



Designation: E1565 – 00 (Reapproved 2019)

Standard Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures¹

This standard is issued under the fixed designation E1565; 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

The stability of biological material stored at low temperatures is dependent on proper handling procedures and the development of adequate safeguards. Because of the sensitivity of many biological materials, care must be taken that critical temperatures are not compromised during retrieval and other activities involving handling of the material. Safeguards must also be established to ensure both adequate temperatures at all times during storage and that inventory control provides a mechanism for ease of retrieval.

1. Scope

1.1 This guide covers recommended procedures for handling material stored at low temperatures in mechanical freezers and liquid nitrogen freezers.

1.2 This guide covers recommendations for implementing procedures for ensuring adequate inventory control.

1.3 This guide covers recommendations for implementing procedures for safeguarding material stored at low temperatures.

1.4 This guide does not cover the development or maintenance of equipment and facilities for low-temperature storage which are covered in Guide E1564.

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

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

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *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

E1564 Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials

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 *liquid nitrogen freezers, n*—freezers that operate by a refrigeration system in which cooling is provided by a refrigerant such as liquid nitrogen.

3.1.3 *mechanical freezers, n*—freezers that operate by a refrigeration system in which cooling is provided by mechanical means such as a compressor.

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 E55.13 on Process Evaluation and Control.

Current edition approved Feb. 1, 2019. Published March 2019. Originally approved in 1993. Last previous edition approved in 2014 as E1565 – 00 (2014). DOI: 10.1520/E1565-00R19.

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.