



Guidance for Remote Inspection of Male Latex Condom Manufacturers in the WHO/UNFPA Prequalification Programme

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Introduction

Inspection of the manufacturing facility by qualified inspectors is an important step in the process of becoming a UNFPA prequalified supplier. Remote inspections may be considered as an alternative to traditional onsite visits when international travel is restricted or difficult or the “social distancing” restrictions of COVID-19 limit the number of staff onsite. Remote inspections may also be useful when reviewing and closing out Corrective and Preventive Actions (CAPAs). They may not be advisable when a new facility is being assessed for prequalification for the first time.

The following procedure may be used to conduct a remote inspection of male condom manufacturing facilities as part of the WHO/UNFPA prequalification programme. Remote inspections often utilize video conferencing via desktop or laptop computers and follow after the document review phase of prequalification.

Following an acceptable remote inspection, provisional requalification of a manufacturer may be acceptable for a period agreed by UNFPA. Confirmation of the provisional inspection will be dependent on a full inspection when this is possible.

1. Equipment requirements

Internet access: Remote assessment is only possible if the manufacturer has adequate equipment and internet connectivity to participate in video conferencing. All meeting participants including the manufacturer and the inspection team involved in the video conferences must ensure they have adequate internet bandwidth to participate in the meetings.

Video conferencing software: All meetings will be arranged by UNFPA using the UNFPA Zoom account. Manufacturers and inspectors do not need active Zoom subscriptions to participate. Zoom Meetings offers a number of very useful facilities to assist video conferencing including the option to use “breakout rooms” so that subgroups can be formed. This permits the inspectors to conduct parallel sessions on different aspects of the inspection.

Manufacturers may require time to acquire or hire additional equipment and extend internet facilities in order to be able to participate in a remote inspection. Also, manufacturers may require time to assemble the additional information identified during the document review phase of prequalification. An allowance will be made for this work when scheduling the remote inspection. Manufacturers should ensure that all equipment and Wi-Fi/internet facilities are functioning properly before committing to a date for the inspection.

1.1 Latest version of Zoom

For security reasons all participants must ensure that the Zoom software being used is the latest version. A check for updates can be made by opening Zoom and clicking on the “Profile” icon on the extreme right-hand side of the menu bar at the top of the Zoom Window. Select “Check for updates” from the dropdown menu that appears. Zoom will then automatically check for updates and download any that are pending. The version of Zoom currently loaded on a device can be checked by opening Zoom and selecting the “Home” page from the menu. Then click on the “Settings” icon in the upper right-hand side of the Zoom Window (located just below the “Profile” icon) followed by selecting “Statistics” from the list on the left-hand menu that appears. The

version number will then be given in the statistics table (at the time of writing the latest version is 5.2.1).

1.2 Hardware

Meeting room set up: A meeting room with large monitors and good quality webcams is recommended for an online video conference. If a manufacturer lacks such hardware, laptops may be used. Share several laptops among small groups; this is preferred to gathering all of the participants in the meeting around a single laptop. Manufacturers may use local external video conferencing facilities if this is feasible. If external facilities are used, take steps to ensure confidentiality for the information and discussions.

Live video set up: Manufacturers should have access to suitable cameras to permit live video of the manufacturing process, testing processes and the manufacturing and storage areas to be shown. These facilities should permit the inspectors to see specific areas of the factory by request. To support the live video, manufacturers may be requested to submit further plans and diagrams of the facilities in addition to those included in the document submission and, ideally, enhance them with photographs and/or annotated 3D layouts describing the facilities, equipment, processes and resources related to each area. Such plans and diagrams are invaluable and will aid in planning and in conducting the remote inspection.

Handheld video cameras or good quality smart phones should be adequate for this purpose subject to suitable Wi-Fi access. To permit live viewing, Wi-Fi should ideally be available throughout the factory; if not, temporary arrangements should be made to provide Wi-Fi using range extenders and/or boosters, for example. Alternatively, mobile network connections may be used to relay video from factory areas. At a minimum, a 3G connection should be available. Manufacturers must assess the quality of factory-wide Wi-Fi and mobile networks in advance and confirm with UNFPA that adequate video quality can be achieved throughout the factory.

In addition, documents will need to be viewed during discussions. Mount at least two cameras on stands to permit the immediate viewing of documents. If cameras are not available, good quality smartphones and/or tablets may be adequate. The equipment should permit full pages of the documents to be viewed. Software can be downloaded from Canon to permit some Canon cameras to be used as high-quality webcams.

Labels: Carefully record the date, time and location for all video and picture records. Additional annotation of topic/subject and related information will be beneficial and could be essential. Zoom meetings can be recorded to the cloud, with searchable transcripts. Click “Add a timestamp to the meeting” in order to have a digital readout of the year, month, date and time of the meeting as it is recorded. Ideally, the date-stamped video is immediately shared to the cloud, with controlled access.

Data charges: It should be noted that connections via mobile networks from smartphones, tablets and laptops might incur high data roaming cost if an international connection to the Zoom server is required. If mobile networks are used, check the location of the server to ensure international roaming charges are not incurred.

2. Interpreters

If required, interpretation will be organized by UNFPA. Depending on circumstances interpreters may be located within the facility under inspection or, if this is not possible, remotely. Prior to

meeting(s), both the inspection team and the manufacturer should provide the interpreters with copies of any documents that require translation. Unless written translations are specifically requested translations may be presented orally in real time by the interpreters.

3. Meeting control and procedures

The video conference will be hosted and controlled by UNFPA to ensure an effective meeting that accomplishes the stated purpose. Zoom breakout rooms may be used to permit the inspectors to conduct parallel sessions on different aspects of the inspection. Steps must be taken to prevent excessive interruptions and background noise.

- Participants wishing to speak should raise their hands if using video. The “Reactions” icon can be used to show consent or flag a wish to speak.
- “Chat” can be used during the videoconference to request permission to speak and/or make comments.
- Participants should “mute” their microphones when not speaking in order to prevent background noise, which can disrupt discussion. This applies particularly in factory areas where there might be substantial levels of background noise.
- Be prepared to turn off video. If bandwidth is restricted, it might be necessary for participants to restrict video use in order to maintain acceptable audio-only communication. In such cases, video should only be turned on when absolutely necessary.

Recording: By mutual agreement part or all of the video conference may be recorded but consideration must be given to the storage capacity required on the host server to hold a complete record of a long meeting. Permission from staff should be sought in advance for use of recorded and live video in factory and laboratory areas. If necessary, face masks may be worn by staff who do not wish to be identified. Manufacturers should discuss with UNFPA in advance any equipment, processes or factory areas considered proprietary, for both recording and/or viewing live. Manufacturers should note that preventing the inspectors from seeing key parts of the operation may result in a failure of the site to be prequalified.

The meeting(s): A number of relatively short meetings may be required to complete an assessment. This is likely given constraints due to different time zones, internet capacity and equipment operation. The length and number of meetings will depend on the issues raised during the document review phase of prequalification. Meetings should be planned with a clear agenda, list of documents required, audit criteria and audit aim; however, they must also address matters raised during the meeting. This may require changes to the meeting agenda and some degree of departure from the plans.

Presentations: In accordance with normal practice, manufacturers will be expected to give an opening presentation that includes a brief history of the manufacturer and manufacturing site, an introduction to key personnel, an overview of the products manufactured and their distribution, and brief descriptions of the manufacturing processes. Other presentations from manufacturers may be required during the remote assessment. The purpose and content of any additional presentations will be discussed and agreed as the inspection proceeds. Presentations prepared in advance by manufacturers to be used during a remote assessment should be sent to UNFPA for distribution to the members of the inspection team to permit prior review and allow clarification of any questions arising to be resolved before the inspection begins.

The number of video sessions required and the duration of each session will depend on the number and types of issues raised during the document review and the progress of the inspection.

Additional time slots should be kept available during the period of the remote inspection. The duration scheduling of these slots should be agreed by discussion between the manufacturer and the inspection team.

Duration of remote inspection: The normal duration of an inspection is three days but it is recognized that remote inspections may take longer than this. A remote inspection should be completed within one working week but in some cases it may be necessary to extend the overall duration into a second week.

Suggested outline: The following outline is suggested for scheduling a remote inspection:

- The opening meeting should include the introduction of key personnel, presentations by UNFPA and the manufacturer, and a virtual factory tour. The virtual factory tour may be pre-recorded for convenience. If a pre-recorded video is used, the inspection team will identify any specific areas of the factory and any equipment and processes that they wish to inspect using live video.
- Plan a series of interface meetings between the manufacturer and the UNFPA inspection team to discuss specific aspects of the inspection, including live videos of manufacturing areas, storage areas, manufacturing procedures, in processes testing, laboratory testing and document review.
- Include offline time for the inspection team to review documentation and data.
- Organize discussion meetings between the members of the inspection team.
- Conclude with a closing meeting at which the inspection team will present their report and the manufacturer will have an opportunity to discuss the findings.

Verification of satisfactory resolution of nonconformities and agreed CAPAs may require subsequent remote video conferencing sessions, due to the lack of in-person site access by the inspection team.

The manufacturer shall identify one contact person per inspector who will coordinate with that inspector in making any requested information available, responding initially to questions and inviting other factory personnel to join discussions when appropriate.

4. Risk assessment

The decision to conduct a remote inspection will be based on a risk assessment conducted by UNFPA and the assessors during the document assessment phase of the prequalification process. Prior to recommending a remote inspection, UNFPA may request additional information from the manufacturer, from independent third-party laboratories that have completed pre-shipment and/or in-country testing on behalf of national and international procurement agencies, and from national and international procurement agencies that have purchased products from the manufacturer.

More information on how to conduct the risk assessment is provided in Annex 1, which describes the procedures. A checklist for conducting the risk assessment is provided in Annex 2.

5. Sampling

During a traditional onsite inspection, the UNFPA inspection team determines which samples should be taken for testing and usually oversees the sampling process. For a remote inspection, manufacturers will be requested to submit in advance the details of lots in stock so that UNFPA

can specify which lots are to be sampled. UNFPA will then arrange for samples from the specified lots to be taken by a local sampling agency, preferably as the inspection is in progress or as soon as is practical after the inspection has been completed. Sampling may be supervised during a remote inspection if one of the inspectors is able to be present onsite to oversee the procedure. The UNFPA standard operating procedure (SOP) on how to draw prequalification product samples for independent testing will be used.

If a suitable local sampling agency is not available or, because of applicable local access restrictions, a local agency is unable to take the samples, UNFPA may consider one of two actions: monitoring the sampling of the requested lots under video observation, or permitting the manufacturer to send samples from the specified lots to the testing laboratory without supervision. In such cases, UNFPA may require further samples to be selected and submitted for testing when a subsequent inspection is possible or a sampling agency can access the site safely and legally.

If a manufacturer's prequalification status is under investigation or has been suspended (e.g. due to excessive numbers of lot rejects), sampling must be carried out by an independent sampling agency nominated by UNFPA or, if possible, under the supervision of at least one of the inspectors.

6. Requalification process

See **Annex 1** for details of the procedure.

All standard procedures for requalification will apply except for the inspection of facilities.

Annex 1: Procedure for prequalification inspection by video conferencing

1 OBJECTIVE

- 1.1 This SOP provides guidance on conducting a remote assessment of male condom manufacturing facilities as part of the WHO/UNFPA prequalification programme.

2 SCOPE

- 2.1 This SOP covers the management of prequalification application document reviews and video conferencing required to carry out a remote assessment.

3 DEFINITIONS (optional if applicable)

- 3.1 Requalification: Prequalification reassessment done every three years
- 3.2 SOP: Standard Operating Procedure

- 3.3 CAPA: Corrective and Preventive Action

4 CROSS-REFERENCES (optional if applicable)

- 4.1 Annex 10, WHO TRS 1025, WHO/UNFPA Male Latex Condom Technical Specification
- 4.2 SOP PQT/CD/01 WHO/UNFPA Prequalification Technical File Assessment

5 RESPONSIBILITIES

- 5.1 UNFPA prequalification programme staff
- 5.2 Inspectors

6 PROCEDURE

- 6.1 The requests for expression of interest, submission of documentation and document review shall be done according to current WHO/UNFPA prequalification guidelines.
- 6.2 In addition to the review of the previous inspection report and associated CAPA responses and reports, there should be review of any other information considered relevant to the assessment including information on quality trends supplied by the manufacturer, any failures reported in post-shipment or in-country testing undertaken on behalf of national and international procurement bodies, and any other relevant information about the manufacturer's performance that may be available.
- 6.3 The assessors shall submit a document review report to UNFPA highlighting any additional information that the manufacturer should submit. If the outcome of the document review is satisfactory and remote inspection is considered possible, additional information should be requested, including the following:
 - 6.4 Any additional information required as identified during the document review. Additional information is likely to include:
 - 6.4.1 Changes to organization systems, resources, people and processes and product changes and all related issues, risks, client and regulatory requirements since the last prequalification not already reported to UNFPA.

- 6.4.2 Photographs of the manufacturing and testing areas to augment the layout plans included in the original documentation.
- 6.4.3 Evidence of closure of any outstanding CAPAs identified during the previous prequalification inspection.
- 6.4.4 Quality control (QC) data in spreadsheet format should be submitted, preferably with control charts for the last six months of production along with associated in-process and final product testing and process verification and the validated process control and testing protocols. The data submitted should be for products manufactured to the WHO/UNFPA specification, if possible. The data shall include results for freedom from holes tests, visible defects and visibly open package seals, burst properties, condom dimensions, lubricant quantity and package integrity. Burst data shall include sample sizes tested, means values, standard deviations and the numbers of nonconforming condoms per test. In addition, summary QC data for the previous three years since the last prequalification inspection should be submitted. This should include monthly average nonconformity rates for freedom from holes, burst testing and package integrity. In addition, monthly average values for burst volume and pressure along with standard deviations should be submitted. The results should cover 53 mm (or 52 mm if 53 mm condoms are not manufactured) and 49 mm (if manufactured) parallel-sided condoms.
- 6.4.5 Pre-shipment and in-country test reports from third party testing laboratories undertaking testing for national and international procurement agencies, where available for the last six months. Reports from any inter-laboratory trials in which the manufacturer has participated within the last three years, including the manufacturer's identification code.
- 6.4.6 An index of the quality management system (QMS) documentation including SOPs, working instructions and reporting/record forms.
- 6.4.7 Complaints records including reports and actions taken since the previous inspection.
- 6.4.8 Details of any product recalls since the last inspection.
- 6.4.9 Summary details of any entries in the change control and CAPA registers since the last inspection.
- 6.4.10 Reports and minutes from the last two Management Review Meetings.
- 6.4.11 Reports from the last two internal audits.
- 6.4.12 Details of any changes made to raw materials, factory or process layout, production/testing processes and equipment since the last inspection.
- 6.4.13 Details of any changes in senior staff since the last inspection.
- 6.4.14 Details of any changes made to the QMS as a result of requirements in Quality and Product Standards and implementation of revised versions of applicable standards.

7.0 DECISION

Following receipt and review of this additional information UNFPA shall determine if a remote assessment is acceptable. When making this decision the following shall be taken into account:

- 7.1 Overall quality record of the manufacturer.
- 7.2 Status of the organization and products in light of newly and already notified changes.
- 7.3 Complaints record and full details of any product recalls.
- 7.4 Past CAPAs and the response to those CAPAs.
- 7.5 The quality of the QC data submitted including the pre-shipment test reports.

- 7.6 Assessment of the validated process capabilities and product compliance in light of statistical process control data and the related in-process and final verification and related post processing and dispatch and supply chain data;
- 7.7 Lack of significant lot rejections or reports quality issues based on pre-shipment and in-country testing conducted on shipped products.
- 7.8 Any changes made to raw materials, layout, sites of manufacture and storage including external warehouses, processes and equipment since the last inspection.
- 7.9 Any major changes in the senior management of the factory and/or management structure.
- 7.10 Internal audit reports.
- 7.11 Minutes and reports from the Management Review Meetings.
- 7.12 The manufacturer's technical capacity to participate in a remote inspection. This will depend on the quality of the video equipment available and the quality of the local internet and mobile phone networks. The minimum requirements are a high-speed internet connection suitable for stable video connection or access to a 3G network.

8 **If a remote assessment is not considered feasible the manufacturer shall be notified.** Prequalification will then be dependent on a physical inspection of the manufacturing site.

9 **Careful and detailed preparation for a remote assessment is essential.** The inspection team shall meet using video conferencing to plan the inspection and agree a timetable. It is anticipated that a minimum of three video conferencing meetings will be required to conduct a remote inspection. The target will be to complete the inspection over a period of one week with planned and necessary extension agreed as required. Specific tasks will be assigned to each member of the inspection team. The use of breakout rooms in Zoom will permit the team members to follow up on issues independently of each other.

10 DOCUMENTS

The inspection team shall agree on the documents required for review in advance for each video conference meeting. These will include documents to address specific issues identified during the inspection. Such documents may include, among others, specific documents or those chosen at random from the following:

- 10.1 Selected SOPS, working instructions and completed record forms.
- 10.2 Selected staff recruitment and training records.
- 10.3 Selected calibration certificates.
- 10.4 Selected equipment and process validation reports.
- 10.5 Selected certificates of analysis.
- 10.6 Selected quality control records.
- 10.7 Selected maintenance records.
- 10.8 Selected validation reports and qualification reports for manufacturing and testing equipment.
- 10.9 Selected design and development reports.
- 10.10 Procedures and records of personnel health and hygiene for selected employees.
- 10.11 Facility management reports including rodent and pest control measures.
- 10.12 Selected vendor qualification and audit reports.

- 10.13 Additional product stability study reports including accelerated and real time study reports over and above those submitted with the Product Dossier or Summary Technical Documentation (STeD).
- 10.14 Reports on control of bioburden, protein level and nitrosamines in addition to those submitted with the Product Dossier or STeD.
- 10.15 Selected records of control of non-conformance and disposal of nonconforming products. Manufacturers should submit any requested documentation for review during the meeting as quickly as possible. Electronic copies that can be shared during the discussions should be available. Preferably, all electronic copies should be the original, or PDFs that can yield text and not be restricted to the image only.

11 MEETINGS

The opening meeting should include introductions of the UNFPA inspection team and members of the manufacturer's team with names, titles and roles. Representatives of senior management should attend the initial opening meeting. Manufacturers shall provide a brief presentation about the company and highlight any significant changes made since the last inspection.

A record of all personnel attending the opening and closing meetings shall be maintained and sent to UNFPA on completion of the inspection. The manufacturer is to use its own internal format of the attendance sheet.

A virtual tour of the factory should then be conducted, led by appropriate managers and staff. Ideally, this should be a live tour using video cameras and/or smart phones to demonstrate key factory areas and processes. It should be related explicitly to plant and facility layouts, 2D and 3D plans and related pictures and video already supplied. Pre-recorded videos may be used with prior permission from UNFPA if a live video tour cannot be organized due to logistical reasons (e.g. lack of Wi-Fi in some or all of the factory areas). A live video should be arranged for specific areas, however, when requested by the inspectors. The tour and associated plans and other facility details are crucial to planning the inspection and may affect agreed meeting schedules.

- 12 Follow-up meetings should be agreed based on progress and the need for the manufacturer to find information requested, which may require documents to be scanned. During follow-up meetings, live video demonstrations may be requested, for example of test procedures and the operation of some of the equipment. Test and equipment validation/verification tests witnessed by live or, with UNFPA prior permission, pre-recorded video may be requested. Interim video conferences will be held between the inspection team members to review progress and determine the agenda for follow-up meetings. Detailed review of documents and data requested during the inspection by the inspectors should be conducted offline as far as possible to improve the efficiency of the inspection.

Careful recording of date, time and location for all video and picture records is essential and additional annotation of topic/subject and related information is recommended. Ideally, the date-stamped video is immediately shared to the cloud, with controlled access

- 13 When the inspection team is satisfied that the review has been completed, a closing meeting will be held. Senior management from the company is expected to attend the closing meeting. A brief report on the review will be submitted to the manufacturer prior to the closing meeting. The report will include a list of any nonconformities identified during the review. These will be classified as major or minor using the definitions currently defined in the WHO/UNFPA guidelines on inspections. Observations will also be included in the report. Subject to feedback and mutual agreement, the summary report may be modified before closing the meeting.
- 14 Once the video conferences have been completed, the standard WHO/UNFPA prequalification procedures will be used to communicate the final decision to the manufacturer.

Annex 2: Checklist for remote inspection risk assessment

Use the following checklist to score the suitability of the manufacturer for a remote inspection of male latex condom manufacturers. This is based on the document review and any further documents/information submitted. A minimum score of 120 is considered acceptable to justify the risk of undertaking a remote inspection for WHO/UNFPA prequalification.

	Requirement	Score
1	Is the manufacturer's overall status with respect to change control, risk management, process and product compliance to client and regulatory requirements acceptable (yes = 20, no = 0)	
2	Is the manufacturing site already prequalified (yes = 20, no = 0)	
3	Assessment of submitted documentation (poor = 0, excellent = 10)	
4	Are the manufacturer's information technology (IT) facilities judged to be acceptable for a remote inspection (poor = 0, excellent = 10)	
5	Assessment of the quality record of the manufacture (poor = 0, excellent = 10)	
6	Assessment of the manufacturer's complaints record (poor = 0, excellent = 10)	
7	Have all past CAPAs been resolved (yes = 10, no = 0)	
8	Assessment of the quality of submitted QC data (poor = 0, excellent = 10)	
9	Assessment of independent pre-shipment test reports (poor = 0, excellent = 10)	
10	Have there been any in-country lot rejections (yes = 0, no = 10)	
11	Have there been any major changes in processes or equipment since last inspection (yes = 0, no = 10)	
12	Have there been any major changes in senior management since last inspection (yes = 0, no = 10)	
13	Assessment of the internal audit reports (poor = 0, excellent = 10)	
14	Assessment of minutes and reports of the Management Review Meetings (poor = 0, excellent = 10)	
	Total score	
	Maximum score	160