# WHO Immunization Devices (IMD)
# Performance, Quality & Safety (PQS)

## The immunization cold chain's first line of defense

World Health Organization

Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

JANUARY 2025

# Situating IMD PQS – WHO Mandate

**WHO is the UN specialized agency for health**

**WHO is the directing and coordinating authority on international health within the United Nations' system**

- setting **norms and standards** and promoting and monitoring their implementation
- articulating **ethical and evidence-based** policy
- **providing leadership** on matters critical to health

PQS – Performance, Quality & Safety
WHO – World Heath Organisation
UN – United Nations

Reference: https://www.un.org/en/about-us/un-system

# Why WHO-IMD PQS?

**PQS has a mandate to define equipment performance characteristics to meet known field conditions and requirements.**

- **Country EPI Programmes:** need to understand and inform the performance characteristics of the products they are ordering.
- **Industry:** needs a fair basis for tendering existing products and for investing in product development.
- **Procurement agencies:** need to know that the products they are purchasing on behalf of their programmes are fit for purpose.

IMD – Immunization Devices
EPI – Expanded Programme for Immunization

# IMD-PQS adds value

**Setting standards** that ensure immunization devices keep life-saving vaccines potent and safe rigorously

**Verifying compliance** of immunization devices with WHO-standards

Signalling future needs through **target product profiles** to help manufacturers develop appropriate technologies and foster innovations

Improving **device durability and reliability**, raising their value across total cost of ownership

**Prequalifying devices** that safeguard a growing range of new and more expensive vaccines* vital to the progress of WHO EPI programmes facilitating

**Consensual standards-development** between WHO, industry and main users

* Vaccines 35 (2017) 2110-2114 "Making the leap into the next generation: A commentary on how Gavi, the Vaccine Alliance is supporting countries' supply chain transformations in 2016-2020" Brooks/Habimana/Huckerby

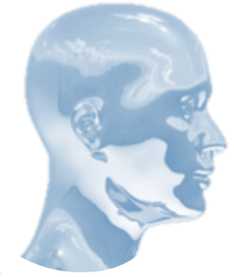
# IMD-PQS mitigates important risks

**Unreliable equipment** can lead to vaccine damage through exposure to extreme temperatures. Reduced potency can hamper global efforts to control Infectious diseases

Continuous performance monitoring systems can help prevent the need for equipment maintenance and reduce the **risks of equipment failure**

New vaccines are providing protection against more and more diseases but are also costlier per dose, so there is more at stake for **protecting populations at risk from life threatening infections**

# Global impact



**14 million** lives saved 2000–2020[1]

**2 billion** doses annually[2]

**70** countries supplied[3]

References L-R: 1. Gavi https://www.gavi.org/sites/default/fles/document/2021/Gavi-Facts-and-fgures-February-21.pdf 2. UNICEF https://www.unicef.org/supply/stories/scaling-vaccine -procurement, 3. *Ibid*. 1

# EPI impact - Coverage

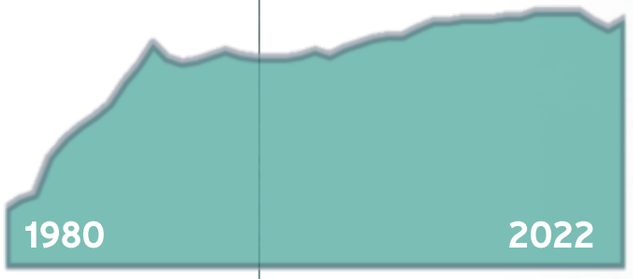
## DTP-containing vaccine

### 1st dose

30% → 89%


### 3rd dose

20% → 84%



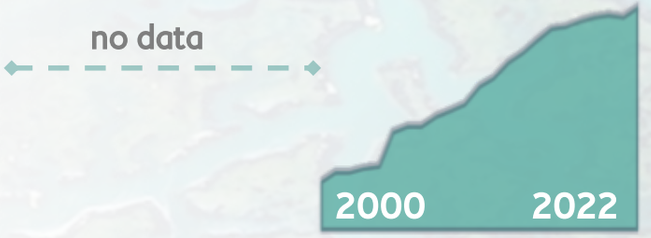

## Measles-containing vaccine

### 1st dose

16% → 83%


### 2nd dose

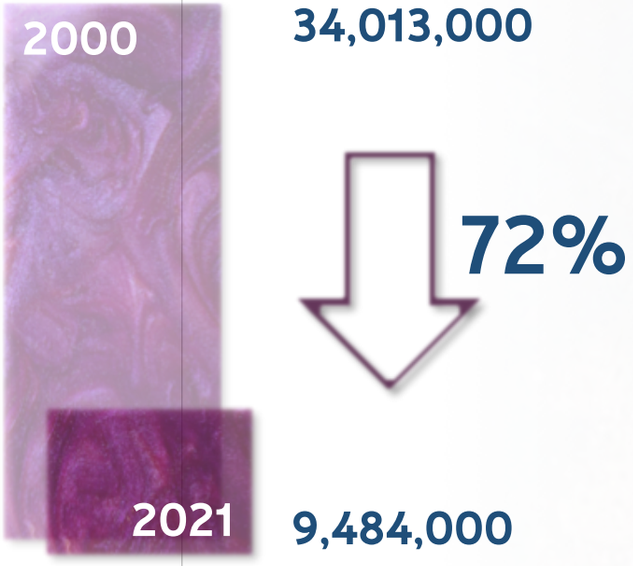
17% → 74%



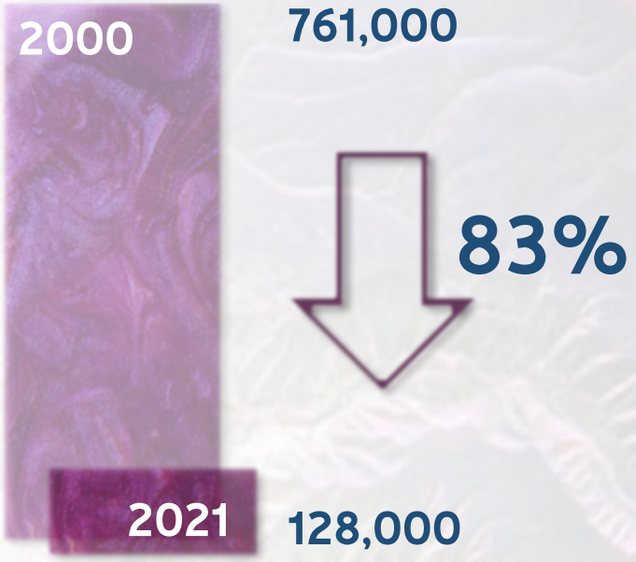

References: WHO
https://immunizationdata.who.int/pages/coverage/POL.html?CODE=Global&ANTIGEN=IPV1&YEAR=

# EPI impact – Morbidity & mortality

Est. Measles
## cases




Est. Measles
## deaths




References: CDC https://www.cdc.gov/mmwr/volumes/71/wr/mm7147a1.htm#F1_down =

# WHO Immunization Devices (IMD) Prequalification

World Health Organization


## 91 Prequalification Holders

of IMD-PQS immunization products across all 6 WHO regions*

WHO Immunization Devices (IMD), Performance, Quality and Safety programme (PQS) has prequalified products for National Immunization Programmes from 91 manufacturers (or resellers), across the 10 WHO IMD-PQS product categories, produced in 30 countries and all 6 WHO Regions, for procurement by United Nations (UN) agencies.

- *as at February 2025*

| | Manufacturers | Categories |
|---|---|---|
| AFRO | 4 | 3 |
| AMRO /PAHO | 12 | 5 |
| EMRO | 5 | 3 |
| EURO | 23 | 9 |
| SEARO | 22 | 8 |
| WPRO | 25 | 10 |

# WHO Immunization Devices (IMD) Prequalification

World Health Organization

## 20 TEST LABORATORIES

accredited by WHO to test products for WHO IMD-PQS

WHO prequalification ensures the availability of quality, reliable products that help safeguard vaccine potency, as well as expand and extend their availability.

Laboratories that test products contribute to this mission by verifying that products submitted for prequalification meet stringent requirements and quality standards. WHO accredits only those laboratories that can demonstrate they conform to international standards of practice.

### North & South America

| | |
|---|---|
| BRAZIL | TÜV Rheinland do Brasil Ltd |
| CANADA | Micom Laboratories INC. |
| USA | Tektronix Service Solutions |
| | UL LLC |

### Europe

| | |
|---|---|
| DENMARK | Danish Technological Institute |
| | ForceTechnology |
| FRANCE | CEMAFROID SAS |
| GERMANY | Nemko GmbH & Co. KG |
| GREECE | Labor SA |
| ITALY | UL International Italia S.r.l |
| NETHERLANDS | Re/Gent B.V |
| SWITZERLAND | METAS |

### Asia Pacific

| | |
|---|---|
| CHINA | Suzhou Institute of Metrology |
| | CHEARI |
| INDIA | Lisaline Lifescience Technologies PVT. Ltd |
| | UL India Private Limited |
| | Intertek India |
| | Techbio Solutions |
| SINGAPORE | TUV SUD PSB Pte Ltd |
| UAE | Dubai Central Laboratory Department |

# WHO IMD-PQS:

## Vital at each stage of the supply chain

- PQS ensures the **availability and quality** of prequalifiIed products to safeguard vaccines & other immunization supplies.

- PQS supports WHO's **disease elimination and eradication** efforts, as well as countries' **preparedness and resilience** for health emergencies.

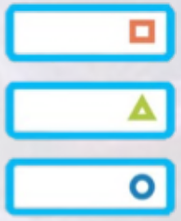
# Achievements & progress

> 100

PQS STANDARDS

443

PRODUCTS PREQUALIFIED



10

PRODUCT CATEGORIES

*Which includes…*

PRODUCT SPECIFICATIONS, VERIFICATION PROTOCOLS, MANUFACTURER GUIDES & MORE

91

MANUFACTURERS

6

ELECTRONIC MONITORING STANDARDS

# IMD-PQS Categories

E001: Cold rooms, freezer rooms & related equipment

E002: Refrigerated vehicles

E003: Refrigerators and freezers

E004: Cold boxes and vaccine carriers

E005: Coolant-packs

E006: Temperature monitoring devices

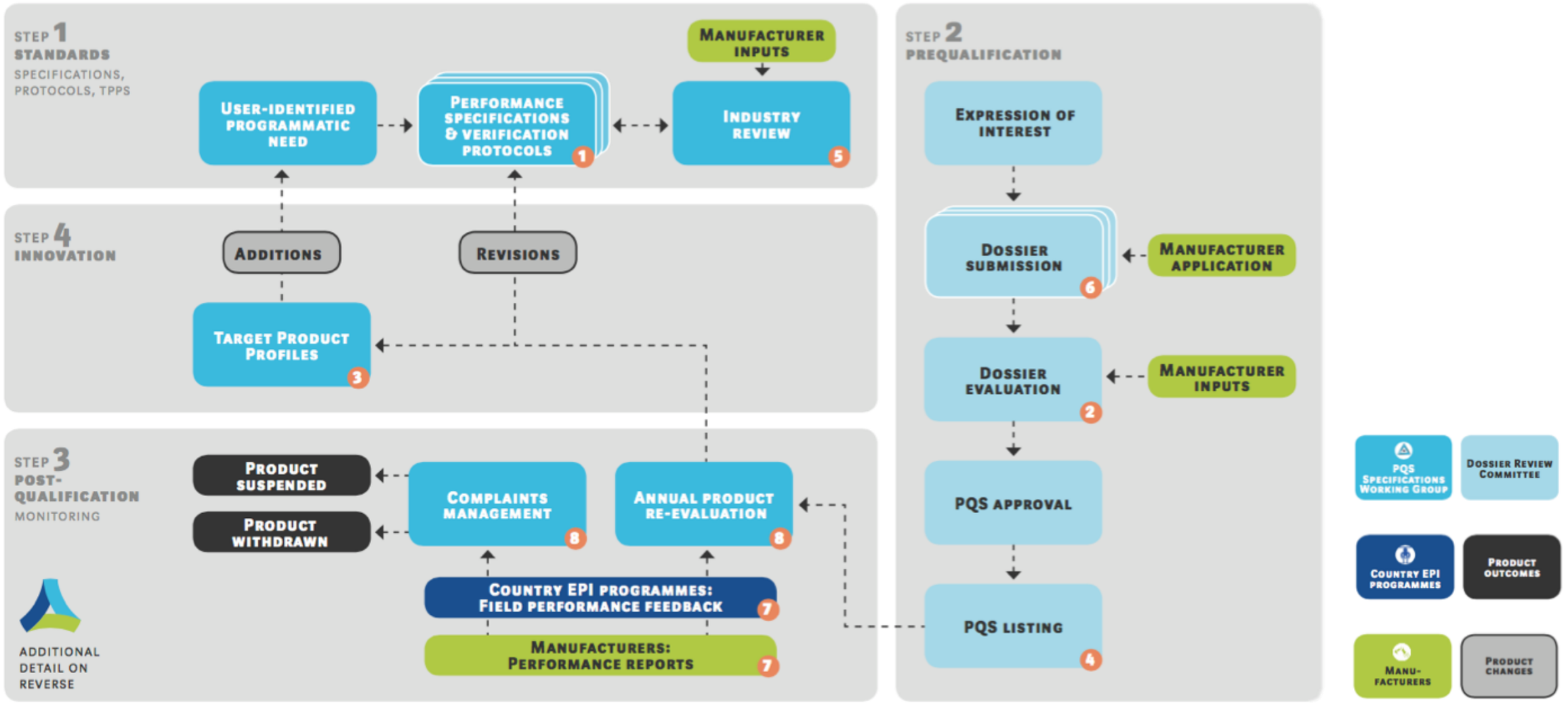
E007: Cold chain accessories

E008: Single-use injection devices

E010: Waste management equipment

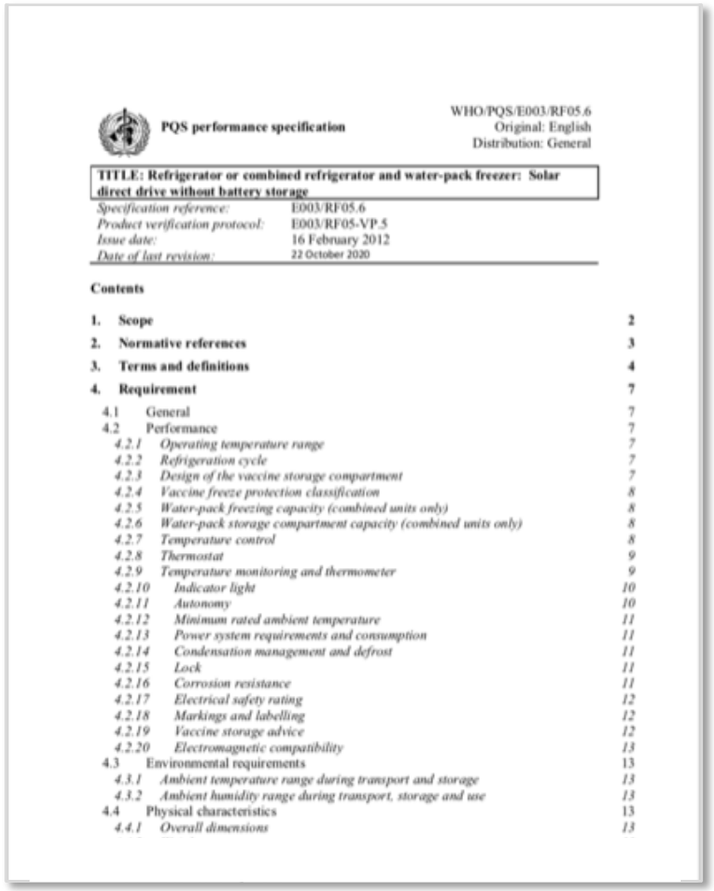
E013: Therapeutic injection devices

# IMD PQS process



# IMD-PQS Standards

## PERFORMANCE SPECIFICATION



PQS performance specification

WHO/PQS/E003/RF05.6
Original: English
Distribution: General

**TITLE: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage**

| | |
|---|---|
| *Specification reference:* | E003/RF05.6 |
| *Product verification protocol:* | E003/RF05-VP.5 |
| *Issue date:* | 16 February 2012 |
| *Date of last revision:* | 22 October 2020 |

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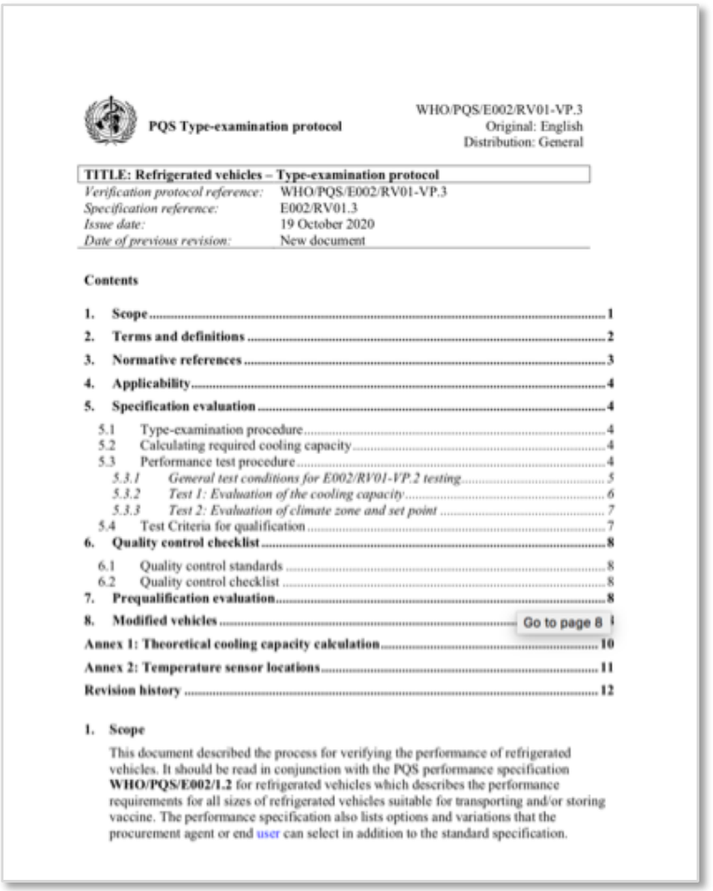
## VERIFICATION PROTOCOL



PQS Type-examination protocol

WHO/PQS/E002/RV01-VP.3
Original: English
Distribution: General

**TITLE: Refrigerated vehicles – Type-examination protocol**

| | |
|---|---|
| *Verification protocol reference:* | WHO/PQS/E002/RV01-VP.3 |
| *Specification reference:* | E002/RV01.3 |
| *Issue date:* | 19 October 2020 |
| *Date of previous revision:* | New document |

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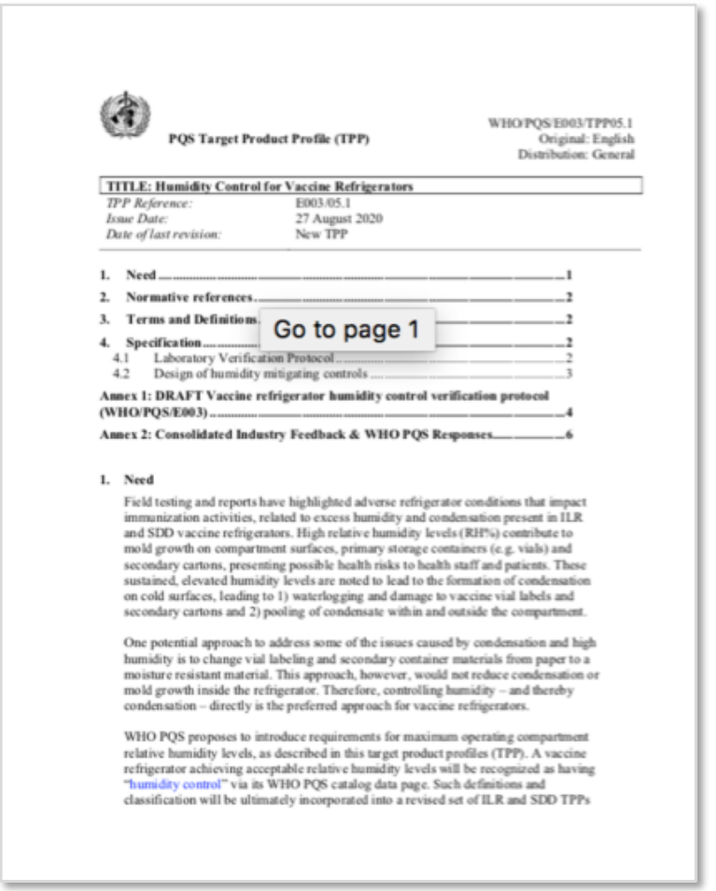
**1. Scope**

This document described the process for verifying the performance of refrigerated vehicles. It should be read in conjunction with the PQS performance specification **WHO/PQS/E002/1.2** for refrigerated vehicles which describes the performance requirements for all sizes of refrigerated vehicles suitable for transporting and/or storing vaccine. The performance specification also lists options and variations that the procurement agent or end user can select in addition to the standard specification.

## TARGET PRODUCT PROFILE



PQS Target Product Profile (TPP)

WHO/PQS/E003/TPP05.1
Original: English
Distribution: General

**TITLE: Humidity Control for Vaccine Refrigerators**

| | |
|---|---|
| *TPP Reference:* | E003/05.1 |
| *Issue Date:* | 27 August 2020 |
| *Date of last revision:* | New TPP |



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**1. Need**

Field testing and reports have highlighted adverse refrigerator conditions that impact immunization activities, related to excess humidity and condensation present in ILR and SDD vaccine refrigerators. High relative humidity levels (RH%) contribute to mold growth on compartment surfaces, primary storage containers (e.g. vials) and secondary cartons, presenting possible health risks to health staff and patients. These sustained, elevated humidity levels are noted to lead to the formation of condensation on cold surfaces, leading to 1) waterlogging and damage to vaccine vial labels and secondary cartons and 2) pooling of condensate within and outside the compartment.

One potential approach to address some of the issues caused by condensation and high humidity is to change vial labeling and secondary container materials from paper to a moisture resistant material. This approach, however, would not reduce condensation or mold growth inside the refrigerator. Therefore, controlling humidity – and thereby condensation – directly is the preferred approach for vaccine refrigerators.

WHO PQS proposes to introduce requirements for maximum operating compartment relative humidity levels, as described in this target product profiles (TPP). A vaccine refrigerator achieving acceptable relative humidity levels will be recognized as having "humidity control" via its WHO PQS catalog data page. Such definitions and classification will be ultimately incorporated into a revised set of ILR and SDD TPPs

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# THANKYOU!