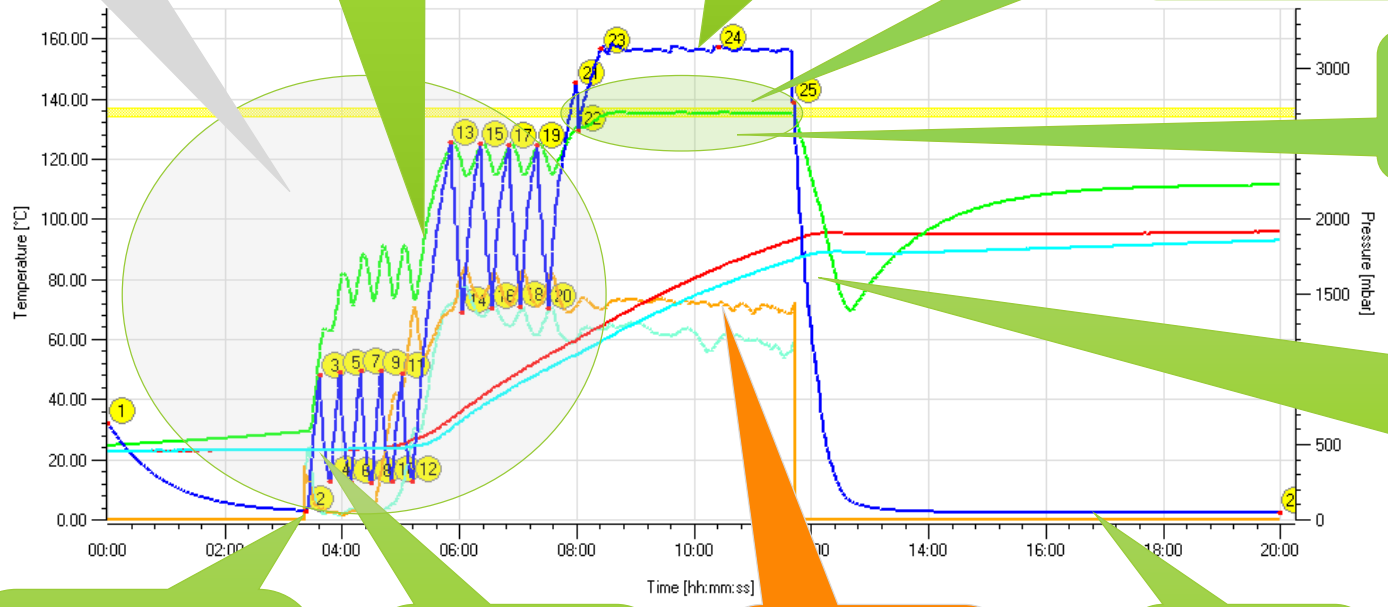
The come up time and rate of pressure change

The ave, min & max pressure during sterilization

The ave, min & max temperature during sterilization

Sterilization hold time

Pressure change rate during drying



The pressure set points achieved on each pulse of the air removal stage.

The rate of change of pressure between each set point.

Measurement of a factor which integrates the overall quality of air removal

Attained vacuum during drying

Chair:	**Karen Johnson**
13:15	Sterilization risks hidden from view – CH198 Research Labs/Other areas *Brian Kirk*
13:45	**The Great Debate: "This house believes we need a revolution in periodic testing"** Moderator: *Richard Bancroft* For: John Prendergast Against: Mark Furmage
15:00	Close of meeting *John Prendergast, CSC Chair*
	Tea / coffee for the road

PCD's – challenge to penetration

- Home Made

- Commercially produced

Chemical Indicators – Types according to ISO 11140-1

ISO 11140-1

Type 1 Process

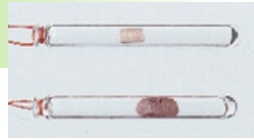
- Applied externally
- Indicates if processed

Type 2 Specific test

- Bowie and Dick Test
- Helix Test

Type 3 Single Variable

Respond to one critical process variable



Type 4 Multi Variable

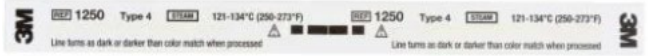
- Respond to two or more critical process variable

Type 5 Integratin

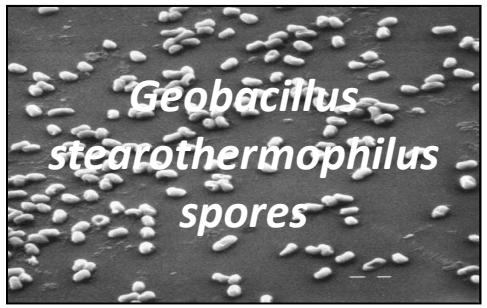
- Respond to all critical process variables = to a BI

Type 6 Emulating

- Respond to all critical process variables for specified process



Biological Indicators – What they are and Standards



Definition: Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

- (ISO 11139, Terminology)

Basic premise: If your process is effective enough to kill a large number of spores, it will also kill a lower number of less resistant organisms on the cleaned, disinfected medical devices.

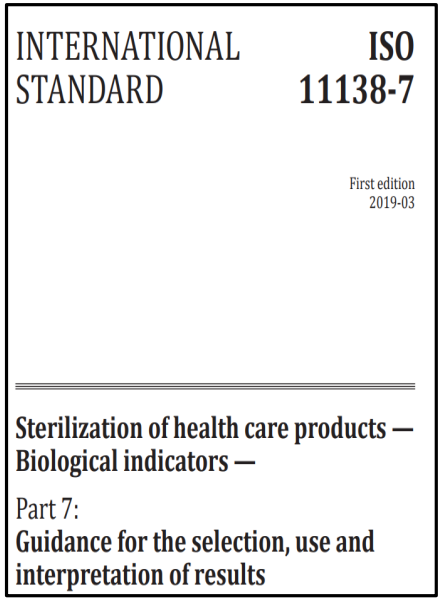
Kill the BI and you will sterilize the load.

BI Performance defined in:

EN ISO 11138 series

- Part 1 – General requirements
- Part 2 – Ethylene oxide
- Part 3 – Moist heat
- Part 4 – Dry heat
- Part 5 – Low temperature steam and formaldehyde
  - LTSF
- Part 6 – Vaporised Hydrogen peroxide
  - This is still in preparation by ISO TC 198 wg4

Guidance for the selection, use and interpretation of results of biological indicators is provided in EN **ISO 1138-7**

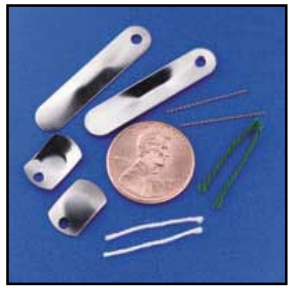

INTERNATIONAL STANDARD **ISO 11138-7**

First edition 2019-03

Sterilization of health care products — Biological indicators —

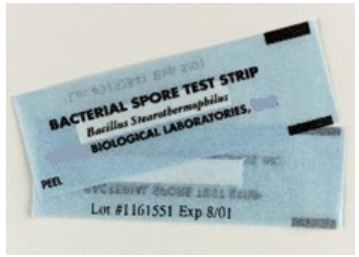
Part 7:
Guidance for the selection, use and interpretation of results

Biological Indicators (ISO 11138) – Type and Formats



Inoculated Carriers / Seeded Product

Spores are deposited on the surface of the device to be sterilized usually from a spore suspension and dried. The device is sterilized and the spores recovered and examined for survivors. Used during validation. Careful aseptic manipulation needed.



Spore Strips

Spores are deposited on strips of (usually) filter paper and enclosed within a permeable packet. The packet or individual strips are placed within product, sterilized and then recovered and examined for survivors by placing in growth medium. Great care must be taken to avoid recontamination and false positives. Aseptic handling needed.

Spore Ampoules

Spores are suspended in a growth medium sealed inside a glass ampoule. After exposure the ampoules are incubated directly and observed for colour change. Only used in liquids in containers.

Self-contained Biological Indicator (SCBI)

Spores are deposited on a carrier located at the base of an enclosure (tube). A vial of growth medium is included in the enclosure. The cap contains a filter allowing sterilant access but preventing recontamination after use. After exposure the glass vial is cracked allowing growth medium to flow onto the spore carrier and then incubated. No microbiological skills needed to use.

Moist Heat Sterilization ?

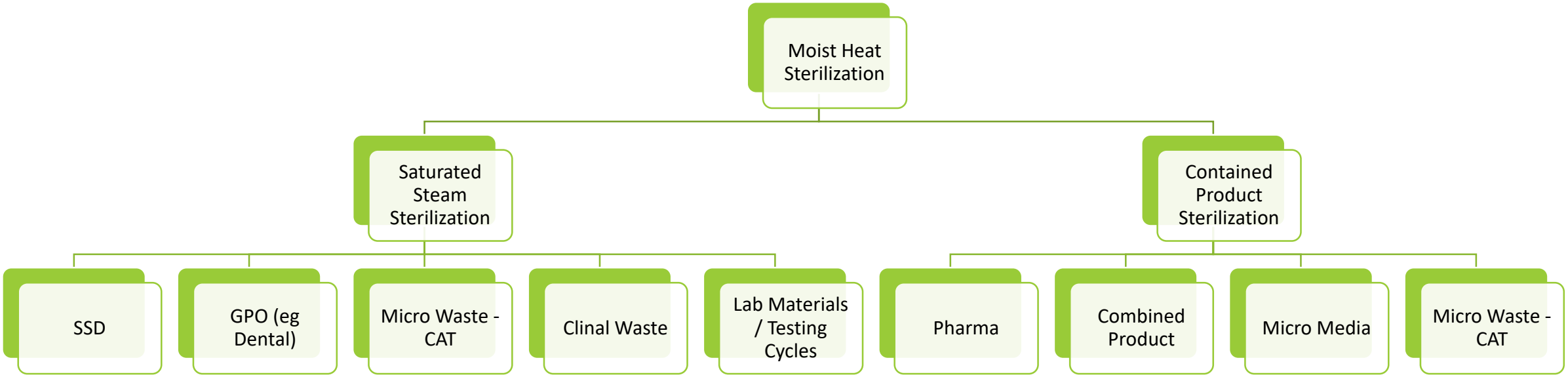
Moist Heat – thermal energy in the presence of moisture released by gaseous or liquid water
ISO 11139:2018 + A1 2024

- ***A physics/engineering based definition***

Moist Heat – thermal energy in the presence of moisture used as the sterilizing agent to achieve the specified requirements for sterility
ISO 17665:2024

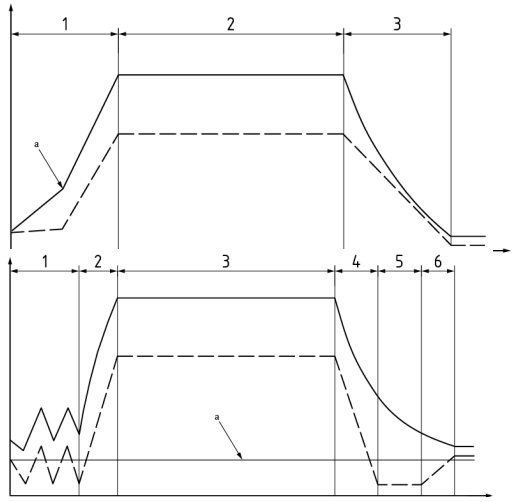
- ***A microbiological based definition***

Application Areas for Moist Heat Sterilization

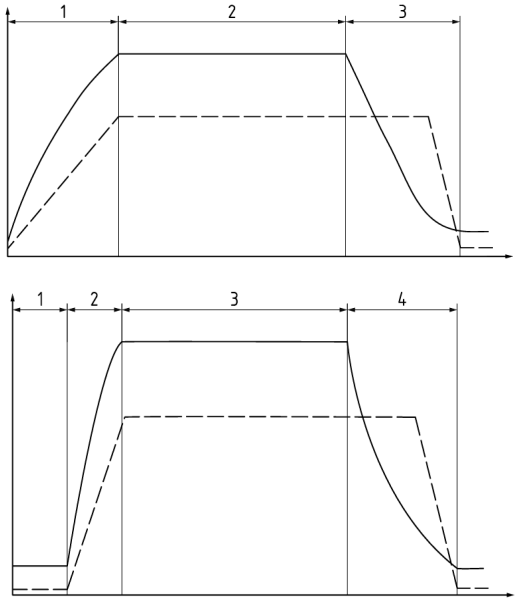


Moist Heat Sterilization - Processes

- Moist Heat Sterilization Processes
  - Saturated Steam Sterilization
    - Gravity Air Removal
    - Active Air Removal
  - Contained Product Sterilization
    - Steam Air Mix
    - Water Spray
    - Water Immersion



In Saturated Steam Sterilization processes chamber P = Saturated Steam Pressure



In Contained Product Sterilization Processes chamber P = Saturated Steam Pressure (Rigid) OR Chamber P = SSP + P NCG overpressure