
 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
TEMPLATE		
Standard format/template for a performance specification		
Doc No: IMD/TP/01a	Version No: 2	Revise before: 15 Jun 2027
Effective date: 15 Jun 2024	Replaces: Annex 1	Page 1 of 3
Approved by:	TL-VAX, date: 10 Jun 2024	UH-PQT, date: 13 Jun 2024
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Standard format for a performance specification

	WHO/XXX		Original: English Distribution: General
	IMD- PQS performance specification		
TITLE: <description>			
<i>Specification reference:</i>		<PQS category>/<unique reference>	
<i>Product verification protocol:</i>		<PQS category>/<unique reference>	
<i>Issue date:</i>		<dd.mm.yy>	
<i>Date of last revision:</i>		<dd.mm.yy>	
Contents: <list the specification content down to level 1.1.1>			
1.	Scope: <briefly describe what product(s) the specification covers>		
2.	Normative references: < list ISO/IEC and other standards that apply to the specification, and list any relevant WHO product verification protocols; cross-refer to any other relevant performance specifications>		
3.	Terms and definitions: <define any specific terms used in the specification, particularly terms which may not be widely understood>		
4.	Requirements:		
4.1	<u>General:</u> <state <i>what</i> is generally required of the product, but <i>not how</i> this is to be achieved; briefly describe the context in which the product is to be used>		
4.2	<u>Performance:</u> <set out the specific performance characteristics required, including limits on energy consumption where relevant>		
4.3	<u>Environmental requirements:</u> <quantitatively define the operating environment in respect of temperature range, humidity, shock, vibration, etc.>		
4.4	<u>Physical characteristics:</u> <set out critical physical characteristics such as limits on weight, size etc., but only to the extent that these data are essential to satisfy human factors and/or interface requirements>		
4.5	<u>Interface requirements:</u> <describe form and fit requirements to the extent that these impact on other related products; e.g. size of icepacks to suit a specific range of cold boxes>		



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4.6	<u>Human factors</u> : <describe ergonomic requirements, including percentile of users; ‘ universal design ’ principles; health and safety issues etc.>
4.7	<u>Materials</u> : <specify materials that are to be used or excluded only to the extent that this is absolutely necessary; e.g. to ensure adequate corrosion or wear resistance, to minimise toxicity, or to comply with international agreements (e.g. the Montreal Protocol)>
4.8	<u>Warranty</u> : <define warranty requirements in quantitative terms and define the conditions under which these requirements must be met>
4.9	<u>Servicing Provision</u> : <define the requirement and specify the terms>
4.10	<u>Maintenance</u> : <define maintenance issues in as quantitative manner as possible; for example, mean time between maintenance, level of maintenance skill needed, etc.>
4.11	<u>Disposal and recycling</u> : <state specific requirements relating to end-of-life disposal, including any requirements for recycling of materials or components>
4.12	<u>Instructions</u> : <if user and/or maintenance instructions are required, state in which languages they are to be supplied >
4.13	<u>Training</u> : <if user training is required, state who is to be trained and for what purpose>
4.14	<u>Verification</u> : <state how product performance is to be verified, by citing the relevant type-testing, type-examination or full quality-assurance protocol>
6.	Packaging : <state any specific requirements for packaging>
7.	On-site installation : ⁴ <where a product requires on-site installation (e.g. solar powered appliances and standby generator) clearly define who is to be responsible for each stage in the process, such as: <ul style="list-style-type: none"> - designing the installation⁵; - identifying a suitable space or building to house the installation; - inspecting and approving the space or building; - making necessary physical changes to prepare for the installation; - inspecting and approving the changes; - carrying out the installation; - testing and commissioning the installation; - user training (when required at the time of installation)>
7.	Product dossier : <state what supporting information and/or production-run product samples the manufacturer (legal manufacturer or reseller) or



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	the approved installer must provide when submitting a product for prequalification, including details of quality systems (QA) in place>		
8.	On-site maintenance: <if on-site maintenance is required, state the desired performance criteria with regard to response rate etc.>		
9.	Change notification: <state that the manufacturer or approved installer is to report future changes in product specification, manufacturing location and manufacturing methods to WHO/UNICEF; define the conditions under which re-testing may be required>		
10.	Defect reporting: <state that the manufacturer or approved installer is to notify purchasers, end-users and WHO/UNICEF in the event of safety-related product recalls, component defects and other similar events>		
Annexes: <special symbols and other supporting information, as required>			
Revision history:			
Date	Change summary	Reason for change	Approved
dd.mm.yy	< change item> < etc.>	< reason for change> < etc.>	<name>