

 <b>World Health Organization</b>	<b>REGULATION AND PREQUALIFICATION DEPARTMENT</b>	
	<b>VACCINES ASSESSMENT TEAM</b>	
<b>TEMPLATE</b>		
<b>EMAIL TO REQUEST UP-TO-DATE INFORMATION FROM A PQS ACCREDITED LABORATORY</b>		
Doc No: IMD/TP/08a	Version No: 2	Revise before: 30 Sept 2027
Effective date: 30 Sept 2024	Replaces: Annex 1	Page 1 of 2
Approved by:	TL-VAX, date: 16 Sep 2024	UH-PQT, date: 17 Sep 2024
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## Email to request up-to-date information from an IMD-PQS accredited laboratory

To be sent via email in February. Check for replies in March with some follow-up if necessary. Formal review in April.

Dear <Contact name from web page>,

WHO PQS is conducting its annual review of accredited laboratories. In order to ensure the retention of your current accreditation, it is very important that you provide us with the following information, within two weeks of receipt of this letter.

The WHO PQS is conducting its annual review of accredited laboratories. To retain your accreditation, it is very important that you respond to the following requests.

In the first instance, please *immediately acknowledge* receipt of this questionnaire by email. Then return the information as requested below in English within two weeks please. Failure to comply with these requests may affect your WHO PQS accreditation.

- Please forward a copy of your IEC 17025 certification. If the original copy is not in English, also include a notarised copy in English. State whether the certifying authority is ILAC registered. Please state the **web site** where this certification can be verified. If the expiry date is within 6 months, laboratory to state date for their next IEC 17025 audit.
- Copies of all other certification (e.g. ISO 9001) in English.
- An up-to-date copy of your quality manual, listing all the changes that have occurred in the last year.
- A list of complaints and corresponding following actions in the past year (CAPA).
- Up-to-date copies of SOPs<sup>1</sup> or TWIs<sup>2</sup> or similar documents in regard to the

<sup>1</sup> SOP: Standard Operating Procedure

<sup>2</sup> TWI: Test Work Instruction



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IMD-PQS verification / testing highlighting the changes. These may relate to setting up of environmental chambers and logging equipment etc.

- Up-to-date copies of the CVs of key personnel, stating their role and responsibilities in regard to IMD-PQS testing / verification or other responsibilities within the organization. This includes the Quality Manager and senior staff who have line manager responsibilities for test engineers and sign test reports.
- A list of IMD-PQS published testing carried out with dates and the name of the product manufacturer / supplier carried out in the past year. (See IMD/TP/08c.)
- An up-to-date “Test laboratory data sheet” .pdf for publication on the PQS web page confirming the PQS categories for test / verification and contact details etc.
- List the IMD-PQS categories / sub-categories you are currently testing and/or wishing to amend.
- Any feedback you would forward to IMD-PQS. e.g. suggestions for improvements or complaints.

Please see IMD/TP/08b for a checklist to help forward all information.

Yours sincerely,

<Name>

For and on behalf of WHO IMD-PQS.