Designation: E1564 – 00 (Reapproved 2019)

Standard Guide for
Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials[1]

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 concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues (Withdrawn 2011)[3]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, n*—temperatures below or equal to −100°C.

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

3.1.3 *passive refrigeration, n*—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.