

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 1

**QUALITY ASSURANCE
IN STERILIZATION**

Susan Hadfield
Director, Sterile Processing Department
Health Sciences Centre
Winnipeg, Manitoba

Hosted by Paul Webber (paul@webbertraining.com)
A teleclass sponsored by Webber Training Inc.
www.webbertraining.com

1

Slide 2

**QUALITY ASSURANCE IN
STERILIZATION**

- How can we consistently produce sterile devices ?
- Sterility Assurance is a total system of which the biological test is only one component-we will discuss the other components
- How can we design a quality assurance plan for sterilization? The knowledge you take away today will help you do that.

2

Slide 3

**QUALITY ASSURANCE IN
STERILIZATION**

- Understanding of what a quality system for sterilization is composed of
- Gain a better understanding of biological and chemical indicators, which ones to use where and when

3

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 4

QUALITY ASSURANCE OF STERILIZATION

- First and foremost, mistake proofing should be built in to your system- predict where errors may occur and what the cause could be-what processes can affect sterilization i.e. cleaning
- Define roles and responsibilities as well as tasks and processes

4

Slide 5

QUALITY ASSURANCE OF STERILIZATION

- We can't culture sterile products to see if they are sterile so we need to use other tools that will give us assurance that the parameters of sterilization can be met
 1. Administrative controls
 2. Biological testing
 3. Chemical testing
 4. Mechanical component
 5. Maintenance and review of records

5

Slide 6

1. ADMINISTRATIVE CONTROLS

- A) Education of employees-are staff graduates of a recognized program? Do they understand the why behind what they are doing
- Do staff have access to ongoing training and educational materials including Standards?
- Core competencies maintained -need to audit

6

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 7

ADMINISTRATIVE CONTROLS

- B) Policies and procedures-must be living and in clear language staff understand
- Definition of roles, responsibility and accountability

7

Slide 8

ADMINISTRATIVE CONTROLS

- C) Make sure all the processes that affect sterilization are done correctly
- Staff must understand that any organic material left on or in the instrument will prevent sterilization- organic material increases the bioburden as well as acting as a protector for material underneath it

8

Slide 9

ADMINISTRATIVE CONTROLS

- Are there validated instructions for cleaning
- For difficult to clean devices (bronchoscopes) make sure there are written directions and that staff have shown you they can clean the item properly and then audit them yearly or more frequently
- Are devices to be sterilized packaged properly so sterilant can enter and leave packaging

9

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 10

ADMINISTRATIVE CONTROLS

- **D) Product identification and Traceability**
 - each item sterilized should have a lot control identifier affixed to it that designates which sterilizer, the date sterilized on and the cycle number
 - Flash sterilizers -document contents, duration and Temperature of exposure phase, identifier for the sterilizer, date and time and signature of operator
 - enables tracing of problems and retrieval of product if a recall

10

Slide 11

STERILIZATION MONITORING

- If instruments are cleaned properly, packaged properly, loaded into sterilizer properly, given the appropriate cycle -even if everything is done properly we still don't know if the sterilizer is working- use biological testing for this

11

Slide 12

2.BIOLOGICAL MONITORING

- Biological monitoring -monitors the effectiveness of the sterilization process
- Goal of sterilization is to provide a product that has only a remote chance of containing a live organism(less then 1 in a million)
- To know if that is possible you require a method of testing that will tell us if the sterilizer is capable of delivering a lethal dose

12

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 13

BIOLOGICAL MONITORING

- Want to be able to kill a large number of the most resistant M.O so test sterilizer with Biological tests that have a greater number and more resistant spores then is expected to be on product being sterilized

13

Slide 14

BIOLOGICAL MONITORING

- Use spores that are resistant to process being monitored but not pathogenic
 - Bacillus Stearothermophilus for steam
 - Bacillus Subtillus for ETO, dry heat and Sterrad

14

Slide 15

TYPES OF BIOLOGICAL MONITORS

1. Paper strips impregnated with spores and in a glassine envelope
 - incubated in a laboratory as require aseptic transfer
 - easy to place in hard to reach areas

15

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 16

TYPES OF BIOLOGICAL MONITORS

2. Self contained biological test*

- contains a spore strip (inoculated carrier) and an ampoule of medium
- activated by crushing to release medium (food for spore)
- incubate in department
- if for steam check to see if suitable for gravity or prevac

16

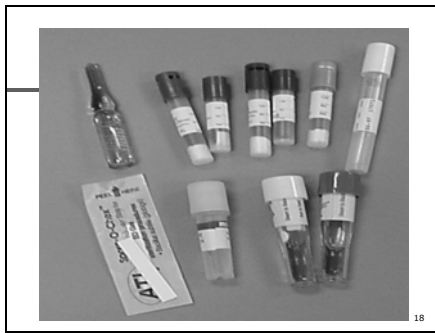
Slide 17

TYPES OF BIOLOGICAL MONITORS

- Spores require heat and food to grow so must add spore strip to a food medium in a lab or crush the self-contained biological in the department to release the food medium
- Growth indicated by a color change to yellow. How does this occur?

17

Slide 18



18

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 19

HOW BIOLOGICALS WORK

- As spores reproduce and multiply they use carbohydrates in the medium and change them to an acid
- The acid changes PH of medium and this change shows up as a color change in the indicators dye

19

Slide 20

INCUBATING BIOLOGICAL TESTS

- Don't contaminate the test after sterilization by dirty hands touching the filter
- Make sure your incubator is working-is light on and will control grow? If concerns will the company calibrate it for you?
- Follow the directions from the manufacturer of the biological test for how long to incubate-usually 48 hr

20

Slide 21

INCUBATING BIOLOGICAL TESTS

- Proper temperature is important as Bacillus Stearothermophilus grows at 55-60 C and if exposed to temperatures much lower they can loose viability-open incubator as infrequently as possible and never remove ampoules from incubator

21

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 22

HOW RAPID READ BIOLOGICALS WORK

- If any spores still alive after sterilization an enzyme in the live spore interacts with a substrate in the growth medium
- Interaction with substrate will show as a fluorescence when BI is exposed to ultraviolet light in the incubator
- Follow manufacturers direction as there is a special incubator and some incubators require calibrating

22

Slide 23

RAPID READ BIOLOGICALS

- Do not require growing out or incubating past the 3 hrs
- When you first start using this technology you could grow the rapid biological out for 48 hr. for 1-2 mos. until comfortable with it

23

Slide 24

DUAL SPECIES INDICATORS

- Indicators that contain both stearothermophilus for moist heat and Subtilis for ETO
- Not normally for flash

24

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 25

BIOLOGICAL INDICATORS USEAGE

- Read Instructions- mode of sterilization flash, prevac or ETO
- expiration date-BI's decline in potency over time
- Recommended storage conditions
- Instructions for disposal
- Should biological be cooled befor activating?

25

Slide 26

BIOLOGICAL INDICATORS USEAGE

- Incubation Time
- Is there a time frame in which you must incubate by ...normally 2 hrs but check with manufacturer

26

Slide 27

BIOLOGICAL INDICATOR CONTROLS

- Canadian Standards state at least one control indicator from the smallest shipping unit should be incubated to assess pre-sterilization viability of the Bacillus
- the standard goes on to say follow manufacturers instructions for subsequent testing of control indicators

27

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 28

BIOLOGICAL INDICATOR CONTROLS

- Most manufacturers tell you a control should be incubated every day that you are testing your sterilizer WHY
- Is incubator working at correct temperature?
- Has biological been stored under correct conditions- are the spores still viable?

28

Slide 29

BIOLOGICAL CHALLENGE TEST PACKS-STEAM

- Special pack containing a biological indicator
- Must follow the directions for making test pack exactly so give sterilizer the same challenge as the sterilizer company
- For steam the same type of pack is used for testing sterilizer after installation as for routine testing of sterilizer

29

Slide 30

BIOLOGICAL TESTS PACKS-STEAM

- Prepare in house test pack**Must follow**
 - For saturated steam other than a table top you make a test from approximately 16 freshly laundered, un-ironed surgical towel
 - Towels are folded lengthwise into thirds and then in half widthwise, then place towels on top of each other with folds opposite
 - indicators between 8th & 9th towel then tape towels together

30

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 31

BIOLOGICAL TEST PACKS- STEAM

- Commercially prepared test pack - Manufacturer must show equivalency to the 16 towel test pack
- Usually a stack of paper materials with hollow space for biological
- More consistent than in-house prepared test - newness, thickness and dryness of towels in the in-house prepared test pack differs as well as how tightly the test is constructed

31

Slide 32

BIOLOGICAL TEST PACKS- ETO

- Different test pack for installation and for routine testing
- Directions in any standards document
- Important to make exactly

32

Slide 33



Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba

A Webber Training Inc Teleclass – April 30, 2003

Slide 34

3.CHEMICAL INDICATORS

- "A sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical parameters with in the sterilizer chamber"
- Detects whether one or more of the critical parameters has reached a predetermined level and then change is produced-can be colour change or colour moving in a window

34

Slide 35

CHEMICAL INDICATORS

- Manufacturer tells us what the end point response or change is
- Must know what parameter the CI is testing as well as the range

35

Slide 36

CHEMICAL INDICATORS

- Many different CI's on the market. In steam some CI's won't reach their endpoint until exposure to steam for a minimum time while others won't change until exposed to a minimum Temperature while still others won't change until exposed to a combination of time and temperature and others still won't change until exposed to a combination of time,temperature and steam

36

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 37

CHEMICAL INDICATORS

- Must reach the endpoint or change the manufacturer has described or the critical parameter (s) you are testing wasn't met
- Detects potential failures from incorrect packaging, incorrect loading of sterilizer or malfunction of sterilizer

37

Slide 38

CHEMICAL INDICATORS

- Types: 1. ink based upon the generation of a black lead sulfide from a mixture of white lead and sulfide; autoclave tape & indicator strip - doesn't show presence of steam
- 2. Colour change based on chemistry - purple to green change and includes presence of steam

38

Slide 39

CHEMICAL INDICATORS

- 3. Melting pellet - filter paper with a special compound that has a certain desired melting point - when exposed to sterilizing conditions compound melts and wicks up the paper strip - can integrate moisture, time & temp

39

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 40

CHEMICAL INDICATORS **CLASSIFICATION**

- 1.Process or throughput indicators,external indicators
- identify processes from unprocessed - prevent using unsterilized package
 - color change of an ink on tape or label
 - not sensitive to temp or time
 - cheapest

40

Slide 41

CHEMICAL INDICATORS **CLASSIFICATION**

- 2.Indicators for specific tests
- same inks used
 - Bowie Dyck Test-a test sheet used in a special pack to test vacuum system of pre-vac sterilizer
 - if air present get incomplete color change

41

Slide 42

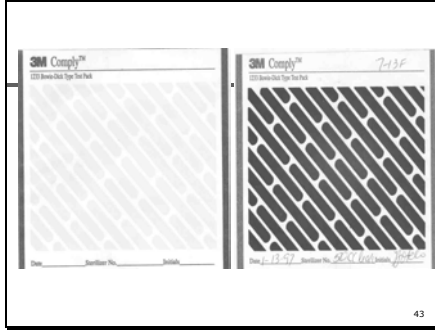


42

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 43



Slide 44

CHEMICAL INDICATORS CLASSIFICATION

3. Single parameter indicators

- indicates exposure to a cycle at a stated value for that parameter
- Limited information i.e. will tell you minimum Temperature but not exposure time or whether steam was present

Slide 45

CHEMICAL INDICATORS CLASSIFICATION

4. Multi parameter indicators-monitor two or more critical parameters

- indicates exposure to a cycle at the stated values of the chosen parameters
 - could be a color change or the migration of a chemical at a defined rate for given temperatures
- may be laminated to regulate sensitivity and response time

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 46

CHEMICAL INDICATORS CLASSIFICATION

5.Integrating indicators- often called integrators
-responds to all critical parameters simultaneously
-performance can be compared to the inactivation of a test organism

46

Slide 47

CHEMICAL INDICATORS CLASSIFICATION

5.Integrating indicators can't
-color change type can be difficult to interpret
-wicking type-temp.specific chemical melts and moves along a wick;have plastic film over pellet &wick to control moisture
-migration of chemical beyond a defined point assures you of a specific time &temp in presence of steam

47

Slide 48

CHEMICAL INDICATORS CLASSIFICATION

Class 5 integrator - instant reading
-easy to interpret
-integrates all parameters
-permanent record
- usually more expensive

- Even though it reacts in a way that parallels performance of a biological indicator--Do not use in place of a biological

48

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 49



Slide 50

CHEMICAL INDICATOR SELECTION

- What sterilization process are you testing
- What type of indicator you require i.e. process indicator, specific test or parameter indicator
- What resources you have

Slide 51

CHEMICAL INDICATOR USAGE

- On outside of each package or container system to show item has been exposed to the conditions in a sterilizer
- Inside each package to be sterilized in area considered to be least accessible to sterilant
- Release of load except implants

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 52

CHEMICAL INDICATOR USEAGE

- If CI doesn't reach endpoint when checked at time of use then don't use items
- Whether the rest of the load should be recalled depends on physical monitoring (time&T), the result of other CI's in the load, and the results of biological monitoring-Quarantine if biological test not available

52

Slide 53

MECHANICAL MONITORING

- Reading of gauges, charts and computer print-outs
- Shows real time how cycle progressing and that conditions have been maintained
- Printout shows cycle used, high & low temp and pressure, exposure time & cycle time

53

Slide 54

MECHANICAL MONITORING

TEMPERATURE MONITORING
-thermocouples or resistive thermal devices directly connected to electronic control system gives visual read out of process by means of electronic display
- measured in chamber drain pipe for larger sterilizers and in chamber for table top sterilizers (isn't the T of pack necessarily)

54

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 55

MECHANICAL MONITORING

PRESSURE MONITORING

- Gauge pressure-difference in pressure in chamber and pressure in environment (atmospheric)
- monitor to see if changes

55

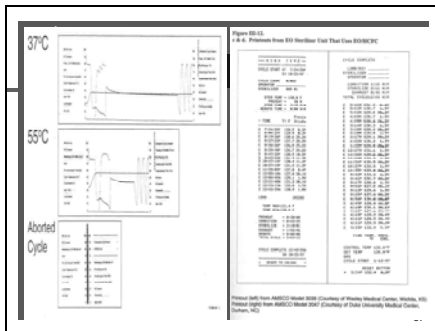
Slide 56

MECHANICAL MONITORING

- Computer printout -Must read and understand what you are reading on the print out
 - tells you that proper parameters are met as well as correct cycle
 - is it taking longer then normal to get sterilizing temp
 - look at each line individually-initial

56

Slide 57



Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 58

STERILIZER TESTING

1. Installation testing
2. Routine testing
3. Product and process change testing

58

Slide 59

INSTALLATION TESTING STEAM

- When install a new sterilizer, after major repairs, relocation or changes to steam supply
- Test 3 consecutive cycles with a biological test pack in an empty chamber
- if a dynamic air removal also test 3 cycles with an air removal test (Bowie Dyck)

59

Slide 60

INSTALLATION TESTING STEAM

- Empty sterilizer, bottom shelf over the drain
- If a 16 towel test you must position horizontally(creates more of a challenge)

60

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 61

INSTALLATION TESTING
ETO

- Test three consecutive cycles with a test pack in an empty sterilizer after installation prior to using
- Also after major repairs, relocation, unexplained failures, changes in ETO supply, changes to loading pattern and annually

61

Slide 62

INSTALLATION TESTING
ETO

- Test pack to be placed in a wire basket or metal cart as do not absorb ETO
- For chamber volume between 1133 and 2237L use two test packs-one in the rear corner and one in the diagonally opposite front corner
- For chamber volume between 453 and 1104 L use one test pack in the front of the chamber near the door

62

Slide 63

INSTALLATION TESTING

Compliance & evaluation

- incubate the biological - negative results
- achievement of defined endpoint of chemical indicator
- established sterilizer parameters as shown on recording chart or printout
- acceptable results of Bowie Dyck test if used

63

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 64

ROUTINE TESTING FOR ETO

- Canadian Standards states "a routine biological indicator test pack shall be included in every load that is to be sterilized"
- If test pack is made in-house directions must be followed exactly
- Commercially prepared test packs - manufacturer must demonstrate equivalency to in -house test

64

Slide 65

ROUTINE TESTING FOR STEAM

CSA states:

- Steam sterilizer shall be tested with a biological test every day sterilizer is used and on every different type of cycle to be used as well as every load containing implants
- Includes biological test pack as well as air removal test for pre-vac sterilizer, Chemical indicator is optional

65

Slide 66

ROUTINE TESTING

PROCEDURE -biological test in 16 towel test pack placed horizontally near drain in *full sterilizer or commercially prepared test pack placed as per manufacturers directions

- Run normal cycle & at end incubate
- note traceability info such as sterilizer # , load #, and date **NB incase positive results

66

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 67

ROUTINE TESTING

- PROCEDURE CONT-run air removal test in an empty sterilizer with no dry cycle daily when in use

67

Slide 68

ROUTINE TESTING

- EVALUATION- established machine parameters as shown on recorder chart
 - negative BI, achieved end point of CI if used
 - acceptable results from air removal test

68

Slide 69

PRODUCT AND PROCESS CHANGE TESTING

- Test using sample packs when :
 - major changes to packaging such as new material, switch to disposable wrap, changed manufacturer or introducing rigid container systems
 - change to load configuration
 - change to size or density of package or wrapping technique

69

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 70

PRODUCT AND PROCESS CHANGE TESTING

PROCEDURE -Place sample pack containing biological & chemical indicators among other packs in a routine load but in most difficult to sterilize spot

BI and CI's should be placed in the pack in the area least accessible to steam i.e. centre of linen or every fold, between basins, corners of containers

70

Slide 71

PRODUCT AND PROCESS CHANGE TESTING

EVALUATION

- negative BI's
- chemical indicator at end point
- *evaluation for moisture

71

Slide 72

RECORD RETENTION

- Specific to each facility but normally 5-7 yr.
- Positives and recalls longer ? 25 yr.
- What to keep
 - Sterilizer print out or recording chart-signed
 - Process recording records that tell us what devices were sterilized on that load
 - load control label
 - Sterility tests-biological tests

72

Quality Assurance in Sterilization

Featuring Susan Hadfield, Winnipeg, Manitoba
A Webber Training Inc Teleclass – April 30, 2003

Slide 73

RECORD RETENTION

- Bowie Dyck -air removal if used
- Chemical indicator if used to release load
- Helps to initiate a recall if records organized
- Recall report should include why the recall was initiated, action taken and who was informed, number of devices located as a % of total devices recalled

73

Slide 74

QUALITY ASSURANCE IN STERILIZATION

- We've talked about the components of a quality assurance program for sterilization and reviewed what is necessary for each component as well as frequency of certain tests
- I hope you have gained a better understanding of biological testing and chemical indicators and that they are just one part of the quality system

74

Slide 75

QUALITY ASSURANCE IN STERILIZATION

- Resources:
 - Canadian Sterilization Standards
 - Sterilization Technology for the Health Care Facility by Reichert & Young
 - Central Service Technical Manual published by the International Association of Healthcare Central Service Materiel Management
 - Provincial Associations

75
