

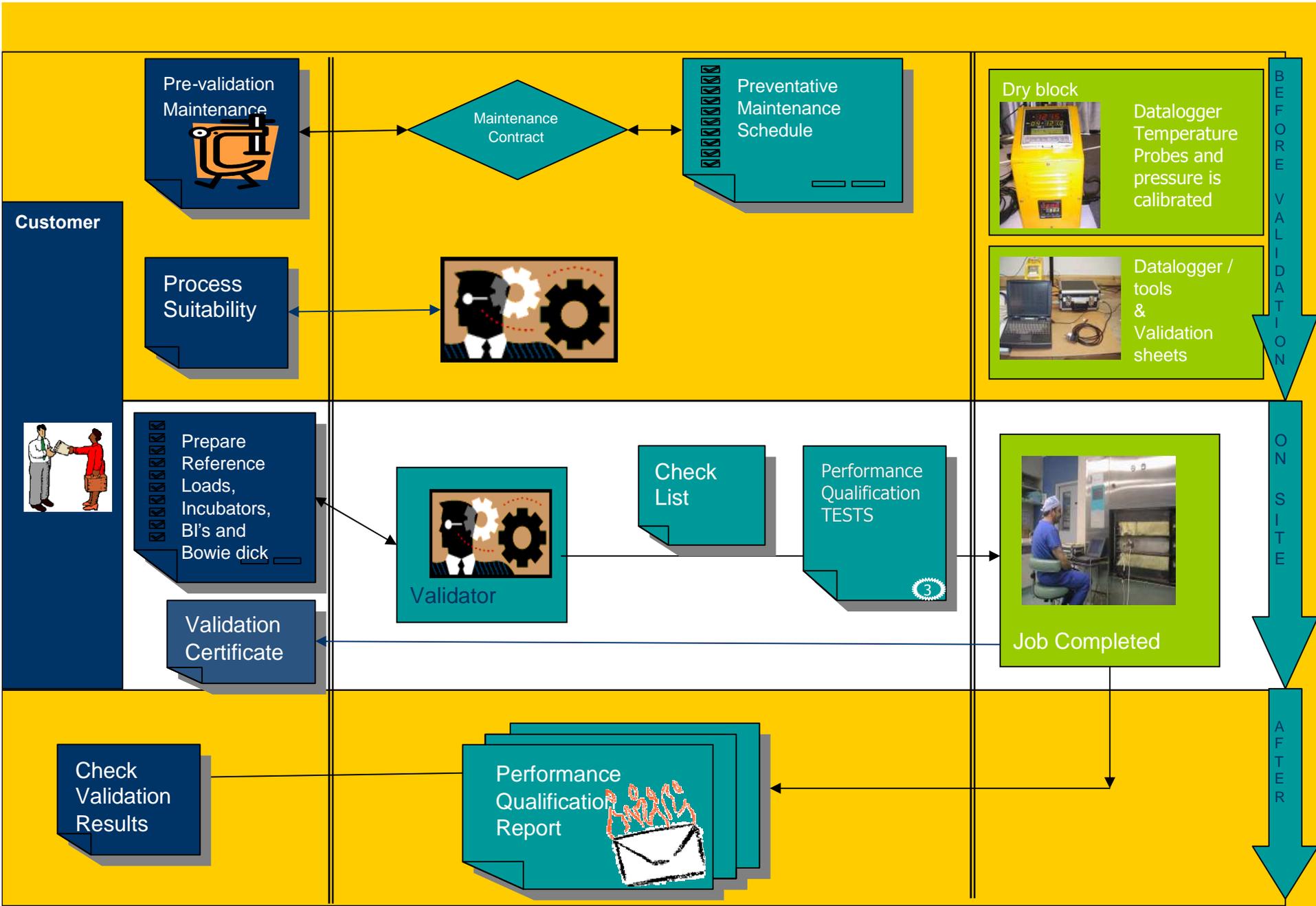
# Validation Process

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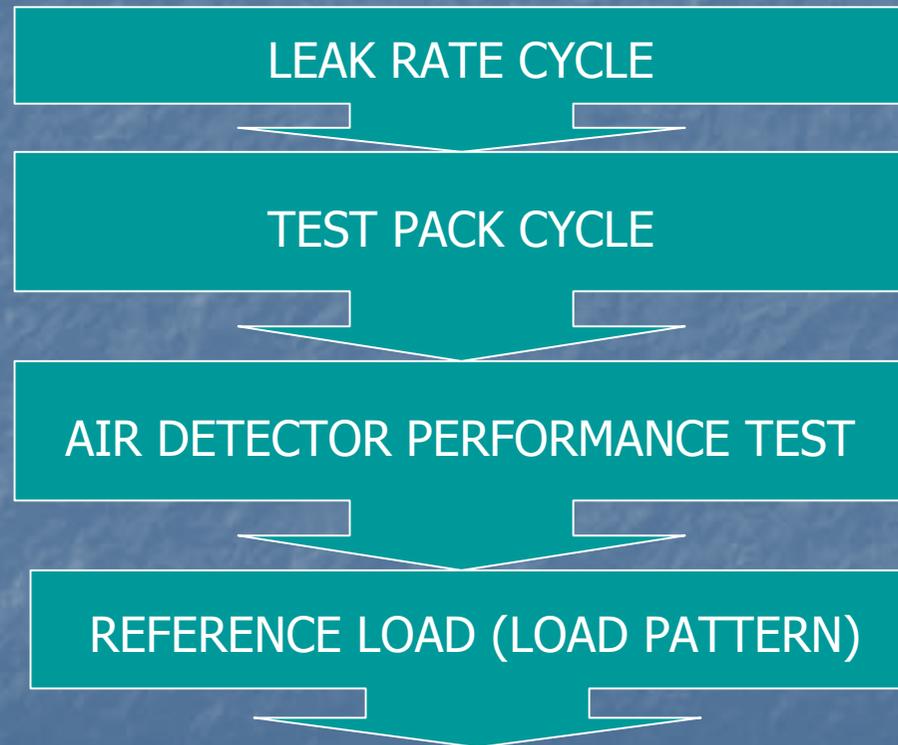


# Validation Process





# Performance Qualification TESTS



Samples

# Reference Load

AS/NZS 4187:2003

PREPARING THE REFERENCE LOAD

VALIDATING THE REFERENCE LOAD

To prepare a reference load; a number of questions will come to our mind.

1. What are the setting parameters for this load?
2. What will be the maximum load and how to Load the trolley?
3. What type, who many and where to position the Biological indicators?
4. Where to place the Temperature sensors?
5. What is the total time for the cycle?

## Reference Load ( Loading patterns) Samples



END





# Conclusions

- Find out the total number of Biological indicators to be used in each load and for all loads.
- How many Biological Incubators?
- How long will the tests all together takes?
- What load and materials will be needed.  
(Kimgaurds, steri-peel, linen & instruments ) ?

Validation Calculator



## Validation Calculator

**Important Note:** A Full Service Maintenance should be done before validation.

Reference/Details	Ref # 1	* 3	Ref # 2	* 3	Ref # 3	* 3	Ref # 4	* 3	Ref # 5	* 3	Ref # 6	* 3	Total
Geneses Crates													
Filters													
Steri-Peels(Size: ? )													
Steri-Peels(Size: ? )													
Steri-Peels(Size: ? )													
Steri-Peels(Size: ? )													
Steri-Peels(Size: ? )													
Total No. of BI's	15	45	8	24	20	60	4	12	10	30	8	24	195
Total No. of Strips	5	15	2	4	10	30	4	12	4	12	4	12	114
Total Cycle Time													
Estimate time between loads													

Estimate from total No. Of BI's and time between cycles how many Biological indicators will be needed.



**Customer Name:**

**Machine Type :**

**Load Type :**



## **Load Parameters:**

**Set Temperature in sterilizing time:**

**Sterilizing time :**

**Drying Time:**

Define the period of time the load needs to stay within the sterilizing phase

Define the period of time load needs to stay within the sterilizing phase

Define the Set temperature for the load within the sterilizing phase



# 1.

## - Washer Sterilizer

- **Wash stage :** this stage has been programmed either to get to 50 C and ends after 5 minutes or a total of 8 minutes.

**Problem:**  
**While monitoring the machine using a datalogger , the maximum temperature in the washing stage, reached 38 at the end of the 8 minutes.**

To result is clear that we are not sure the machine was

- identify the problem by the user?
- 1. There was no chart recorder on that machine.
- 2. No Test was done.
- 3. This Validation was done on the machine after been used for 7 years .

5:34:02 PM

 Start

 Stop

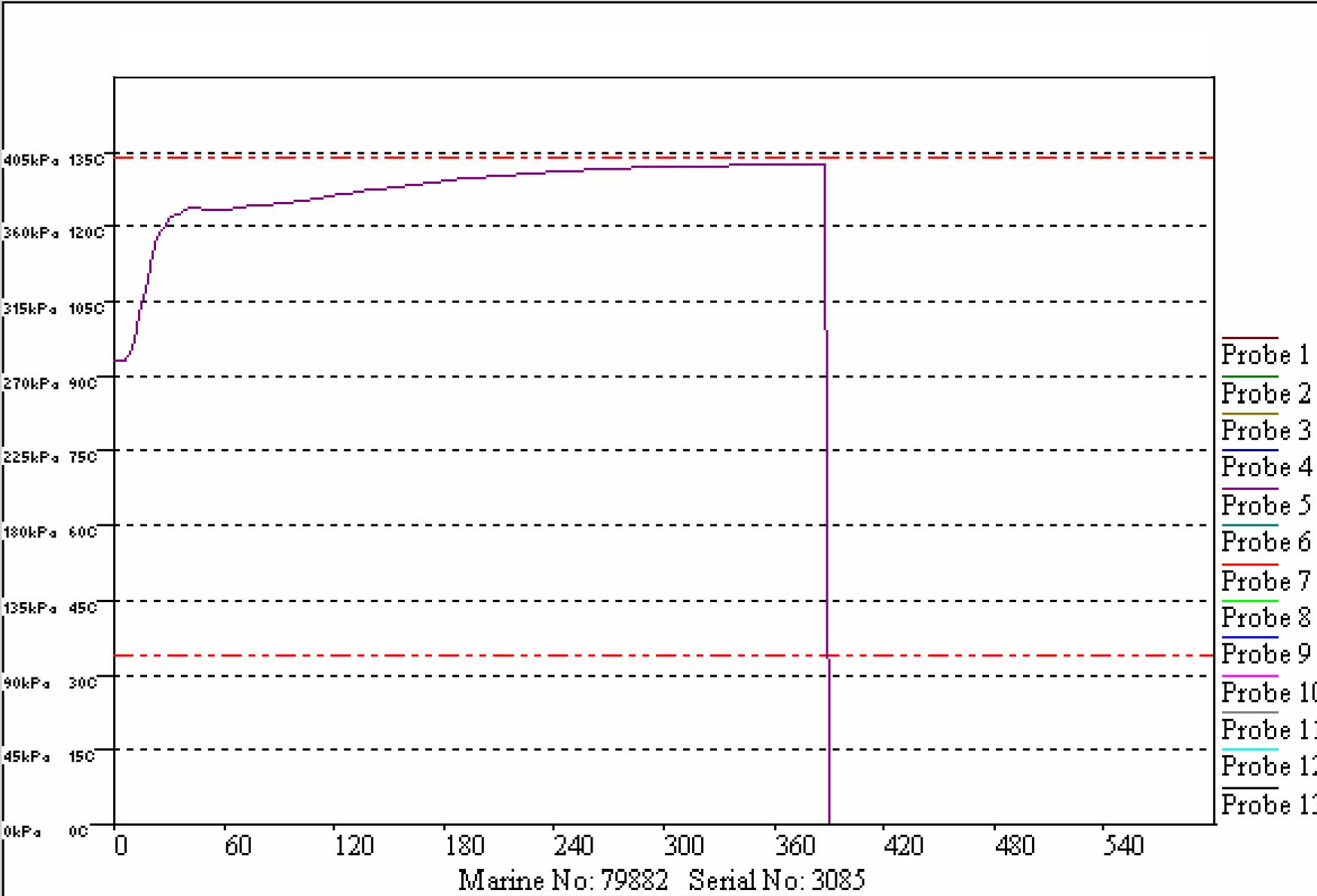
 Close

 Oops

 Print

 Config

3/29/2004



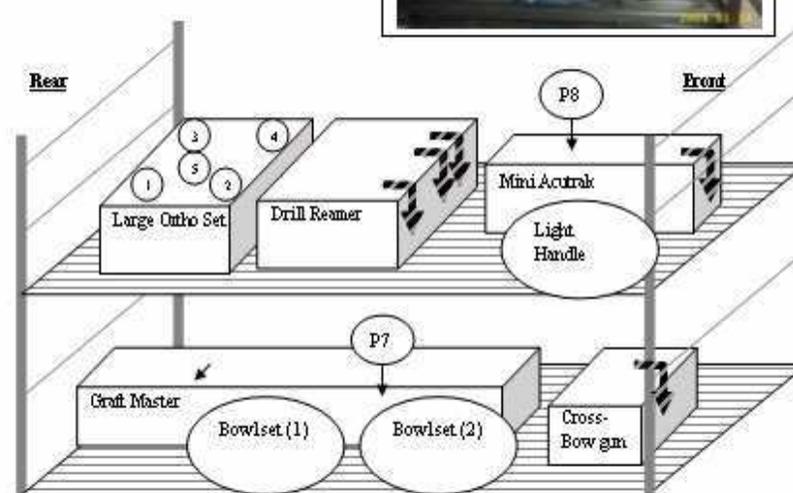
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Probe 1  
Probe 2  
Probe 3  
Probe 4  
Probe 5  
Probe 6  
Probe 7  
Probe 8  
Probe 9  
Probe 10  
Probe 11  
Probe 12  
Probe 13

## Autoclave Reference Load Ref #1

Machine Type: Steamum Sterilizer S1  
Load Type: Hard Goods 30min

Load To measure:  
Set Temperature in circulating time: 134 °C  
Sterilizing time: 4 Minutes  
Drying Time: 30Minutes



### Instruments/Steer-need/Bowls/Others Biological indicator

Description	Quantity	Weight	BI Batch #	BI 1	BI 2	BI 3	BI 4	BI 5
Drill Reamer	1	1.1 Kg	2005-09 PE		<input checked="" type="checkbox"/>			
Large Ortho Set	1	3.29 Kg	2005-09 PE	<input checked="" type="checkbox"/>				
Mini Acutrak	1	0.91 Kg	2005-09 PE	<input checked="" type="checkbox"/>				
Graft Master	1	3.78 Kg	2005-09 PE	<input checked="" type="checkbox"/>				
Cross-Bow Gun	1	0.53 Kg	2005-09 PE					<input checked="" type="checkbox"/>
Bowlset (1)	1	1.43 Kg	2005-09 PE					<input checked="" type="checkbox"/>
Bowlset (2)	1	1.43 Kg	2005-09 PE					<input checked="" type="checkbox"/>

### PROBE PLACEMENT. (p)

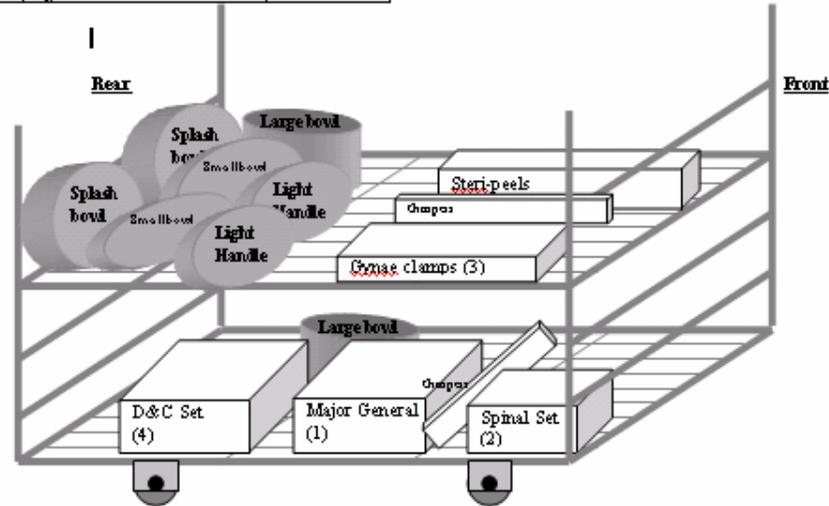
(p1,p3 Down drain ) ( p7 Inside Graft Master ) ( p8 Inside the Mini Acutrak )  
(p11 Top front left & right of chamber ) (p12 Top rear left and right of chamber )



## Autoclave Reference Load

Machine Type: Pre-vacuum  
 Sterilizer: S2  
 Load Type: Wrapped goods 35 min

Load Parameters:	
Set Temperature in sterilizing time:	134 C
Sterilizing time	4:00 Minutes
Drying Time	35:00 Minutes



### Biological indicator

Crates #	Description	Batch #	BI 1	BI 2	BI 3	BI 4	BI 5
1	Major General (4kg)	2005-06 AR	<input checked="" type="checkbox"/>				
2	Spinal Set (2kg)	2005-06 AR	<input checked="" type="checkbox"/>				
3	Chaps clamps (1 kg)	2005-06 AR	<input checked="" type="checkbox"/>				
4	D&C Set (2.5 kg)	2005-06 AR	<input checked="" type="checkbox"/>				
5	Large bowl (0.5 kg)	2005-06 AR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
6	Splash bowl (0.5 kg)	2005-06 AR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			

### Steri-pled Instruments

Description	Quantity	Weight
Nelson Scissors	1	} ? KG
Travers retractor	1	
West retractor	2	
Hibbs retractor	1	
Large Liga clip applicator	2	
Evans retractor	1	
Kongour	1	
Deaver	1	
Flat nose Grasper	1	
Dolphin nose dissector	1	



# Biological Indicators

- What indicator type will be used?
- Include the Batch Number at the time of the validation to be documented in the report ?
- How many biological Indicators will be used?

P 67 :Table 8.1 Guide



# Bio-logical Positions

- As indicated in AS/NZS 4187:2003 Biological/enzymatic indicators should be placed adjacent to the temperature probes.
- In order to validate steam penetration in oblong or square-based rigid reusable sterilization container systems, physical, chemical and biological/enzymatic indicators should be placed in each corner and in the center

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## Probe Placement ( Temperature Sensors)

- Two in the drain.
- The rest in coldest spots, Hardest Load packs and in different positions where needed.



# Reference Load ( Loading patterns)

- To Validate a Pre-vacuum Sterilizer we need to pass special tests
- ( Leak Rate Cycle...)( Test Pack ...)( Air Detector Performance Test ...)
- the last test which is the most important is the Load Reference Test.
- **The Purpose for this test : The killing of all spores on the biological indicators shall evidence acceptance assurance of sterility; three consecutive test runs are required for each cycle in which the sterilizer values are not altered.**

# Reference Load ( Loading patterns) Samples

**Hard Goods**  
4 minutes timing  
30 minutes drying

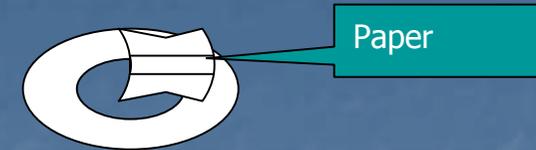
**Wrapped Goods**  
4 minutes Timing  
35 minutes drying

# Validating the reference load

- After loading the trolley, my job is to check that the load have been set according to the reference load and indicators are in place.
- Place all Temperature sensors in place.
- Run the cycle and monitor all parameters( Time, Temperature and pressure ) within all stages and document all readings.
- At the end of the cycle check the dryness ,all contents will be opened and checked, if any contents are wet, the pack shall be deemed un sterile(28) or in other words any items that are moist at the end of the drying stage should be rejected(91).
- Be sure the all biological indicators are incubated.
- Make sure that everything has been cooled down and repacked before being used again.
- In case of failure result caused by overload, wrong packing, etc .. The problem should be solved until passing 3 successive repeated cycles.(119).

Observations

# Observation



- This is a bowl sets load, at first the end user where aiming to get 8 Sets on a load.
- Each Bowl Set Contain a Big bowl,2 median bowls and four small bowls.( all Metal ).
- First run: a lot of water was inside the Sets.
- Second run: down to 6 sets, separate the big bowl from the others, Add paper on the bottom edge of the Big Bowl.
- Third Run: all passed only on of the big bowls .
- From Experience I thought that the load should pass, and after concentrating and looking for the reason I found that the Bowls failing had a very big carve lip on the edge that kept a lot of water.
- Running 3 successive repeated load without using those with carve lips.



# Installation Qualification ( IQ )

- IQ shall show that the sterilizer and the area in which it is installed comply with the manufacturer's specifications.



# Operational Qualification ( OQ )

- OQ shall prove that the installed equipment operates within the set limits when used in accordance with the operational procedures.



Thank you for your time

