

### REGULATION AND PREQUALIFICATION DEPARTMENT

#### **VACCINES ASSESSMENT TEAM**

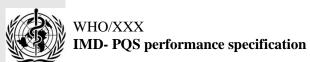
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Standard format/template for a performance specification

Doc No: IMD/TP/01aVersion No: 2Revise before: 15 Jun 2027Effective date: 15 Jun 2024Replaces: Annex 1Page 1 of 3Approved by:TL-VAX, date: 10 Jun 2024UH-PQT, date: 13 Jun 2024

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#### Standard format for a performance specification



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



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#### **TEMPLATE**

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4.6	Human factors: <describe 'universal="" and="" design'="" ergonomic="" etc.="" health="" including="" issues="" of="" percentile="" principles;="" requirements,="" safety="" users;=""></describe>
4.7	Materials: <specify are="" be="" excluded="" materials="" only="" or="" th="" that="" the<="" to="" used=""></specify>
	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	Warranty: <define and="" define="" in="" quantitative="" requirements="" terms="" th="" the<="" warranty=""></define>
	conditions under which these requirements must be met>
4.9	<u>Servicing Provision</u> : <define and="" requirement="" specify="" terms="" the=""></define>
4.10	Maintenance: <define as="" as<="" in="" issues="" maintenance="" manner="" quantitative="" th=""></define>
	possible; for example, mean time between maintenance, level of
	maintenance skill needed, etc.>
4.11	<u>Disposal and recycling</u> : <state end-of-life<="" relating="" requirements="" specific="" th="" to=""></state>
	disposal, including any requirements for recycling of materials or
	components>
4.12	<u>Instructions:</u> <if and="" are="" in<="" instructions="" maintenance="" or="" required,="" state="" th="" user=""></if>
	which languages they are to be supplied >
4.13	<u>Training:</u> <if and="" be="" for="" is="" required,="" state="" th="" to="" trained="" training="" user="" what<="" who=""></if>
	purpose>
4.14	<u>Verification</u> : <state be="" by="" citing="" how="" is="" performance="" product="" th="" the<="" to="" verified,=""></state>
	relevant type-testing, type-examination or full quality-assurance
_	protocol>
6.	Packaging: <state any="" for="" packaging="" requirements="" specific=""></state>
7.	On-site installation: <sup>4</sup> < 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> <li>designing the installation<sup>5</sup>;</li> </ul>
	<ul> <li>identifying a suitable space or building to house the installation;</li> </ul>
	<ul> <li>inspecting and approving the space or building;</li> </ul>
	- making necessary physical changes to prepare for the installation;
	- inspecting and approving the changes;
	- carrying out the installation;
	<ul> <li>testing and commissioning the installation;</li> </ul>
	<ul> <li>user training (when required at the time of installation)&gt;</li> </ul>
7.	Product dossier: <state and="" information="" or="" production-<="" supporting="" th="" what=""></state>
	run product samples the manufacturer ( <u>legal manufacturer</u> or <u>reseller</u> ) or



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