



LOT 2: Male and female condom prequalification – technical documentation assessment and on-site inspection services

In 2001 WHO established the prequalification programme for condoms and delegated the daily management of the scheme to UNFPA in 2006. WHO still maintains the lead in setting the norms and standards in the procedures and development of the guidelines for prequalification. UNFPA conducts the prequalification programme for male and female condoms on behalf of other UN agencies and the prequalified factories are open to bid for tenders for UN agencies, national governments and NGO procurement that supply the public sector.

The prequalification procedure is designed to assess the quality, safety, and manufacturing data of the product and the manufacturer to ascertain whether the manufacturer meets the latest requirements defined in the *WHO/UNFPA Male Latex Condom: Specification, Prequalification and Guidelines for Procurement* guideline document or the *WHO/UNFPA Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012** and in compliance with the relevant international standards (*ISO 4074 Natural Latex Rubber Condoms: Requirements and test methods* or *ISO 25841 Female Condoms: Requirements and test methods*). Note that the Male Latex Condom and Female Condom Generic Technical Specifications are currently undergoing revisions and the WHO/UNFPA Prequalification Programme Guidance for RH Commodities is undergoing development.

The prequalification process involves the following key stages for which the expertise of the consultants is required: review of submitted technical documentation for prequalification and factory inspection including product sampling.

a. Background

Two key steps in the prequalification process are the technical assessment of documentation submitted by applicants and the on-site inspection that is conducted for applicants that have successfully passed the document review stage. The aim of the assessment of the documentation submitted for prequalification is to determine whether the applicant meets the minimum requirements set out in the relevant ISO standards and WHO/UNFPA Specification in respect of product quality and safety, production and quality management, regulatory approval and capacity of production.

b. Document review for prequalification (product dossiers, site master files, regulatory approvals, certifications and licenses)

Male and female condom manufacturers willing to be prequalified by UNFPA submit the following documentation:

- Product Dossier and Site Master File¹
- Regulatory approvals/authorizations, manufacturing licenses
- Product certifications and quality management systems certifications

The document review should verify that the manufacturer meets all the requirements as detailed on pages 65 – 72 of the [WHO/UNFPA Male Latex Condom Specification](#) and/or pages 73-82 of the [WHO/UNFPA Female Condom Generic Specification](#), and/or the latest version of the specification

¹ Note that the prequalification programme is moving towards adopting the Summary of Technical Documentation (STED) developed by the Global Harmonization Task Force. The new format essentially combines the information from the Product Dossier and Site Master File, in line with conventional medical device technical files.

c. Expected services and deliverables for document review

- Review applicant documentation provided electronically by UNFPA. The consultant shall critically assess to documentation in order to verify compliance with the requirements detailed on pages 65-72 of [Male Latex Condom: Specification, Prequalification, and Guidelines for Procurement, 2010](#). The review shall be completed within two weeks of receipt unless otherwise agreed with UNFPA. This review includes:
 - Review of all the basic information about the manufacturer regarding their regulatory and legal standing as a manufacturer in the country they operate in.
 - Review and verification of all the certifications, licenses, approvals submitted.
 - Detailed assessment and review of all the technical data/documents on product safety, manufacturing process, risk management (Product Dossier and Site Master File) including the production capacities.
- Preparation of a document review report that can be presented to the prequalification applicant and includes a clear summary of recommendations from the review outlining next steps for factory inspection if requirements have been met and any follow ups/verifications that should be done during inspection. The document review report shall be prepared in accordance with the document review templates for male and female condoms.

To see the templates to be used, refer to *Template for MLC* and *Template for FC* attached under the tender notice. They are provided for reference purposes. UNFPA reserves the right to modify the templates during the course of the LTA.

There may be multiple rounds of document reviews.

- Conduct document reviews of manufacturer and/or product reports as requested.

Submissions that are found to meet the minimum requirements after document review proceed to factory inspection.

d. Factory inspection including sampling of male and female condoms for independent quality control testing (Lead Inspector and Co-Inspector capacities)

The scope of the prequalification factory inspection goes beyond the ISO 13485 audit and covers more rigorous inspection that places heavy emphasis on both documentation and product manufacturing processes. In addition sampling is performed during the inspection on 3 random Lots which will be dispatched to an independent ISO 17025 accredited laboratory for quality control testing.

The factory inspection is conducted typically over a period of 2 days by a technical team consisting of the Lead-inspector, Co-inspector, UNFPA staff member, and may include representative from a local or international regulatory authority as well as an interpreter/translator if applicable.

The Lead Inspector and Co-Inspector will take the lead in the technical inspection of the factory to cover all manufacturing processes, quality management procedures, technical files, quality control facilities, processes and procedures. The UNFPA staff member will accompany the inspectors as part of the inspection team to assess other elements of the factory in line with UN mandate e.g human rights and environmental issues.

e. Expected services and deliverables for factory inspection and product sampling

- Develop an inspection programme for submission to UNFPA two weeks in advance of any scheduled inspection.
- Conduct on-site factory inspection in capacity of either Lead Inspector or Co-Inspector covering the following in line with the requirements detailed in [Male Latex Condom: Specification, Prequalification, and Guidelines for Procurement, 2010](#) and supporting guidelines which includes:
 - General overview of the factory, infrastructure, human resources, quality management systems and production capacity
 - Raw materials source and handling, management and maintenance of equipment and technology for all the manufacturing processes.
 - Product quality records, quality control laboratory, internal quality control and final release processes, management and handling of rejections.
 - Batch traceability, process control, validations, sampling and inspection plans
 - Product release and management of customers and supply chain processes.
 - Sampling of condoms from 3 random Lots according to sampling procedures in ISO 2859.
- Provide a full inspection report in English for on-site inspections that includes an analysis of the test results from the Lots sampled during the inspection, summary of the overall outcome in relation to prequalification progress, a clear recommendation of next steps for the manufacturer and conclusions for UNFPA's review.
- Inspection reports are expected to be produced for UNFPA within four weeks of the inspection subject to receipt of product testing results, unless there is a delay with the testing and new time period for the report to be completed is agreed upon between UNFPA and the inspector.
- The inspection reports shall be prepared in accordance with the templates *Template MLC inspection report* and *Template FC inspection report*, attached as separate files under the tender notice. The lead inspector is expected to sign the report. UNFPA reserves the right to make changes to reporting templates.
- During the inspection, there may be non-conformities raised that require submission of evidence of corrective and preventive actions by the prequalification applicant. The Inspection Team shall be responsible for the evaluation of any corrective and preventive actions submitted for review.
- The **Lead Inspector** is required to:
 - During the inspection, outline the inspection plan for the manufacturer and areas to be covered during the opening and lead summary comments during the closing meeting.
 - Coordinate with the Co-Inspector any work performed remotely
 - Submit final assessment reports to the Prequalification Team within the timeline specified. In the event of disputes, provide the resolution.
- The **Co-Inspector** is required to:
 - Work hand in hand with lead inspector and focus on areas as outlined by the lead inspector.

f. Required qualifications and experience

- For both Lead Inspectors and Co-inspectors, qualifications or training is required in a relevant field such as: Chemistry, Biomedical Technology, Biochemistry, Epidemiology, Biostatistics, Engineering, Pharmaceutical, Clinical Research, Biotechnology, Microbiology, Public Health.
 - Additional points will be given for ISO certification for performing ISO 13485 audits or Good Manufacturing Practice inspections with documented evidence of knowledge in male or female condoms as required for factory inspections.
 - Additional points will also be given for experience in conducting inspections for a national regulatory authority or in conducting ISO 13485 audits for condoms.
 - Additional points will be given for qualifications for ISO 14001 auditing.
 - Additional points will be given for experience with conducting WHO/UNFPA prequalification reviews.
 - Previous similar experience working for UNFPA or International agency or public sector agency
 - For Lead Inspectors only, additional points will be given for Lead Auditor certification for medical devices to support Lead Inspector role.
- For both Lead Inspector and Co-inspector, at least three completed projects each of similar nature and scope in various countries.
- For proposed Lead Inspector(s), at least 10 years of experience in one or more of the following: quality management systems for condom manufacturing, condom manufacturing production processes or inspections, clinical trial and review of clinical safety and efficacy data of condoms, and quality control of condoms
- For proposed Co-inspector(s), at least 7 years of experience in one or more of the following: quality management systems for condom manufacturing, condom manufacturing production processes or inspections, clinical trial and review of clinical safety and efficacy data of condoms, and quality control of condoms.
- For both Lead Inspector and Co-inspector, fluency in English as demonstrated through previous formal training, qualifications, or work experience.
- For both Lead Inspectors and Co-inspectors, ability and willingness to travel, and willingness to comply with the travel arrangements as detailed in the respective section of the Terms of Reference document. Vast majority of inspections are in China, Malaysia, India and Thailand. A list of factory sites currently prequalified is published on www.unfpaprocurement.org.
- For both Lead Inspectors and Co-inspectors, willingness to comply with UNFPA's prequalification confidentiality and conflict of interest rules.
 - Manufacturer's information
 - UNFPA's prequalification confidentiality and conflict of interest rules as detailed on page 15 of [WHO/UNFPA TCu380A Intrauterine Contraceptive Device \(IUD\): Specification, Prequalification, and Guidelines 2016](#).
- Willingness to work under a staff augmentation modality as described in the respective section of the Terms of Reference document.

END OF TERMS OF REFERENCE FOR LOT 2: MALE AND FEMALE CONDOM PREQUALIFICATION