



*NSF International Standard /
American National Standard*

NSF/ANSI 456 - 2021a

Vaccine Storage



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NSF International Standard /
American National Standard
for Vaccine Storage –

Vaccine Storage

Standard Developer
NSF International

Designated as an ANSI Standard
April 25, 2021
American National Standards Institute

Prepared by
The NSF Joint Committee on Vaccine Storage

Recommended for adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
March 2021

Revised May 2021

Published by
NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation
“NSF/ANSI 456 – 2021a.”

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Printed in the United States of America.

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Foreword²

The purpose of this Standard is to establish minimum requirements for design and performance of refrigerators and freezers intended to store vaccine and/or other medical supplies.

This is the first published edition of the Standard.

This Standard was developed by the NSF Joint Committee on Vaccine Storage using the consensus process described by the American National Standards Institute.

This Standard and the accompanying text are intended for voluntary use by certifying organizations, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a continuous maintenance schedule and can be opened for comment at any time. Comments should be sent to: Chair, Joint Committee on Vaccine Storage at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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NSF/ANSI Standard for Vaccine Storage – Vaccine Storage

1 General

1.1 Purpose

This Standard is intended to define the appropriate criteria for storage units used to store vaccines.

1.2 Scope

Equipment covered by this Standard includes, but is not limited to, refrigerators, freezers and combination units that are comprised of separate refrigerator and freezer sections.

Equipment components and materials covered under other NSF or NSF/ANSI Standards or Criteria shall also comply with the requirements therein. This Standard is not intended to restrict new unit design, if such design meets the minimum specifications described herein.

1.3 Alternate materials, design, and construction

While specific materials, design, and construction may be stipulated in this Standard, equipment that incorporates alternate materials, design, or construction may be acceptable when such equipment meets the intent of the applicable requirements herein.

1.4 Measurement

Decimal and SI units are primary for this Standard and conversions provided parenthetically are only provided for convenience. Metric conversions and significant figure rounding have been made according to IEEE/ASTM SI 10.

2 Normative references

The following documents contain requirements that, by reference in this text, constitute requirements of this Standard. At the time of publication, the indicated editions were valid. All of the documents are subject to revision and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below. The most recent published edition of the document shall be used for undated references.

Australian Government Department of Health and Aging National Vaccine Storage Guidelines³

³ Australian Government, Department of Health. GPO Box 9848, Canberra ACT 2601, Australia.
<www.health.gov.au>

IEC 61010-1, Ed 3.0 b:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements*⁴

Queensland Health, *Guideline for Storage, Transportation for Handling of Refrigerated Medicines, Vaccines, and Blood in Queensland Health Facilities*⁵

UL 471, *Standard for Commercial Refrigerators and Freezers*⁶

3 Definitions

3.1 accuracy: Closeness of agreement between a measured value and a true value of a quantity to be measured.

3.2 air velocity: The rate of motion of air in a given direction.

3.3 ambient temperature: The temperature of the test room.

3.4 audible and visual alarm: An alarm with two indicators, one audible and one visual.

3.5 barriers: Physical obstacles that prevent vaccine storage outside of the usable interior space.

3.6 calibration: a set of operations that establish, under specified conditions, the relationship between temperature values indicated by a temperature measurement device (TMD), and the corresponding temperature values realized by standards.

3.7 calibration certificate: a document recording the measurement results and uncertainties of a calibration, compliant with measurement and reporting guidelines referenced in Annex I-2. May also be called a calibration report.

3.8 closure device: Physical components or mechanism of a vaccine storage unit's dispense portal or load portal that forms a seal and insulating barrier between the vaccine storage volume and the ambient conditions of a vaccine storage unit's physical location.

3.9 cold shelf: Refrigeration construction which has the cooling surface integrated into the design of the shelves within the chamber of the refrigerator or freezer.

3.10 cold wall: Refrigeration construction which has the inner lining of refrigerator or freezer serving as the cooling surface by having the evaporator located inside the walls.

3.11 combination (combo) unit: Combination refrigerator and freezer unit that has separate refrigeration systems and/or controls for each section to allow for changes in heat load for each section.

3.12 defrost: The action of removing accumulated ice or frost from the inside of a unit. There are three different types:

3.12.1 automatic defrost: A system in which the defrost cycle is automatically initiated and terminated. On completion of the defrost operation, the unit automatically resumes temperature control at the specified set point.

⁴ International Electrotechnical Commission. 3 rue de Varamb , 1st floor, PO Box 131, CH-1211 Geneva 20, Switzerland. <www.iec.ch>

⁵ Queensland Government, Queensland Health. GPO Box 48, Brisbane, Queensland 4001, Australia. <www.health.qld.gov.au>

⁶ UL LLC. 33 Pfingsten Road, Northbrook, IL 60062. <www.ul.com>