



PERFORMANCE QUALITY SAFETY

Pre-qualification of cold chain-related products
under the PQS system

Guidelines for manufacturers of temperature monitoring devices

PQS/E006

December 2006

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Glossary

ANSI	American National Standards Institution
CE	Conformité Européenne'
EMAS	European Union Eco-Management and Audit Scheme
EN	Euro Norm
EPI	Expanded Programme on Immunization
EU	European Union
IAPSO	Inter-Agency Procurement Services Office (UN agency)
ISO	International Standards Organization
IVB	Immunization, Vaccine and Biologicals (WHO Department)
NGO	Non-governmental Organization
PIS	Product Information Sheets
PQS	Performance, Quality, Safety
QA	Quality Assurance
QSS	Quality, Safety and Standards
SOP	Standard Operating Procedure
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Refer to Annex 5.1 for definitions of words and phrases highlighted [in blue](#).

1.0 Introduction

This guideline is one of a series which tells you how to make an application to the World Health Organization (WHO) for the pre-qualification of cold chain-related products for procurement by United Nations (UN) agencies. This document covers PQS category E006 – Temperature monitoring devices.

Under the WHO's new PQS system, you may offer products which you believe will comply with current WHO performance specifications for the following categories of equipment¹:

- E01: Cold rooms, freezer rooms and related equipment;
- E03: Refrigerators and freezers;
- E04: Insulated containers;
- E05: Icepacks and chilled water packs;
- E006: Temperature monitoring devices;
- E07: Cold chain accessories;
- E08: Single-use injection devices;
- E10: Waste management equipment;
- E11: Specimen collection equipment.
- E13: Therapeutic injection devices

This document describes what pre-qualification means, it gives a step-by-step guide to the pre-qualification process, and it outlines how your pre-qualified status can be maintained and also how it can be lost.

2.0 Background

The QSS group within WHO's Department of Immunization, Vaccines and Biologicals (IVB) provides technical advice and support aimed at achieving a reliable high quality cold chain for the world's immunization programmes and we publish performance specifications and verification protocols for cold chain and other immunization-related equipment and devices. These documents have been developed over the years in consultation with end-users, with industry and with testing laboratories and we have a long-established and rigorous procedure for evaluating and pre-qualifying suitable equipment.

By selecting from the list of pre-qualified equipment, UN procurement agencies, governments and NGOs can be sure that they are purchasing products that are fit for purpose.

The role of the cold chain equipment industry in the PQS process is to continue to provide a reliable stream of safe, affordable, high quality products designed to meet the needs and constraints of the developing world.

¹ Guidelines for categories in grey are forthcoming.

3.0 Procedural guide

3.1 What is the PQS system?

Since 1979 WHO, in collaboration with UNICEF Supply Division, have developed and maintained a series of performance specifications and test procedures for cold chain equipment, injection devices, and other immunization-related products. Products that conform to these specifications and test procedures are listed in the WHO/UNICEF *Product Information Sheets* (PIS)². In the quarter of a century since it was first introduced the PIS has become the principal source of information and advice for those responsible for purchasing products for use in immunization programmes.

The PIS system is now being updated and re-launched as the PQS system (Performance, Quality, Safety). All existing PIS performance specifications and test procedures in the E006 category have been re-drafted and have received final comments by industry. The new PQS-compatible documents will be released by the end of 2006.

We will evaluate products and devices against the new documents; those that conform will immediately be listed as pre-qualified products on the WHO website at:

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=35

At a date to be announced later, it is intended that details of all PQS pre-qualified products will be listed in a PQS-specific on-line database.

3.2 What does PQS pre-qualification mean?

The grant of PQS pre-qualification status does not constitute a guarantee of purchase. Pre-qualification indicates only that the product is technically satisfactory for procurement by United Nations Agencies for the purpose for which it is intended, and subject to any limitations set out in the PQS database or catalogue. You, as the manufacturer of the product, are entirely responsible for making a commercial arrangement with a potential purchaser and for ensuring that the quality of the delivered product is acceptable to that purchaser. In this context the word 'purchaser' can mean any one of the UN agency procurement units, including UNICEF, IAPSO, UNFPA, and WHO. You should also be aware that the individual UN procurement agencies reserve the right to impose additional conditions and limitations when seeking offers for the supply of pre-qualified products.

3.3 Can my company be considered?

Generally speaking we will only pre-qualify products which are offered to us by the [legal manufacturer](#) of the product. We will consider pre-qualifying products offered by a [reseller](#) provided a formal licensing arrangement exists between the [legal manufacturer](#) and the [reseller](#) giving the [reseller](#) exclusive rights and responsibilities

² The 2000 edition of the *Product information Sheets* can be downloaded from the WHO website at: www.who.int/vaccines-documents/DocsPDF00/www518.pdf

over the marketing, distribution, warranty arrangements and product maintenance, either globally, or within a large geographical area – see also Annex 5.1.

3.4 What products are eligible for pre-qualification?

The products you offer must comply with one of the PQS E006 performance specifications. Products are eligible for pre-qualification once they have been formally submitted to WHO and have passed the verification process. We will only pre-qualify one version of a product sourced directly from the [legal manufacturer](#) or licensed [re-seller](#). Re-badged or re-packaged variants will not be considered.

3.5 How do I apply for pre-qualification?

You should contact us [in writing](#) at the PQS Secretariat at WHO, Geneva, giving the following information:

- provide a contact name, address, telephone number and email address so that we can communicate with you;
- provide technical details and photographs of the product or product range that you have to offer and specify which of the PQS performance specifications you believe you are able to meet;
- provide brief details of the location and capacity of your manufacturing site(s).
- if you are a [reseller](#), provide full details of your contractual relationship with the [legal manufacturer](#) of the product(s) you are offering.

There is no need to send a separate comprehensive dossier for each product at this stage – the PQS Secretariat will write to you listing the specific information that is required.

Envelopes or packages should be clearly marked: **PRELIMINARY PQS PRE-QUALIFICATION APPLICATION** and addressed to:

PQS Secretariat
Department of Immunization, Vaccines & Biologicals/QSS
World Health Organization
CH-1211
Geneva 27
Switzerland

Email submissions are acceptable, but must consist of a covering page with formal attachments on the company's electronic stationary in PDF or JPEG format. Attachments should be similarly marked and addressed. We will not accept substantive correspondence in plain text format. All emails should be sent to pqsinfo@who.int

We may contact you by telephone or email if we have specific queries.

Once we have received your introductory letter we will write to you to confirm which products are of interest to us and we will list the information that you will have to submit in order to make a formal application for pre-qualification – see Section 3.6. If it is clear from the information contained in your introductory letter that one or more of your products is unsuitable, we will advise you accordingly.

3.6 How do I prepare a product dossier?

You must send us a separate and complete product dossier for each product that you have offered and which we have accepted as being suitable for evaluation. For example, if you are offering more than one type of data logger, we will need one dossier for each model you propose to offer for evaluation.

If you are offering a product that is manufactured at more than one manufacturing site we will require a separate dossier for each named site. Alternatively you may specify that the product will be supplied from one named manufacturing site only³.

We will email you listing the information that we require and we will attach the relevant background documents, including a further copy of this guideline. Each dossier you prepare must contain the following:

1. A covering letter.
2. A countersigned copy of the letter of invitation received from WHO, headed: **Application for pre-qualification of a product under the PQS system: Pre-qualification information pack.** By countersigning this letter you confirm that you have read and agreed to abide by WHO's standard Terms and Conditions for pre-qualification.
3. The non-refundable Dossier Examination Fee; the amount requested will be the fee current at the date of application.
4. All the other supporting information which is listed in Section 7 of the PQS performance specification applicable to the product you are offering.
5. Product sample(s) where this requirement is listed in Section 7 of the PQS performance specification.
6. A completed *Product Summary Sheet Questionnaire* (see Annex 5.3)

Packages should be clearly marked: **PQS PRE-QUALIFICATION APPLICATION** and addressed to:

PQS Secretariat
Department of Immunization, Vaccines & Biologicals/QSS
World Health Organization
CH-1211
Geneva 27
Switzerland

We will also accept formal electronic submissions in PDF or JPEG format as described in section 3.5 above.

Reminder: Submit one dossier for each product. [If the product is manufactured at more than one manufacturing site, you must submit one dossier for each site.]

³ We are only interested in the manufacturing site where product assembly, testing and packing takes place. We are not interested in the manufacturing sites from which you obtain your components.

3.7 How much will I pay?

We will charge you on a cost recovery basis for the initial evaluation of your dossier. If your product is pre-qualified you will also be required to pay an annual re-evaluation fee. The current fee scales, which are shown in Table 1.

Table 1 - Cost recovery fees to be paid to WHO

Step	Fee to be paid to WHO
Dossier examination fee	US\$ 2,400.00
Annual re-evaluation fee	US\$ 1,200.00

Note that these fees will be charged for each and every product you submit. If the dossier examination is successful we will ask you to send the required sample(s) of the product to one of the WHO-accredited testing laboratories for evaluation against the relevant PQS verification protocol (type-examination or type-testing). You will be required to pay for laboratory testing as described in Section 3.9.

3.8 The dossier evaluation process

We will review the contents of your dossier. If anything is missing we will contact you [in writing](#) giving you a period of one month to provide the missing information, dossier fee or samples. If you fail to respond by the end of this [period of grace](#) we will return your dossier; the dossier examination fee will not be refunded. Note that we will not evaluate your dossier until the dossier fee has been paid in full.

Once we have a complete dossier and have cleared your Dossier Examination Fee, we will evaluate the information and samples you have supplied. We may appoint an independent [evaluator](#) to carry out this work. In order to avoid conflicts of interest and to protect your proprietary information, all our [evaluators](#) will be required to sign a confidentiality agreement— see Annex 5.2, clause 10. If queries arise during the dossier evaluation process, you may be contacted.

If we consider that the product merits full verification we will write to you requesting you to submit the necessary samples to a WHO-accredited test laboratory for a full evaluation against the relevant PQS verification protocol.

If we consider that your product is unlikely to pass the formal verification process we will write to you to confirm this and will give you our reasons for rejecting the product.

3.9 The verification process

Depending upon the product type and the anticipated market volume, there are three types of PQS verification protocol:

1. *Type-examination* is used for products that are not ‘programme critical’ and which are likely to be purchased in relatively small quantities.
2. *Type-testing* is used for products that are purchased in large quantities. Typically the reliable operation of these products will also be critical to the success of the immunization programme.

3. *Quality assurance (QA)* is used for products - for example event logger systems - specific instances of which are configured for a particular application and have to be assembled and commissioned on site. Generally speaking a quality assurance evaluation will form part of a contractual agreement between the manufacturer and the end user of the equipment. Consequently the QA route is not covered by this guideline. Products that comprise a system of standard components which can be assembled on site in various ways may require both a *type-testing* protocol and a *quality assurance* protocol⁴.

In the case of *type-examination* and *type-testing* you will be responsible for shipping the necessary samples to the nominated testing laboratory, for paying the verification fee and for supplying any supplementary information that they request during the course of the verification process.

3.10 Verification results and the approval process

The PQS Secretariat will monitor the verification process and will deal with applications as rapidly as resources allow; it will also receive and review the verification report.

On the basis of the report's conclusions, the PQS Secretariat will recommend whether or not the product should be pre-qualified. The PQS Steering Group will make the final decision on pre-qualification.

If the results of the verification are satisfactory we will write to tell you that your product has been pre-qualified for procurement by United Nations Agencies and that it will be listed on the PQS database. You will receive a copy of the verification report and we will highlight any remaining concerns. We will expect you to deal with these before the next annual product review, the date of which we will also confirm.

If the evaluation results are unsatisfactory we will inform you that the product is not suitable in its current form; you will also receive a copy of the verification report. Our decision is final and we will not enter into correspondence with unsuccessful candidates.

3.11 Maintaining pre-qualified status

The performance of your product and of your company will be kept under continual review through the formal PQS review procedure and throughout the procurement process at the various UN procurement agencies.

It is essential that you keep us fully informed about any change you make to your product, to the manufacturing process or to the manufacturing site. If you do not do so, your product may lose its pre-qualified status – see section 3.12.

3.11.1 The extra-ordinary PQS review process

If serious problems arise with the product, we reserve the right to re-evaluate your pre-qualification status at any time. A serious problem would be a premature product failure or other circumstance requiring immediate action. Generally, we will tell you

⁴ Event logger systems fall into this category.

about the problem and ask you to resolve it by an agreed date. However, if the problem is severe, we may suspend your pre-qualification status until it is resolved. Under some circumstances – for example bankruptcy or receivership – we will withdraw your pre-qualification status permanently.

3.11.2 The annual PQS review process

All PQS pre-qualified products will be reviewed once a year at a single fixed time against a standard checklist, as shown in Annex 5.5. We will confirm the date of the annual review when pre-qualification is granted.

The annual review panel will consider all relevant aspects of your product. If we have previously highlighted problems which you need to resolve by an agreed date, you must keep us informed about your progress.

At least one month in advance, we will remind you of the date of the review and you must ensure that we receive the annual re-evaluation fee before the review date. You must also send us [certified copies](#) of any licences or certificates that apply to the product and which have been renewed in the previous 12 months.

Envelopes or packages for the annual review should be clearly marked: **PQS ANNUAL RE-EVALUATION DOSSIER**, and addressed to:

PQS Secretariat
Department of Immunization, Vaccines & Biologicals/QSS
World Health Organization
CH-1211
Geneva 27
Switzerland

We will also accept electronic submissions in PDF or JPEG format as described in section 3.5 above.

You should be aware that the first annual review may be less than one year after your product is initially pre-qualified. This is because the review takes place on a fixed date each year; this date may fall before a 12 month period has passed since your product was pre-qualified. If your product is pre-qualified more than four months before the next annual review date you will still be required to pay the re-evaluation fee and to submit any necessary paperwork.

We will only inform you of the results of the annual review if we identify specific problems that require your attention. We will also inform you if your pre-qualification status is suspended or withdrawn as a result of the review.

3.12 Losing pre-qualified status

There are several ways in which you could lose your status as a pre-qualified manufacturer. These include, but are not confined to, the following:

- if you change the manufacturing site with or without notifying us of your intention to do so (Annex 5.2, clause 8);

- if you change the product in an unacceptable way (one that negatively effects the performance of the product) with or without notifying us of your intention to do so (as defined in Annex 5.2, clause 8);
- if you change the product specification in an unacceptable way (Annex 5.2, clause 8);
- if you fail to provide evidence of annual license renewal(s) for the product or any other relevant time expiring documentation(Annex 5.2, clause 8);
- if we receive reports from the UN procurement agencies showing that your production quality control is poor or inconsistent (Annex 5.2, clause 8);
- if the functioning of the product in the field is shown not to be meeting the performance requirements (Annex 5.2, clause 9);
- if you go into bankruptcy or receivership.

4.0 Checklists

Use the following three checklists to ensure that you send us all the information that we require at each of the stages specified.

4.1 Preliminary application checklist

Refer to Section 3.5 – Have you included the following?	
1. Covering letter.	<input type="checkbox"/>
2. Contact details	<input type="checkbox"/>
3. Technical details of each of the products that you are offering for evaluation.	<input type="checkbox"/>
4. Photographs of each product.	<input type="checkbox"/>
5. Details of the PQS performance specification against which you want us to assess the product.	<input type="checkbox"/>
6. Brief details of each of your manufacturing sites.	<input type="checkbox"/>
7. Confirmation of the production capacity of each of your manufacturing sites.	<input type="checkbox"/>
8. If you are a reseller , provide details of your contractual relationship with the legal manufacturer of the product(s) you are offering.	<input type="checkbox"/>
9. A correctly labelled and addressed package OR formal electronic submission in PDF or JPEG format.	<input type="checkbox"/>

Reminder: Your preliminary application can include information about more than one product and more than one manufacturing site.

4.2 Dossier submission checklist

Refer to Section 3.6 - Have you included the following items for each product and for each manufacturing site?	
1. A covering letter.	<input type="checkbox"/>
2. A countersigned copy of the letter of invitation received from WHO.	<input type="checkbox"/>
3. The correct Dossier Examination Fee, in US dollars.	<input type="checkbox"/>
4. All the supporting information which is listed in Section 7 of the PQS performance specification applicable to the product you are offering.	<input type="checkbox"/>
5. Product sample(s) where listed in Section 7 of the PQS performance specification applicable to the product you are offering.	<input type="checkbox"/>
6. A completed Product Summary Sheet Questionnaire and all relevant attachments (see Annex 5.3 and associated notes)	<input type="checkbox"/>
7. A correctly labelled and addressed package, OR formal electronic submission in PDF or JPEG format.	<input type="checkbox"/>

Reminder: You must submit one dossier for each product. If the product is manufactured at more than one manufacturing site, you must submit one dossier for each site.

4.3 Annual review checklist

Refer to Section 3.11.2 - Have you included the following items for each pre-qualified product and for each manufacturing site?	
1. A covering letter specifying the product to which the dossier refers.	<input type="checkbox"/>
2. The annual re-evaluation fee in US dollars.	<input type="checkbox"/>
3. Certified photocopies of time-expiring documentation that you have renewed since you made your last submission.	<input type="checkbox"/>
4. Details of changes to the company name or status (for example, if you have been taken over by another company).	<input type="checkbox"/>
5. Details of changes to the manufacturing site since you made your last submission.	<input type="checkbox"/>
6. Details of changes to the manufacturing process since you made your last submission.	<input type="checkbox"/>
7. Details of changes to the product since you made your last submission.	<input type="checkbox"/>
8. Details of all significant product failures reported to you during the past year.	<input type="checkbox"/>
9. Progress report on the resolution of any problems reported to you by the PQS Secretariat.	<input type="checkbox"/>
10. A list of other matters that you wish to draw to our attention.	<input type="checkbox"/>
11. A correctly labelled and addressed envelope/package OR formal electronic submission in PDF or JPEG format.	<input type="checkbox"/>

Reminder: You must submit one dossier for each product. If the product is manufactured at more than one manufacturing site, you must submit one dossier for each site.

5.0 Annexes

Annex 5.1 - Definitions

The following definitions apply to this document:

Certified copy	Wherever a certified copy or certified photocopy is requested, the copy must be certified as a true copy of the original document by a person registered to practice law in the Legal Manufacturer's country of origin and must be endorsed with the legal practitioner's official stamp and signature.
Correspondence	Includes mail, fax and email.
Device	In this document, where the word device is used, it generally refers to a cold chain-related product unless specifically described as an 'injection device'.
Evaluator	An individual or organization (including a WHO-accredited testing laboratory) responsible for evaluating or assessing any aspect of a product as described in this document.
in writing	Where the phrase in writing is used this means correspondence must be transmitted by mail, fax or by email in PDF or JPEG format.
Manufacturer	In the context of this document the word manufacturer means the Legal Manufacturer .
Legal Manufacturer	Legal Manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or product before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party ⁵ .
Period of grace	Period allowed to provide information or to complete a transaction, after formal notice in writing has been given.
Product	In this document, where the word product or device is used, it generally refers to a cold chain-related product.
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 .
Verification	A verification protocol describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the PQS product pre-qualification procedure.

⁵ Definition derived from Article 1 2(f) of the EU Medical Device Directives.

Annex 5.2 – Standard Terms and Conditions

The Terms and Conditions and Definitions set out below will apply to all manufacturers of PQS pre-qualified products, other than injection devices. You should familiarize yourself with this document and ensure that you comply fully with the on-going reporting requirements set out therein. Failure to do so may result in the suspension or withdrawal of your pre-qualification status. At the ‘product dossier’ stage you must countersign the letter to which these terms and conditions are attached as acknowledgement that you agree to be bound by them.

TERMS AND CONDITIONS	
1. Examination of dossier:	The Product Dossier will be screened by WHO for completeness prior to the evaluation of the dossier. The dossier can be rejected on grounds of incompleteness and returned to the manufacturer. Complete dossiers will be retained for evaluation purposes.
2. Dossier Examination Fee:	The Dossier Examination Fee is non-refundable and must be paid in full, in the specified currency, before the dossier can be formally examined by WHO.
3. Product Verification Fee:	The Product Verification Fee is non-refundable and must be paid in full, in the specified currency, before the evaluation process can commence.
4. Evaluation:	The WHO unit responsible for the evaluation will be independent from all UN agency procurement units. Every product, device or service will be evaluated against the relevant PQS performance specification and product verification protocol, current at the time of the evaluation. The manufacturer will receive a letter from WHO advising on the outcome of the evaluation process with regard to the specific product(s) of that particular manufacturer.
5. Laboratory testing:	Where laboratory testing is specified in the Relevant Product Verification Protocol, these test will be carried out on samples supplied by the Manufacturer in a testing laboratory designated by WHO. All the tests specified will be carried out each and every time a product is submitted for testing. A Manufacturer whose product has failed one or more of the tests is entitled to resubmit a revised product for the complete sequence of tests; he is not entitled to resubmit solely for the tests that his product has previously failed.
6. Meaning of pre-qualification:	The grant of pre-qualification status following the evaluation process indicates that the product, device or service is technically satisfactory for use in immunization programmes, subject to any limitations set out in the PQS website or catalogue. However, the grant of pre-qualification status does not guarantee that an acceptable commercial arrangement can be reached between the supplier of the product, device or service and the purchaser; nor does it guarantee that the quality of the delivered product, device or service will be acceptable to the purchaser. In this context the word, 'purchaser', could cover more than one of the UN agency procurement units, including UNICEF, IAPSO, UNFPA, and WHO.
7. Publication:	Following satisfactory evaluation, the product, as manufactured at the specified manufacturing site, will be included in the list of ‘pre-qualified’ PQS products and WHO will inform the interested UN agency procurement unit(s) accordingly. Details of the product will then be posted on the PQS website and may also be published in a hard copy catalogue
8. Re-evaluation:	The product will be subjected to review once a year, unless major changes occur in the meantime. Manufacturers will be required to communicate evidence of the annual renewal of any relevant licence and of any changes that may have an impact on the safety, performance, efficacy or quality of the product to WHO, or sooner should any change regarding manufacturing method, or manufacturing site be implemented by the manufacturer. However, the manufacturer must inform WHO of any contemplated changes to the product, changes in manufacturing process or manufacturing site. Re-evaluation may also be carried out in the following situations: <ul style="list-style-type: none">• If any omission by the manufacturer in the initial evaluation procedure, or during the follow-up activities, is evident in relation to the requirements, including compliance with quality system standards and failure to notify complaints. If any batch or batches of supplied product(s) are documented by WHO, or one or more of the UN agencies or organizations, not to be in

<p>compliance with the agreed specifications of the product or to reveal failure(s) regarding safety, performance or quality of the device;</p> <ul style="list-style-type: none"> • If the investigation of a complaint considered leads to the conclusion that the quality and/or safety of the product is in question. <p>Under normal circumstances there will be no requirement for the manufacturer to re-test the product as part of the re-evaluation process. However, circumstances may arise where re-testing is necessary.</p>
<p>9. Monitoring of complaints: Upon request, WHO or other relevant UN agencies will investigate reported complaints concerning a product, in collaboration with the manufacturer. WHO will maintain a database of complaints. Following investigation, WHO will provide UN agencies with a written report of the problem with recommendations for action, if any.</p>
<p>10. Confidentiality undertaking: WHO will treat, and will require evaluators of product dossiers to treat all information to which they will gain access during the evaluation, or otherwise in connection with the discharge of their responsibilities in regard to the pre-qualification of PQS products as confidential. In addition, the evaluators of product dossiers will be required to sign a Declaration of Interest. A sample of the confidentiality and declaration of interest undertaking for evaluators of product dossiers can be obtained on request. If based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they will discharge their functions exclusively as advisers to WHO.</p>
<p>11. The following disclaimer applies to all products that are accepted for inclusion on the PQS database.</p> <p><i>Disclaimer:</i> Inclusion in the PQS database does not constitute an endorsement, or warranty of fitness, of any product for a particular purpose, including in regard to its safe and appropriate use in immunization programmes. WHO does not furthermore warrant or represent that: 1) the database is complete or error free and/or that 2) the products that have been found to meet the standards recommended by WHO, will continue to do so and/or that 3) the products listed have obtained regulatory approval for use in every country of the world or that its use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. In addition, WHO wishes to alert procuring UN agencies that the improper storage, handling and transportation of products may affect their quality, efficacy and safety. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of products included in the list.</p>

Annex 5.3 – Product Summary Sheet Questionnaire

		Information item	PRODUCT SUMMARY SHEET (Complete one questionnaire per product and per manufacturing site)					
1	<input type="checkbox"/>	Relevant PQS category	<input type="checkbox"/> E01 <input type="checkbox"/> E03 <input type="checkbox"/> E04 <input type="checkbox"/> E05 <input type="checkbox"/> E006 <input type="checkbox"/> E07 <input type="checkbox"/> E08 <input type="checkbox"/> E10 <input type="checkbox"/> E11					
2	<input type="checkbox"/>	Relevant PQS specification						
3	<input type="checkbox"/>	Product description						
4	<input type="checkbox"/>	Unique ID for product type				Remarks		
5	<input type="checkbox"/>	Vendor status	<input type="checkbox"/> Legal manufacturer <input type="checkbox"/> Reseller <input type="checkbox"/> Other (specify)					
			Name	Address	Phone and Fax	Contact person for quality assurance	Web-site, e-mail	
6	<input type="checkbox"/>	Vendor						
7	<input type="checkbox"/>	Manufacturer						
8	<input type="checkbox"/>	Manufacturing Site						
9	<input type="checkbox"/>	Parent company (if any)						
10	<input type="checkbox"/>	Type approvals	Regulatory authority (list all applicable)		Number/reference		Product name as submitted to authorities	
			<input type="checkbox"/> European Union		CE mark number:			
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
11	<input type="checkbox"/>	Conformity with quality system and environmental management standards	Standards used (check applicable)		Certification body. Specify name & country & attach copy of the certificate. (See note 1)		Last audit date	Expiration date
			<input type="checkbox"/> ISO 9000 2001					
			<input type="checkbox"/> ISO 14001					
			<input type="checkbox"/> EMAS					
			<input type="checkbox"/>					
12	<input type="checkbox"/>	Conformity with international, regional and national standards (e.g. ISO, ANSI, EN, etc)	Standards used (list those applicable)		Test laboratory used. Specify name & country & attach a copy of the certificate.		Laboratory accreditation body	
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
			<input type="checkbox"/>					
13	<input type="checkbox"/>	PIS and other evaluation reports	<input type="checkbox"/>					

Notes: 1) For example: Notified bodies in the European Union; Quality Systems Registrars in North America.

Instructions for completing the Product Summary Sheet Questionnaire

General note: Applicants must complete all entries.

Item 1: Refer to Annex 6 and check the relevant category.

Item 2: Refer to Annex 6 and enter the relevant specification reference.

Item 3: Give a brief description of the product.

Item 4: Enter your unique product identification for the product.

Item 5: Check the appropriate box to indicate the status of the Vendor. Refer to Section 3.3 for eligibility rules and, if you are a [Reseller](#), provide full details of your contractual relationship with the [Legal Manufacturer](#) of the product(s) you are offering.

Items 6 and 7: In many cases the vendor will also be the manufacturer. In such cases, provide all the requested information under both headings, even if the details are identical.

Item 9: If the manufacturer is a subsidiary of a parent company, or is under contract to another company, please supply the necessary information. Traceability of the product to the [Legal Manufacturer](#) must be clearly stated on all packaging. The [Legal Manufacturer's](#) documentation system must also include traceability of the product to the original manufacturing site.

Item 10: CE marking is mandatory. List all other type approvals for the product.

Item 11: Check/list all quality system standards applicable to the manufacturing site. Against each checked standard state the name and country of origin of the [Certification Body](#) which verified compliance with the standard and provide a [Certified Copy](#) of the quality system certification. State the date of the last certification audit and the date of expiry.

Item 12: Check all product standards applicable to the device. Against each of the checked standards state the name of the test laboratory which carried out the test and state the name of the body which accredited the laboratory.

Item 13: If the product has previously been tested against one of the WHO PIS performance specifications and test procedures, provide full details. If available, provide any other third party evaluation reports.

Annex 5.4 – List of WHO-accredited testing laboratories

Transitional arrangements: The list of accredited laboratories can be found at:

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/laboratory.aspx

Manufacturers wishing to have their products tested at a different accredited ISO 17025 laboratory must arrange to have the laboratory submit a formal application to WHO for accreditation before the test is carried out. Details of the procedure can be obtained by application to pqsinfo@who.int

Annex 5.5 – Annual review checklist

PQS product re-evaluation report		Date: <dd.mm.yyyy>
PQS reference: <ref>		Pre-qualification date: <dd.mm.yyyy>
<product description>		
1.	UNICEF-SD QAC reports: <brief description>	
2.	Results of structured field performance monitoring: <brief description>	
3.	Performance feedback from governments and donor agencies: <brief description>	
4.	Manufacturers' <i>Change Notifications</i>: <brief description>	
5.	Manufacturers' <i>Product Defect Reports</i>: <brief description>	
6.	Questionnaires: <brief description>	
7.	Anecdotal reports from the field: <brief description>	
8.	Relevant policy decisions: <brief description>	
9.	Recommendation: <brief description>	
Re-validate product: <input type="checkbox"/> Suspend product: <input type="checkbox"/> Remove product: <input type="checkbox"/>		
Date of suspension notification: <dd.mm.yyyy>		

6.0 References

6.1 PQS performance specifications and verification protocols

E006: Temperature monitoring devices

WHO/PQS/E006/AL01.1: *WHO Performance Specification for acoustic and/or visual alarm units.*

WHO/PQS/E006/AL01-VP.1: *WHO Independent type-testing protocol for acoustic and/or visual alarm units.*

WHO/PQS/E006/IN02.1: *WHO Performance Specification for Cold Chain Monitors.*

WHO/PQS/E006/IN02-VP.1: *WHO Independent type-testing protocol for Cold Chain Monitors.*

WHO/PQS/E006/IN03.1: *WHO Performance Specification for irreversible freeze indicators.*

WHO/PQS/E006/IN03-VP.1: *WHO Independent type-testing protocol for irreversible freeze indicators.*

WHO/PQS/E006/IN05.2: *WHO Performance Specification for Vaccine Vial Monitors.*

WHO/PQS/E006/IN05-VP.2: *WHO Independent type-testing protocol for Vaccine Vial Monitors.*

WHO/PQS/E006/TH01.1: *WHO Performance Specification for portable electronic thermometers.*

WHO/PQS/E006/TH01-VP.1: *WHO Type-examination protocol for portable electronic thermometers.*

WHO/PQS/E006/TH02.2: *WHO Performance Specification for wall-mounted pen recording thermometers.*

WHO/PQS/E006/TH02-VP.2: *WHO Independent type-testing protocol for wall-mounted pen recording thermometers.*

WHO/PQS/E006/TH03.1: *WHO Performance Specification for alcohol stem thermometers.*

WHO/PQS/E006/TH03-VP.1: *WHO Independent type-testing protocol for alcohol stem thermometers.*

WHO/PQS/E006/TH06.2: *WHO Performance Specification for integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.*

WHO/PQS/E006/TH06-VP.2: *WHO Independent type-testing protocol for integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.*

WHO/PQS/E006/TR03.1: *WHO Performance Specification for programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.*

WHO/PQS/E006/TR03-VP1.1: *WHO Independent type-testing protocol for programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.*

WHO/PQS/E006/TR03-VP2.1: *WHO Quality Assurance Protocol for Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.*

WHO/PQS/E006/TR04.1: *WHO Performance Specification for wall-mounted pen recording thermometer.*

WHO/PQS/E006/TR04-VP.1: *WHO Independent type-testing protocol for wall-mounted pen recording thermometer.*

WHO/PQS/E006/TR05.1: *WHO Performance Specification for user-programmable temperature data loggers.*

WHO/PQS/E006/TR05-VP.1: *WHO Type-examination protocol for user-programmable temperature data loggers.*

WHO/PQS/E006/TR06.3: *WHO Performance specification for 30 day electronic refrigerator loggers.*

WHO/PQS/E006/TR06-VP.3: *WHO Independent type-testing protocol for 30 day electronic refrigerator loggers.*

WHO/PQS/E006/TR07.2: *WHO Performance Specification for electronic shipping indicators.*

WHO/PQS/E006/TR07-VP.2: *WHO Independent type-testing protocol for electronic shipping indicators.*

6.2 Other references

WHO/V&B/00.13. *WHO/UNICEF Product Information Sheets - 12th Edition 2000.*

REVISION HISTORY FORM

Guideline number	Original: WHO/PQS/E006/GUIDE.1 Present: WHO/PQS/E006/GUIDE.1.3	
Date of original version: 01 December 2006		
REVISIONS		
Date	Reason	Authorized by (Signature and Name)
22 December 2008	Extension fee until end 2009	DM
22 October 2013	Fee increase and references update	DM