



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

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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 E 1342.

1.4 The values stated in SI units are to be regarded as the 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:

E 1342 Practice for Preservation by Freezing, Freeze-Drying, and Low Temperature Maintenance of Bacteria, Fungi, Protista, Viruses, Genetic Elements, and Animal and Plant Tissues²

E 1565 Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures²

E 1566 Guide for Handling Hazardous Biological Materials in Liquid Nitrogen²

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 E 1565).

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.

5. Procedure

5.1 Low-Temperature Mechanical Freezers:

5.1.1 Ensure that adequate dedicated electrical power is available to support the number of mechanical freezers required in the facility.

5.1.2 Provide for emergency electrical power to maintain the freezers when commercial power disruptions occur.

5.1.3 Place the freezers in a temperature- and humidity-controlled area with adequate ventilation.

5.1.4 Obtain a source of service support for the refrigeration

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² *Annual Book of ASTM Standards*, Vol 11.05.