

Autoclave Validation and Training Methods

Sean Williams
OHS/Biosafety Team
404-639-2286
sew2@cdc.gov

Introduction

- The Autoclave
- Methods used in Daily Validation
- Monthly Validation Methods
- Training Methodology

Principles of Steam Sterilization

- ◆ **Sterilization:** the complete destruction of all forms of microbial life, including bacterial spores
 - ◆ Steam under pressure reaches high temperatures
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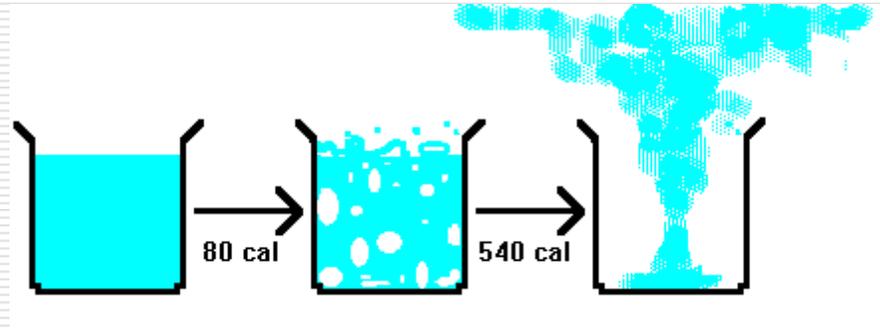
Standard Temperature and Pressure

- ◆ **Calorie:** The amount of energy required to heat one gram of water one degree Celsius

 - 250 °F (121 °C) and 15 p.s.i.
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Principles of Steam Sterilization (cont.)

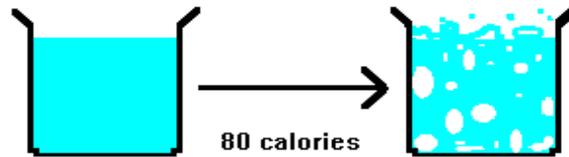
- ◆ The “killing power” of steam is due to its **latent heat of vaporization**
 - 80 calories: 1 L water to boiling
 - 540 calories: 1 L boiling water to steam



Latent Heat of Vaporization

□ For example:

To take one liter of water to boiling:



To take one liter of boiling water to steam:



Action of Steam

- ◆ Steam contacts a cooler surface, condenses, causing a huge decrease in volume and setting up a negative pressure that draws more steam
 - ◆ Condensation occurs as long as there is a temperature differential
 - ◆ Action of steam ensures: Surface heating, penetration, and protein coagulation
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Daily Methods of Validation

- Steam Sterilization Tape
 - Steam Sterilization Integrator
 - Autoclave Printer Readout
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Autoclave Steam Tape



Steam Sterilization Integrator



 **GETINGE**

PASS

FAIL

U.S. Pat.D347585

STEAM STERILIZATION INTEGRATOR

 **GETINGE**

PASS

FAIL

U.S. Pat.D347585

STEAM STERILIZATION INTEGRATOR

Autoclave Printer Readout



EXPOSURE TEMP 121 DEG C.
EXPOSURE TIME 01:00
DRY TIME 00:05
LOAD CONTENTS

CONDITIONING YES
EXPOSURE 01:01 YES
TEMP MIN 122 MAX 122 DEG C.
PRES MIN 32.6 MAX 33.0 PSIA
CYCLE COMPLETE YES
CYCLE TIME 04:42
CYCLE HAD NO WARNING
CAUTION 06 12:57:27AM
VERIFIED BY

QUALITY ASSURANCE

01:13:56 -0.02 219.4
GRAVITY DRY

01:12:21 16.83 251.4
EXHAUST

00:12:20 16.88 251.3
EXPOSURE

00:10:52 0.43 210.4
HEAT-UP

00:09:14 0.46 210.5
CONDITIONING5

00:07:34 0.48 210.5
CONDITIONING4

00:05:52 0.42 210.2
CONDITIONING3

00:04:01 0.46 209.8
CONDITIONING2

00:02:16 8.22 229.1
CONDITIONING1

00:00:17 2.46 120.1
PURGE

PROGTIME DF03 A100

PROGRAM: P1 GRAV WRAP 1

A100 CHAMBER TEMP
DF03 CHAMB PRESS/PSIG
SIGNALS

DRY TIME 00:00:00

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- Autoclave Steam Tape: Only use is to denote that something needs to be autoclaved
 - Steam sterilization Integrator: Time released wax window will indicate whether or not a complete autoclave run was achieved, use more than one per run
 - Autoclave Printer Readout: Electronic, hard copy record of everything the autoclave experiences during the course of a decon run
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Biological Indicators



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- The conventional biological indicator is a carrier that is inoculated with *Geobacillus stearothermophilus*, placed into its primary pack, which is a self-contained unit that also houses a unit of growth medium, and is ready for use.
 - provides a defined resistance to the specified sterilization process.
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Questions

Raymond G. Lewis, PE
Pharmaceutical Engineering

Sean Williams
CDC/OHS
(404)639-2286
