Committee F02 on
Flexible Barrier Packaging

Package Integrity: Methods of Detection

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Agenda

- Define package integrity
- Define Leak
- Methods of detection (ASTM options)
  - Visual Inspection
  - Dye Penetration
  - Bubble Emission
  - Container Closure
  - Helium Tracer gas

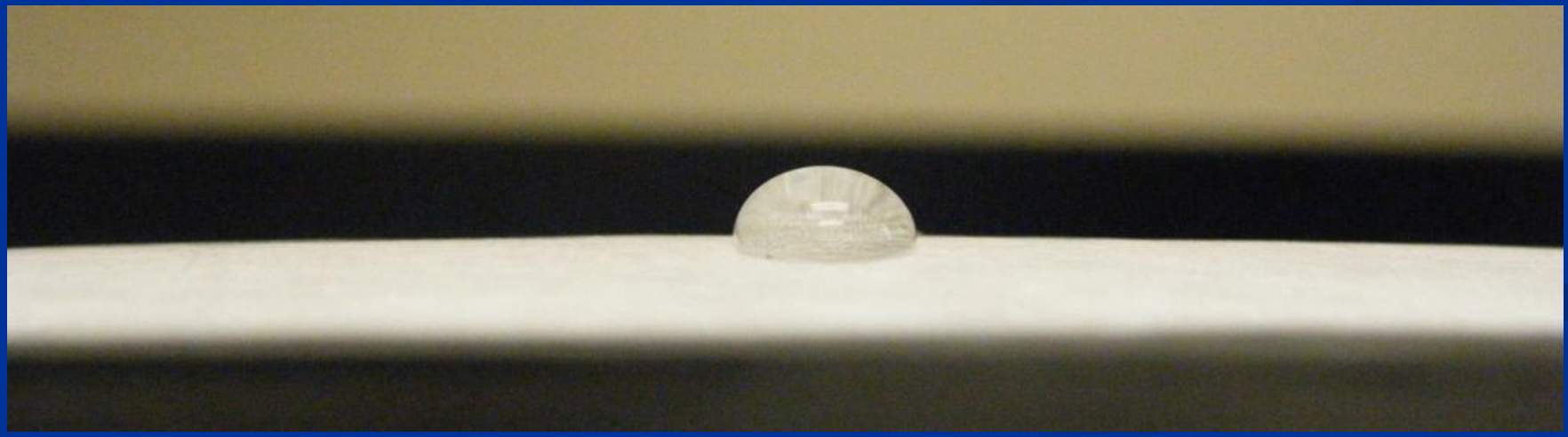
What is Package Integrity?

ASTM F17-08

"the physical capability of a given package to protects its contents with the desired level of protection over a defined period of service."

Package Integrity

A barrier to physical, microbiological or chemical challenges

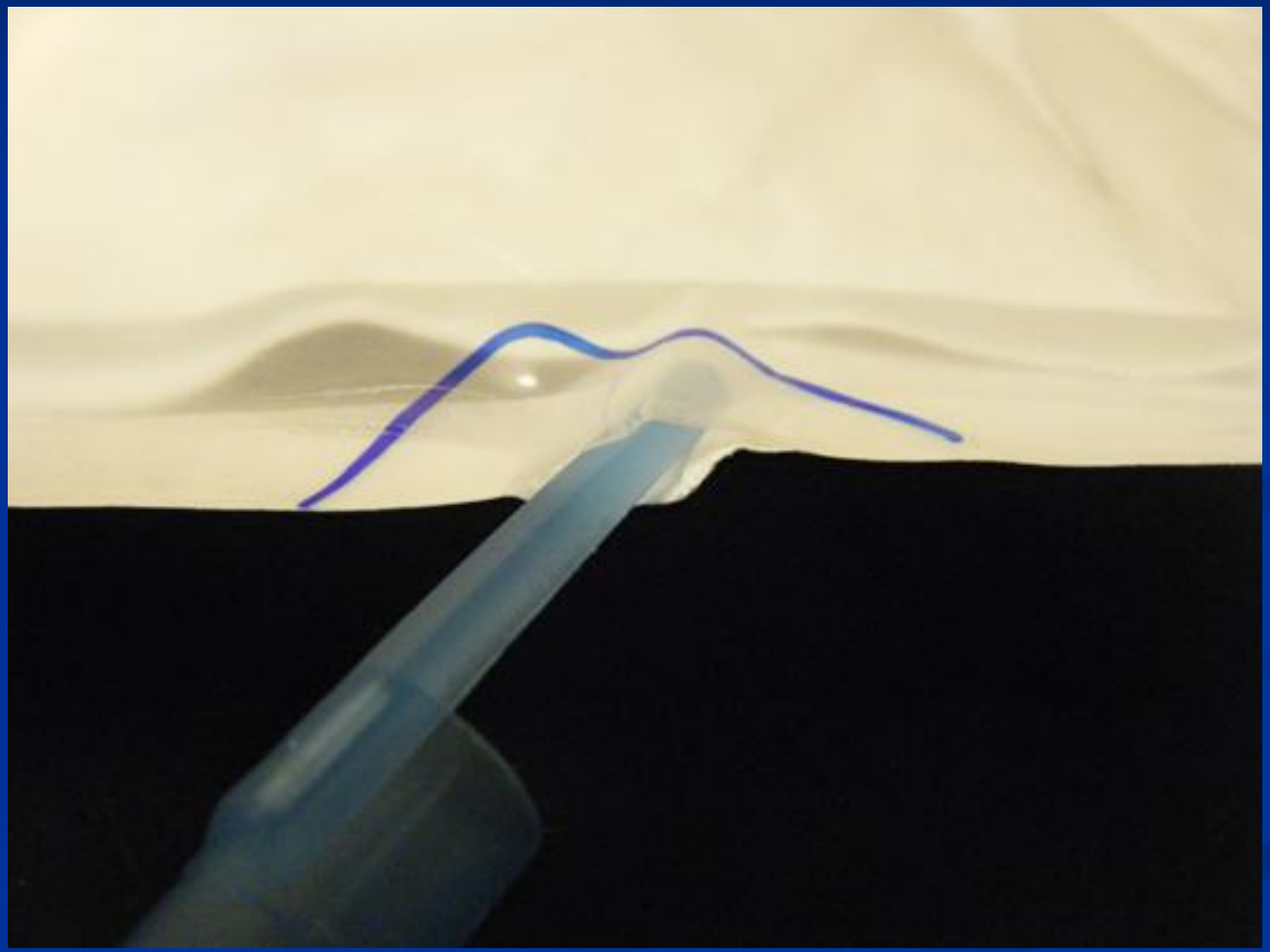


What is a Leak?

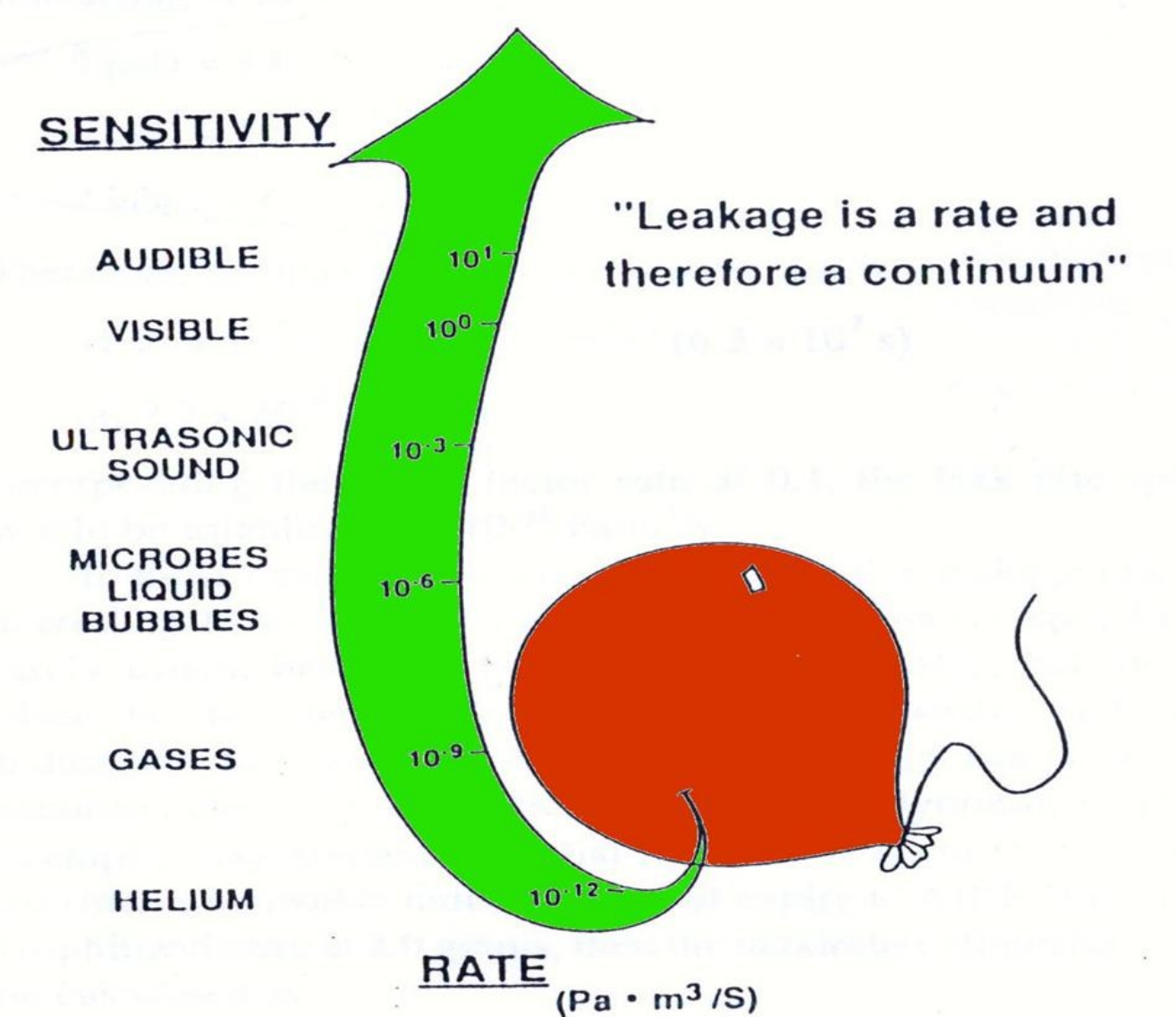
ASTM Definition – F17-08

" Any opening in a flexible packaging that is contrary to intention and either lets contents escape or permits substances to enter."

Example of Leak



Leak rates are continuous



ASTM test methods

Non-destructive	Destructive
Visual Inspection	Bubble Emission
Pressure Decay	Dye Penetration
Tracer Gases	Tracer Gases
	Vacuum Decay

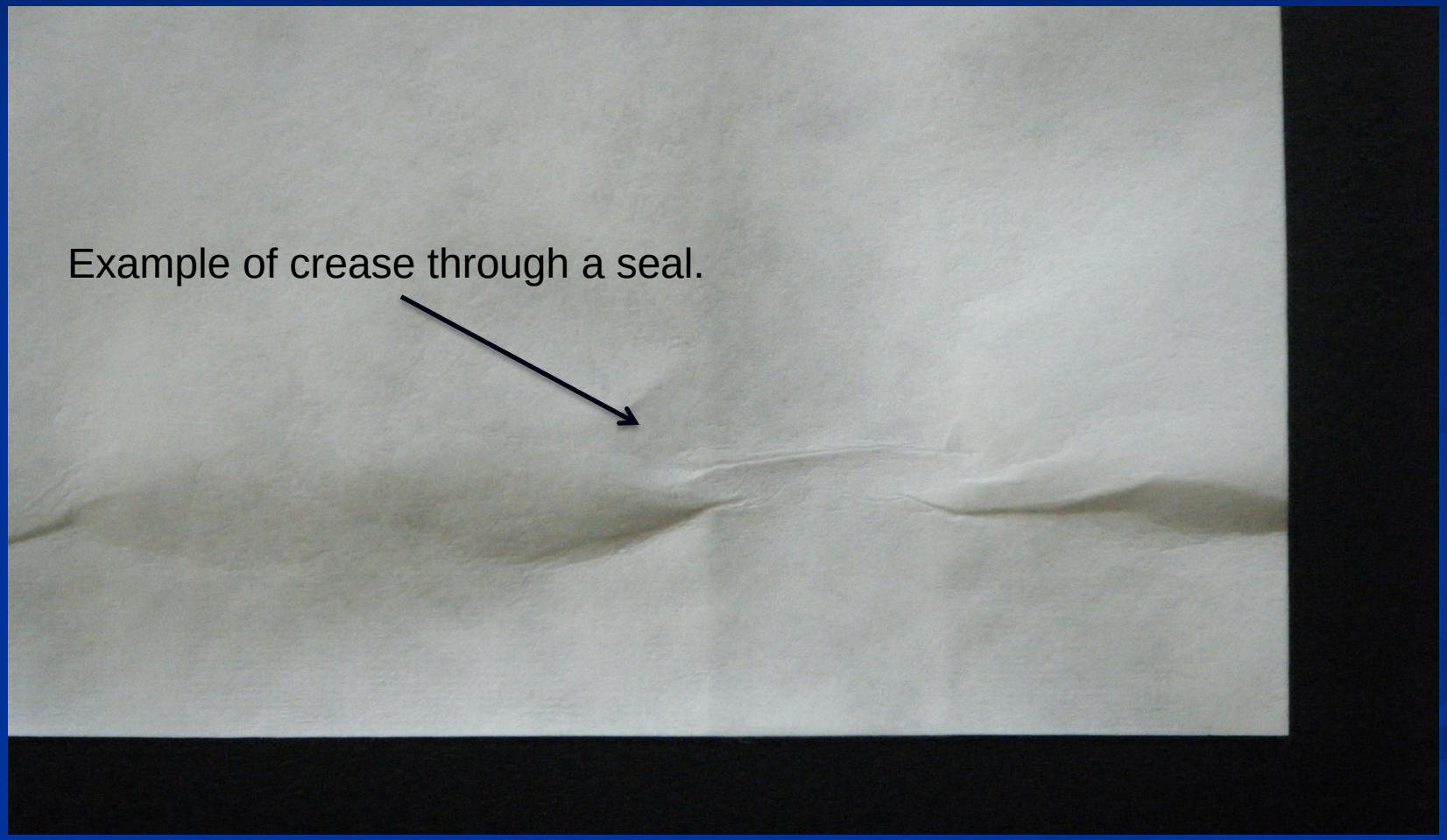
Visual Inspection

Internal/External evaluation:				
Irregularities in or on the sterile barrier materials (i.e., tears, holes)	Presence of foreign material	Dimensional accuracy	Seal integrity (open or incomplete seals)	Presence of humidity, moisture, or staining

Visual Inspection

- Human Leak Inspector
- Easiest and Least Expensive
- Least Sensitive (10-1 cm3/s threshold)
- Limitation - Human Ocular Resolution = ~40-50 mm
- Operator skill variability, fatigue, error, training

Visual Inspection



Dye Penetration

- Involves injecting dye into the package
  - Placing the weight of the solution against each portion of the seal for a specific length of time
- Examine package for evidence of seal failure
  - Examination by visual or microscopic
  - Demonstrated by dye slipping through the seal
- Sensitivity dependent on the solution used
  - Alcohol, surfactants change the surface tension

Dye Penetration

Dye Penetration

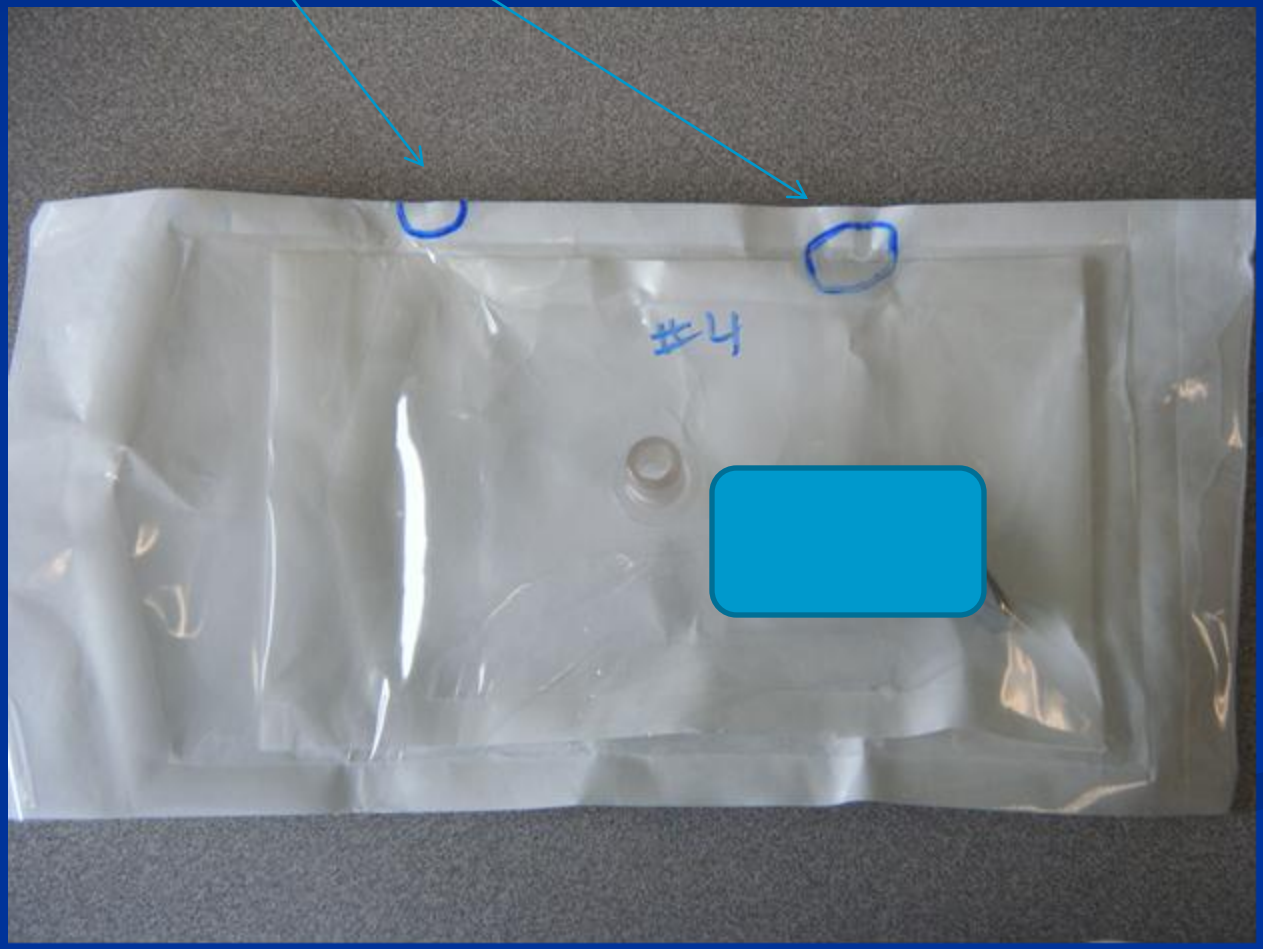
Bubble Emission

- Involves inflating the package and submerging it into a surfactant solution
- Package examined for evidence of seal failure or holes in packaging, demonstrated by bubbles emerging through the seal

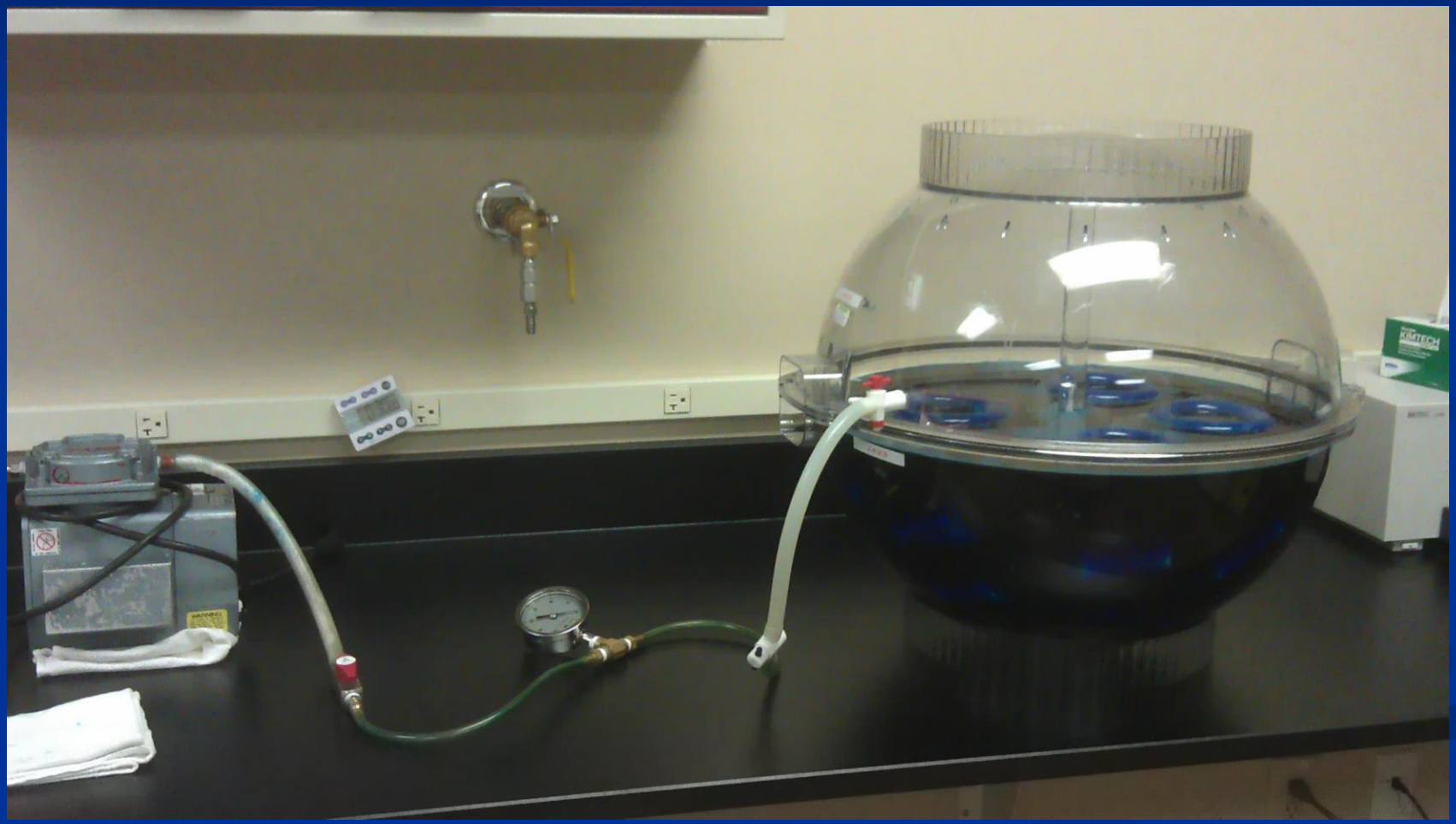
Bubble Emission

Bubble Emission

Tyvek® folds



Container Closure Integrity



Container Closure

- An integrity test for rigid containers, based on concepts from ASTM D4991
- Samples are exposed to methylene blue dye for a specific time under vacuum.
- Samples can be verified for the presence of the dye in the sample matrix with either visual inspection or UV/Vis
- Ensure the dye is not inhibited by the matrix

Pressure Decay

An inflation leak test in which a non-porous package or product is pressurized to a preset level. After the package has stabilized, the decay in pressure over a preset test time is evaluated to determine if a leak is present.

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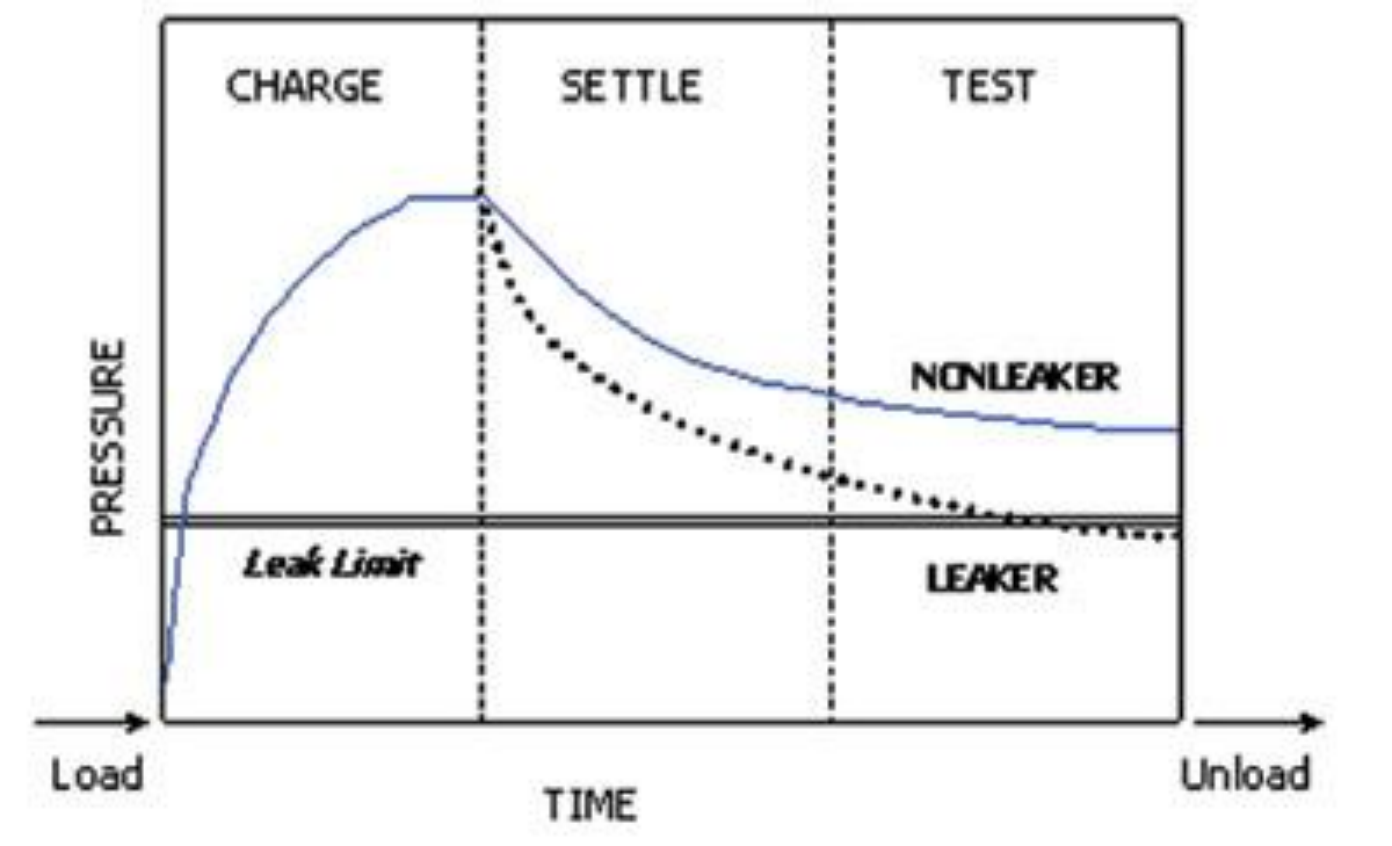
Pressure/Vacuum Decay chart



Helium Tracer Gas

- Two methods outlined in the ASTM method
  - Sniffer Mode
    - The package is scanned externally
    - Higher variability based on how the package is handled
  - Vacuum Mode
    - Package is filled with helium and sealed closed
    - Placed in a chamber and pressurized

Helium Tracer Gas

- Can apply to a variety of packages including:
  - Flexible
  - Semi-rigid
  - Rigid
- Not a test for porous materials
- Vacuum chamber is completely customizable

Other options..

- O2, ASTM F2714 Oxygen Headspace Analysis Using Fluorescent Decay and ASTM New Standard Oxygen Analysis of Packages Using Headspace Sampling
- CO2, ASTM F2227 Nondestructive Detection of Leaks in Trays by CO2 and ASTM F2228 Nondestructive Detection of Leaks in Porous Packaging by CO2
- Water Vapor
- H2, ongoing research

ASTM test methods

- F1886 Test Method for Determining Integrity of Seals for Medical Packaging
- F1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging
- D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- F2095 Test Method for Pressure Decay Leak Test for Flexible Packages With or Without Restraining Plates

ASTM test methods

- F2096 Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization
- F2227

Questions?

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