



Designation: E1564 – 00 (Reapproved 2014)

Standard Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials¹

This standard is issued under the fixed designation E1564; 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.

INTRODUCTION

Storage facilities for maintaining cryopreserved biological materials are generally comprised of two types of low-temperature systems: (1) freezers that are cooled by mechanical refrigeration and (2) freezers that are cooled passively with liquid nitrogen. Either system can be used for the storage of frozen biological materials as long as it meets the criteria specific to the material being stored for ensuring stability. Each system has its own unique handling requirements.

1. Scope

1.1 This guide covers recommended procedures for developing and maintaining low-temperature storage facilities for freezers with mechanical refrigeration.

1.2 This guide covers recommended procedures for developing and maintaining low-temperature storage facilities for freezers cooled with liquid nitrogen.

1.3 This guide does not cover practices for preservation by freezing which are covered in Practice E1342.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This standard does not purport to address all of the safety problems, 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

E1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi,

Protista, Viruses, Genetic Elements, and Animal and Plant Tissues (Withdrawn 2011)³

E1565 Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures

E1566 Guide for Handling Hazardous Biological Materials in Liquid Nitrogen

3. Terminology

3.1 *Definitions:*

3.1.1 *cryogenic temperatures*—temperatures below or equal to -100°C .

3.1.2 *mechanical refrigeration*—a refrigeration system in which cooling is provided by mechanical means such as a compressor.

3.1.3 *passive refrigeration*—a refrigeration system in which cooling is provided by a refrigerant such as liquid nitrogen.

4. Significance and Use

4.1 The proper design of low-temperature storage facilities ensures that sensitive biological materials are maintained under conditions providing maximum storage stability.

4.2 Properly designed and operated low-temperature storage facilities ensure that the handling of sensitive biological materials at low temperatures does not compromise stability (see Guide E1565).

4.3 Properly designed low-temperature storage facilities ensure that adequate safeguards are provided to prevent untoward events from compromising the stability of sensitive biological materials.

¹ This guide is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.04 on General Biopharmaceutical Standards.

Current edition approved Dec. 1, 2014. Published January 2015. Originally approved in 1993. Last previous edition approved in 2006 as E1564 – 00 (2006). DOI: 10.1520/E1564-00R14.

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.