WHO/UNITED NATIONS POPULATION FUND (UNFPA)
PREQUALIFICATION PROGRAMME GUIDANCE FOR
CONTRACEPTIVE DEVICES: MALE LATEX CONDOMS,
FEMALE CONDOMS AND INTRA-UTERINE DEVICES

(July 2019)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) by 20 September 2019.

Working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the “Current projects” link. If you wish to receive our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

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Please send any request for permission to:

Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms, Department of Essential Medicines and Health Products, World Health Organization, CH-1211 Geneva 27, Switzerland, email: kopps@who.int.

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SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.789:

WHO/UNITED NATIONS POPULATION FUND (UNFPA) PREQUALIFICATION PROGRAMME GUIDANCE FOR CONTRACEPTIVE DEVICES: MALE LATEX CONDOMS, FEMALE CONDOMS AND INTRA-UTERINE DEVICES

<table>
<thead>
<tr>
<th>Description of Activity</th>
<th>Date</th>
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<tr>
<td>UNFPA identified the need to update the existing <em>Procedure for Assessing the Acceptability, in Principle, of Male Latex Condoms for Purchase by United Nations Agencies</em>, adopted by the Forty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meeting and published as Annex 2 in the WHO Technical Reports Series, No. 948, 2008. The text had been developed by the UNFPA and WHO specialists.</td>
<td>May – September 2018</td>
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<tr>
<td>Informal discussions amongst UNFPA and WHO specialists on the management of this updating process.</td>
<td>18 October 2018</td>
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<tr>
<td>Presentation of a possible updating process of the prequalification guidance for contraceptive devices and condoms at the Fifty-third ECSPP.</td>
<td>November 2018 – May 2019</td>
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<tr>
<td>Following the recommendation of the Fifty-third ECSPP meeting, various phases of reworking and restructuring of the specific texts by UNFPA.</td>
<td>Mid July 2019</td>
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<tr>
<td>Mailing of working document for public consultation, including to the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations</td>
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(EAP) and UNFPA specialists, inviting comments and posting of the working document on the WHO website.

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<th>Activity</th>
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<tr>
<td>Compilation of comments received by WHO.</td>
<td>September 2019</td>
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<tr>
<td>Review of comments received by a group of specialists.</td>
<td>October 2019</td>
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<tr>
<td>Preparation of discussion document.</td>
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<tr>
<td>Presentation to the Fifty-fourth ECSPP in Geneva, Switzerland.</td>
<td>14-18 October 2019</td>
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<td>Further follow-up action as required.</td>
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WHO/UNITED NATIONS POPULATION FUND (UNFPA) PREQUALIFICATION
PROGRAMME GUIDANCE FOR CONTRACEPTIVE DEVICES: MALE LATEX
CONDOMS, FEMALE CONDOMS AND INTRA-UTERINE DEVICES

BACKGROUND

Extract from the Fifty-third World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meeting report:

“Ms Seloi Mogatle and Dr William Potter from the United Nations Population Fund (UNFPA) gave an update on the prequalification guidance for contraceptive devices and condoms at the Fifty-third Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) that took place at the World Health Organization (WHO) headquarters in Geneva, Switzerland, October 2018. The UNFPA had contacted WHO to inquire how best to start a process to update the process of the following texts that were adopted by the ECSPP and published in 2008. The Expert Committee agreed to the importance of updating these materials in view of the changes in the contraceptive field globally over the previous decade. The two organizations committed to work together to bring the documents up-to-date. It was suggested by UNFPA to separate out the current existing procedure for condoms to include the following aspects:


5. Condom Quality Assurance and Annexes.


7. Condom Storage and Transportation.


UNFPA also raised the issue of specifications for lubricants (both water-based and silicon-bases) which needs to be considered when developing the new guidelines.

The Expert Committee supported the development of the relevant documents in consultation with the WHO Secretariat, the preparation of these for public consultation and took note that they will be reported back to the Expert Committee.”

The following documents are undergoing a public consultation as part of this series:


6. QAS/19.806 - WHO/UNFPA Specifications for Plain Lubricants.

WHO/UNITED NATIONS POPULATION FUND (UNFPA) PREQUALIFICATION

PROGRAMME GUIDANCE FOR CONTRACEPTIVE DEVICES: MALE LATEX CONDOMS, FEMALE CONDOMS AND INTRA-UTERINE DEVICES

1. Introduction

2. The prequalification programme for reproductive health devices
   2.1 Eligibility to participate
   2.2 Application for prequalification: Expression of Interest
      2.2.1 Calls for and submission of Expressions of Interest
      2.2.2 Assessment of documents submitted
         2.2.2.1 Initial screening of documentation
         2.2.2.2 Assessment of the Summary Technical Documentation
         2.2.2.3 Technical experts hired by UNFPA
   2.3 Site inspection
      2.3.1 Inspection team
      2.3.2 Scope and scheduling
      2.3.3 Transparency
   2.4 Product testing
   2.5 Reporting and decision to prequalify
   2.6 Listing of prequalified contraceptive devices and manufacturing sites
   2.7 Maintenance of prequalification status
   2.8 Periodic monitoring of the quality of products produced by prequalified manufacturing sites
   2.9 Reassessment of prequalified manufacturing sites – requalification
   2.10 Language
   2.11 Fees
   2.12 Resolution of disputes

3. Confidentiality undertaking

4. Conflict of interest

Annex I: Prequalification of contraceptive devices Letter of Application

Annex II: International standards
1. INTRODUCTION

The United Nations, through its procurement agencies, supplies medicines and other health products to countries throughout the world in order to improve access to a choice of products of acceptable quality, safety and efficacy.

WHO, UNFPA and other key partners developed an evidence-based list of Reproductive Health Essential Medicines (2005) which was subsequently approved by the WHO Expert Committee on Selection and Use of Essential Medicines. From this list, and the recommendations of members of the Reproductive Health Supplies Coalition, it was agreed that WHO would include a core group of contraceptive essential medicines in the Prequalification Programme, the implementation of which began in 2006. As part of this activity, it was agreed that UNFPA would take responsibility for the prequalification of copper-bearing intrauterine devices (IUDs) and male latex condoms, and that the UNFPA scheme would be harmonized with that of the WHO Prequalification Programme.

This document describes the implementation of the WHO UNFPA Prequalification Programme for contraceptive devices (male latex condoms, female condoms and intra-uterine devices).

The Prequalification Programme was approved in principle and subject to confirmation following an external review for publication by the Forty-second ECSPP in October 2007\(^1\).

The Prequalification Programme is supported by a specific UNFPA management system with detailed standard operating procedures (SOPs).

The WHO/UNFPA Prequalification Programme involves the following key activities:

- the evaluation of documents submitted in response to an invitation for Expression of Interest (EOI);
- the inspection of each manufacturing site per product;
- product testing;

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• the review of testing and inspection reports to make a decision about the acceptability of each product and its specific manufacturing site; and
• the periodic reassessment of the prequalification status of products and manufacturing sites.

1.1 Objectives

The overall objective is to implement a scheme to prequalify manufacturers of contraceptive devices of assured quality, at specific manufacturing sites, for procurement by United Nations agencies and other bulk procurement agencies. Specific objectives are to:

• promote the procurement of contraceptive devices from manufacturing sites that have been ascertained to have the capacity to produce good-quality products;
• establish a system that promotes the procurement of good-quality products that retain their effectiveness throughout their stated shelf-life and conform to the latest edition of the international standard\(^2\) for the product;
• broaden the base of suppliers for contraceptive devices that are deemed acceptable, in principle, for procurement by United Nations agencies and other bulk procurement agencies; and
• maintain and publish the list of prequalified suppliers.

2. THE PREQUALIFICATION PROGRAMME FOR REPRODUCTIVE HEALTH DEVICES

2.1 Eligibility to participate

The Prequalification Programme is intended for manufacturers who carry out all key manufacturing steps as specified by UNFPA in the call for an EOI referred to in clause 2.2, below.

\(^2\) Refer to Annex II: for full list of relevant standards
For male latex condoms, this entails manufacturers who undertake the processes of formulation, compounding and dipping, lubrication, testing, as well as for manufacturers using pre-vulcanized latex.

For female condoms, this entails manufacturers who undertake the processes of formulation, compounding and dipping, lubrication, testing, and who undertake at least the formation of the sheath, testing and packing.

For intra-uterine devices, this entails manufacturers that undertake the process of moulding, assembly, packaging and control of sterilization. One or more of these processes may be carried out on a contract basis but the manufacturer retains overall responsibility for product quality.

The Prequalification Programme does not apply to agents, distributors or suppliers engaged only in testing, lubricating and primary packaging.

2.2 Application for Prequalification: Expression of Interest

2.2.1 Calls for and submission of Expressions of Interest

Invitations to interested parties to submit EOI are published at regular intervals on the web sites of UNFPA (http://www.unfpa.org/public/procurement).

The invitation is open and transparent and invites manufacturers and/or their agents, as described in clause 2.1 above, to submit EOIs for the products listed in the invitation. The manufacturers should submit their EOIs to the UNFPA focal point with the relevant information requested in the invitation. Manufacturers that are applying for a requalification/assessment should submit the EOI the year before the re-inspection is to take place (see clause 2.9, Reassessment). If a manufacturer has more than one site, each site must submit a separate application. The manufacturers will be given a specified period to submit their responses from the time of publication of the
advertisement. The information must be submitted in English (see clause 2.10, Language).

UNFPA will receive and record the EOI from each manufacturer and issue an acknowledgement of receipt.

WHO and UNFPA will provide further guidance on the submission of documentation for prequalification and make such guidance available on the UNFPA and WHO web sites.

When submitting an EOI, the manufacturer should send to the UNFPA focal point the following:

- a covering letter expressing interest in participating in the WHO/UNFPA Prequalification Programme and confirming that the information submitted in the Summary Technical Documentation (STED) is complete and correct; refer to Annex I for a sample cover letter.
- a STED as specified in the WHO/UNFPA technical specification for male latex condom, female condoms or intra-uterine devices for submitting product data and information; and
- ten product samples in its primary package, as examples of products produced; for each type mentioned in the STED (if applicable).

The STED must be accompanied by copies of all current certifications/accreditations; all manufacturing licences/registrations held; a copy of the company registration; copies of certificates and relevant documentation as applicable in the country of manufacture; documentation of the principal place of incorporation (for those that are corporations); specific certification/licences required in the country for manufacturing and exporting; and other legal documents, such as trading certificates.

The documentation must be submitted in English, as described in Section 2.11 below. Documents not in English must be submitted with certified translations. The
manufacturer must provide an electronic version (CD or USB key to be sent by courier or registered mail or email) of this material.

### 2.2.2 Assessment of documents submitted

The aim of the assessment of the submitted documentation is to determine whether the manufacturer is certified to ISO 13485 and other appropriate ISO standards, and has appropriate regulatory approvals, manufacturing capacity, factory documentation and legal status, and in principle is capable of meeting the WHO/UNFPA Specification with respect to product quality and safety to warrant inspection by UNFPA.

#### 2.2.2.1 Initial screening of documentation

UNFPA will aim to screen the documentation within 30 days of the closing date for receipt of responses to ascertain whether or not it contains all the required information.

If the submission is incomplete, the manufacturer will be informed and requested to complete the STED within a specified time period. If the dossier remains incomplete, it may be rejected.

STEDs that are considered complete following the administrative screening will be retained by UNFPA for evaluation.

UNFPA will exchange letters with the manufacturer covering provisions of confidentiality and the process of assessment of submitted information and the scheduling and procedure of the site inspection.

#### 2.2.2.2 Assessment of the Summary Technical Documentation
UNFPA will appoint suitably qualified and experienced experts to complete the assessment of the STED within 90 days of the closing date for receipt of responses.

The assessment of the submitted documentation will be done in accordance with SOPs established by UNFPA for that purpose. To ensure uniformity in evaluation and timeliness of assessment activities, UNFPA will, if needed, provide training to the assessors on the procedures that are specific to UNFPA.

In making its assessment, UNFPA may take into account information submitted by the manufacturer during previous applications that may be in UNFPA’s possession, including results from previous site inspections and laboratory test results on the relevant products produced by the manufacturer.

UNFPA aims to advise the manufacturers of the outcome of the assessment of the documentation within 30 days after its completion. If applications are found to be in compliance with the requirements of UNFPA, as detailed in the operational guidance for the product, and on the WHO and UNFPA web sites, the manufacturing site will be scheduled for inspection.

2.2.2.3 Technical experts hired by UNFPA

Profile

Document assessments and inspections are carried out by technical experts appointed by UNFPA. The technical experts are selected through an international competitive bidding process to select individuals that have documented qualifications, detailed knowledge of the process for manufacturing contraceptive devices, experience in auditing and quality management systems, and specific experience inspecting manufacturing sites of contraceptive devices.
The document assessment and inspection may include one or more experts. The assessor may be responsible for subsequent inspections of the manufacturing site, depending on the contraceptive device. The experts must comply with the confidentiality and conflict of interest rules of UNFPA as laid down in clauses 3 and 4 of this guidance document.

2.3 Site inspection

UNFPA will plan and coordinate inspections at the manufacturing sites to assess:

- the manufacturing facilities
- the manufacturing process
- the quality management systems
- product quality

for compliance with the requirements of the WHO/UNFPA Specification and good management practice, including the international standards relevant to the product as in Annex II.

2.3.1 Inspection team

The inspection will be performed by a team of inspectors consisting of experts appointed by UNFPA, who will conduct the assessment on behalf of UNFPA. The inspectors must have documented qualifications, detailed knowledge of manufacturing processes, expertise in auditing and quality management systems, and specific experience in inspecting condom and IUD manufacturing sites. The inspectors must comply with the confidentiality and conflict of interest rules of UNFPA, as detailed in clauses 3 and 4 of this guidance document. To ensure uniformity in inspection procedures, UNFPA has prepared an SOP and, if necessary, can provide training to these experts.
Where possible, UNFPA will appoint at least one inspector able to communicate in and read the local language. Failing this, an interpreter selected by UNFPA will be used. One member of the team will be designated by UNFPA as the “lead inspector” and will be responsible for directing the on-site inspection activities and the production of the report. The team may include observers from UNFPA. UNFPA will advise and seek the involvement of the national competent body in the on-site inspection.

UNFPA will advise the manufacturer in advance of the composition of the team performing the site inspection and the identity of each inspector. The manufacturer has the opportunity to express possible concerns regarding any of the inspectors to UNFPA prior to the visit. If such concerns cannot be resolved in consultation with UNFPA, the manufacturer may object to a team member’s participation in the site visit. Such an objection must be made known to UNFPA by the manufacturer within 10 days of receipt of information on the composition of the proposed team. UNFPA will consider the objection and, if it is upheld, a replacement inspector will be appointed.

So as to ensure a standardized approach, each team will perform the inspections and report on its findings to UNFPA in accordance with the SOPs established by UNFPA for that purpose.

Information submitted in response to the invitation for EOI and the assessment report will be made available to the inspectors. All inspectors must comply with the confidentiality and conflict of interest rules of UNFPA as detailed in clauses 3 and 4.

2.3.2 Scope and scheduling

Prior to the inspection, the manufacturer will be informed of the scope of the inspectors’ planned activities. The key components of the inspection are described in the operational guidance of the relevant technical specification of the product and on the WHO and UNFPA web sites. The inspection may not be limited to these components. Manufacturers must be prepared to show the inspectors all aspects of the facility, including records and data that relate to the production of the condoms.
UNFPA aims to advise the manufacturer of the date of inspection at least 30 days in advance. UNFPA and the inspectors will make efforts to accommodate reasonable requests by the manufacturers and national regulatory authorities to change the date of inspection.

UNFPA will inform the manufacturer that the inspectors may request copies of specific documents for review during inspection and may request permission to take photographs during the inspection, subject always to considerations of confidential information as referred to in clause 3 of this document.

2.3.3 Transparency

The inspection team is paid by UNFPA to inspect the facilities and the members are reimbursed for their hotel and transport expenses by UNFPA. The manufacturer will not pay for hotel accommodation or make any payments for or to the inspectors and/or UNFPA staff. The manufacturer may be requested to assist in making reservations at an appropriate hotel and arrangements for local transportation between the hotel and manufacturing facilities.

The inspectors (and UNFPA staff who accompany the inspectors) cannot accept any gifts from the companies they visit. UNFPA requires that manufacturers do not make any offers of gifts of whatever value to the inspectors and/or UNFPA staff.

By participating in the Prequalification Programme, the manufacturer agrees to allow full access to:

- any of the facilities that are in any way involved in the production, packaging and storage of the product(s) concerned; and
- all documentation related to that production.

If such access is not provided, the inspection will not be completed, and the manufacturing site and specific products cannot be prequalified.
Any evidence of fraud or serious omissions by the manufacturer in the initial
assessment procedure or the inspection will lead to termination of the site inspection.

2.4 Product testing

Products will be sampled for independent testing according to the sampling requirements for
prequalification testing specified in the Technical Specification: WHO/UNFPA Male Latex
Condom Specification or the WHO/UNFPA Female Condom Generic Specific Specification
or the Tcu380A Technical Specification.

Products will be sampled for independent testing prior or subsequent to the inspection under
the supervision of, or by, an independent sampler appointed by UNFPA or by the inspectors at
an appropriate point during the site inspection. As a component of their prequalification
application, manufacturers shall submit a copy of their production plan for the coming year to
enable UNFPA to communicate the number of samples from each production Lot the
manufacturers should retain for prequalification testing and/or to schedule the inspection
during a time when ample Lots will be available for sampling. Sampling and testing will be
conducted in accordance with the requirements detailed in the WHO/UNFPA TCu380A IUD
Technical Specification. All product testing will be undertaken by independent test
laboratories selected by UNFPA, of defined and documented competence and experience, as
demonstrated by accreditation to the current ISO 17025 standard with testing of IUDs within
the scope of its accreditation. The sample will be packed and sealed by the inspector or the
independent sampler as appropriate. The inspectors may take the sample with them or arrange
for the manufacturer to have the sealed box sent to the selected laboratory by courier at
UNFPA’s expense.

The manufacturer will be provided with a copy of this test report.
2.5 Reporting and decision to prequalify

At the conclusion of the inspection, the inspectors will prepare a brief written summary report outlining the key findings and observations discussed with the manufacturer during the site inspection. This report will be provided to UNFPA with a copy to the manufacturer.

Manufacturers should not submit corrective actions to UNFPA in response to this summary report but only in response to the official inspection report that is issued. The official inspection report prepared by the inspection team will be issued by UNFPA to the manufacturer four to six weeks following the inspection.

The report will indicate one of the following recommendations:

- requalify the product manufactured at a specific site without conditions. This will only be the case when there is no evidence that corrective action is required.
- Require the manufacturer, where deemed necessary, to undertake specified corrective and preventive action(s) (CAPA).
- Determine that product and manufacturing site is ineligible for prequalification (without any requirement for corrective action being offered). This will not, however, preclude the manufacturer from resubmitting an application in response to future invitations for EOIs.

If any additional information is required, or corrective action has to be taken by the manufacturer(s), UNFPA will postpone its decision on the acceptability of the site(s) involved until such information has been evaluated or the corrective action has been taken and found satisfactory in accordance with the time frame and recommendations made by the inspectors.

The inspection report may contain non-conformities and observations. The findings of the inspection may include non-mandatory observations aimed at highlighting potential for improved manufacturing and quality management practices. Non-conformities are classified as major or minor. A manufacturer that receives a major non-conformity cannot be prequalified and, if already prequalified, status may be suspended. A major non-conformity will require
submission of corrective and preventative actions and a possible re-inspection. Minor non-conformities require corrective and preventative action to be submitted to UNFPA by the manufacturer in the stated period in order to achieve or maintain prequalification. Observations made by the inspectors are intended to highlight opportunities to improve quality management practices. It is strongly recommended that manufacturers consider acting upon any observations made, but prequalification is not dependent upon this.

Where the UNFPA recommends corrective action, the manufacturer must advise UNFPA within an agreed period of time that corrective action has been completed and provide the relevant evidence, if required. The recommendation for corrective action may include further independent product testing or re-inspection. After review of the evidence, UNFPA will decide whether or not to schedule a further inspection.

Corrective and preventive action (CAPAs) submissions should be submitted to UNFPA electronically in response to the official inspection report. Evidence of action shall be provided. Evidence of actions taken should be supplied to UNFPA in the form of SOPs, pictures or other appropriate formats. The files submitted shall be organized and clearly labelled. Each manufacturer will normally be permitted two rounds of CAPA reviews. The first submission of corrective and preventive actions shall be in possession of UNFPA within 90 days of receipt of the official inspection report unless otherwise agreed with UNFPA. If a manufacturer has not successfully addressed all non-conformities raised during the inspection following the second CAPA review, the manufacturer may be asked to submit a fresh EOI for prequalification. The EOI should only be submitted when the manufacturer demonstrates compliance with the Prequalification Programme requirements. Any exceptions to this will be evaluated on a case-by-case basis.

If a further inspection is deemed necessary, the inspection process and assessment will be implemented in accordance with the procedure detailed in clauses 2.3, 2.4, 2.5 and 2.6 of this document. Any re-inspection may be at the expense of the manufacturer.

If evidence supporting mandatory improvement actions or additional information is required, or other corrective actions have to be taken by the manufacturer, UNFPA will postpone its final
decision until such information has been evaluated or the corrective action has been taken and found satisfactory.

If the manufacturer has not submitted a satisfactory response within 12 months of submission of the report from UNFPA, the application will lapse and the manufacturer will need to reapply in response to a future invitation for an EOI.

Each manufacturer will receive a letter from UNFPA informing it of the outcome of the quality assessment process. UNFPA aims to inform the manufacturer formally of the results of the process within 30 days of receipt of all final reports.

UNFPA reserves the right to terminate the procedure of quality assessment of a specific product if the manufacturer is:

- not able to provide the required information; and/or
- unable to implement the corrective actions in a specified time period; and/or
- if the information supplied is inadequate to complete the quality assessment process.

Each manufacturer will receive a letter from UNFPA informing the manufacturer of the outcome of the quality assessment process. UNFPA aims to inform the manufacturer of the results of the process within 30 days of receipt of all final reports. Manufacturers will verify the final report that is produced for accuracy. In the event of any disagreement between a manufacturer and UNFPA, an SOP established by UNFPA detailing the handling of appeals and complaints will be followed to discuss and resolve the issue. The ownership of any of the reports produced during the course of, or as the result of the assessment of documentation, product testing and inspection of the manufacturing site, lies with UNFPA. Thus, UNFPA shall be entitled to use and publish such reports and/or a summary of a report, subject always, however, to the protection of any commercially confidential information of the manufacturer(s).
Confidential information may include:

• confidential intellectual property, “know-how” and trade secrets (including, e.g. formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks and/or patents); and
• commercial confidences (e.g. structures and development plans of a company).

Provisions of confidentiality will be contained in the exchange of letters, to be concluded before the assessment of the STED or inspection of the manufacturing site(s), between UNFPA and each manufacturer.

Notwithstanding the foregoing, UNFPA and WHO may share a summary and/or the full evaluation and inspection reports with the relevant authorities of any interested Member State of UNFPA and/or WHO. Confidential information submitted by the manufacturer that is marked “confidential” will not be included in the full evaluation and inspection reports without the permission of the manufacturer.

2.6 Listing of prequalified contraceptive devices and manufacturing sites

Once UNFPA is satisfied that the quality assessment process is complete and where the STED and corresponding manufacturing site have been found to meet the prequalification requirements, the product produced at the specified manufacturing site(s) will be listed on the WHO and UNFPA prequalification web sites.

The list of prequalified contraceptive devices and corresponding manufacturing sites will be compiled and updated in accordance with an SOP established by UNFPA for this purpose.

2.7 Maintenance of prequalification status

Once the product and the corresponding manufacturing sites are included in the list of prequalified manufacturers, the manufacturer is required to advise UNFPA, within four weeks,
of any matter that affects the information on which the approval was based. This includes but is not limited to:

- change of premises;
- change in production and testing equipment;
- change in senior management;
- product recalls;
- change in certifications or licences held by the manufacturer;
- reports of adverse events;
- change in device design;
- change in suppliers key raw materials and components not previously listed in the STED;
- change in specification of raw materials, components and primary packaging materials;
- change in packaging;
- change in formulation;
- change in process and/or technology;
- change in production capacity; and
- new information about shelf-life.

It is the manufacturer’s responsibility to provide UNFPA with the appropriate documentation (referring to relevant parts of the STED) to prove that the implementation of any intended variation will not have an adverse impact on the quality of the product that has been prequalified. UNFPA will undertake an evaluation of variations according to established UNFPA guidelines and SOPs and communicate the outcome to manufacturer. Compliance with the requirement to report changes will be checked during the requalification inspection and processes carried out by UNFPA.

2.8 Periodic monitoring of the quality of products produced by prequalified manufacturing sites

At periodic intervals, UNFPA may, through an independent sampler, take random samples of contraceptive devices produced by listed manufacturers. Samples will be taken from intact lots
stored in the manufacturer’s or distributor’s warehouse. The sample size will be in accordance
with the current international standard for the contraceptive devices. The range of tests to be
conducted will be in accordance with lot-by-lot pre-shipment compliance testing as detailed in
the WHO/UNFPA Technical Specification of the product.

All product testing will be undertaken by an independent test laboratory, selected by UNFPA,
of defined and documented accreditation to the current ISO 17025 international standard. In
the event of failure to meet the established requirements for testing, UNFPA will investigate
the problem and communicate this to the manufacturer and/or, if different from the
manufacturer.

UNFPA may request reports from consumer or regulatory authorities or from other
procurement agencies relating to the quality and supply of the prequalified contraceptive
device.

Complaints communicated to UNFPA concerning contraceptive devices procured through this
Prequalification Programme will be investigated in accordance with an SOP established by
UNFPA for that purpose. After investigation, UNFPA will provide a written report of the
complaint investigations, including recommendations for action, to the manufacturer. UNFPA
will require evidence of effective action taken, where relevant.

UNFPA will make the report available to the appropriate authorities of the country where the
manufacturing site is located when necessary in the interest of public health, subject always to
consideration of commercially confidential information, as referred to earlier in this document.
UNFPA reserves the right to make such reports public, if it considers this to be of public health
importance. In addition, UNFPA reserves the right to share the full report and/or
recommendations for action with WHO and relevant authorities of interested Member States
of the WHO. At periodic intervals, UNFPA may request a summary of the statistical analysis
of product production from the manufacturer for demonstration of continued capability to
manufacture to the WHO/UNFPA Technical Specification. This may be accompanied by a
request for selected evidence from management review, risk management, production,
measurement and analysis and other records.
2.9 Reassessment of prequalified manufacturing sites – requalification

UNFPA aims to undertake a reassessment of products manufactured at a specific site at intervals of three years and no more than five years. Such reassessments will consist of a comprehensive evaluation of documentation, site inspection and product testing similar to the initial prequalification assessment, as determined by a risk based assessment. Prequalified manufacturers should submit a EOI (application) for reassessment the year before they are due for a requalification inspection.

Reassessment may also be required in the following situations:

- if the contraceptive devices supplied by the manufacturer are considered by UNFPA or by one or more of the other United Nations agencies not to be in compliance with the agreed WHO/UNFPA Specification and pre-shipment compliance testing requirements;
- if a complaint considered serious in nature has been received by UNFPA or one or more of the other United Nations agencies or organizations; and
- if there is a significant change in the manufacturing process in respect to one or more of the items listed in clause 2.7, above.

All relevant information, including the reassessment of submitted documentation and site inspection reports, together with monitoring information, will be considered by the designated UNFPA official, and a decision will be made to either:

- maintain the contraceptive device and its manufacturing site on the list of prequalified products without need for corrective actions; or
- maintain the prequalification status of the contraceptive device and its manufacturing site with a requirement for corrective actions and, where agreed to by UNFPA, further product testing and/or a site inspection; or
- suspend the prequalified status.
UNFPA aims to advise the manufacturer of the result of the reassessment and make any necessary amendments to the list of prequalified manufacturing sites and products within 30 days of receipt of the data on the basis of which the decision is made. The updated list will be published on the WHO and UNFPA prequalification web sites.

UNFPA will de-list any prequalified product and manufacturing site if the submitted information is subsequently found to be incorrect or fraudulent. UNFPA will issue a notice of listing and delisting and inform appropriate authorities.

2.10 Language

The official language of the programme is English. All documents submitted as part of an application for prequalification will be in English. If the original of any required document is not in English, the manufacturer must submit a copy of the original plus a certified translation into English. All correspondence between UNFPA and the manufacturer should be in English. All reports issued by the assessors, inspectors and UNFPA on the assessment and inspections will be in English.

Inspections will be conducted in English, where necessary with the aid of an interpreter. It is the responsibility of the manufacturer to advise UNFPA and for UNFPA to agree whether or not an interpreter is required for the inspection.

2.11 Fees

At present, UNFPA will cover the expenses of the assessments, inspections and product testing. Manufacturers are responsible for their own costs related to providing the necessary information and help required under the Prequalification Programme. Currently, the prequalification and re-qualification process is conducted by UNFPA free of charge. Subject to future decisions, UNFPA reserves the right, to charge a fee on a cost-reimbursement basis.
2.12 Resolution of disputes

If there is any disagreement between a manufacturer and UNFPA, an SOP established by UNFPA for the handling of appeals and complaints will be followed to discuss and resolve the issue.

3. CONFIDENTIALITY UNDERTAKING

The assessors and inspectors will treat all information to which they gain access during the evaluations and inspections or otherwise, in connection with the discharge of their responsibilities in regard to the above mentioned project, as confidential and proprietary to UNFPA and parties collaborating with UNFPA in accordance with the terms set out below.

Assessors and inspectors will take all reasonable measures to ensure that:

• confidential information is not used for any other purpose than the evaluation/inspection activities described in this document; and
• confidential information is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

Assessors and inspectors will not, however, be bound by any obligations of confidentiality and non-use to the extent they can clearly demonstrate that any part of the confidential information:

• was known to them prior to any disclosure by or on behalf of UNFPA (including disclosure by manufacturers); or
• was in the public domain at the time of disclosure by or on behalf of UNFPA (including by manufacturers); or
• has become part of the public domain through no fault of theirs; or
• has become available to them from a third party not in breach of any legal obligations of confidentiality.
4. CONFLICT OF INTEREST

Before undertaking the work, each assessor and inspector will also (in addition to the above-mentioned confidentiality undertaking) be required to sign a declaration of interest.

If, based on this declaration of interest, it is felt that there is no risk of a real or perceived conflict of interest (or it is felt that there is only an insignificant and/or irrelevant conflict of interest), and it is thus deemed appropriate for the evaluator or inspector in question to undertake this work, he/she will discharge his/her functions exclusively as adviser to UNFPA. In this connection each assessor and inspector is required to confirm that the information disclosed by him/her in the declaration of interest is correct and complete, and that he/she will immediately notify UNFPA of any change in this information.
ANNEX I

Prequalification of Contraceptive Devices Letter of Application

All product dossiers and site master files submitted must be accompanied by a cover letter expressing interest in participating in the UNFPA prequalification process and confirming that the information submitted in the Summary Technical Documentation (STED) summary is complete and correct. Below is an example of such a letter.

Letter of Application

Date ……………………………

To: United Nations Population Fund
    Procurement Services Branch
    Marmorvej 51
    DK 2100 Copenhagen 0
    Denmark

Sir/Madam:

Being duly authorized to represent and act on behalf of [name of manufacturer] (hereinafter referred to as the “Applicant”) and having reviewed and fully understood all the information on prequalification provided, the undersigned hereby applies to be prequalified by UNFPA as potential suppliers of [indicate relevant device].

Attached to this letter are copies of original documents defining:

- the Applicant’s legal status
- the Summary Technical Documentation (STED)
- Sample products (if applicable).
UNFPA and its authorized representatives are hereby authorized to conduct any enquiries or investigations to verify the statements, documents and information submitted in connection with this application and to seek clarification from our bankers and clients regarding any financial and technical aspects. This Letter of Application will also serve as authorization to any individual or authorized representative of any institution referred to in the supporting documentation to provide such information deemed necessary and requested by yourselves to verify statements and information provided in this application or with regard to the resources, experience and competence of the Applicant.

The Applicant declares that all the information provided with the application is valid.

Name of Applicant [Organization] ________________________________________________

Name of Responsible Officer ________________________________________________

Signature ________________________________________________

Position/Title ______________________________________ Date ________________
ANNEX II

International Standards


|-------------------|-----------------------------------------------------------------------|
| Female Condoms | ISO 25841. *Female Condoms—Requirements and Test Methods.*  
| Tcu380A - IUD | ISO 7439 *Copper-Bearing Intrauterine Contraceptive Devices - Requirements, Tests.*  
ISO 14001 *Environmental Management*  
ISO 14971 *Medical Devices - Application of Risk Management to Medical Devices.*  
ISO/IEC 17025 *General Requirements for the Competence of* |
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<thead>
<tr>
<th><strong>Testing and Calibration Laboratories.</strong></th>
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<tbody>
<tr>
<td>ISO 10012 Measurement management systems - requirements for measurement processes and measuring equipment.</td>
</tr>
<tr>
<td>ISO 10993 Biological Evaluation of Medical Devices - relevant sections as specified</td>
</tr>
<tr>
<td>ISO 10993-1. ISO 11135 Medical devices - Validation and Routine Control of Ethylene Oxide Sterilization - relevant sections as specified in ISO 11135-1.</td>
</tr>
<tr>
<td>ISO 11137-3 Guidance on Dosimetric Aspects.</td>
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<tr>
<td>ISO 11607 Packaging for Terminally Sterilized Medical Devices - relevant sections as specified in ISO 11607-1.</td>
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<tr>
<td>ISO 19011 Guidelines for Quality and/or Environmental Management Systems Auditing.</td>
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