Standard format for a quality assurance protocol

WHO/XXX
PQS Quality assurance protocol

Original: English
Distribution: General

TITLE: <Description>

Product verification protocol:	<PQS category>/<unique reference>
Applies to specification ref(s):	<PQS category>/<unique reference>
Issue date:	<Date>
Date of last revision:	<Date>

- **Contents:** <list the content down to level 1.1.1>

1. Scope: <briefly describe the purpose of the quality assurance protocol>

2. Normative references: < list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocols>

3. Terms and definitions: <define any specific terms used in the protocol, particularly terms which may not be widely understood>

4. Applicability: <state who will carry out the quality assurance assessment and (where relevant) state who will carry out on-site inspection of the manufacturer's production facilities and site work>

5. Specification checklist

5.1 Specification requirements: <list the performance specification requirements against which manufacturers' own specifications are to be checked>

5.2 Criteria for qualification: <state the minimum requirements for prequalification>

6. Quality control checklist

6.1 Quality control standards: < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>

6.2 Manufacturing quality control checklist: <list the production quality control features that are to be checked. State whether on-site inspection of the production facility is required>

6.3 Site work quality control checklist: <list the site work quality control features that are to be checked. State whether on-site inspection of an assembly site(s) is required. Including ergonomic, health and safety and 'universal design' features>

6.4 Criteria for qualification: <state the minimum requirements for prequalification, including provision of evidence of 'approved installer' status>

7. Customer reference checklist

7.1 Number of references: <specify the minimum number of customer references that are required>

7.2 Reference questionnaire: <draw up the questionnaire to be circulated to selected customers>

7.3 Questionnaire evaluation: <state how questionnaire results are to be evaluated>

8. Prequalification evaluation: <state the overall minimum criteria for prequalification taking account of results from Clauses 5.2, 6.4 and 7.3 and including any weighting system that may be needed >

9. Modified products: <describe the procedure for re-checking manufacturers that are already prequalified, but who have subsequently modified their product. This procedure may not involve full re-verification.>

Annexes: < as required>

Revision history

Date	Change summary	Reason for change	Approved
dd mm yy	< change item> < etc.>	< reason for change> < etc.>	<name>