



**International
Standard**

ISO 31513

**Temperature validation methods of
temperature-controlled storage and
land transport**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 315, *Cold chain logistics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Proper cold chain management is a critical element in storing and distributing temperature-sensitive goods in a temperature-controlled environment. As supply chains expand and become more complex, this area becomes more important.

For example, during the global rollout of COVID-19 vaccines, certain vaccines required ultra-low temperature storage of approximately -70 °C, which increased complexity to the existing pharmaceutical cold chain system. Different vaccines had different transport and storage requirements, requiring multiple temperature supply chains within the same logistics network. In particular, vaccines were distributed globally, including in remote and rural areas with limited infrastructure.

Collaboration between governments, pharmaceutical companies, logistics providers, and health systems was required, as well as coordination and validation of the proper maintenance of cold chains in each country. However, the challenge was to validate that land transport and warehouses operating in different countries and regions was able to maintain the required temperature continuity for the vaccine.

Quality must be maintained as planned by properly managing all processes, from manufacturing to distribution. In order to validate the integrity of cold chain, it is expected that it is possible to perform risk-based analyses and inspections at the highest scientific level possible, and to be documented within a quality system.

Temperature validation of storage and land transport must be possible in order to enable the integrated supply chain management of cold chain logistics. It aims to help ensure the quality and integrity of temperature-sensitive goods in cold chain management.

If the temperature is not properly controlled or guaranteed, the quality of temperature-sensitive goods will be affected, so the safety, stability and efficiency of users cannot be guaranteed. This document applies to the temperature validation of storage and land transport for quality control during distribution of temperature-sensitive goods.

This document is intended to help logistics service providers, such as trucking companies and warehouse companies and all parties handling temperature-sensitive goods, to ensure the integrity of the goods through a temperature validation process throughout the distribution process.

This document does not apply to warehouses and storage within production facilities, as these are typically governed by existing good manufacturing practices (GMP) standards and integrated quality control systems within manufacturing environments. The focus of this document on temperature validation methods in external storage and land transport to ensure integrity during distribution.

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Temperature validation methods of temperature-controlled storage and land transport

1 Scope

This document specifies temperature validation procedures and methods for temperature-controlled storage and land transport. This document applies to all types of temperature controlled goods except food.

This document is not intended to evaluate the safety and technology of storage and land transport equipment or facilities. Warehouses and storages within production facilities are excluded from the scope of this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31510, *Cold chain logistics — Vocabulary*

EN 12830, *Temperature recording devices for the transport, storage and distribution of temperature-sensitive goods - Testing, performance and suitability*

EN 13486, *Temperature recorders and thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Periodic verification*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 31510 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 temperature-sensitive goods

products whose quality can be adversely affected by temperature extremes

Note 1 to entry: The acceptable temperature range varies by product type. For example:

- pharmaceutical and biological products: typically 2 °C to 8 °C (per WHO Good Distribution Practices and ISO 23416);
- certain chemicals and industrial materials: specific ranges as per manufacturer guidelines;
- other regulated products (e.g., cosmetics, electronics) can follow industry-specific storage and handling requirements.

Note 2 to entry: Qualified personnel and/or organizations shall perform validation process design and qualification temperature requirements for specific products and should follow applicable standards such as ISO 23416 (temperature-sensitive medicinal packages), WHO GDP guidelines, and relevant national regulations.

[SOURCE: ISO 23416, 3.3, modified — The word “medicinal” is deleted from the term and the definition, and Notes to entry have been added.]