Surgical Gowns Manufacturing Basics

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June 16th, 2020

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Surgical vs. Non-surgical Gowns

- A number of different terms used: surgical gowns, isolation gowns, surgical isolation gowns, non-surgical gowns, cover gowns, comfort gowns, procedural gowns, and operating room gowns.

Cardinal Level 4 Surgical Gown

Halyard Procedure Gown

Medline Isolation Gown

Surgical vs. Non-surgical Gowns

- ANSI/AAMI PB70 definition of **"surgical gowns"** - "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of *microorganisms*, *body fluids*, and *particulate matter [material]"*
- FDA issued a guidance document "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" in 2015, basically defined **Level 1 and Level 2 can no longer be called "surgical gowns"**, and **only level 3 and level 4 gowns can be called "surgical gowns", including "surgical isolation gowns".**
- Choosing which gown to use:

https://www.cdc.gov/HAI/pdfs/ppe/PPEslides6-29-04.pdf

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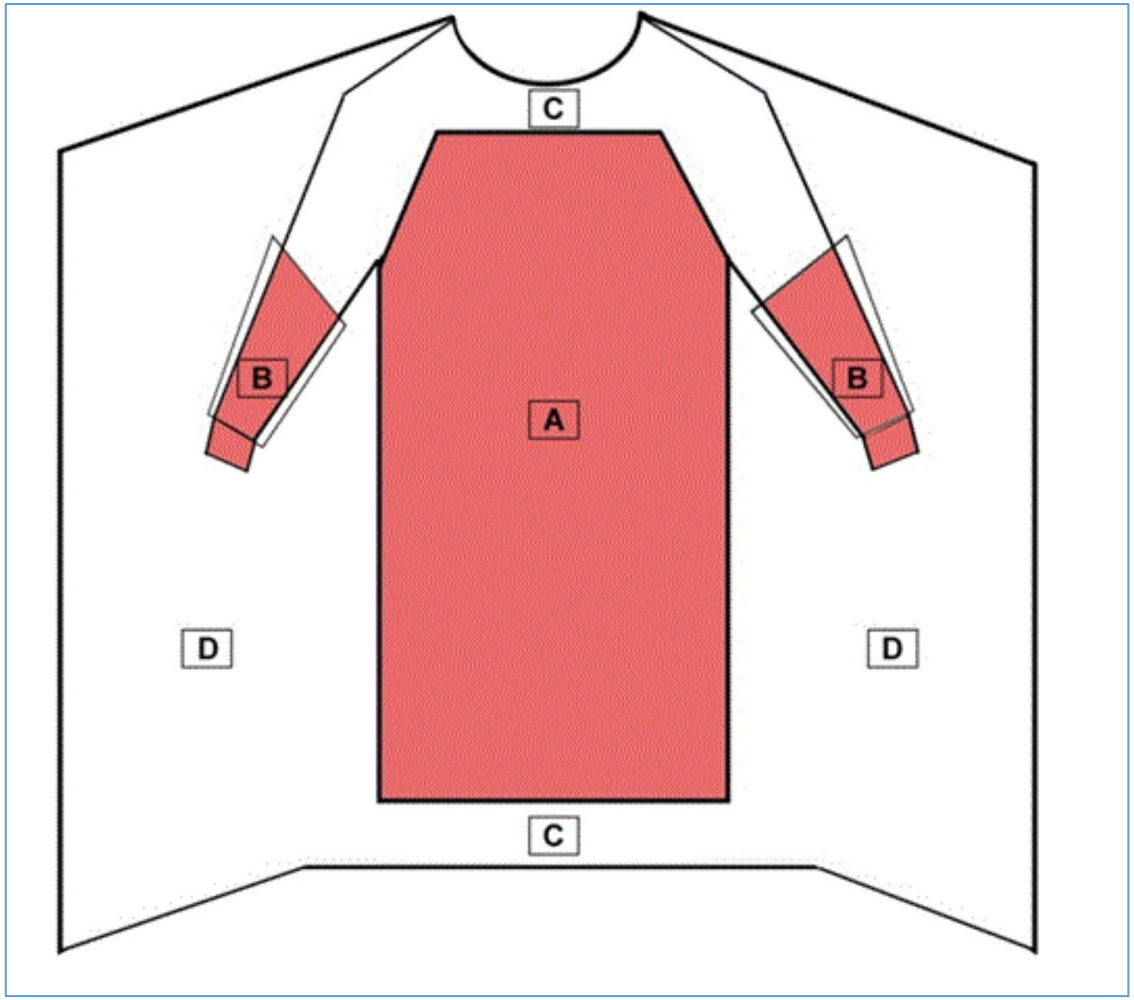
Gown Level Classifications

ANSI/AAMI PB70 divides **barrier performance** into 4 levels.

- **Level 1:** is used for **Minimal** Risk of exposure situations, *such as providing basic care and cover gowns for visitors.*
- **Level 2:** is used for **Low** Risk of exposure situations, *such as during common blood drawing procedures and suturing.*
- **Level 3:** is used for **Moderate** Risk of exposure situations, *such as surgical procedures and inserting an intravenous (IV) line.*
- **Level 4:** is used for **High** Risk of exposure situations, *such as during long, fluid intense surgical procedures.*

"Critical Zones" of a Surgical Gown



ANSI/AAMI PB70:2012

- **Area A&B – Critical Zone**

The classification is based on the lower performing component of the two areas A&B.

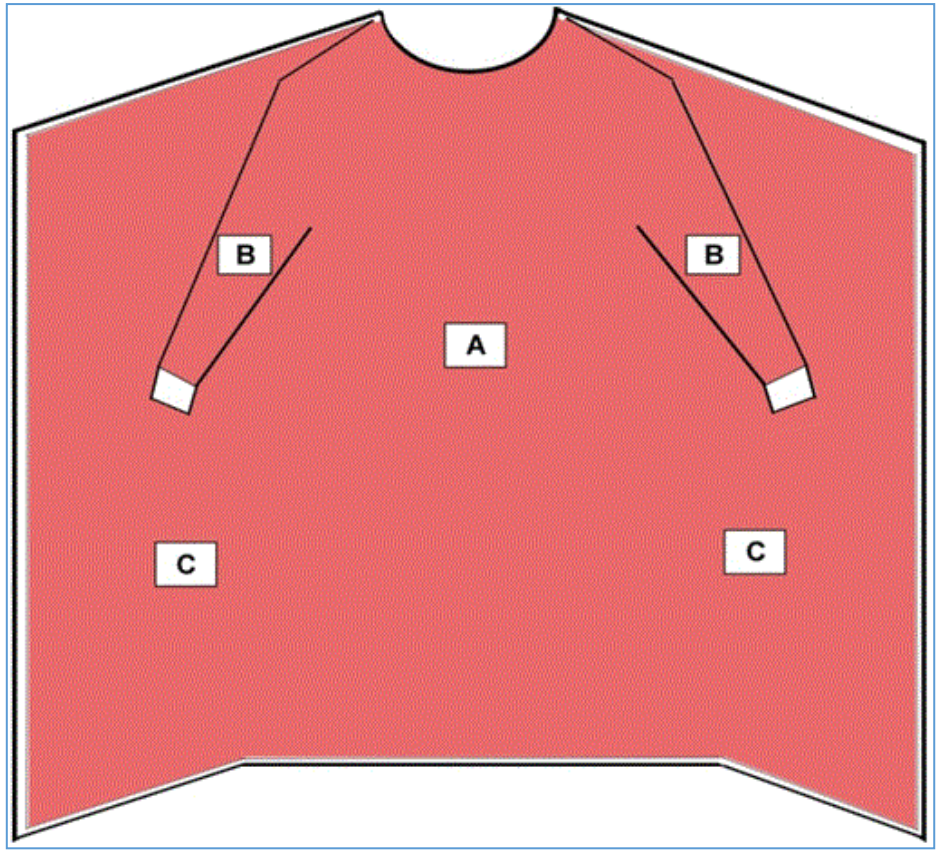
- **Area C – Non-critical Zone**

It is required to meet minimum of level 1 barrier performance.

- **Area D – Non-protective zone**

It can be non-protective.

"Critical Zones" of a Surgical Isolation Gown and a Non-surgical Gown



ANSI/AAMI PB70:2012

Area A, B, C – Critical zone

The entire gown is the "critical zone ".

Surgical isolation gowns are used when there is a medium to high risk of contamination and **need for larger critical zones** than traditional surgical gowns.

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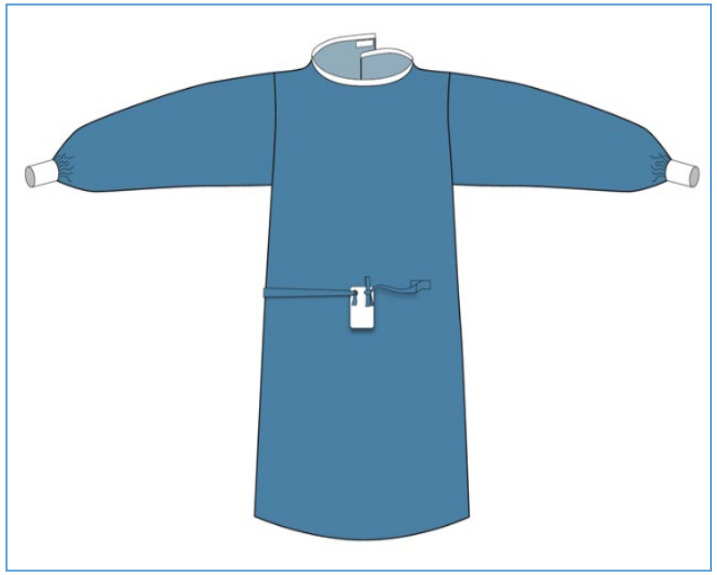
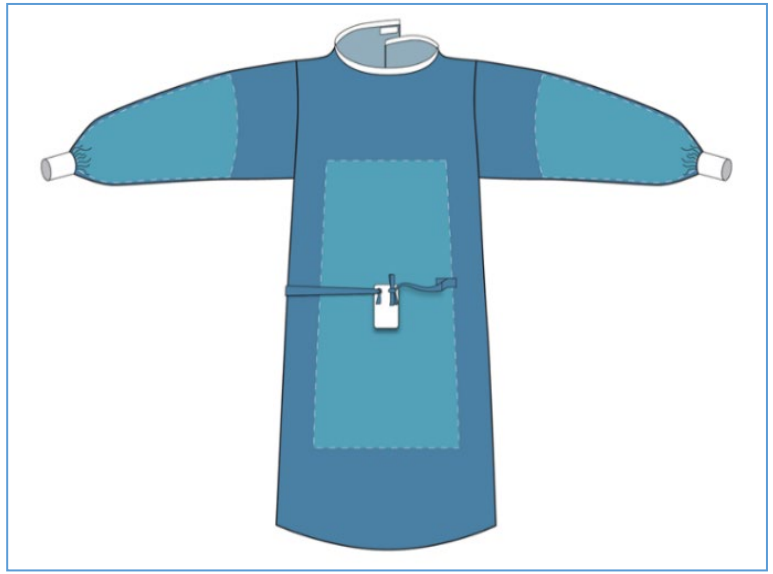
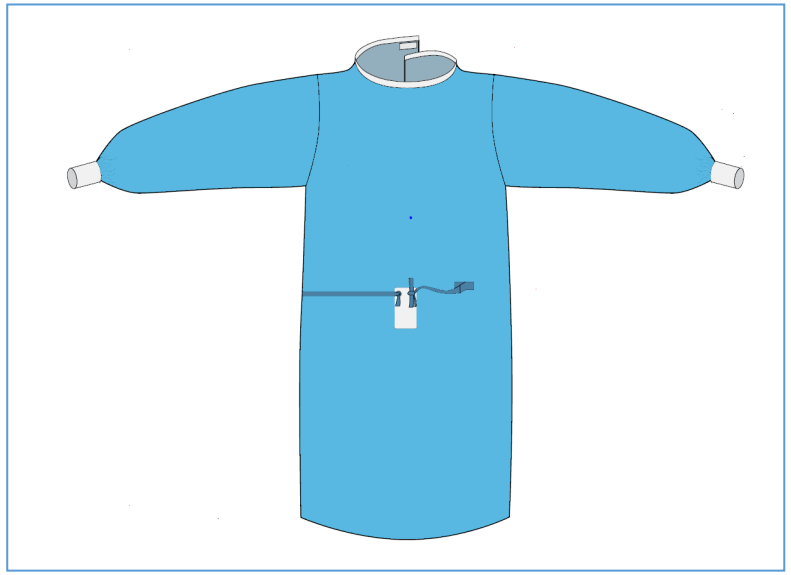
Surgical Gown Overall Designs



Invenio Level 3 Non-Reinforced Surgical Gown (K162442)



Invenio Level 4 Film-Reinforced Surgical Gown (K163191)



Invenio Level 4 Breathable Surgical Gown (K172445)

Surgical Gown Overall Designs

Medline Level 3 Non-Reinforced Surgical Gown

Halyard Level 4 Ultra Film-Reinforced Surgical Gown

Cardinal Health Smart Level 4 Breathable Surgical Gown

Surgical Gown Accessory Designs

Neck Binder – neck length adjustable with Velcro at back

Knitted cuff – interface with gloves, fit and comfort

Cool Back Panel – use light SMS for ventilation and cost deduction

Tie patch design – without compromising the material integrity

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Surgical Gown Materials

Delta-medi **Spunlace** Surgical Gown

Halyard Ultra **Poly Film Laminate** Surgical Gown

Cardinal **Breathable Tri-laminate** Smart Surgical Gown

Medline **SMS** Non-Reinforced Surgical Gown


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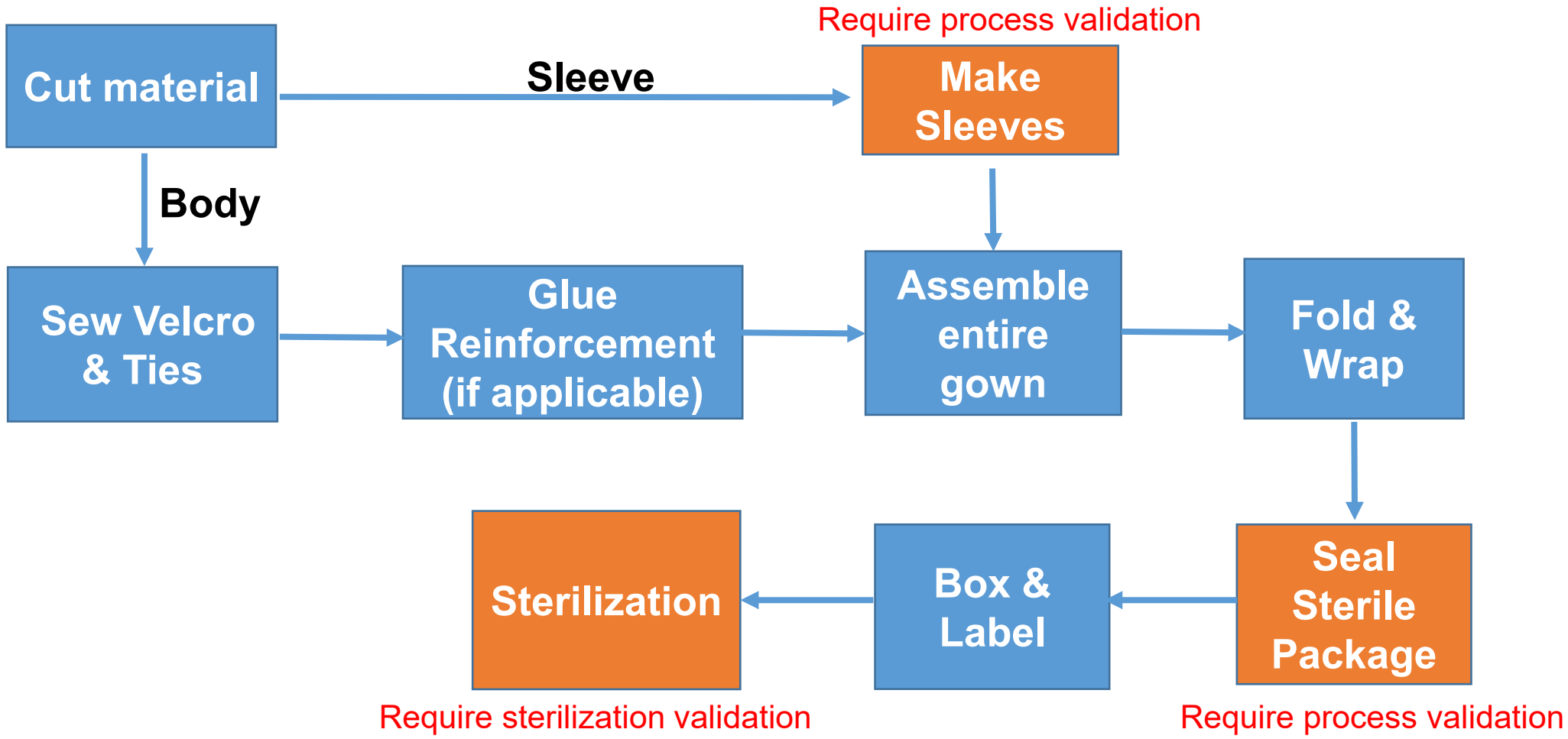
Manufacturing Process Flow Chart

Manufacturing environment: Clean room



Process Validation

IQ
Installation Qualification

- Equipment installed correctly?
- Can it produce my product?

OQ
Operational Qualification

- Input & Output relationship?
- Operational range?
- Check output (testing) at **high, low** and **nominal** settings

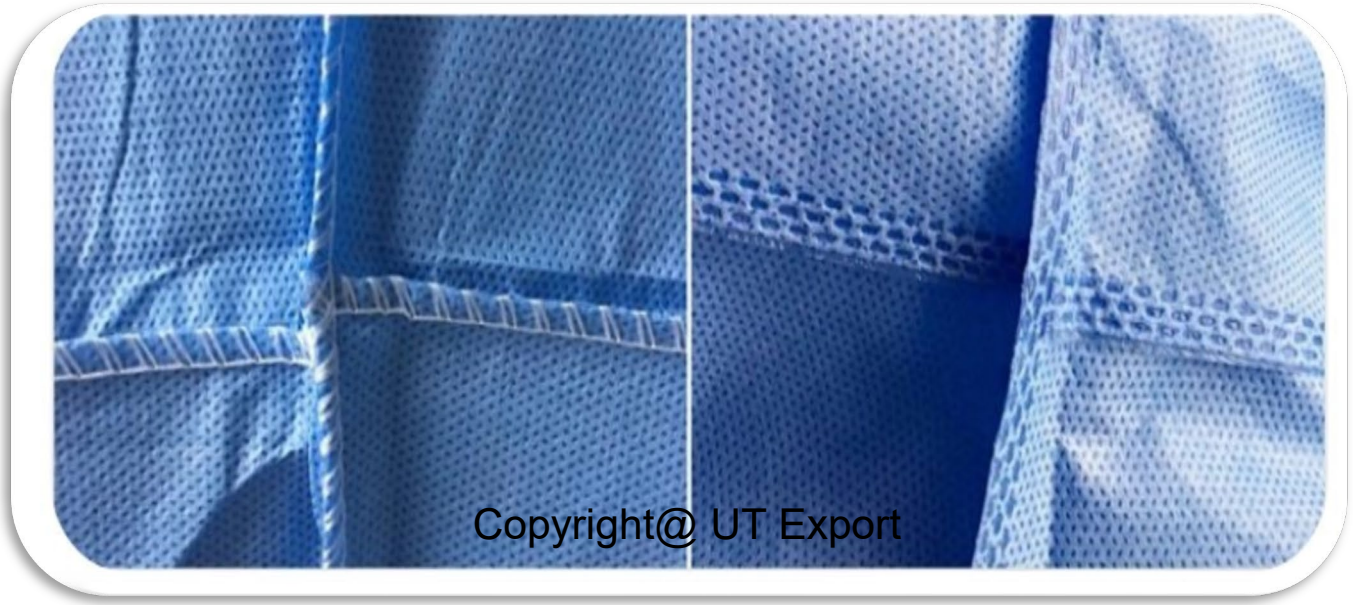
PQ
Performance Qualification

- Run at least 3 lots under nominal setting and test product performance
- To ensure the consistency of the process

Seam Types

Stitched Seam

Ultrasonic welding Seam



Used in non-protective zones

Used in non-critical & non-protective zones

Heat Seal Seam

Used in critical zones (sleeve seams)

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Barrier Performance ANSI/AAMI PB70:2012

Sampling requirement: AQL=4%, α=0.05, RQL=20%, β=0.10

Level 1 AATCC 42: Impact Penetration </= 4.5gm (IPR)

Level 2 AATCC 42: Impact Penetration </= 1.0gm (IPR)

AATCC 127: Hydrostatic Pressure >/= 20cm (Hydrohead)

Level 3 AATCC 42: Impact Penetration </= 1.0gm (IPR)

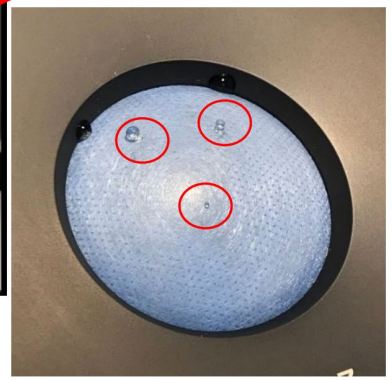
AATCC 127: Hydrostatic Pressure >/=50cm (Hydrohead)

Level 4 ASTM F 1671 Viral Penetration: PASS

Photo Credit: NIOSH NPPTL

AATCC 42 Impact Penetration

Photo Credit: NIOSH NPPTL



Test Fabric

AATCC 127 Hydrohead

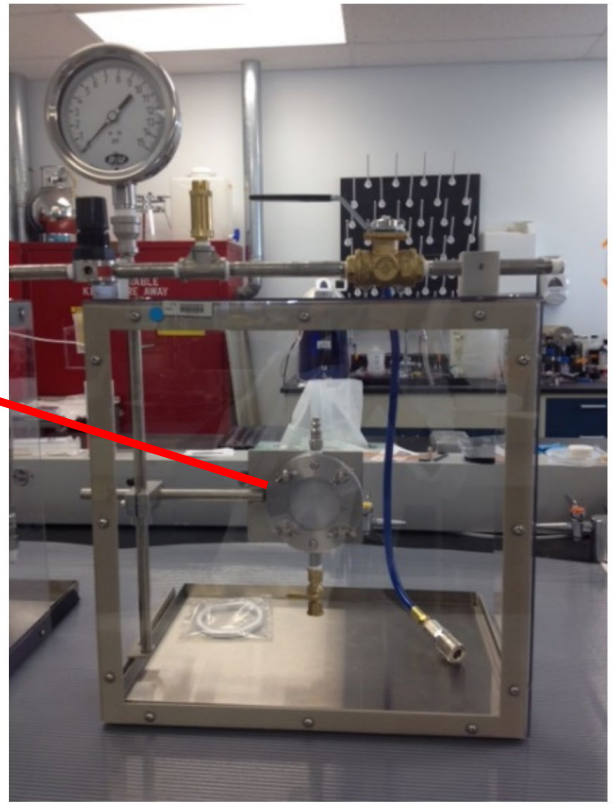


Photo Credit: NIOSH NPPTL

ASTM 1670 Blood Penetration
&
ASTM 1671 Viral Penetration

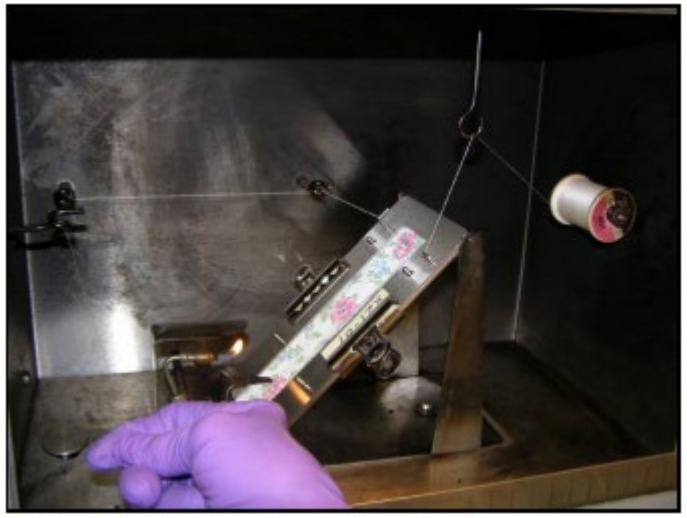
Other Required Testing

ISO 10993-1 Biocompatibility

- Cytotoxicity
- Irritation
- Sensitization

Flammability (16CFR Part 1610)

- Meet class 1 requirement



16CFR Part 1610 Test Manual

Device Categories			Biological Effect							
Device Type	Body Contact	CONTACT DURATION Limited: ≤ 24 Hr Prolonged: 24 Hr - 30 Days Permanent: >30 Days	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	System(Acute) Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatability
Surface Devices	Skin	Limited	X	X	X	·	·	·	·	·
		Prolonged	X	X	X	·	·	·	·	·
		Permanent	X	X	X	·	·	·	·	·
	Mucosal Membrane	Limited	X	X	X	·	·	·	·	·
		Prolonged	X	X	X	0	0	·	0	·
		Permanent	X	X	X	0	X	X	0	·
	Breached or Compromised Surfaces	Limited	X	X	X	0	·	·	·	·
		Prolonged	X	X	X	0	0	·	0	·
		Permanent	X	X	X	0	X	X	0	·
External Communicating Devices	Blood Path, Indirect	Limited	X	X	X	X	·	·	·	X
		Prolonged	X	X	X	X	0	·	·	X
		Permanent	X	X	0	X	X	X	0	X
	Tissue/Bone/Dentin Communicating†	Limited	X	X	X	0	·	·	·	·
		Prolonged	X	X	0	0	0	X	X	·
		Permanent	X	X	0	0	0	X	X	·
	Circulating Blood	Limited	X	X	X	X	·	0‡	·	X
		Prolonged	X	X	X	X	0	X	0	X
		Permanent	X	X	X	X	X	X	0	X
Implant Devices	Tissue/Bone	Limited	X	X	X	0	·	·	·	·
		Prolonged	X	X	0	0	0	X	X	·
		Permanent	X	X	0	0	0	X	X	·
	Blood	Limited	X	X	X	X	·	·	X	X
		Prolonged	X	X	X	X	0	X	X	X
		Permanent	X	X	X	X	X	X	X	X

X = ISO 10993-1 tests
O = Additional tests that may be applicable
† = Tissue includes tissue fluids and subcutanous spaces
‡ = For all devices used in extracorporial circuits

Other Non-essential Testing

Strength Requirements

- Grab Tensile (dry & wet)
- Trapezoid Tear (dry & wet)
- Bursting Strength (dry & wet)
- Seam Strength

Others

- Linting
- Water Vapor Transmission
- European Standard: EN13795

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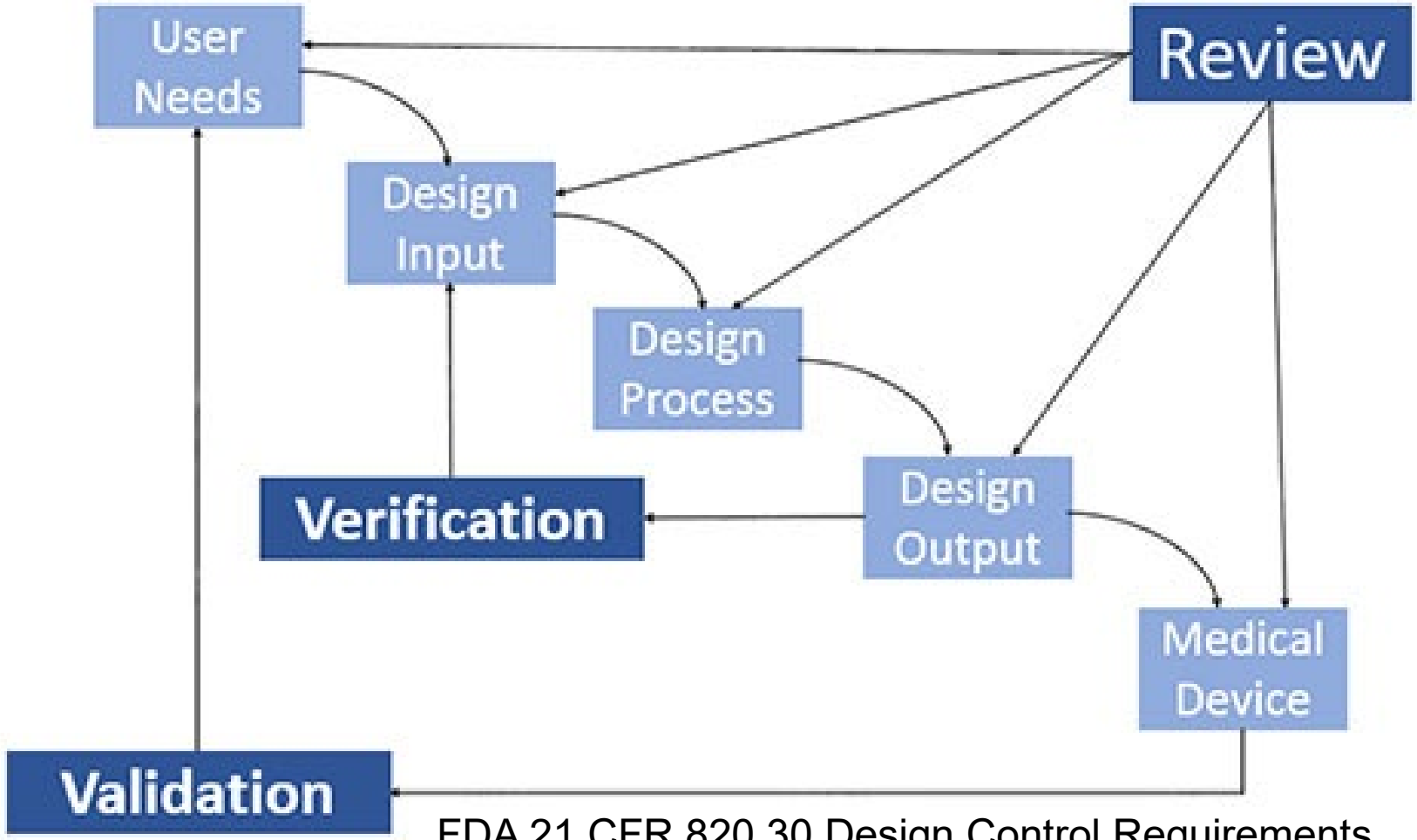
Design Control



FDA 21 CFR 820.30 Design Control Requirements

Design Control

- 21 CFR 820.30, Design Controls Elements:
  - ❑Design Planning *(Start date, budget e.tc)*
  - ❑Design Input *(Marketing & Engineering specs)*
  - ❑Risk Analysis *(DFMEA and PFMEA, living documents)*
  - ❑Design Output /DMR *(specs, tooling, BOMs, SOPs, DHR formats…)*
  - ❑Design Changes *(material, process, supplier change e.tc)*
  - ❑Design Reviews *– including an independent reviewer*
  - ❑Design Verification *(design input = design output, inspection/testing)*
  - ❑Design Validation *[Product, Equipment (DQ, IQ, OQ, PQ), software]*
  - ❑Design Transfer *(from PD to manufacturing, Engineering run, Trial run)*
  - ❑Design History File *(documentation to demonstrate the above)*

510(k) Submission

- Surgical gowns are **Class II medical devices -** require 510(k) clearance.
- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least **as safe and effective**, that is, **substantially equivalent**, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.
- Guidance document FDA 510(k) Program: https://www.fda.gov/media/82395/download
- First priority is to **find predicate devices**: https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices
- If you have a novel design and there is no predicate available, consider **the De Novo Process**. https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request

Other Resources

- FDA Guidance On Medical Gowns: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns
- FDA Process Validation: https://www.fda.gov/media/94074/download
- FDA Design Control: https://www.fda.gov/media/116762/download
- Available databases: 510k(s), Total Product Life Cycle (TPLC)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

- PPE Donning (Put on) https://www.youtube.com/watch?v=Ca66dpjPWZc
- PPE Doffing (Take off) https://www.youtube.com/watch?v=bZA424c5sWQ

Questions?

If there are any further questions which we were not able to cover today, please feel free to contact us:

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