PQS performance specification

TITLE: Data standards for cold chain equipment monitoring	
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Contents

1. Scope

Collecting and analysing cold chain equipment (CCE) temperature and performance data is critical for ensuring safe vaccine storage. It is also crucial for informing actions that could include planning and conducting maintenance, improving global CCE standards and developing safer, more reliable CCE. A common set of CCE data and its common formatting is required to enable centralized management information systems to analyse data effectively.

The dual objectives for this specification are:
1. To standardize the format of data generated by appliances.
2. To allow and promote management information system developers to integrate multiple sources of temperature and/or performance data reported by different mechanisms and systems.

This specification describes minimum requirements for data objects for recording by CCE monitoring devices and systems, and the data format of those data objects. In addition to the list of possible environmental, performance, and use data objects, several administrative data objects are required to associate monitored data to an appliance.

2. Normative references

ISO 3166-1: 2020 Codes for the representation of names of countries and their subdivisions — Part 1: Country code
ISO 6709: 2008 Standard representation of geographic point location by coordinates
ISO 8601-1: 2019 - Date and time - Representations for information interchange - Part 1: Basic rules
ISO/IEC 27001: 2013 Information technology—Security techniques—Information security management systems--requirements

3. Terms and definitions

Absolute time: Coordinated Universal Time (UTC) time derived from an independent verified source (e.g. cellular tower, GPS, Internet time server), standardized according to ISO 8601 Internet Date Time profile, using days, hours, minutes, and seconds without separators, and including the time zone specifier "Z", short for "Zulu" and indicating zero offset from UTC (YYYYMMDDThhmmssZ).

Alarm: An audio and/or visual indication of appliance or device performance that is outside safe or normal operating conditions, and where the cause is driven primarily by appliance use or environmental conditions. Alarms are defined by WHO and/or immunization programs.

Appliance: The cold chain appliance or device that is the subject of monitoring. This may be a vaccine refrigerator, freezer, cold room, refrigerated vehicle, transportable storage, or other device which is being prequalified under specification **WHO/PQS/E006/DL01.**

- AC supply appliance: A cold chain storage device that operates on an input supply of alternating current.
- DC supply appliance: A cold chain storage device that operates on an input supply of direct current.

Communication latency: The maximum allowable period between data transfers between logger and EMD.

Data object: A standardized identifier of a unique administration, performance, use or environmental metric that is used to record and analyse data.

Employer: The organization responsible for ownership and/or utilization of an appliance or device within an immunization program, health system or initiative.

Energy Harvest Control (EHC): A control device or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices, in addition to an immunization appliance, when that electricity is not needed for cooling.

Equipment Monitoring System (EMS): The general term used to describe the associated components, sensors, devices, appliances, and data systems that enable cold chain equipment monitoring.

Equipment Monitoring Device (EMD): A device that functions to 1) retrieve data from the appliance's logger and other onboard sensors and 2) store, analyse and communicate data, errors, and alarms, and is the subject of specification **WHO/PQS/E006/EM01.** An EMD may be integrated within or external to the appliance as further defined below:

- **External Equipment Monitoring Device (E-EMD):** An EMD that is not integrated in the appliance and utilizes the M2M connection for data transmission and optional power supply.
- **Integrated Equipment Monitoring Device (I-EMD):** An EMD that has some or all its components built into the appliance at the point of manufacture. The I-EMD does not utilize the M2M for data transmission or power supply. The M2M affords access to the integrated logger for E-EMDs.

Error code: An alphanumeric code that is used to determine the nature of an appliance or device technical problem, and why it occurred. Errors are defined as related to equipment functionality that is not primarily user or environmentally related, but rather indicates hardware or software malfunction, defect, damage, or other issues.

Host: The party responsible for managing the Remote Data System.

Ice-lined refrigerator (ILR): A mains-powered compression-cycle appliance meant for vaccine storage or combined vaccine storage and water-pack freezing. These appliances are designed for operation in areas with intermittent electricity supply.

In writing: Communication by letter, fax, or email.

Key Performance Indicator (KPI): A metric computed using raw data object recordings, which provides a more summarized or aggregated assessment of the environment, performance, safety and/or use of cold chain equipment.

Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.

Logger: A data recording device that is integrated within an appliance or transport device and is the subject of specification **WHO/PQS/E006/DL01**. It stores data for use and analysis and provides access to its data.

Machine-to-Machine (M2M) interface: The standardized data and power transfer interface between logger and E-EMD, enabling interoperable function of EMDs and appliances. The M2M also enables portable devices like laptop computers and mobile phones to access logger data. The M2M is physically part of the appliance.

Relative time: A timestamp with an arbitrary but constant reference point (e.g. device commissioning is t=0), standardized according to **ISO 8601** Durations profile, represented by the format PnDTnHnMnS, where the [n] is replaced by the value for each of the day and time elements that follow the [n].

Remote Data System: A networked, server-based storage system for the collection, management, and communication of EMD data. The Remote Data System is managed by the host.

Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

Solar Direct Drive (SDD) refrigerator: A vaccine refrigerator or combined vaccine refrigerator and water-pack freezer powered by a solar electric system with no battery used to power the compressor or cooling circuit.

4. Data requirements

4.1 Time management

4.1.1 Relative time

The timestamp shall be established so that the most recent recordings are registered as more recent compared to previously recorded data objects. Logger (or other device using relative time) timestamps should always be strictly increasing (i.e. never reset to zero, do not repeat timestamps), even if a brownout occurs due to total power loss. Upon retrieval of data from a logger the current relative timestamp shall be recorded so that past data can be compared.

Relative timestamps shall be standardized according to **ISO 8601** Durations profile, represented by the format PnDTnHnMnS, where the [n] is replaced by the value for each of the day and time elements that follow the [n].

Details of duration format:
- **P** is the duration designator (referred to as "period") and is always placed at the beginning of the duration.
- **D** is the day designator that follows the value for the number of days, with a maximum number of digits of four.
- **T** is the time designator that precedes the time components.
- **H** is the hour designator that follows the value for the number of hours, with a maximum number of digits of two.
- **M** is the minute designator that follows the value for the number of minutes, with a maximum number of digits of two.
- **S** is the second designator that follows the value for the number of seconds, with a maximum number of digits of two.

Notes on format:
- Elements including their designator may be omitted if their value is zero.
- Leading zeros are not required with any element.
- "P" is not a valid representation for a duration of 0 seconds.

Examples of relative time format:
- "P968DT23H30M5S" represents 968 days, 23 hours, 30 minutes, 5 seconds.
- "PT1H13S" represents 1 hour, 13 seconds.
- "PT0S" and "P0D" are both valid representations of 0 seconds.

4.1.2   Absolute time

Time format shall comply with the **ISO 8601** Internet Date Time format, specified in UTC: YYYYMMDDThhmmssZ.

4.2   Alarms

The following alarms and default thresholds for triggering an alarm are defined as follows:

- Heat alarm setting:
  - For stationary refrigeration appliances: Exposure to a single temperature event of +8°C or above for 10 hours.
  - For mobile refrigeration appliances: Exposure to a single temperature event of +10°C or above for 10 hours.
  - For freezer appliances: Exposure to a single temperature event of -15°C or above for 60 minutes.
  - Alarm data object code: HEAT
- Freeze alarm setting:
  - For refrigeration appliances: Exposure to a single temperature event of -0.5°C or below for 60 minutes.
  - For freezer appliances: No low temperature alarm required.
  - Alarm data object code: FRZE
- Door/lid open alarm setting:
  - For all appliances other than cold/freezer rooms: Greater than 5 minutes of continuous door or lid opening.
  - For cold/freezer rooms: Greater than 30 seconds of door opening.
  - Alarm data object code: DOOR
- Power outage alarm setting:
  - For both mains-powered and solar powered stationary appliances, greater than 24 hours of continuous no power.
  - For mobile appliances, including refrigerated vehicles, no alarm requirement.
  - Alarm data object code: POWR
- External EMD disconnect alarm setting: an external EMD shall trigger an alarm if it has been disconnected from the M2M data port for greater than 30 minutes; such an alarm shall only be triggered if there has been a disruption to recording as a result of the M2M data connection being disconnected; the alarm shall not be triggered if the EMD has not been operational and actively downloading data via the M2M.
  - Alarm data object code: DCNT

A logger or EMD may optionally indicate that an alarm condition still exists but has been acknowledged in some way by a user (e.g. by muting). In this case, the string "ACK" may be added to the relevant alarm code. For example, with an ILR, after 10 hours above +8°C, an EMD would record the code HEAT each recording interval. One hour after the alarm begins, a user mutes the alarm and starts a generator to run the ILR.

The EMD would then record the code HEATACK (instead of HEAT) until the ILR's compressor had cooled the vaccine chamber below +8°C, at which time the EMD would stop recording any heat-related alarm code.

Therefore, codes that represent a continuing alarm condition that has been acknowledged are:
- HEATACK
- FRZEACK
- DOORACK
- POWRACK
- DCNTACK

4.3   Key Performance Indicators (KPIs)

KPIs are defined with the following default settings:
- Heat alarm KPIs:
    o Number of heat alarms in the past 30 days.
    o Number of heat alarms with a duration of 48 hours or longer in the past 30 days.
    o Total cumulative time heat alarms were active in the past 30 days (hours).
    o Average heat alarm duration in the past 30 days (hours).
- Freeze alarm KPIs:
    o Number of freeze alarms in the past 30 days.
    o Number of freeze alarms with a duration of 48 hours or longer in the past 30 days.
    o Total cumulative time freeze alarms were active in the past 30 days (hours).
    o Average freeze alarm duration in the past 30 days (hours).
- Door alarm KPIs:
    o Average number of door openings per day in the past 30 days.
    o Average door opening duration in the past 30 days (hours).
    o Number of door alarms in the past 30 days.
    o Total cumulative time door alarms were active in the past 30 days (hours).
- Power availability KPIs:
    o Average time of available power per day for the past 30 days (hours).
    o Number of power alarms in the past 30 days.
    o Total cumulative time power alarms were active in the past 30 days (hours).
    o Average power alarm duration in the past 30 days (hours).
- Functional status of appliance: "1" for functional, "0" for non-functional; a refrigerator is deemed 'non-functional' if any of the following conditions are met for the last 30-day time period:
    o Refrigerator had 5 or more heat alarms of over 10-hour duration
    o Refrigerator had 1 or more freeze alarms of over one-hour duration

- o Refrigerator had 1 or more heat alarms of 48-hour duration or longer
- Uptime score: percentage of time in the past 30 days when there was no active alarm condition.

4.4 Data Objects and format

All generated and recorded cold chain data shall utilize a standardized set of data object identifiers and formatting. See **Annex 1** for the complete list of defined data objects, definitions, and data format specifications.

All raw data available for download shall be available in JavaScript Object Notation (JSON). See **Annex 2** for the required JSON schema based on the data objects in Annex 1.

Required values that are obviously erroneous, for example from a broken temperature sensor, should be reported using JSON's null object rather than using a valid but non-physical value (e.g. -128°C).

4.5 Manufacturer-specific data objects

Legal manufacturers may define and include data objects in the JSON raw data files that are not in the data objects list defined in Annex 1, provided compliance with the following:
- If a data object already exists in the EMS data object list for the measured value, the legal manufacturer must use the defined data object.
- Custom data object field names should be lower case, prefixed with the character 'z'. For example, "ztpcm" could be a phase change material temperature data object created by a legal manufacturer.
- Custom JSON objects should be kept to a reasonable character length and frequency to limit data transmission costs.
- A JSON schema definition must be documented and made publicly available (e.g. code repository or website) for all custom objects that as a minimum describes the custom field name, description, and type (string, number, array, Boolean).

5. Data delivery to external systems

The employer shall have exclusive rights in determining who may access all data hosted by the legal manufacturer or reseller.

The legal manufacturer or reseller shall make all recorded data accessible to other software applications at the request of the employer.

When requested by the employer, the legal manufacturer or reseller providing remote communication services shall regularly send cold chain data via a HTTPS POST request to a universal resource locator (URL) endpoint, using access credentials and URL endpoint defined by the employer. This URL endpoint may be used by third-party

management information systems (e.g. LMIS) to consolidate multiple streams of monitoring system data (e.g. separate remote monitoring providers). Alternate industry-standard data transmission methods, such as MQTT, AMQP, Web Sockets, etc., may be utilized instead of HTTPS if there is agreement from both the employer and the legal manufacturer or reseller, but HTTPS must remain an available option.

Each HTTPS POST shall contain a structured JSON message or file payload, which at a minimum contains:

- Country identification for where the remote monitoring device is physically located.
- Monitoring device identification from which data is being sent.
- Legal manufacturer or reseller identification.
- All monitored data objects, alarms, error codes.

If the structured message contains any manufacturer-specific data objects, the legal manufacturer or reseller must also make the JSON schema for the manufacturer-specific data objects readily available per Clause 4.5. This schema must be transmitted periodically (e.g. every 24 hours or less). Alternatively, it is also acceptable to provide the schema or a reference to the schema (e.g. a link to a publicly accessible website where the schema is located) with each data payload.

Data should be sent to the employer within 24 hours of receiving it from a remote EMD other device (or at an alternative minimum frequency otherwise specified by the employer). Note that delays in or disruptions to communications networks may result in variable latency, so the minimum specified frequency should be considered a "best effort" specification.

The legal manufacturer or reseller of remote communications services may choose to forward these data to external systems either from their server infrastructure after receipt from the monitoring device, or directly from the monitoring device.

Unless otherwise specified by the employer, this HTTPS POST shall contain all sensor data collected by the monitoring system, except for debug messages or other measurements that are only relevant for monitoring module diagnostics.

The legal manufacturer or reseller may define an application programming interface (API) where the employer or their designees can pull data, but this alone does not satisfy the requirement for remote communication service providers to send data to the URL provided by the employer or their designee.

6. **Packaging**

Not applicable.

7. **On-site installation**

Not applicable.

8. Product dossier

Not applicable.

9. On-site maintenance

Not applicable.

10. Change notification

Not applicable.

11. Defect reporting

Not applicable.

Annex 1: Cold chain data objects

[reference separate document: PQS_E006_DS01_Annex 1_Cold Chain Data Objects_20231108.xlsx]

Annex 2: JavaScript Object Notations (JSON) Schema for Cold Chain Data

[reference separate document: PQS_E006_DS01_Annex_2_JSON_Schema_20211105.json]

Annex 3: JavaScript Object Notations (JSON) Verification Schema for Cold Chain Data

[reference separate document: PQS_E006_DS01_Annex_3_JSON_Verification_Schema_20211105.json]

Revision History