



Standard Practice for Determination of Expiration Dating for Medical Gloves¹

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1. Scope

1.1 This practice covers all surgeon's and examination gloves made from either synthetic or natural rubber latex. The purpose of this practice is to establish methods for testing medical gloves and analyzing the data to determine their shelf life.

1.2 *This standard does not purport to address all of the label claims and 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

- D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- D573 Test Method for Rubber—Deterioration in an Air Oven
- D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- D3577 Specification for Rubber Surgical Gloves
- D3578 Specification for Rubber Examination Gloves
- D5151 Test Method for Detection of Holes in Medical Gloves
- D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application
- D6319 Specification for Nitrile Examination Gloves for Medical Application
- D7161 Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
- F88 Test Method for Seal Strength of Flexible Barrier Materials

F1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

F1980 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

2.2 ISO Standards:³

ISO 2859 Sampling Procedures for Inspection by Attributes

ISO 4074 Natural Latex Rubber Condoms—Requirements and Test Methods

2.3 Other:

ICH Q1D Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products⁴

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *accelerated aging*—conducted by storing samples at an elevated temperature for a reduced amount of time to simulate a longer period of real time aging.

3.1.2 *date of manufacture*—date of the final processing step. For sterile products, the last processing step is sterilization.

3.1.3 *real time aging*—the storage of samples under conditions that the product is expected to experience over its shelf life. Storage conditions should include exposure to elevated temperatures that product may experience during shipping.

3.1.4 *real time expiration date*—calculated by adding the shelf life to the date of manufacture.

3.1.5 *shelf life*—determined by the longest storage interval (from time zero) for which there is data demonstrating that the product meets the specifications defined in this practice. The data should be generated utilizing the test plan and methods defined in this practice.

3.1.6 *time zero*—the date of manufacture and the starting point for the shelf life studies.

4. General Information

4.1 The need for an expiration date is primarily based on the potential for a critical aspect of the product to deteriorate,

¹ This practice is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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 Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, <http://www.iso.ch>.

⁴ Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, 9, chemin des Mines, P.O. Box 195, 1211 Geneva 20, Switzerland, <http://www.ich.org>.