

## Outline of the Content of an Annual Report on Activities of a Prequalified Quality Control Laboratory (QCL)

According to the "Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies" (published as Annex 12 to WHO Technical Report Series No. 961, 2011), each prequalified Quality Control Laboratory should, after its prequalification, be re-evaluated on a routine basis at regular intervals (annually) or earlier, when information requiring re-evaluation is obtained by WHO. To enable the WHO Prequalification team to perform the re-evaluation, all laboratories listed in the WHO List of Prequalified Quality Control Laboratories are requested to submit a brief annual report on their activities.

A report should cover activities related to quality control of medicines within a calendar year and should be submitted by the end of March of the subsequent year. The following items should be included in the report:

- Summary of services provided to UN agencies, other public health organizations procuring medicines and other customers.
- Summary of number of samples analysed, differentiating between compliant and non-compliant samples.
- List of analytical methods used.
- Summary of complaints concerning results of analysis performed by the laboratory received from customers.
- Brief details of any proficiency testing schemes (organizing party, methods involved, outcomes and, if appropriate, adopted corrective measures).
- Listing of inspections and audits performed by external parties, identifying the party and scope of the inspection or audit.
- In the case that changes have been implemented, which have an impact on the content of the laboratory information file (LIF) (such as changes to facility, equipment or key personnel), a summary of these changes should be included in the report and an updated LIF should be attached.