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17	**上市后产品报告**	上市后产品报告
18	**易用性（可用性）报告**	IEC_62366-可用性报告
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20	**风险管理报告（国内）**	
21	**工艺用水确认报告**	符合国内医疗器械规范（医疗器械gmp）的方案报告等
22	**飞行检查符合性（国内）**	检查符合性、不合格整改，让企业符合gmp规范，避免停产
23	**确认培训（灭菌、包装、工艺用水、热封、CE法规）**	培训ppt，课程1-2天
24	**国内医疗器械飞检培训**	课程1-2天
25	**降解方案及报告**	编写降解方案（符合国内、ce、FDA要求），检测报告

Designation: F1980 – 16

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices[1]

This standard is issued under the fixed designation F1980; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides information for developing accelerated aging protocols to rapidly determine the effects, if any, due to the passage of time on the sterile integrity of the sterile barrier system (SBS), as defined in ANSI/AAMI/ISO 11607–1:2006 and the physical properties of their component packaging materials.

1.2 Information obtained using this guide may be used to support expiration date claims for medical device sterile barrier systems.

1.3 The accelerated aging guideline addresses the sterile barrier systems in whole with or without devices. The sterile barrier system material and device interaction compatibility that may be required for new product development or the resulting evaluation is not addressed in this guide.

1.4 Real-time aging protocols are not addressed in this guide; however, it is essential that real-time aging studies be performed to confirm the accelerated aging test results using the same methods of evaluation.

1.5 Methods used for sterile barrier system validation, which include the machine process, the effects of the sterilization process, environmental challenge, distribution, handling, and shipping events, are beyond the scope of this guide.

1.6 This guide does not address environmental challenging that stimulates extreme climactic conditions that may exist in the shipping and handling environment. Refer to Practice D4332 for standard conditions that may be used to challenge the sterile barrier system to realistic extremes in temperature and humidity conditions. See Terminology F1327 for a definition of "environmental challenging."

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

E337 Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures)

F17 Terminology Relating to Flexible Barrier Packaging

F1327 Terminology Relating to Barrier Materials for Medical Packaging (Withdrawn 2007)[3]

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

2.2 *AAMI Standards:*

ANSI/AAMI/ISO 11607–1: 2006, Packaging for Terminally Sterilized Medical Devices[4]

AAMI TIR 22–2007, Guidance for ANSI/AAMI/ISO 11607, Packaging for Terminally Sterilized Medical Devices[4]

3. Terminology

3.1 *Definitions*—For general definitions of packaging for medical devices, see ANSI/AAMI/ISO 11607. For terminology related to barrier materials for medical packaging see Terminology F17.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *accelerated aging (AA), n*—storage of samples at an elevated temperature (T_{AA}) in order to simulate real time aging in a reduced amount of time.

3.2.2 *accelerated aging factor (AAF), n*—an estimated or calculated ratio of the time to achieve the same level of physical property change as a sterile barrier system stored at real time (*RT*) conditions.

[1] This guide is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.2.3 *accelerated aging temperature (T_{AA}), n*—the elevated temperature at which the aging study is conducted, and it may be based on the estimated storage temperature, estimated usage temperature, or both.

3.2.4 *accelerated aging time (AAT), n*—the length of time the accelerated aging is conducted.

3.2.5 *ambient temperature (T_{RT}) , n*—storage temperature for real-time aging (*RT*) samples that represents storage conditions.

3.2.6 *sterile barrier system shelf life, n*—the amount of real time that a sterile barrier system can be expected to remain in storage at ambient conditions, or under specified conditions of storage, and maintain its critical performance properties.

3.2.7 *real-time aging (RT), n*—storage time of samples at ambient conditions.

3.2.8 *real-time equivalent (RTE), n*—amount of real-time aging to which given accelerated aging conditions are estimated to be equivalent.

3.2.9 *zero time (t_0), n*—the beginning of an aging study.

3.3 *Symbols:*

Q_{10} = an aging factor for 10°C increase or decrease in temperature.
T_m = temperature at which a material melts.
T_g = glass transition temperature.
T_α = alpha temperature; heat distortion temperature.

4. Significance and Use

4.1 The loss of sterile barrier system integrity may occur as a result of physical properties of the materials and adhesive or cohesive bonds degrading over time and by subsequent dynamic events during shipping and handling.

4.2 ISO 11607–1:2006, clause 6, states that "the packaging system shall provide physical protection and maintain integrity of the sterile barrier system. The sterile barrier system shall maintain sterility to the point of use or until the expiry date. Stability testing shall demonstrate that the sterile barrier system maintains integrity over time. Stability testing using accelerated aging protocols shall be regarded as sufficient evidence for claimed expiry date until data from real time aging studies are available."

4.3 Real time aging programs provide the best data to ensure that sterile barrier system materials and sterile barrier system integrity do not degrade over time. However, due to market conditions in which products become obsolete in a short time, and the need to get new products to market in the shortest possible time, real time aging studies do not meet this objective. Accelerated aging studies can provide an alternative means. To ensure that accelerated aging studies do truly represent real time effects, real time aging studies must be conducted in parallel to accelerated studies. Real time studies must be carried out to the claimed shelf life of the product and be performed to their completion.

4.4 Conservative accelerated aging factors (AAFs) must be used if little is known about the sterile barrier system material being evaluated. More aggressive AAFs may be used with documented evidence to show a correlation between real time and accelerated aging.

4.5 When conducting accelerated aging programs for establishing expiry dating claims, it must be recognized that the data obtained from the study is based on conditions that simulate the effects of aging on the materials. The resulting creation of an expiration date or shelf life is based on the use of a conservative estimate of the aging factor (for example, Q_{10}) and is tentative until the results of real time aging studies are completed on the sterile barrier system.

NOTE 1—Determining AAFs are beyond the scope of this guide.

5. Apparatus

5.1 *Room (or Cabinet)* of such size that samples may be individually exposed to circulating air at the temperature and relative humidity chosen.

5.1.1 *Control Apparatus,* capable of maintaining the room at the required atmospheric conditions within the tolerance limits.

5.2 *Hygrometer*—The instrument used to indicate the relative humidity should be accurate to ±2 % relative humidity. A psychrometer may be used either for direct measurement of relative humidity or for checking the hygrometer (see Test Method E337).

5.3 *Thermometer*—Any temperature-measuring device may be used provided it can accurately indicate the temperature to within 0.1°C or 0.2°F and be properly recorded. The dry-bulb thermometer of the psychrometer may be used either for direct measurement or for checking the temperature-indicating device.

6. Accelerated Aging Theory

6.1 Accelerated aging of materials refers to the accelerated variation of their properties over time, the properties of interest being those related to safety and function of the material or sterile barrier system.

6.2 In an aging study, the material or sterile barrier system is subjected to an external stress, which is more severe, or more frequently applied than the normal environmental stress, for a relatively short period of time.

6.3 Accelerated aging techniques are based on the assumption that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. This function states that a 10°C increase or decrease in temperature of a homogeneous process results in, approximately, a two times or ½-time change in the rate of a chemical reaction (Q_{10})[5].

6.4 Determining the Q_{10} involves testing materials at various temperatures and defining the differences in reaction rate for a 10° change in temperature. Modeling the kinetics of material deterioration is complex and difficult and is beyond the scope of this guide.[6]

[5] Hemmerich, K. J., "General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices," *Medical Plastics and Biomaterials*, July/August 1998, pp. 16–23.

[6] Nelson, W., "Accelerated Testing Statistical Models, Test Plans, and Data Analyses," John Wiley and Sons, New York, 1999.

6.5 A humidity factor to calculate the accelerated aging time (AAT) is not applicable for accelerated aging protocols. Unrealistic or extreme temperature and humidity conditions may be of interest in overall sterile barrier system performance. However, this must be evaluated in a separate study and is not related to aging of the materials. See Appendix X3 for more details on the use of humidity in accelerated aging protocols.

7. Accelerated Aging Plan

7.1 *Characterization of Materials*—AA theory and its application are directly related to packaging material composition. Material properties that may affect the results of accelerated aging studies include:

7.1.1 Composition,

7.1.2 Morphology (glassy, amorphous, semi-crystalline, highly crystalline, % crystallinity, and so forth),

7.1.3 Thermal transitions (T_m , T_g, T_α), as defined in 3.3,

7.1.4 Additives, processing agents, catalysts, lubricants, residual solvents, corrosive gases, and fillers.

7.2 *Accelerated Aging Plan-Design Guidelines:*

7.2.1 Temperature boundaries, based on the characterization of the device and sterile barrier system materials, must be considered in order to ensure that initial, conservative aging factors are applied appropriately. The temperatures used should be based on the characterization of the packaging materials and the intended storage conditions. Material characterization and composition are factors in establishing the accelerated aging temperature boundaries. Temperature selection should be limited to prevent any physical transition of material.

7.2.2 *Room or Ambient Temperature (T_{RT})*—Select a temperature that represents the actual product storage and use conditions.

NOTE 2—This temperature is typically between 20 to 25°C. A temperature of 25°C is considered a conservative approach.

7.2.3 *Accelerated Aging Temperature (T_{AA})*—Considering the characterization of the materials under investigation, select a temperature for the accelerated aging testing. The higher the accelerated temperature, the greater the AAF and, thus, the shorter the accelerated aging time. Care must be taken not to elevate aging temperatures solely for the shortest possible accelerated aging time. Excessively high temperatures may have an effect on the material that may never occur during real time or at room temperature (see Appendix X1). Guidelines for selecting an aging temperature are as follows:

7.2.3.1 T_{AA} should be below any material transitions or below where the sterile barrier system distorts. Consider the thermal transitions of the materials under investigation. (For more information on this topic, see AAMI TIR 22–2007.)

7.2.3.2 Keep T_{AA} at or below 60°C unless a higher temperature has been demonstrated to be appropriate. Temperatures higher than 60°C are not recommended due to the higher probability in many polymeric systems to experience nonlinear changes, such as percent crystallinity, formation of free radicals, and peroxide degradation. (For more information on this topic, see AAMI TIR 22–2007.)

NOTE 3—If sterile barrier systems containing liquid or other volatile components are tested, lower temperatures may be required for safety reasons.

NOTE 4—Tolerances of ±2°C for the test temperature and ±5 % for the humidity are acceptable. Since the shelf life of the finished sterile barrier system is based on a conservative aging factor (Q_{10}) of 2.0 for the accelerated aging protocol, any long term deviation in the temperature less than the specified temperature in the protocol can be compensated for by increasing the total test duration time without invalidating the intent of the aging protocol.

NOTE 5—Where excursions in the test temperature occur over a long period of time, an assessment on the temperature effects to the packaging materials and/or the test duration adjustments required to achieve the desired estimate of shelf life must be determined.

7.2.3.3 When elevated temperature aging is not feasible due to material characteristics, then real-time aging is the only option.

7.3 *Accelerated Aging Factor (AAF) Determination:*

7.3.1 Using the Arrhenius equation with Q_{10} equal to 2 is a common and conservative means of calculating an aging factor.

NOTE 6—A more aggressive reaction rate coefficient, for example, Q_{10} = 2.2 to 2.5, may be used if the system under investigation is sufficiently well characterized in the literature. The level and nature of damage must be similar to that reported in the literature to ensure that the reaction rate coefficient and accelerated aging temperature are maintained within appropriate boundaries. This is the responsibility of the manufacturer. For more information on this topic see AAMI TIR 22–2007.

7.3.2 An accelerated aging factor (AAF) estimate is calculated by the following equation:

$$AAF \equiv Q_{10}^{[(T_{AA} - T_{RT})/10]} \quad (1)$$

where:

T_{AA} ≡ accelerated aging temperature (°C), and

T_{RT} ≡ ambient temperature (°C).

7.3.3 The accelerated aging time (AAT) needed to establish equivalence to real time aging is determined by dividing the desired (or required) shelf life by the AAF.

$$\text{Accelerated Aging Time (AAT)} \equiv \text{Desired (RT)/AAF} \quad (2)$$

NOTE 7—See Appendix X1 for a graphical representation of the time versus temperature. Also, see Appendix X2 for a sample test plan with examples of the calculations using Eq 1 and 2.

7.3.4 When little information is known about the sterile barrier system under investigation, the guidance above is provided for selecting and verifying an appropriately conservative aging factor for the specific scenario. Risk to the manufacturer may be large since the method may predict an unduly short shelf-life; however, consideration must be given to maximizing patient safety since the necessary information to obtain a more accurate and aggressive shelf-life prediction is not readily available.

7.4 *Accelerated Aging Protocol Steps:*

7.4.1 Select the Q_{10} value.

7.4.2 Define the desired shelf life of the sterile barrier system, such as, marketing needs, product needs, and so forth.

7.4.3 Define aging test time intervals, including time zero.

7.4.4 Define test conditions, room temperature (T_{RT}), and accelerated aging temperature (T_{AA}).

7.4.5 Decide if humidity conditions will be used in the aging study. If used, define the relative humidity (RH) conditions and allowable tolerances to be utilized around a targeted

value. (See Appendix X3 and chart in Perry's Chemical Engineering Handbook for realistic absolute humidity conditions.)

7.4.6 Calculate the test duration using the Q_{10}, T_{RT}, and T_{AA}.

7.4.7 Define the sterile barrier system material properties, seal strength and integrity tests, sample sizes, and acceptance criteria.

7.4.8 Age samples at T_{AA}. In parallel, age samples at real-life aging conditions (T_{RT}).

7.4.9 Evaluate the sterile barrier system performance after accelerated aging relative to the initial sterile barrier system requirements, for example, package seal strength and package integrity.

7.4.10 Evaluate the sterile barrier system after real time aging relative to their initial design requirements. The initial AAF method is a simple and conservative technique for evaluating the long-term affects on the materials and seals, however, like all accelerated aging techniques, it must be confirmed by real time aging data.

8. Post-Aging Testing Guidance

8.1 Sterile barrier systems that have been subjected to aging (for example, accelerated and real time) are evaluated for both physical properties and integrity.

8.2 Tests selected for evaluation should challenge the material or package functionality that is most critical or most likely to fail as a result of aging.

8.3 Sterile barrier systems that have been subjected to aging without devices should be evaluated for any degradation of strength properties and the ability to maintain integrity both in the individual materials of the system and any seals or closures. Refer to Guide F2097 for test method guidance and selection.

8.4 Aging or stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the products in response to the stresses imposed by the manufacturing, sterilization processes, and the handling, storage, and shipping environment. Aging of a specific sterile barrier system is independent of the physical configuration or contents; the materials and seals are expected to age the same regardless of their physical configuration or contents as long as the processing of that sterile barrier system is the same, that is, sterilized to the same processes.

8.5 If known package failure or performance limits, such as seal strength, puncture, or impact resistance, and so forth, have been documented and meet the requirements for the intended packaging system, then physical testing data should be sufficient.

8.6 On occasion, package performance testing may be performed on packaging systems after aging to evaluate the performance of the aged packaging system during simulated distribution, handling, and storage as well as to gather evidence of the device components aging characteristics. If this is an objective, all aging samples will include the devices, or simulated devices, and all the packaging materials that make up the packaging system.

8.7 Acceptance criteria are established prior to any aging testing. Several different methods of evaluation may be used. One is to use the zero-time performance data as a comparison to final performance data at the end of the shelf life test; another is to trend the data over all periods of evaluation; use only the final period test results.

9. Report

9.1 *Accelerated Aging:*

9.1.1 A written test protocol specifying the accelerated aging conditions (test temperature, humidity, cycle, ambient temperature), time frame, sample sizes, sterile barrier system description, time intervals of sampling, and specific tests at each time interval must be developed prior to testing.

9.1.2 Document the temperature and relative humidity of the chamber used and the calibrated instruments used for measuring and monitoring the aging conditions.

9.1.3 Document the test standard references and methods used for the sterile barrier system evaluation.

9.1.4 List the equipment used for physical and microbial testing, including the calibration dates.

9.1.5 Document the post-aging test results, including any statistical methods used to determine whether the sterile barrier system meets the performance specification criteria.

10. Keywords

10.1 accelerated aging; Arrhenius reaction rate; Q_{10}; shelf-life

APPENDIXES

(Nonmandatory Information)

X1. ACCELERATED AGING OF POLYMERS

X1.1 Accelerated aging (Fig. X1.1) equivalent to one year of room-temperature aging when the sterile barrier system is heat-aged at a selected temperature (°C).

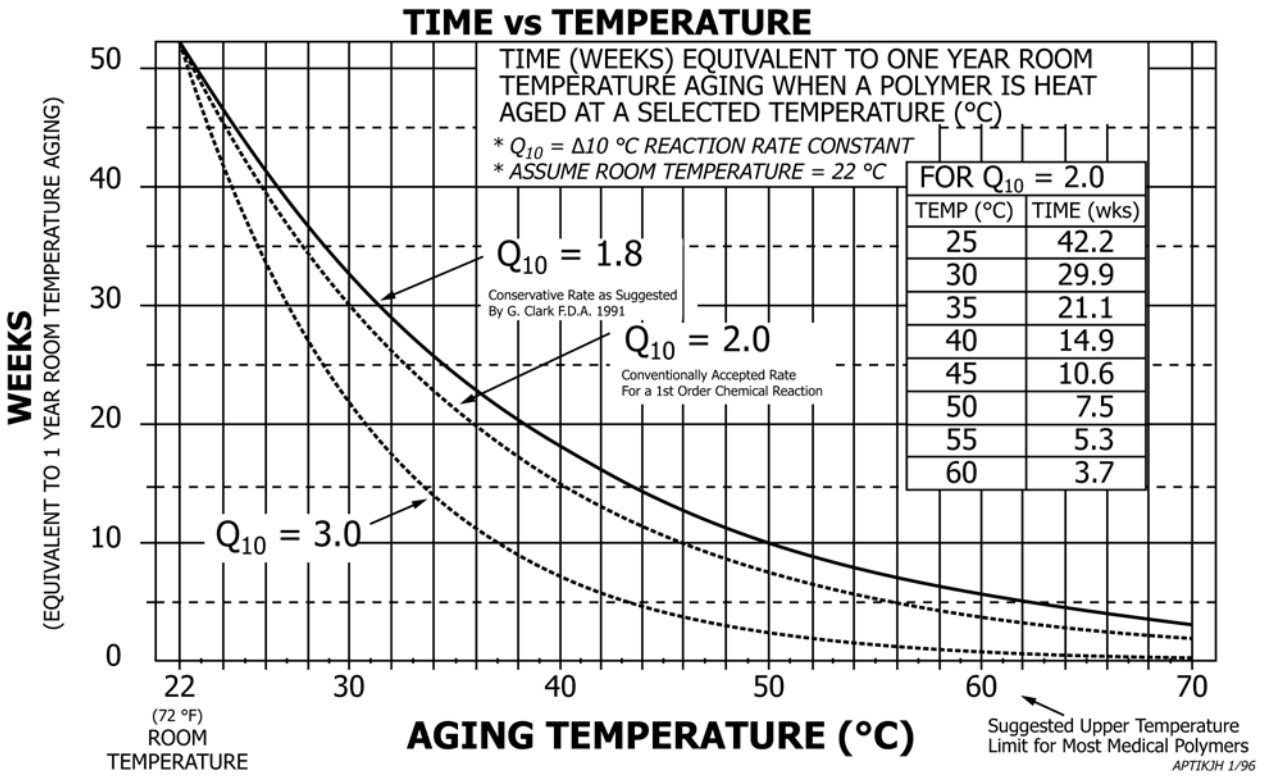

FIG. X1.1 Accelerated Aging of Polymer

X2. EXAMPLE STERILE BARRIER SYSTEM SHELF-LIFE TEST PLAN

X2.1 Select a conservative AAF estimate, for example, Q_{10} = 2. (See Fig. X1.1.)

X2.2 Define aging time points corresponding to the desired shelf life, for example, two points, such as 2-year and 3-year.

NOTE X2.1—Trending often is helpful when characterizing the aging effects on material and sterile barrier system properties. The number of accelerated aged time points, minimally, is one. The one mandatory time point is at the time equivalent to the desired shelf-life (desired shelf-life divided by aging factor); however, the practice of using only one accelerated time point leaves the risk of failure without prior warning from an earlier accelerated aged time point. At least three time points should be considered when trending.

X2.3 Build the test samples in accordance with a validated production process.

NOTE X2.2—Sterile barrier systems used for zero-time, sterilization, and accelerated aging may be produced without actual or simulated product.

X2.4 Sterilize the sterile barrier systems using validated sterilization process. The sterilization process may affect the stability of the materials or sterile barrier system. Materials and sterile barrier systems should be exposed to the maximum process conditions, or number of cycles intended to be used prior to the aging study, or both.

X2.5 Condition the samples according to Practice D4332.

NOTE X2.3—Sterile barrier system performance testing may be performed as a part of the aging protocol to determine the long-term effects of distribution, handling, and storage when devices are included in the protective package. Whether performed before aging or after aging will depend on whether the study is to simulate storage on the hospital shelf or on the manufacturer's shelf and then shipped. There may be instances, however, when performance testing may not be necessary. If known sterile barrier system failure or performance limits, such as seal strength, puncture, or impact resistance, and so forth, have been documented adequately and met for the specific intended product, then physical testing data should be sufficient.

X2.6 Initiate real-time and accelerated aging. Use the defined accelerated aging temperature for the appropriate period of time. The time duration for samples to be placed in the elevated temperature oven can be calculated from Eq 1 and 2 in 7.3.2 and 7.3.3, where AAF is the accelerated aging factor and AAT is the accelerated aging time.

For example, where Q_{10} = 2; ambient temperature = 23°C; test temperature = 55°C;

AAF = $2.0^{(55-23)/10}$;

AAF = $2.0^{3.2}$ = 9.19;

AAT = 365 days/9.19; and

AAT ≡ 39.7 days at accelerated aging conditions fror a shelf life test of 12 months (real-time equivalent).

NOTE X2.4—Humidity effects can be evaluated as part of the package system design performance qualification testing. See Appendix X3 for more guidance on the use of humidity in aging protocols.

X2.7 Evaluate sterile barrier system performance after accelerated aging relative to the sterile barrier system requirements.

X2.7.1 If the accelerated aging results meet the acceptance criteria, then the product's shelf-life conditionally is validated depending upon the results of the real-time aging study.

X2.7.2 If the accelerated aging results fail to meet the acceptance criteria, then either investigate the production process, redesign the failed medical device or sterile barrier system, attempt to validate a shorter shelf-life, or wait for real time aging results. The shelf-life is validated if real time aging results are acceptable. In this scenario, the accelerated aging program is more rigorous than reality.

X2.8 Evaluate sterile barrier system performance after real-time aging relative to the sterile barrier system requirements.

X2.8.1 If the real-time aging results meet the acceptance criteria, then the sterile barrier system's shelf-life is validated.

X2.8.2 If the real-time aging results fail to meet the acceptance criteria, the shelf-life must be reduced to the longest shelf life for which real time testing has been successful. If product has been released to the market at risk based on the accelerated aging data, a careful review must be performed and documented, and the appropriate action taken.

X3. USING RELATIVE HUMIDITY IN AGING PROTOCOLS

X3.1 Aging damage for many materials may be exacerbated in the presence of high or low relative humidity levels. Therefore, care should be exercised in using humidity levels that, when combined with temperature, produce moisture levels that may not be representative of expected ambient storage moisture conditions and may cause unnatural physical changes to materials (for example, delamination of water based laminates and coextrusions).

X3.2 The calculation to estimate time for accelerated aging is based on temperature regardless of the addition of humidity. If the use of humidity or control of humidity is necessary to prevent a material from damage, relative humidity level ranges at the target temperature should be established based on knowledge of the material, material supplier recommendations, or historical information. Limitations to equipment or process used for controlling humidity should also be considered. If use of or control of humidity is not required, this document can provide guidance for temperature range and excursions once a target temperature is determined and used to calculate aging time.

NOTE X3.1—Table X3.1 provides some examples of the relationship of relative humidity to a constant moisture content and variable temperature.

TABLE X3.1 Relationship of Relative Humidity to Constant Moisture Content and Variable Temperature

Elevated Temperature (°C)	Relative Humidity (%)	Water Content (ppm)
23	50.0	13 750
40	19.1	13 750
50	11.4	13 750
55	9.0	13 750
60	7.1	13 750

NOTE X3.2—Psychometric calculators are available on the internet for calculating equivalent water vapor at various temperature and relative humidities.

X3.3 Use chart Fig. X3.1 to determine the appropriate concentration (ppm) of H_20 in air at various temperatures for your application, keeping in mind material and process limitations referred to in X3.1 and X3.2.

X3.4 The inclusion of relative humidity in aging protocols is not intended as an assessment of the impact of humidity on packaging materials. If such an assessment is desired, it should be performed under a separate, non-aging protocol that includes pre-defined humidity extremes.

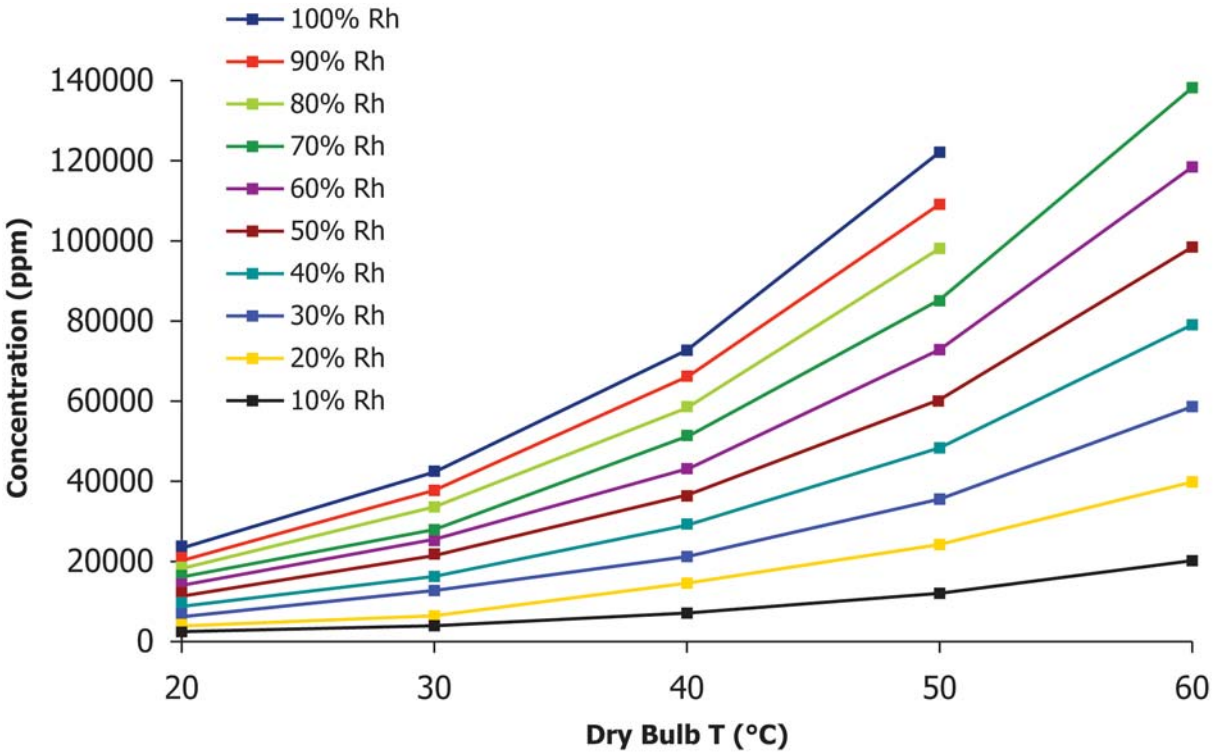

FIG. X3.1 Concentration of Water in Air as a Function of Temperature and Relative Humidity