# An Overview of Dating Claim Verification Testing

## (Otherwise Known as Shelf Life Testing)

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# 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?**

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# 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**

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# 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.**

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# 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.**

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# 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.**

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# 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***

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# 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.**

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# 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)**

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# 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, $T_{RT}$**

  **$AAF = Q_{10}^{(TAA - TRT)/10}$**

- **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**

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# 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.**

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# 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**

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# 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.**

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# 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.**

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# 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.**

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# 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”***

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# 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.**

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# ASTM F1980-07 (cont.)

**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**

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# 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**

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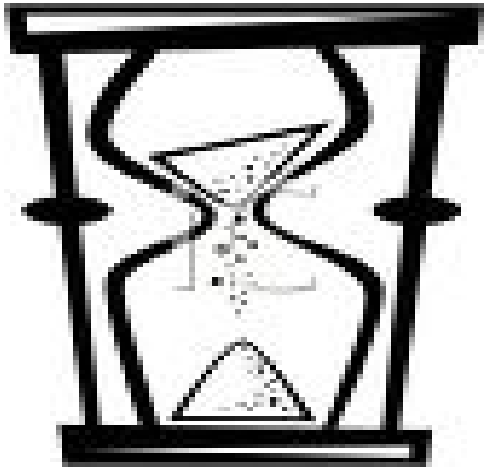
# Summary (Cont'd)



- ***Real time aging is the requirement***

  **– Accelerated aging for speed to market....IDEA….make the Real Time ones 1st !!!!?**

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# Summary (Cont'd)

- ***Try not to set your packages on fire!***

  **- Don't get crazy with your Accelerated Aging temperatures**

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# Summary (Cont'd)

**This is supposed to be ASTM/ISO providing guidance to a packaging engineer**

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

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# Summary (Cont'd)

- ***It's not <u>always</u> a jungle out there!***
  - **Use ambient humidity**

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# 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!!!

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