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

Guidelines for manufacturers of cold rooms and freezer rooms

PQS/E001

August 2007

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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 E001 – Cold rooms and freezer rooms.

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 equipment[1]:

- E001: Cold rooms, freezer rooms and related equipment;
- E03: Refrigerators and freezers;
- E04: Insulated containers;
- E05: Icepacks and chilled water packs;
- E06: 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). The existing PIS specification WHO/V&B/02.33: E1 - *Cold rooms and freezer rooms* has been re-drafted. The new PQS documents include a performance specification, a type-examination procedure for the pre-qualification process and a quality assurance procedure for managing the procurement, commissioning and final inspection of site-specific installations. The new documents have received final comments by industry and will be released in the autumn of 2007.

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=15

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?

Under the PIS system, cold rooms and freezer room manufacturers were not formally pre-qualified by WHO, although a list of vaccine cold room suppliers was included in the *Product Information Sheets*. Under the PQS system, UN procurement agencies will be advised to purchase this category of equipment from PQS pre-qualified companies only.

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

[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

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[3] 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 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 product you offer must comply with the relevant PQS 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 a product where the principal elements are sourced directly from the legal manufacturer or licensed re-seller.

3.5 Transitional arrangements

Products that are purchased under the existing arrangements will continue to be procured by UN agencies for a period of 6 months starting on 30th September 2007. After the expiry of this period, products that have not achieved pre-qualification under the procedures described in this document will no longer be considered suitable by WHO for use in immunization programmes.

3.6 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.

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[3] In this context the word 'product' refers to a package of components or systems required to build a fully functioning cold room or freezer room complying with specification WHO/PQS/E001/CR-FR01.3: *WHO Performance Specification for cold rooms and freezer rooms.* It does not imply any specific assemblage of these components.

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 3.7. 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.

3.7 How do I prepare a product dossier?

Your product dossier must include information on all the major component categories needed to construct a fully operational cold room and/or freezer room. If you are offering more than one range of components – for example two different ranges of refrigeration unit – you must supply details for each range.

If you are sourcing major system components from other manufacturers you must supply us with details of these component manufacturers and you must confirm that their components are covered by your warranty.

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 3.6 above.

Reminder: Submit one dossier for each product.

3.8 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 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$ 1,400.00

If the dossier examination is successful we will ask you to send the required component samples to an independent evaluator for full technical evaluation against the type-examination protocol WHO/PQS/E001/CR-FR01-VP1.3 *Cold rooms and freezer rooms*. You will be required to pay for this type-examination process as described in Sections 3.9 and 3.10.

3.9 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 or dossier fee. 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 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 a further copy of the dossier and the specified component samples to an independent evaluator[4] for a full technical evaluation. The fee for this exercise will be $3,000.00.

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.

3.10 The verification process

Cold rooms and freezer room systems will be evaluated against the type-examination protocol WHO/PQS/E001/CR-FR01-VP1.3 *Cold rooms and freezer rooms*. Based on the information and samples you supply, the evaluator will assess the technical performance of the system(s) you are offering, the quality of your sample documentation and your ability to provide a satisfactory installation and maintenance service in the countries and regions for which you are applying. The evaluator will then submit detailed recommendations to WHO. You may be asked to supply supplementary information during the course of the verification process.

3.11 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.

3.12 How will site-specific installations be procured?

Pre-qualified companies will be approached by UN procurement agencies or UN member governments and will be asked to submit bids for individual installations based on the pre-qualified system components. The proforma document WHO/PQS/E001/CR-FR01-VP2.3: *WHO Quality assurance protocol for cold rooms and freezer rooms* will be used to specify the required installation and to provide

[4] If we have appointed an evaluator to carry out the initial dossier examination, this will generally be the same person. In this case, a further copy of the dossier may not be required.

details of the installation site. Depending upon the requirements of the procurement organization, this proforma is likely to be accompanied by other contractual documentation.

3.13 Maintaining pre-qualified status

The performance of your product, of your company and of your nominated installation and maintenance contractors 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 major changes you make to system components (for example, a change of refrigeration unit supplier), to the manufacturing process or to the manufacturing site. If you do not do so, your product may loose its pre-qualified status – see section 3.14.

3.13.1 The extra-ordinary PQS review process

If serious problems arise with your installations, we reserve the right to re-evaluate your pre-qualification status at any time. A serious problem would be a high incidence of premature component failure, a consistently unsatisfactory installation and/or maintenance service, or other circumstance requiring immediate action. Generally, we will tell you 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, or limit its geographical scope, until it is resolved. Under some circumstances – for example bankruptcy or receivership – we will withdraw your pre-qualification status permanently.

3.13.2 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. You will be advised of the review date at the time of pre-qualification.

The annual review panel will consider all relevant aspects of your product and your installation and maintenance services. 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 3.6 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 advise you by email if your product has been re-validated. We will write to you formally if we identify specific problems that require you attention. We will also write to you formally if your pre-qualification status is suspended or withdrawn as a result of the review.

3.14 Loosing pre-qualified status

There are several ways in which you could loose 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 your system components 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 system component specifications 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 and/or your system installation and/or your system maintenance services are poor or inconsistent (Annex 5.2, clause 8);
- if the functioning of installations 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 3.6 – Have you included the following?	
1. Covering letter.	☐
2. Contact details	☐
3. Technical details of each of the major system components that you are offering for evaluation.	☐
4. Photographs illustrating some typical installations.	☐
5. Details of the PQS performance specification against which you want us to assess the product.	☐
6. Brief details of each of your manufacturing sites.	☐
7. Confirmation of the production capacity of each of your manufacturing sites.	☐
8. If you are a reseller, provide details of your contractual relationship with the legal manufacturer of the product(s) you are offering.	☐
9. Details of the countries/regions in which you can offer a full installation and maintenance service.	☐
Provide this information in a correctly labelled and addressed envelope/package OR formal electronic submission in PDF or JPEG format.	

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 3.7 - Have you included the following items for each product and for each manufacturing site?	
1. A covering letter.	☐
2. A countersigned copy of the letter of invitation received from WHO.	☐
3. The correct Dossier Examination Fee, in US dollars.	☐
4. All the supporting information which is listed in Section 7 of performance specification WHO/PQS/E001/CR-FR01.3	☐
5. A completed Product Summary Sheet Questionnaire and all relevant attachments (see Annex 5.3 and associated notes)	☐
Provide this information in a correctly labelled and addressed envelope/package OR formal electronic submission in PDF or JPEG format. In all cases we must have the original certified hard copies of your license renewal and quality system certification.	

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 3.13.2 - 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.	☐
2. The annual re-evaluation fee in US dollars.	☐
3. Certified photocopies of time-expiring documentation that you have renewed since you made your last submission. If none, confirm this.	☐
4. Details of changes to the company name or status (for example, if you have been taken over by another company). If none, confirm this.	☐
5. Details of changes to the manufacturing site since you made your last submission. If none, confirm this.	☐
6. Details of changes to the manufacturing process since you made your last submission. If none, confirm this.	☐
7. Details of changes to the system components since you made your last submission. If none, confirm this.	☐
8. Details of all significant component and/or installation failures reported to you during the past year. If none, confirm this.	☐
9. Progress report on the resolution of any problems reported to you by the PQS Secretariat. If none, confirm this.	☐
10. A list of other matters that you wish to draw to our attention. If none, confirm this.	☐
Provide this information in a correctly labelled and addressed envelope/package OR formal electronic submission in PDF or JPEG format. In all cases we must have the original certified hard copies of your license renewal and quality system certification.	

Reminders:

- You must submit one dossier for each pre-qualified product. If the product is manufactured at more than one manufacturing site, you must submit one dossier for each site.
- You must provide us with a complete dossier, including 'zero reporting' as noted above.

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. Self-certification of documents is not acceptable.
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 tests 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:

   - 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 compliance with the agreed specifications of the product or to reveal failure(s) regarding safety, performance or quality of the device;

- If the investigation of a complaint considered leads to the conclusion that the quality and/or safety of the product is in question.

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.

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.

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.

11. The following disclaimer applies to all products that are accepted for inclusion on the PQS database.

Disclaimer: 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.

Annex 5.3 – Product Summary Sheet Questionnaire

		Information item	PRODUCT SUMMARY SHEET (Complete one questionnaire per product and per manufacturing site)				
1	☐	**Relevant PQS category**	☒ E001 ☐ E03 ☐ E04 ☐ E05 ☐ E06 ☐ E07 ☐ E08 ☐ E10 ☐ E11				
2	☐	**Relevant PQS specification**	WHO/PQS/E001/CR-FR01.3				
3	☐	**Product description**					
4	☐	Unique ID for product type				**Remarks**	
5	☐	Vendor status	☐ Legal manufacturer ☐ Reseller ☐ Other (specify)				
			Name	**Address**	**Phone and Fax**	**Contact person for quality assurance**	**Web-site, e-mail**
6	☐	Vendor					
7	☐	Manufacturer					
8	☐	Manufacturing Site					
9	☐	Parent company (if any)					
10	☐	Type approvals for system components	**Regulatory authority (list all applicable)**	**Number/reference**		**Product name as submitted to authorities**	
			❑ European Union	CE mark number:			
			❑				
			❑				
			❑				
			❑				
			❑				
11	☐	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**
			❑ ISO 9000 2001				
			❑ ISO 14001				
			❑ EMAS				
			❑				
12	☐	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**	
			❑				
			❑				
			❑				
			❑				
			❑				
			❑				
			❑				
13	☐	PIS/other evaluation reports	❑				
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

Not applicable to this category.

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' *Change Notifications*:** <brief description>	
5.	**Manufacturers' *Product Defect Reports*:** <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: ☐ Suspend product: ☐ Remove product: ☐	
	Date of suspension notification: <dd.mm.yyyy>	

6.0 References

6.1 PQS performance specifications and verification protocols

E001: Cold rooms and freezer rooms

WHO/PQS/E001/CR-FR01.3: *WHO Performance Specification for cold rooms and freezer rooms*
WHO/PQS/E001/CR-FR01-VP1.3: *WHO Type-examination protocol for cold rooms and freezer rooms.*
WHO/PQS/E001/CR-FR01-VP2.3: *WHO Quality Assurance protocol for cold rooms and freezer rooms.*

E06: Temperature monitoring equipment

WHO/PQS/E006/AL01.1: *WHO Performance Specification for acoustic and/or visual alarm units.*
WHO/PQS/E006/TH02.2: *WHO Performance Specification for fixed gas or vapour pressure dial thermometer.*
WHO/PQS/E006/TR03.1: *WHO Performance Specification for programmable electronic temperature and event logger systems with integral alarm and auto-dialer options.*
WHO/PQS/E006/TR03-VP2.1: *WHO Quality Assurance protocol for programmable electronic temperature and event logger systems with integral alarm and auto-dialer options.*
WHO/PQS/E006/TR04.1: *WHO Performance Specification for wall-mounted pen recording thermometers.*
WHO/PQS/E006/TR05.1: *WHO Performance Specification for user-programmable temperature data loggers.*

6.2 Other references

WHO. *From PIS to PQS: A new system for specifying, testing and pre-qualifying products for use in immunization programmes.*
http://www.who.int/entity/immunization_standards/vaccine_quality/pis_to_pqs_final.pdf
WHO/V&B/00.13. *WHO/UNICEF Product Information Sheets - 12th Edition 2000.*

REVISION HISTORY FORM		
Guideline number:		Original: WHO/PQS/E01/GUIDE.1 Present: WHO/PQS/E001/GUIDE.1.3
Date of original version: 8th August 2007		
REVISIONS		
Date	Reason	Authorized by (Signature and Name)
22 Dec 2008	Extension of fee to end 2009	DM
22 Oct 2013	Fee increase and doc references update	DM