**Important note**

No information will be shared with any third party but it may be necessary to discuss some aspects with the WHO IMD-PQS Secretariat.

Please advise the auditor if there is anything of particular sensitivity which should not be shared with another person.

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| **Record type of product** | |
| **Record PQS E00 category** | |

**Add a column to record the laboratory's response.**

| | | Notes | ISO 17025 reference |
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| **1,0** | **General questions about the laboratory** | | |
| 1,1 | Please give some general background to the lab: e.g. How old is the lab? What is its purpose generally? How did the lab originate? | | NA |
| 1,2 | How many people are employed in relevant section(s) of the laboratory? (Sections relevant to the testing of E00X and E00Y products.) | Please list names of test staff including line manager within the section applicable to the testing. Do not include administration staff unless it is helpful to understand your procedural processes. | NA |
| 1,3 | Who are the senior personnel in charge of testing and quality? | Please forward their CVs for the lab manager, quality manager and engineers who will oversee the testing. | NA |
| 1,4 | Does the lab have current accreditation or certification in accordance with ISO or with a national accreditation body? Please state | E.g. to ISO 17025. All current accreditations and certifications and whether | NA |

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| | accreditation authority and lab reference number if applicable. | affiliated to an international body like ILAC. | |
| 1,5 | Briefly describe your quality management system (QMS). Is this in accordance with ISO 9001:2015 or other internationally recognized quality standard? | Please forward at least the contents pages of the Quality Manual.. | Clause 8 |
| 1,6 | What is the procedure for “control of documents” (in the QMS)? | E.g. “uncontrolled” copies. | Clause 8.3.2.f |
| 1,7 | Please state previous audit visits (type of authority and dates). | | NA |
| 1,8 | Describe the frequency and type of *internal* audits? | Please forward an example of an internal audit. | Clause 8.8 |
| 1,9 | Does the lab audit its suppliers or other companies or other organizations? | e.g. suppliers of instrumentation or lab consumables important to testing. | Clause 6.6.1 |
| 1,10 | Does the lab participate in any "Ring Testing" or Round Robin Testing where the same test sample(s) is circulated to a number of different labs to compare test results? If so, please state when and how often this might occur. | | Clause 7.2.2.1 e; 7.6; 7.7; 7.7.1 j; & 7.7.2 b |

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| **2,0** | **Test experience** | | |
| 2,1 | Please list the current standards or protocols similar to the testing of fridges or cold boxes if applicable. | I.e. have you carried out any testing similar to fridge or cold box testing - state which standard. | Clause 7.2.1.5 |
| 2,2 | Do members of the team actively participate in any national or international standard or similar organizations e.g. IEC committees. | Please state which committees or trade associations. | NA |
| 2,3 | Please describe the training and experience of staff who will perform the tests. Please show **training records** during the audit visit. | Only staff concerned with the above tests please. All staff should have a training record | Clauses 6.2.2 & 6.2.5 |

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| | | even if they are only temporary. | |

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| **3,0** | **Test procedure** | | |
| | Note: there are many test protocols in E003 and E004 so please respond in general terms here. | | |
| 3,1 | Describe the sample handling procedure (in accordance with your QMS). | Samples or goods-in, samples or goods-out and tracking in-between. Damaged test samples. | Clause 7.4 |
| 3,2 | Please list or describe environmental test chambers. Ambient temp range, ambient humidity range etc. | | Clause 7.2.1.1 |
| 3,3 | Briefly describe your procedure to follow a test protocol, planning, checking progress, anticipating report date etc. (References to SOPs or TWIs may be made.) | Some labs have “Test Work Instructions” or “SOP” with notes how to set up and carry out testing but these, or a "manual", are not actual requirements. Please forward SOPs or similar. | Clauses 7.8.2.1. f & n; A.2.1 d |

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| **4,0** | **Measuring instruments and accuracy** | | |
| 4,1 | How are all the relevant parameters measured and logged e.g. temperatures, humidity, power (if applicable) energy and time? | Briefly outline the logging system | Clause 6.4 |
| 4,2 | Describe the type of temperature sensors are used to measure temperatures with specified accuracies. Which type of end or "slug" do the temperature sensors have? | E.g. thermocouples Type T. This is the thermal mass on the end of the TC, e.g. Brass cylinder according to IEC 62552 Clause 8.7.1. | Clause 6.4.5 |
| 4,3 | For calibration purposes, how are temperature and other sensors individually identifiable? | They should have a unique ID reference. | Clause 7.4.2 |
| 4,4 | What is the accuracy of logged temperatures? | Ideally the accuracy of the whole system from the end of | Clause 6.4.5 |

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| | | the temp sensor to the display on a screen or the reading on a print-out should be known. | |
| 4,5 | What is the accuracy of logged humidity? | | Clause 6.4.5 |
| 4,6 | What is the accuracy of power (if applicable) and energy measurements? | | Clause 6.4.5 |
| 4,7 | Are instruments calibrated internally or externally? | Can I see calibration certificates on the day please? | Clause 6.4.6; 6.4.7 & 6.4.8 |
| 4,8 | How does the lab quarantine out of calibration instruments? | | Clause 6.4.9 |
| 4.9 | Please show the lab treatment for uncertainty calculations. | 2-3 examples in a separate document perhaps. | Clauses 7.5.1 & 7.6 |

| **5,0** | **Reporting** | | |
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| 5,1 | Can the lab provide a recent exemplar test report (from a similar type of testing)? | The client and the product can be deleted if you wish. It is the ***style*** of the report I wish to examine. Please forward in advance. | Clause 7.8.2 |
| 5,2 | How is regular feedback provided to the client? | E.g. weekly emails updating on progress? | Clause 7.1.8 |
| 5,3 | What is the lab procedure for control of tested samples? | What happens to test samples at the end of testing? | Clause 7.4.1 |
| 5,4 | What is the follow up with the client? | Do you phone to record client satisfaction? | Clause 8.6.2 & 8.9.2 |

| **6,0** | **Corrective actions** | | |
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| 6,1 | Describe the the lab procedure for "complaints" with corrective action and preventative action. | Examples (without reference to particular clients) would be useful. | Clause 7.9 |