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

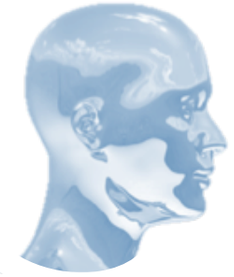
The immunization cold chain's first line of defense

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)

July 2025

Global impact



14 million lives saved 2000–2020[1]

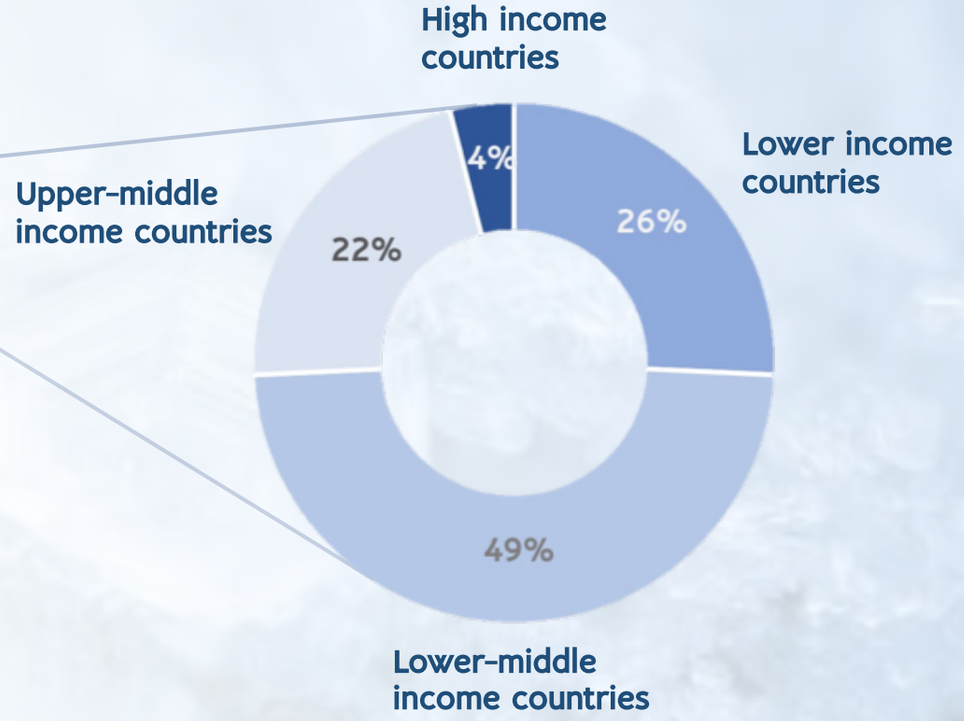
2 billion doses annually[2]

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 – Deaths averted

51,5 Million deaths averted
by global vaccination by 2030



References: *Vaccine* https://www.sciencedirect.com/science/article/pii/S0264410X2300854X

EPI impact - Coverage

DTP-containing vaccine

1st dose

30%

89%

3rd dose

20%

84%

Measles-containing vaccine

1st dose

16%

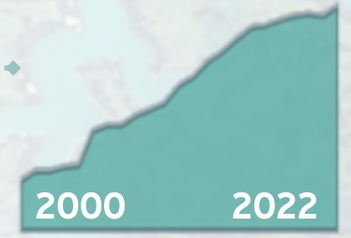
83%

2nd dose

17%

74%

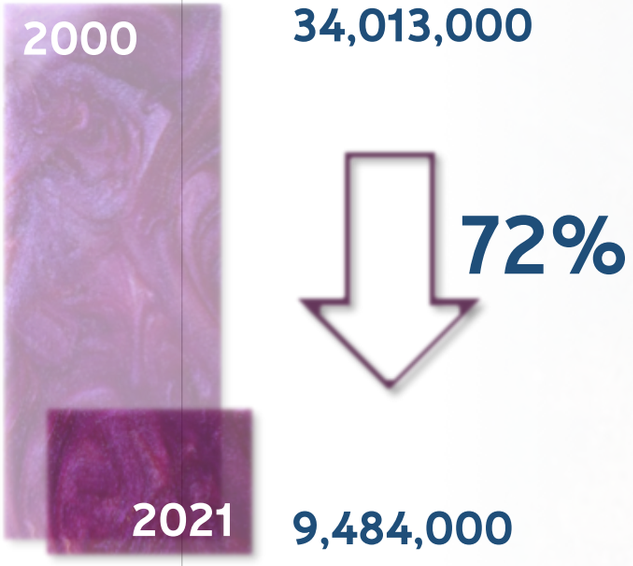
no data



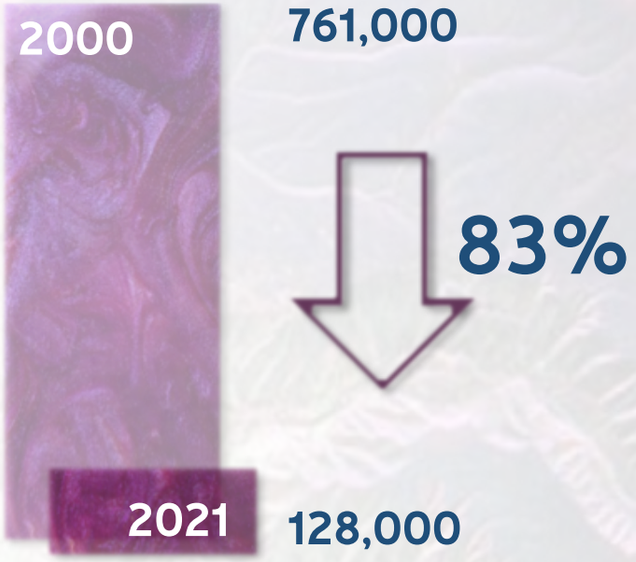
References: WHO
https://immunizationdata.who.int/pages/coverage/POL.html?CODE=Global&ANTIGEN=IPV1&YEAR=

EPI impact – Morbidity & mortality

Est. Measles
cases



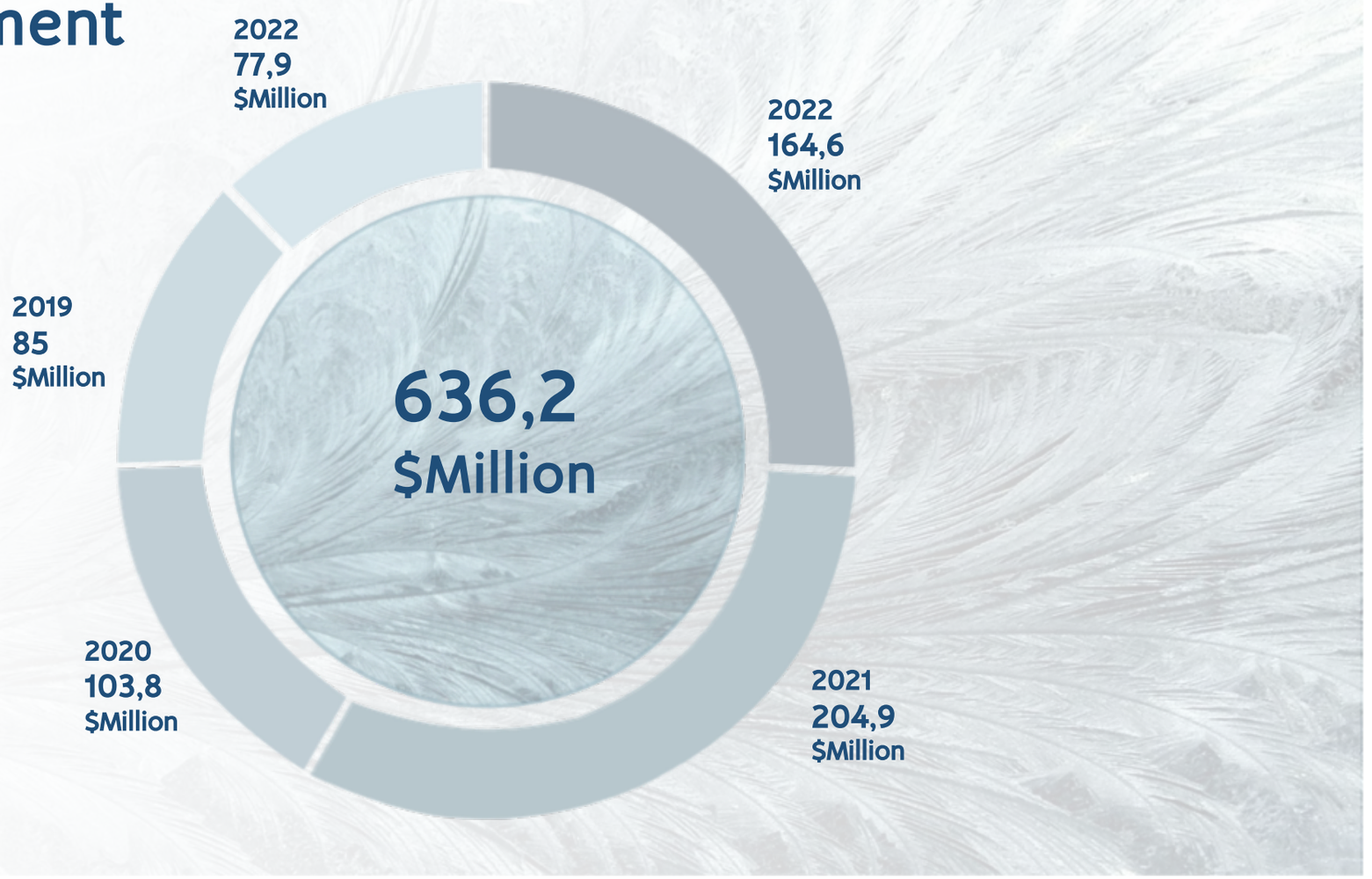
Est. Measles
deaths



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

CCE procurement – UNICEF

UNICEF CCE Procurement (5-Yrs 2018-2022)



References: UNICEF Annual Supply reports
https://www.unicef.org/supply/resources/annual-reports

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?

IMD-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

WHO privileges & immunities

By virtue of WHO's status as a specialized agency of the United Nations, WHO, its officials and experts performing missions for WHO enjoy privileges and immunities under national and international laws and conventions.

These conventions include the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the "1947 Convention").

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

Ensuring **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's EPI.

Facilitating **consensual standards-development** between countries, EPIs, WHO, UNICEF, Gavi, and PAHO's Revolving Fund, the Gates Foundation and industry technical experts.

* 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 temperature excursions and reduced potency or spoiling of vaccines, possible adverse health consequences and wasted investments.

Equipment failure, which can lad to costly downtime and compromised equipment. Proactive monitoring ensures early detection, better maintenance and extended equipment lifespan.

New vaccines provide protection against more and more diseases, but also tend to cost more per dose. Safe, effective and reliable cold chain equipment is crucial to **protect the public health value of vaccines.**

WHO Immunization Devices (IMD) Prequalification

World Health Organization

88 Prequalification Holders

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

WHO Immunization Devices (IMD), Performance, Quality and Safety programme (IMD-PQS) has prequalified products for National Immunization Programmes from 88 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 July 2025*

AFRO	5 Manufacturers	3 Categories
AMRO /PAHO	5 Manufacturers	3 Categories
EMRO	3 Manufacturers	3 Categories
EURO	24 Manufacturers	9 Categories
SEARO	19 Manufacturers	8 Categories
WPRO	32 Manufacturers	10 Categories

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

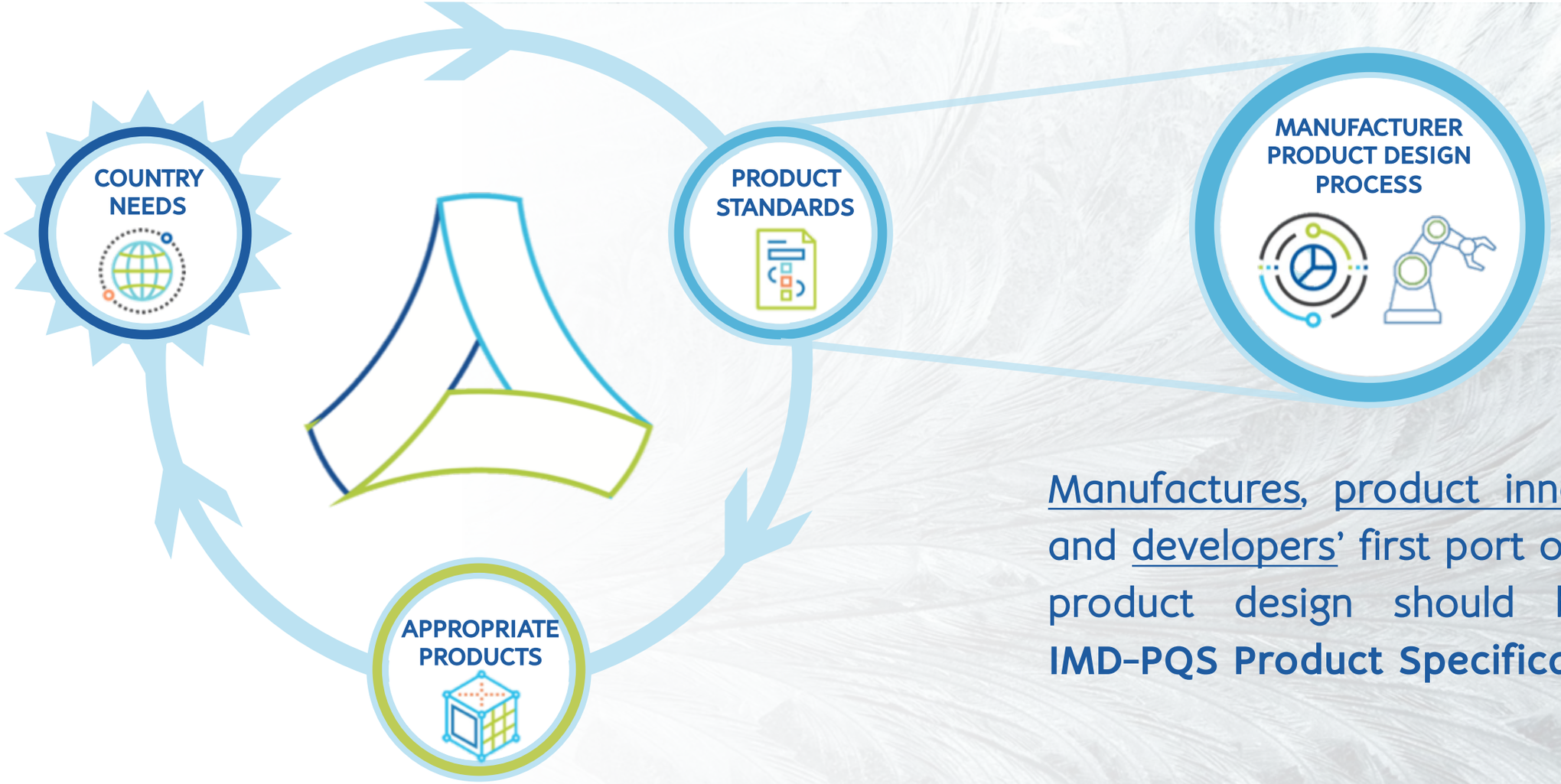
Europe

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

IMD-PQS Specs respond to Country needs



Manufactures, product innovators and developers' first port of call in product design should be the **IMD-PQS Product Specifications**

WHO IMD-PQS:

Vital at each stage of the supply chain

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

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

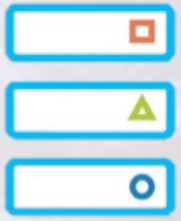
Current status (July 2025)

> 140

IMD-PQS STANDARDS

421

PREQUALIFIED PRODUCTS



10

PRODUCT CATEGORIES

Which includes…

PRODUCT SPECIFICATIONS, VERIFICATION PROTOCOLS, MANUFACTURER GUIDES & MORE

88

PREQUALIFICATION HOLDERS

6

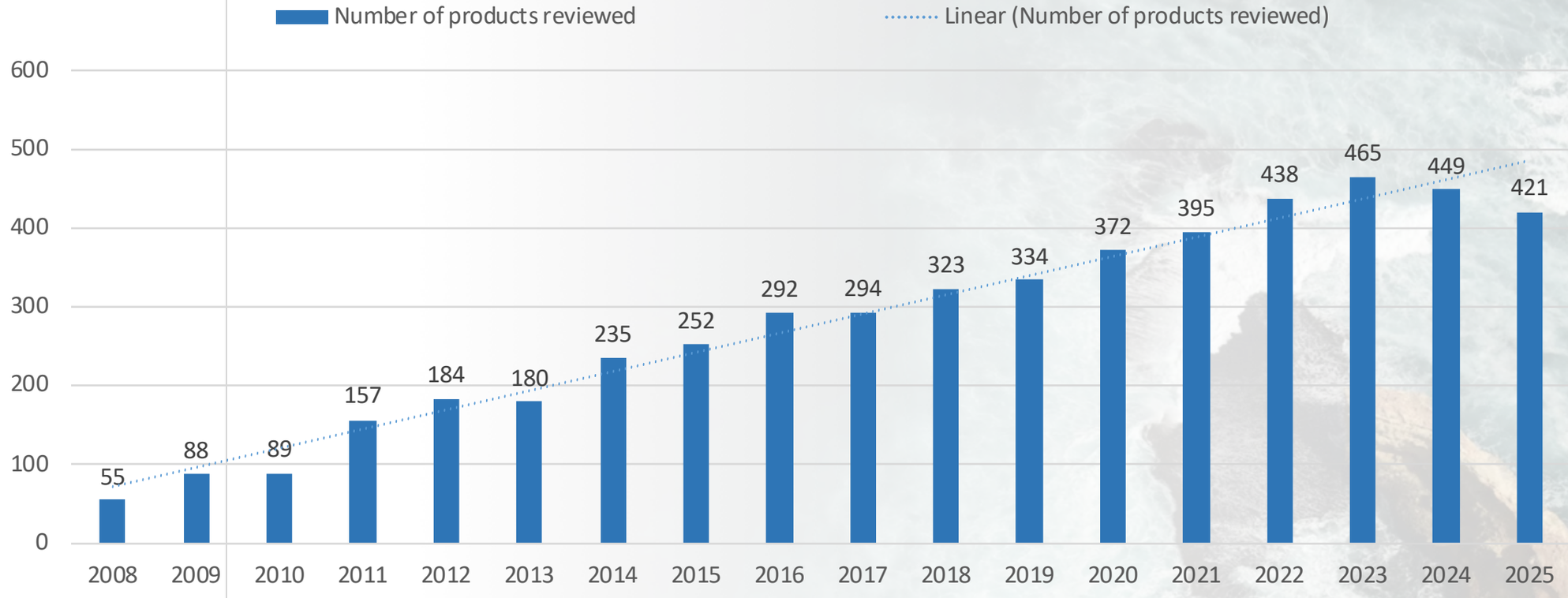
ELECTRONIC MONITORING STANDARDS

IMD-PQS Categories

- E001: Cold rooms, freezer rooms & related equipment
- E002: Refrigerated vehicles
- E003: Refrigerators and freezers
- E004: Cold boxes & 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

Evolution of prequalified IMDs

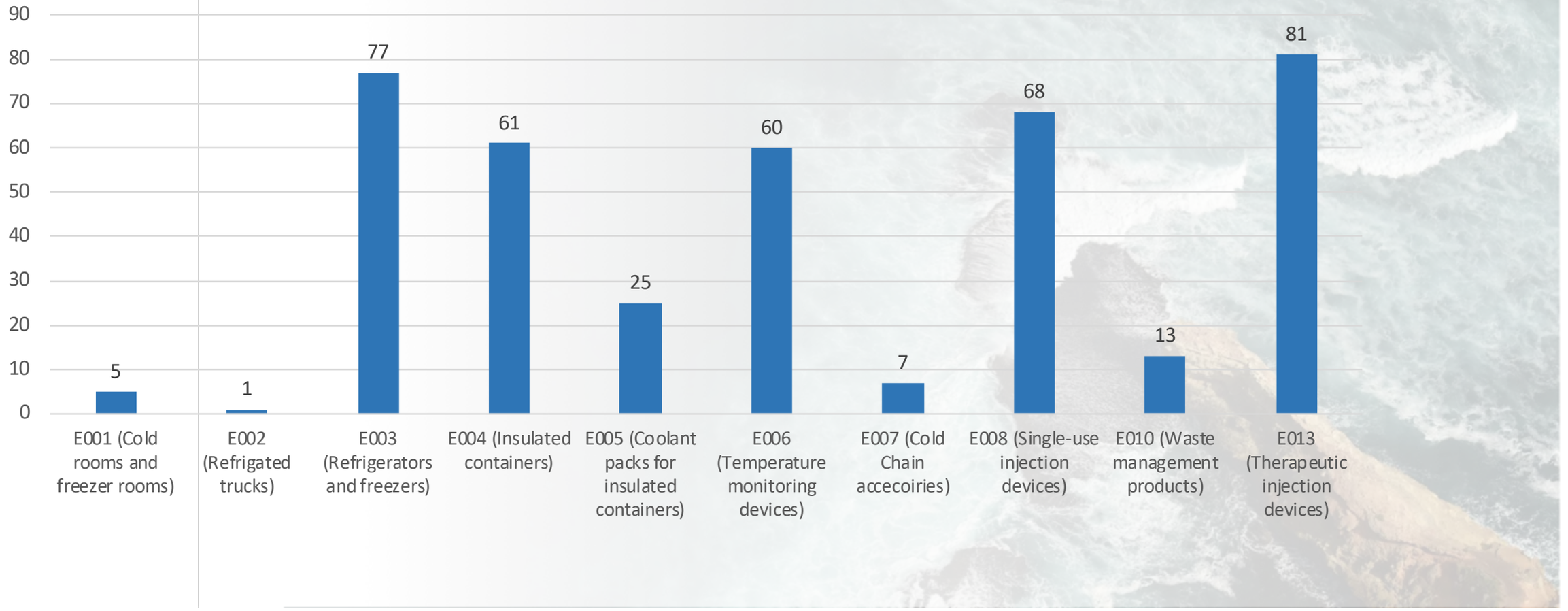
Number of products reviewed each year*



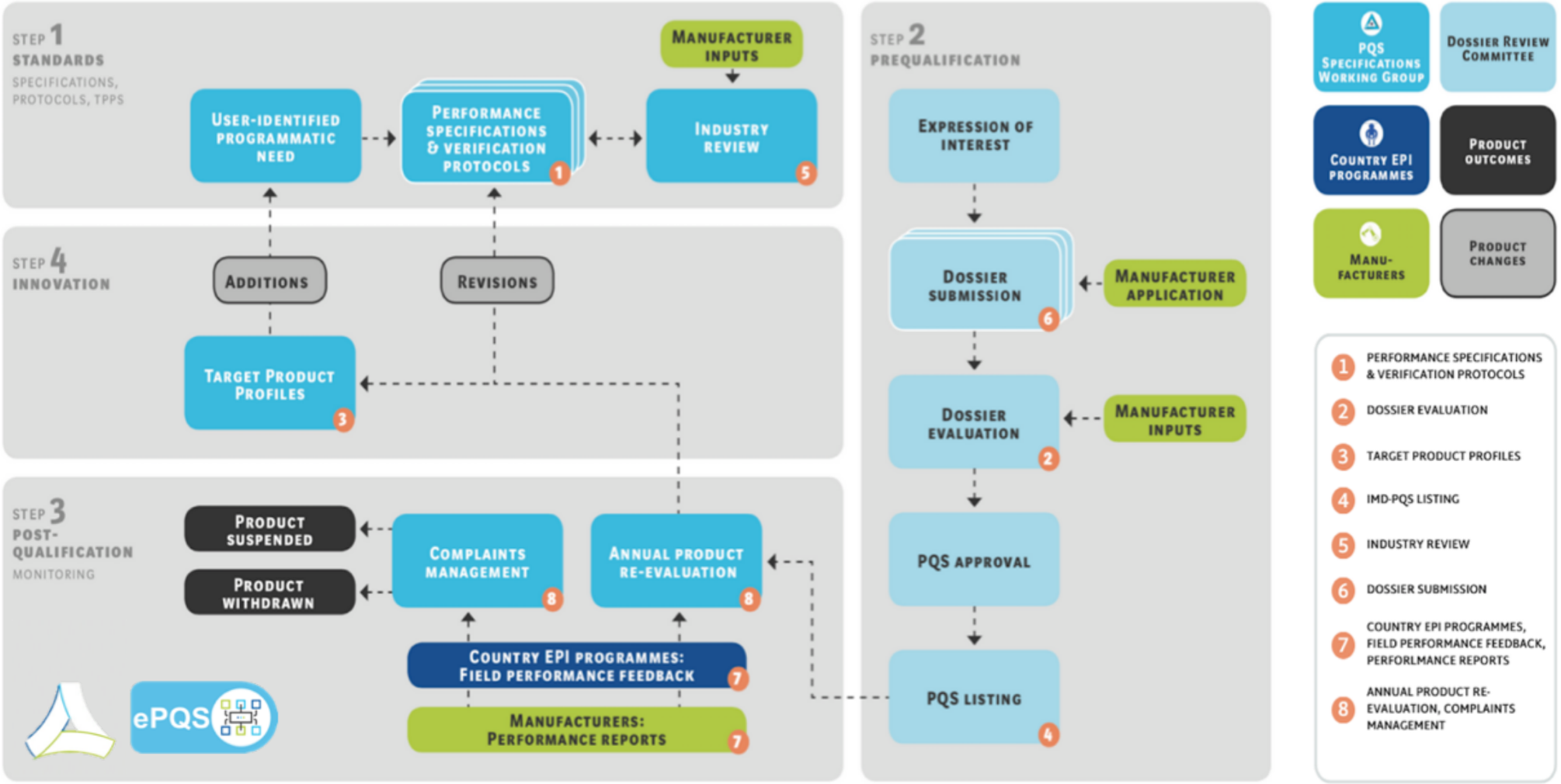
** Going into each annual review. NOT number of prequalified products each year*

Product by IMD-PQS category

Products by category following the 2025 Annual Review

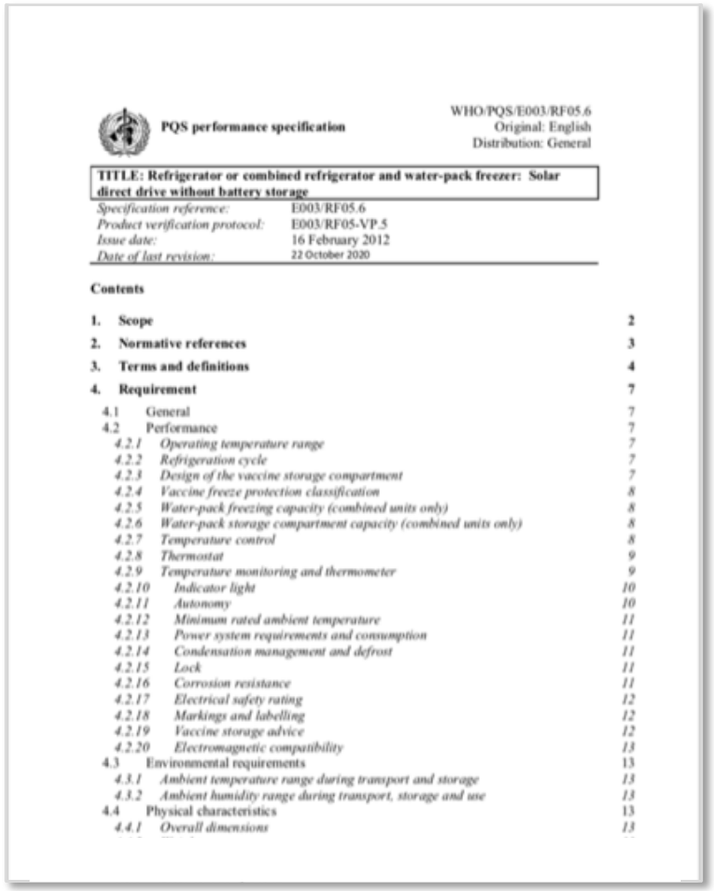


IMD PQS process



IMD-PQS Standards

PERFORMANCE SPECIFICATION



PQS performance specification

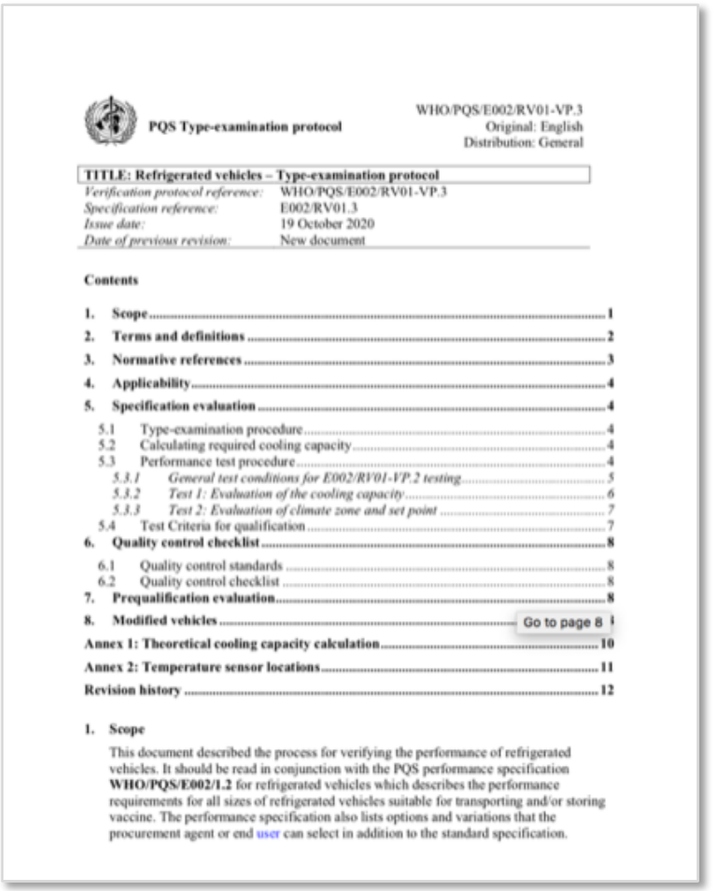
WHO/PQS/E003/RF05.6
Original: English
Distribution: General

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

Contents

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

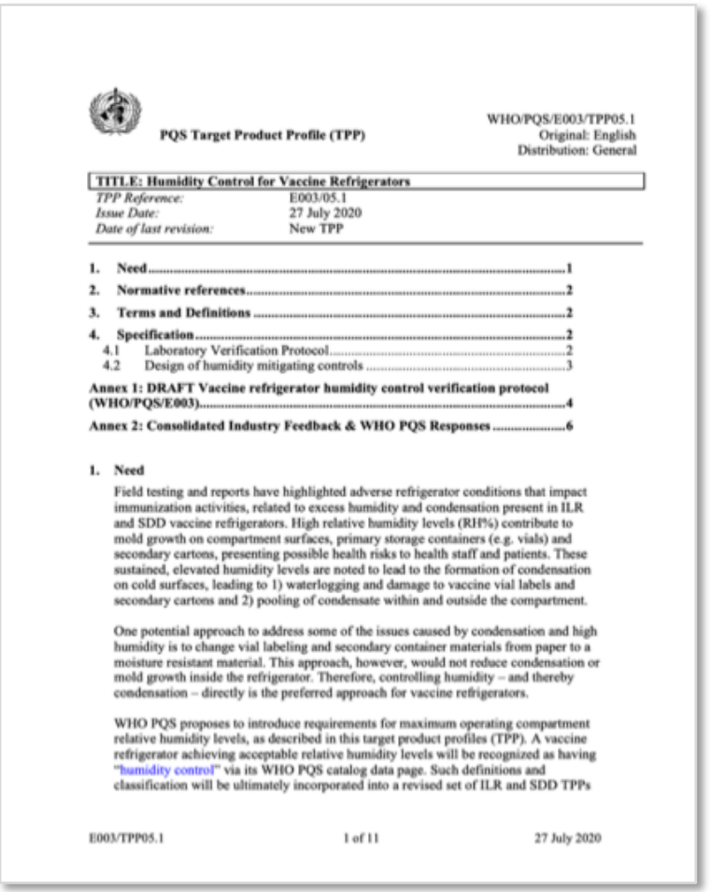
Contents

Go to page 8

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 July 2020
Date of last revision: New TPP

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

Post-prequalification obligations

Post-prequalification commitments and procedures ensure that WHO's endorsement of the performance, quality and safety of prequalified immunization devices remains valid.

All prequalification-holders are obliged to:

Report any product failures or other complaints in real-time.

Report all product changes (variations) in real-time.

Complete a successful annual review

Once a product has been prequalified, and as long as no serious complaints have been received from product users, it will maintain its prequalified status for up to 12 months, or until the next scheduled annual review of products (whichever occurs first).

WHO Immunization Devices website

https://extranet.who.int/prequal

- ❑ Catalogue
- ❑ Search & compare
- ❑ PQ guidelines
- ❑ Product complaints form
- ❑ Product testing guidance
- ❑ Standards library
- ❑ PMM toolkit

- ❑ PQ-holder review
  Product Data Sheets

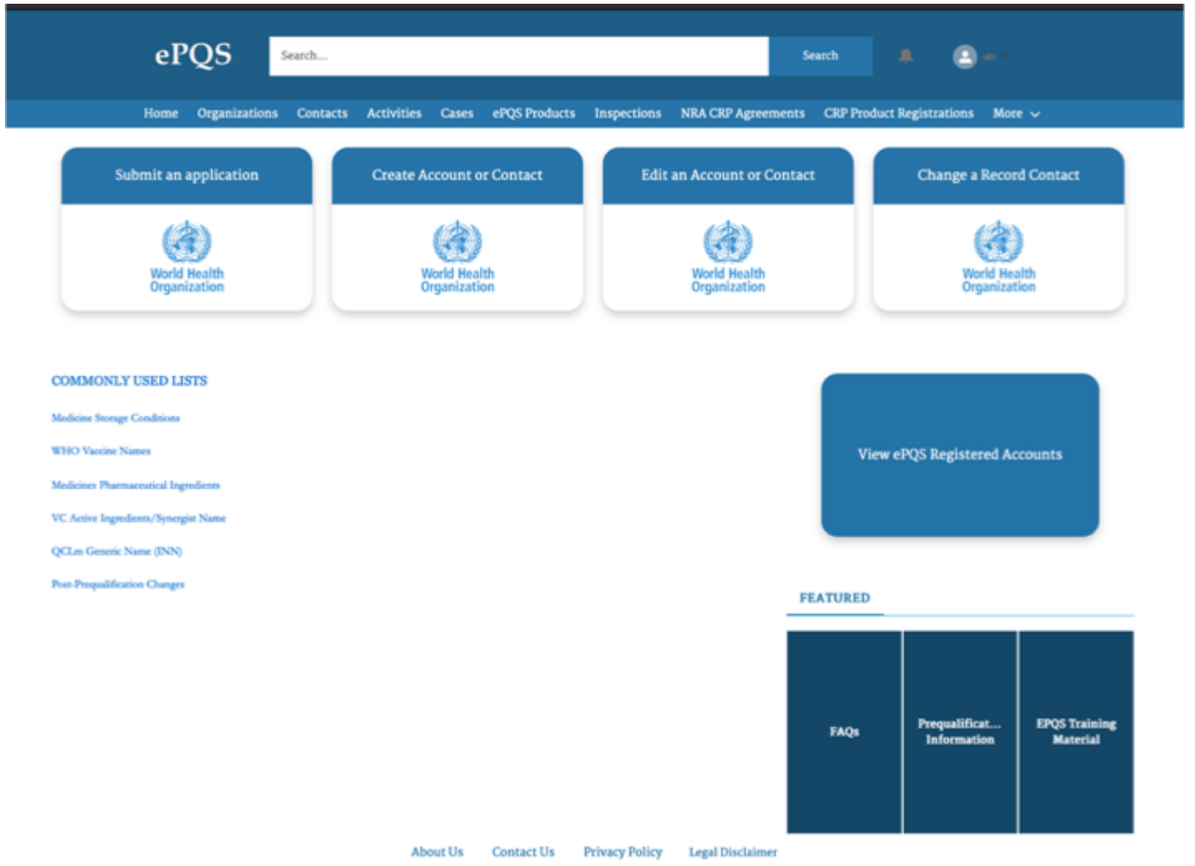
WHO e-Prequalification System (ePQS)

https://extranet.who.int/prequal/epqs/epqs-portal

As of June 2025 IMD-PQS can only accept new applications through the WHO ePQS platform.

WHO ePQS provides prequalification-holders with tools to apply, manage post-prequalification obligations, and maintain product data up to date.

Applicants are provided with guidance on registration and use after a successful Pre-submission.



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THANKYOU!