An Overview of Dating Claim Verification Testing
(Otherwise Known as Shelf Life Testing)

Presented by
Curt Larsen and John Spitzley
Spartan Design Group
The Knowns & the Unknowns

• The Requirement:
  If you sell a medical device that deteriorates over time and/or is sold outside of the USA, you will need to have an expiration date on your packaging system labeling.

• Questions Needing Answers:
  What is this date? What does it mean? How is it arrived at? How does this affect the packaging engineer? Why and how do you verify the labeling dating claims?
The Agenda

- Why Are Dates Needed?
- Expiration Date Requirements
- Events Related to Loss of Sterility
- Real-Time Aging
- Accelerated Aging
- Accelerated-Aging Testing (Stressing)
- Calculating Accelerated – Aging Time
- Shelf-Life Test Protocol Considerations
- Humidity and Accelerated Aging
- Aging and Performance Testing
- ASTM F1980-07
Why Are Dates Needed?

- Many medical devices contain materials or components that have a finite shelf life.

- Polymers can oxidize or plasticizers can volatilize/bloom, changing the physical properties of the material.

- Changes may affect the functionality or cosmetic appearance of the device and could be viewed as evidence of poor quality.
Why Are Dates Needed? (cont.)

- For marketing reasons, removal of older designs from the field as newer designs are developed is often desirable.

- Expiration dates aid stock rooms and warehouses to practice a FIFO (first in, first out) stock rotation policy.

- EC requires dates.
Expiration Date Requirements

– An expiration date based on the demonstrated shelf life of the device materials and components & must be printed on the package.

– Demonstration that the package will maintain sterility of that device at least as long as the declared shelf life of the device.

– NO LINKAGE TO STERILITY & S.B.S.
Real-Time Aging

– Real-time aging is required to demonstrate that a package will maintain sterile integrity over time….it is the requirement, accelerated aging is allowed.

– Real-time aging tests must be performed on fully processed production packages using the same materials for saleable product.
Real-Time Aging (cont.)

To include or not include the package contents? (Applies to Accelerated Aging as well)

- Yes, if looking at device aging.  
  *Recommendation – Stability testing for devices should be done separately*
- Yes, if doing concurrent performance testing.  
  *Recommendation – Avoid combining these tests if at all possible*
- No, if only looking for package aging data.  
  *Recommendation – The ideal configuration for SBS stability testing is an empty package*
Accelerated Aging

– Accelerated-aging results are acceptable for initial product introduction as long as parallel real-time aging is in progress.

– There are no clear and concise standards for establishing an accelerated-aging test for SBS materials – BUT – They also must be evaluated for stability over time.
Accelerated Aging (cont.)

ASTM International F 1980-07, Standard Guide for Accelerated Aging of Sterile Medical Device Packages, is a guide, not a test method. It provides…

- Procedures for calculating the duration of the aging test to achieve an equivalent real-time aging period.
- Guidelines for setting the accelerated-aging temperature.
- Guidance for establishing room or ambient temperature.
Accelerated-Aging Testing

– It is based on theoretical calculations of reaction rates in an ideal gas.

– In an ideal gas, a temperature increase of 10°C approximately doubles the reaction rate, a $Q_{10}$ of 2. (Defined by F1980 as a “conservative” means of calculating the Aging Factor)
Accelerated-Aging Testing (cont.)

- The aging temperature \( (T_{AA}) \) must be selected based on the limits of sample materials.

\[ T_{AA} \] should not exceed 60°C due to the higher probability of nonlinear changes, such as percent crystallinity changes, formation of free radicals, and peroxide degradation.
Calculating Accelerated – Aging Time

- The accelerated-aging factor (AAF) is calculated based on the difference between the accelerated-aging temperature ($T_{AA}$) and the expected storage temperature, $T_{RT}$

$$AAF = Q_{10}^{(T_{AA} - T_{RT})/10}$$

- F1980 states – “Select a temperature that represents the actual product storage and use conditions (This is typically between 20°C to 25°C)

If $Q_{10} = 2$; $T_{RT} = 22°C$; $T_{AA} = 55°C$, then

$$AAF = 2^{(55 - 22)/10} = 3.3$$

- The number of days to simulate 1 year of real-time aging in these conditions is

365 days/3.3 = 110 days
Shelf-Life Test Protocol
Considerations

The essential requirements of a protocol are…

– The evaluation the SBS materials and seals over time (Real-time as well as accelerated).

– The SBS’s must sterilized (to maximum expected levels), aged, and then tested.
Shelf-Life Test Protocol Considerations (cont.)

- Un-aged control SBS’s and un-aged sterilized SBS’s provide a baseline for comparing the effects of aging and sterilization on the samples.

- Sample evaluation must include integrity tests and strength tests plus additional tests for certain circumstances.

- SBS material strength attributes must be evaluated for stability over time
Humidity and Accelerated Aging

– ASTM F 1980-07 strongly suggests ambient humidity should used for accelerated aging.

– Humidity has two effects in this type of environment:
  • It can act as a reactant in a chemical reaction.
  • It can modify the characteristics of a material.
Some Possible Effects of Humidity

– Increased water content in the air can accelerate a chemical reaction, such as corrosion, far beyond what would be predicted by the increased temperature.

– A material that naturally adsorbs water from the air will dry out as relative humidity drops, thus introducing unexpected stress and possible failure.
Effects of Humidity (cont.)

– Addition of moisture might cause a component to adsorb more moisture than possible in normal conditions resulting in swelling, softening, loss of adhesion, or in extreme cases, dissolution.

– POINT: Use ambient humidity for elevated temperature

(F1980-07 revised approach)
Aging and Performance Testing

When to do both at once?
NEVER…(*Avoid these situations if at all possible!!*)

- Schedule Limitations…..no time to do SBS stability and packaging system performance separately.

- Significant lose of material and seal strengths are anticipated.
Aging and Performance Testing

Why do them separately?

- Repeat work already performed - Cost time & money.....only do performance if materials are known.

- Failure of SBS - difficult to determine root cause.....aging or design?

- Stability data is becoming more and more available from SBS materials convertors and manufacturers.
Aging and Performance Testing (cont.)

- Allows for changes in designs and configurations of SBS systems without repeating the aging.

- Combining the two tests exposes the packaging systems to conditions and stresses never seen in handling, distribution & storage environments.

- Allows new designs using existing tested (stable) materials to be used in new product designs….speed to market!

- ISO 11607-1 states that, “Stability testing and performance testing are separate entities”
ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Medical Device Packages

Significant changes made to F1980-02 version

• Main Changes
  – Incorporation of references to ISO11607-1 and –2.
  – Requirements, terminology and definitions as well as the philosophy behind the separation of aging from performance testing.
Clarification was added regarding……

• Aging as the focus and only aging

• Design Qualification Performance Testing flow chart removed and guidance added recommending separation of stability and performance testing

• Clarification regarding the use of humidity

• Guidance regarding the use of temperature extremes in an Aging Protocol
Summary

- It’s a good idea to do stability testing for SBS’s even when it’s not required
  - Allows for global distribution
  - You don’t ever want to use unstable materials for an SBS
Summary (Cont’d)

• **Real time aging is the requirement**
  – Accelerated aging for speed to market....IDEA....make the Real Time ones 1st !!!!?
Summary (Cont’d)

• *Try not to set your packages on fire!*
  - Don’t get crazy with your Accelerated Aging temperatures
Summary (Cont’d)

- Stability protocols should include the requirements of 11607-1 and the guidance provided by ASTM F1980-07

This is supposed to be ASTM/ISO providing guidance to a packaging engineer
Summary (Cont’d)

- It’s not always a jungle out there!
  - Use ambient humidity
AND- LAST BUT NOT LEAST

- Don’t shoot yourself in the foot and create a self inflicted wound
  - Separate SBS stability from performance testing
QUESTIONS????

Thank you!!!

Curtis L. Larsen, CPP, Fellow
John Spitzley, CPP, Fellow
Spartan Design Group
952-380-1458
MSUGreen@aol.com (Curt)
JohnSpitzley@comcast.net (John)
www.SpartanDesignGroup.com