World Health Organization

WHO/UNITED NATIONS POPULATION FUND (UNFPA)

CONDOM QUALITY ASSURANCE

(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.

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.807:

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Description of activity	**Date**
UNFPA identified the need to update the existing *Procedure for Assessing the Acceptability, in Principle, of Male Latex Condoms for Purchase by United Nations Agencies*, 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.	
Informal discussions amongst UNFPA and WHO specialists on the management of this updating process.	May – September 2018
Presentation of a possible updating process of the prequalification guidance for contraceptive devices and condoms at the Fifty-third ECSPP.	18 October 2018
Following the recommendation of the Fifty-third ECSPP meeting, various phases of reworking and restructuring of the specific texts by UNFPA.	November 2018 – May 2019
Mailing of working document for public consultation, including to the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) and UNFPA specialists, inviting comments and posting of the working document on the WHO website.	Mid July 2019
Compilation of comments received by WHO.	September 2019

Review of comments received by a group of specialists. Preparation of discussion document.	October 2019
Presentation to the Fifty-fourth ECSPP in Geneva, Switzerland.	14-18 October 2019
Further follow-up action as required.	

43

WHO/UNITED NATIONS POPULATION FUND (UNFPA)
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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:*
>
> 1. *Prequalification Guidance for Contraceptive Devices.*
> 2. *Prequalification Programme for Male Latex Condom and Annexes.*
> 3. *Technical Specification for Male Latex Condom and Annexes.*
> 4. *Male Latex Condom Prequalification Inspection Aide Memoire.*
> 5. *Condom Quality Assurance and Annexes.*
> 6. *Guidance on Testing Male Latex Condoms.*
> 7. *Condom Storage and Transportation.*
> 8. *Post Market Surveillance of Condoms.*

9. Public Assessment Reports for Contraceptive Devices - Condoms and Intrauterine devices (IUDs).

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:

1. QAS/19.789 - WHO/UNFPA Prequalification Programme Guidance for Contraceptive Devices: Male Latex Condoms, Female Condoms and Intra-Uterine Devices..
2. QAS/19.790 - WHO/UNFPA Technical Specification for Male Latex Condoms.
3. QAS/19.803 - WHO/UNFPA Guidance on Conducting Post Market Surveillance of Condoms.
4. QAS(19.804 - WHO/UNFPA Recommendations for Condom Storage and Shipping Temperatures.
5. QAS/19.805 - WHO/UNFPA Guidance on Testing of Male Latex Condoms.
6. QAS/19.806 - WHO/UNFPA Specifications for Plain Lubricants.
7. QAS/19.807 - WHO/UNFPA Condom Quality Assurance.

WHO/UNITED NATIONS POPULATION FUND (UNFPA)

CONDOM QUALITY ASSURANCE

This document describes and details the key elements of condom quality assurance.

1. STANDARDS

Standards are developed and published by national and international standards bodies to establish requirements for a wide range of products and services. Standards may be generic or product-specific. Standards for medical devices, such as male latex condoms, tend to focus on essential requirements for performance, quality and safety.

Many different types of organizations and bodies participate in the development of standards. In the case of standards for medical devices, the organizations include manufacturers, national regulatory authorities, researchers, consumer groups, international agencies and testing laboratories. International standards, e.g. *ISO 4074*, are agreed by consensus based on balloting by national standards organizations (member bodies) that participate in their development.

National regulatory authorities establish local procedures for the regulation and control of medicinal products and medical devices. In many cases, these authorities require that a product complies with the appropriate national or international standards before it can be marketed. Compliance can be voluntary but, in many cases, governments or regulatory authorities have made compliance with an appropriate standard mandatory.

In addition to specifying safety, performance and quality requirements, standards also specify test methods that can be used to verify that products conform to these requirements. These test methods may be included in the standard or specified by reference.

The principal international standards authority is the International Organization for Standardization (ISO), the worldwide federation of national standards bodies. ISO is responsible for drafting international standards based on the best available evidence and practice. ISO Technical Committee 157 (ISO/TC 157)—Non-Systemic Contraceptives and STI Barrier Prophylactics is responsible, inter alia, for developing the international standard for male latex rubber condoms, *ISO 4074 Natural Latex Rubber Condoms—Requirements and Test Methods*. The committee has a membership of 25 countries, with representatives drawn from a wide range of interested parties including manufacturers, test laboratories, regulatory authorities and consumer associations.

There are also many regional and national standards organisations producing standards that are widely used both locally and globally. Examples include ASTM International based in the USA and CEN, CENELEC or ETSI in Europe. It is very common for national and regional standards to be based on to equivalent to ISO standards.

The third edition of *ISO 4074* was published in September 2015. This edition includes a number of very important changes, all of which are designed to make male condoms made from natural rubber latex safer and more effective. The changes include:

- The procedures for determining the shelf lives of condoms have been improved and simplified.
- A wider range of different condom sizes is permitted.
- Maximum lot size limited to 500 000.
- Requirements specified for biocompatibility assessments based on *ISO 10993-1*.
- Recommendations included for the monitoring and control of microbial contamination (bioburden) on finished condoms including methods for determining bioburden on condoms, advisory limits for total viable counts and a list of specific pathogens that should be absent.

- Any claims for improved efficacy or safety have to be substantiated by clinical investigation.
- Extended range of minimum airburst volumes depending on condom size.
- Minor changes to the design of the clamping collar used in the burst test.
- Changes to the electrical test for freedom from holes to improve the detection of holes in the closed end of the condom.
- Inclusion of the "hang and squeeze" test from ASTM D3492 - 16 Standard specification for rubber contraceptives (male condoms) as an alternative method for assessing freedom from holes.
- A limit set for the number of individual containers with visibly open seals.
- Recommended requirements for minimum airburst properties and freedom from holes testing introduced for condoms narrower than 45 mm and/or shorter than 160 mm.
- Amendments made to the methods for determining the shelf life of condoms including a simplified procedure for determining the shelf life by accelerated stability studies based on fixed ageing periods at 50 °C.
- Stability studies to include testing for freedom from holes, airburst properties and package integrity.
- Detailed procedure included for determining the thickness of a condom by the micrometre.
- An alternative method included for removing the lubricant from the condom using an aqueous surfactant solution when determining the amount of lubricant on the condom.
- Revised labelling requirements.

The World Health Organization Department of Reproductive Health and Research (WHO/RHR), UNFPA Procurement Services Branch (PSB) and other partner agencies work with *ISO/TC 157* to broaden the standard to provide for situations in which economic and social circumstances dictate the need for:

- Appropriate length, width and strength of the condom in relation to effectiveness, comfort and size.
- Establishment of requirements for stability data (both real-time and accelerated) to support shelf life claims and stated expiry dates.

- Adequate protection against harsh environmental conditions due to inadequate systems of storage and distribution.
- Appropriate packaging, labelling and information on how to use condoms.
- Appropriate design options to meet users' needs.

The current 2015 edition of *ISO 4074* can be purchased from national standards organizations or from:

International Organization for Standardization (ISO)
ISO Central Secretariat
1 chemin de la Voie-Creuse CP 56
1211 Geneva 20
Switzerland
Telephone: +41 22 749 0111
Fax: +41 22 733 3430
Email: central@iso.org

Copies of the standard can also be downloaded (for a fee) from the ISO website (http://www.iso.org) and the websites of other national standards organizations.

2. SPECIFICATIONS

A specification is a statement of the procurer's requirements and covers all of the product attributes necessary for procurer acceptance. These include the essential general and performance requirements, as well as discretionary design requirements. A specification includes and/or references test methods used to verify the quality of a product and may demand a different level of quality than a published standard requires. WHO/UNFPA and partners have prepared a specification that is internationally accepted for the bulk procurement of male latex condoms.

The *WHO/UNFPA Specification for Male Latex Condoms* is based, where appropriate, upon *ISO 4074* and includes specific requirements for bulk packaging for public-sector distribution.

The *WHO/ UNFPA Specification*, if used in conjunction with the Prequalification Scheme and procurement procedures, will help ensure that a quality product is manufactured, purchased and distributed to the end user.

3. WHO/UNFPA PREQUALIFICATION SCHEME

Prequalification is a procedure designed to assess the capability and capacity of a manufacturer to supply a quality product before a contract is awarded. Prequalification reduces the risk of awarding a contract to a manufacturer that is unable to meet the quality requirements defined in the *WHO/UNFPA Specification*. The purpose of prequalification is to ensure that the male condoms procured are safe, of good quality and efficacious. The prequalification scheme is intended to protect both the procurer and the end user.

WHO/UNFPA have established a Prequalification Scheme for male latex condoms. This scheme was developed in collaboration with the manufacturing community, international agencies, the donor community and experts. The scheme was originally harmonized with the WHO Prequalification Scheme for Essential Medicines. The draft WHO/UNFPA Male Latex Condom Prequalification Scheme was approved for publication, subject to external review by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2007. The WHO/UNFPA Prequalification Scheme was then extensively reviewed electronically by a wide spectrum of public- and private-sector experts and during three workshops, held in Bangkok, Thailand; Beijing, China; and New Delhi, India, between December 2007 and March 2008. WHO published the Prequalification Scheme in May 2008; refer to WHO Technical Report Series, No. 948, Annex 2, page 71. The guidance for the WHO/ UNFPA Prequalification Scheme for male latex condoms is given in Section 2 of this document.

The scheme has now been updated based on many years of experience of operation. The update reflects the changes that have taken place in the general procedures for regulating medical devices globally, feedback from manufacturers and users of the scheme.

UNFPA maintains a list of prequalified products manufactured at a manufacturing site. This list is available on the WHO and UNFPA prequalification websites. It is strongly recommended that only prequalified manufacturers be used for the procurement of condoms for public-sector distribution.

4. REGULATORY AUTHORITIES

Condoms are classified as medical devices and, as such, are regulated by various regulatory authorities around the world. These bodies license drugs and medical devices for use in a particular country or region. In addition, some carry out or commission factory audits and product testing. They generally have the power to refuse to license manufacturers, to recall products and to close factories in the event of continued noncompliance with their regulations.

It is important for purchasers to work closely with national regulatory authorities and inform them of the procurement procedures and testing protocols that will be used to verify the quality of the condoms before they are shipped to the country. Purchasers also need to be aware of and comply with any specific local regulations or requirements.

If the regulatory authority requires in-country testing, then the local laboratory should be accredited and capable of testing to internationally recognized standards. Local laboratories that are accredited can undertake, subject to a contractual agreement with the procurer, the pre-shipment compliance-testing regime recommended in to avoid the need for further testing when the products arrive in country".

The national regulatory authority may undertake confirmatory testing and in-market compliance testing of the product to ensure that it has not deteriorated during shipping, handling and storage. Procedures for confirmatory testing are outlined in Section 3 of this document. In such cases, national regulatory authorities should use accredited laboratories that participate in appropriate inter-laboratory proficiency trials.

Two well-established regulatory procedures for condoms are the U.S. Food and Drug Administration (USFDA) 510(k) pre-market clearance procedure and the European Union CE marking scheme.

- **USFDA 510(k) pre-market clearance:** Prior to marketing a condom in the United States of America (USA), the manufacturer must submit documentation to the USFDA and obtain a pre-market clearance (510(k)). The documentation has to demonstrate that the product is equivalent to one that is already on the market. A 510(k) pre-market clearance means that the manufacturer has submitted acceptable safety data on the product and complies with USFDA requirements for the manufacture and distribution of the product. Factory audits are conducted periodically to monitor compliance.

- **CE marking in Europe:** Condoms intended for sale or distribution within the European Union must carry the CE mark which verifies that the product meets the essential requirements of the medical device directive 93/42/EEC, as amended. Manufacturers are required to follow specific conformity assessment procedures that include submitting a technical file to a European Notified Body. Compliance with *EN ISO 4074* (European designation for the standard) can be taken as evidence of compliance with some of the essential requirements of the medical device directive. Manufacturing facilities are required to have certification of *ISO 13485.*

Most countries have their own regulatory procedures, which should cite relevant published standards. It is always necessary to review national regulatory policy and guidelines before importing condoms into and, in some cases, exporting condoms out of a country.

5. QUALITY MANAGEMENT SYSTEM

A well-run condom manufacturing company will have an audited, documented and effective quality management system conforming to *ISO 13485*. *ISO 13485* is a quality management scheme specifically designed for medical device manufacture. This standard specifies requirements for documentation, procedures and structures to be followed in all types of establishments that manufacture medical devices.

The essential components a quality management system include fully documented:

- quality objectives;
- management responsibilities;
- provision of required infrastructure;
- training procedures;
- process and quality assurance procedures;
- systematic record-keeping;
- corrective and preventative action in case of product quality problems; and
- risk management.

Factories must maintain control over all incoming raw materials and have adequate in-process testing and controls, appropriate in-process remedial procedures, adequate testing of finished products and a functional record-keeping system.

Condoms are non-sterile products but nevertheless should be free from contamination and adulteration. The products therefore need to be manufactured in a controlled environment. Periodic monitoring of the environment and the product is required to ensure that bioburden levels are maintained within acceptable limits and specified pathogens are absent.

The site must be audited and certified to *ISO 13485* by an accredited certification body. In most countries, these certification organizations are private companies, although in some cases they are government agencies. To determine consistency of manufacturing, the certification schemes generally focus on the effectiveness of and compliance with the factory's documented management system. The certifying organization should be registered with an appropriate body, such as the national standards body of the country where the manufacturer or the certifying organization is located.

6. LOTS

A lot (Batch) is a collection of condoms of the same design, colour, shape, size and formulation.

A lot must be manufactured at essentially the same time, using the same process, same specification of raw materials, common equipment, same lubricant and any other additive or dressing and be packed in the same type of individual container, using the same packaging materials. All condoms comprising a lot will:

- have an identical formulation;
- have the same design, dimensions, colour, shape and surface texture;
- be manufactured on the same production line;
- be vulcanized under identical conditions;
- be in the same packaging;
- have the same lubricant; and
- have the same date of expiry printed on the package.

Lot sizes over 500,000 are not permitted due to the risk that the lot may not be homogeneous. Managing such large lots, for example if there is a product recall, can also be difficult.

Manufacturers should retain samples from every lot to assist in the resolution of any disputes relating to quality. It is recommended that the retained samples be kept under approved controlled temperature conditions consistent with the manufacturer's recommended storage conditions for the duration of the shelf life of the product.

7. LOT-BY-LOT PRE-SHIPMENT COMPLIANCE TESTING

The quality of condoms can be influenced by many different manufacturing and raw material factors. The consequences of purchasing and distributing poor-quality condoms in the public sector are severe. For these reasons, WHO/UNFPA also recommends that independent lot-by-lot pre-shipment compliance testing of the finished product be undertaken, using an appropriate sampling plan from *ISO 2859–1:1999 Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection,* before the condoms are accepted for shipment to the purchaser. Manufacturers with a good track record and a sustained level of delivering quality condoms with process averages significantly below the AQL may, subject to meeting specified performance criteria, qualify

for reduced inspection for burst properties and skip lot sampling for dimensions, lubricant quantity, package integrity, packaging and labelling. Purchasers can consider the option of a reduced level of lot-by-lot testing, for example using the procedures specified in *ISO 2859–1:1999* for reduced inspection and *ISO 2859-3:2005 Sampling procedures for inspection by attributes - Part 3: Skip-lot sampling procedures*.

The methods of sampling the condoms for pre-shipment compliance testing and the relative merits of testing prior to delivery are discussed in Clause 8. Either an accredited sampling agency or the testing laboratory should take the samples. The manufacturer must not select the samples. The selection of suitable test laboratories is discussed in this document in Clause 12. It is recommended that only one set of pre-shipment compliance testing be carried out and this must be done by an accredited laboratory.

Manufacturers must satisfy themselves that individual lots meet the specification before lots are submitted for pre-shipment compliance testing.

Post-shipment testing may be performed as well depending on the country of destination of the condoms. It is recommended that this testing be performed by an accredited laboratory.

8. SAMPLING

The quality of a lot is estimated by testing a random sample of condoms from that lot. The inspection levels and AQLs are specified in *ISO 4074* using sampling plans specified in *ISO 2859–1 Sampling Procedures for Inspection by Attributes.* These are the most widely used sampling plans for assessing attribute criteria (i.e. whether the product conforms or does not conform to the requirements detailed in the specification).

Sampling for independent testing should be done by an organization accredited for sampling, by the UN inspector during inspection or by the testing laboratory and not by the factory producing the condoms. Such sampling is required for Prequalification and Pre-shipment compliance testing.

The sampler must verify that each lot that is sampled complies with the definition of a lot, as specified in Clause 7.

Samples must be:

- taken in accordance with pre-agreed sampling procedures;
- representative of the lot of condoms;
- randomly selected (preferably based on random numbers); and
- taken by or under the personal full-time supervision of the sampler.

The sample, once taken, must be sealed and dispatched under the sampler's supervision.

Recommended detailed sampling procedures are described in Annex 1.

At the request of the manufacturer or the procurer, a duplicate sample may be taken for use in case of disputes. The sampling agency must issue a report giving full details of the sampling process. The report shall include the sampling procedures, identification of the cases from which samples are taken and the total number of cases offered for sampling. The sampler should mark the cases from which samples are taken for procurer reference at receipt.

9. ACCEPTANCE QUALITY LIMIT (AQL)

In *ISO 4074* and the *WHO/UNFPA Specification*, the limits for the maximum percentage of defective condoms are specified in terms of Acceptance Quality Limits (AQLs). The AQL is the maximum acceptable average percentage of nonconforming products in a continuing series of manufacturing lots offered for testing. The technical definition of an AQL is given in the glossary in Annex 3.

For important performance properties, the AQLs are set as low as practically possible. For example, the limit for freedom from holes is set at 0.25% to ensure that the end user is adequately protected. For properties that are less important and do not affect the performance of the condom, such as non-critical visible defects, slightly higher AQLs are acceptable.

Conformance with the specified AQLs is assessed by testing a sample from each lot. Testing a sample can only give an estimate of the percentage of defective products in a lot. The reliability of this estimate will increase with the size of the sample. The average percentage of defective products—the process average— can be estimated by pooling the results of testing from many lots. For further details on process average, refer to Annex 2.

As discussed in the previous section, testing is conducted according to sampling plans specified in *ISO 2859–1*. This standard contains sets of tables giving the maximum number of nonconforming products that are allowed in a sample taken from a lot. The sampling plans are designed to give a high probability (usually greater than 95%) of a lot being accepted if the process average of defective products is equal to or less than the AQL. In the long run, therefore, the percentage of lots being rejected should not exceed 5%. If it does, then there is a risk that the manufacturer is not conforming to the relevant AQL. More information on AQLs and sampling is given in Annex 2. If you need assistance, contact the UNFPA quality assurance team at qa-team-group@unfpa.org.

10. MONITORING QUALITY

As well as reviewing the results of pre-shipment compliance testing on a lot-by-lot basis, it is recommended that purchasers monitor quality on an ongoing basis. This can be done by calculating the process averages and using control charts (e.g. Shewhart® charts). Monitoring quality using these methods provides excellent information about trends in product quality and/or early warning of potential problems. Refer to Annex 2 for details.

11. TESTING LABORATORIES

Laboratories may be:

- manufacturers' laboratories;
- independent accredited test laboratories; and
- national regulatory laboratories.

Laboratories that test condoms for regulatory or compliance purposes need to have systems in place to ensure the reliability of their results. ISO has developed a quality management system specifically for laboratories: *ISO 17025*. Laboratories that comply with *ISO 17025* will also operate in accordance with *ISO 9001*. *ISO 17025* covers the essential elements of *ISO 9001* as well as laboratory-specific requirements, such as technical requirements for equipment, calibration, uncertainty management and technical competence of the staff. The laboratory must conduct regular, traceable calibration of its measuring equipment, have an adequate maintenance system, and have systems in place to ensure the technical competence of their staff. Condom testing laboratories used for prequalification and pre-shipment compliance testing should be accredited to *ISO 17025*. The laboratories should also participate in international inter-laboratory proficiency trials and, if applicable, local inter-laboratory proficiency trials for male condom testing.

There are a number of international mutual recognition agreements among accreditation bodies, which audit each other for quality. The international umbrella body is:

International Laboratory Accreditation Cooperation (ILAC)
The ILAC Secretariat
P.O. Box 7507
Silverwater
NSW 2128
Australia

(ILAC) Delivery Address:
The ILAC Secretariat
7 Leeds Street
Rhodes
NSW 2138
Australia
Tel: +61 2 9736 8374
Fax: +61 2 9736 8373
Email: ilac@nata.com.au

http://www.ilac.org.

Regional accreditation bodies that collaborate with ILAC include EA in Europe, APAC in Asia Pacific, IAAC in the Americas, AFRAC in Africa, SADCA in Southern Africa and ARAC in the Arab region.

It is recommended that all laboratories - national, independent and manufacturers - confirm their competence by participation in inter-laboratory proficiency trials for testing male condoms. In such trials, laboratories test samples of condoms supplied by the trial organizers. The results of the tests are returned to the organizers who analyse them and provide feedback to each participating laboratory. The test results are reported anonymously to all the test laboratories allowing participants the opportunity to investigate any tests in which their results disagree with those of other participants.

When assessing a testing laboratory, the following factors should be considered:

- whether the laboratory is accredited by an internationally recognized body;
- whether the laboratory participates in inter- laboratory proficiency trials; and
- the reputation of the laboratory among large-volume purchasers.

12. TESTING COSTS

Some procurers question the cost of independent lot-by-lot pre-shipment compliance testing when they deal with a supplier with whom they have experience and in whom they have developed confidence.

Some have experimented with “consignment testing”, i.e. regarding the whole shipment as a single lot. The trouble with this method is that it is unlikely that the whole shipment has been manufactured under the same conditions. The shipment is therefore unlikely to meet the definition of a lot, as described in Clause 7. Since the homogeneity of the shipment cannot be guaranteed, the statistical principles behind lot sampling and testing are likely to be

compromised. Furthermore, it is difficult to detect problems that may be present in individual lots.

The use of this method increases the risk of a poor lot being accepted. Procurers who have experimented with it have found that the savings were a false economy.

13. POST-SHIPMENT TESTING AND CONFIRMATORY TESTING

In many countries, national regulatory authorities review the data and conclusions reached by the accredited independent laboratory that has been contracted by UNFPA or another procurement agent to undertake the pre-shipment compliance testing. In some countries, in contrast, the national regulatory authority may require in-country testing prior to distribution, i.e. post-shipment testing.

In this case, post-shipment testing would be considered as confirmatory testing. Where feasible, the confirmatory testing should be undertaken by the same laboratory that undertook the pre-shipment compliance testing to reduce the risk of contradictory results. Where possible, confirmatory (post-shipment) testing, if required, should replace rather than repeat pre-shipment compliance testing. These requirements should be written into the contractual agreement between the purchaser and the receiving country and/or procuring agency. The testing should be undertaken by a laboratory accredited to *ISO 17025*.

If pre-shipment compliance testing and post-shipment testing are undertaken, there is a risk of contradictory results, primarily due to the sampling uncertainties associated with attribute sampling.

On occasion, the national regulatory authority may have a valid concern regarding possible deterioration of the product during transportation. If this is the case, then confirmatory testing may be undertaken. Therefore, confirmatory testing serves better when applied as part of risk-based quality assurance system.

Local regulatory authorities are encouraged to take into account the results of pre-shipment compliance testing before reaching any conclusions about the quality of the product.

Confirmatory testing can be restricted to selected a few lots, i.e. skip lot testing, chosen at random from a shipment or consignment. If one or more of the selected lots fail to comply with the specifications, the remaining lots should be tested.

It is recommended that, when such testing is undertaken, priority be given to the critical performance parameters of airburst properties and pack integrity. The risk of statistical lot failures due to sampling error should be considered when interpreting such tests. Occasional differences in results between the pre-shipment compliance tests and the confirmatory tests must be expected. Guidance on action to take in such circumstances can be found in Section 2: Resolution of Disputes.

SECTION 2: RESOLUTION OF DISPUTES

1. INTRODUCTION

There are a number of possible causes of disputes relating to quality during a contract to supply condoms. These may involve:

- interpretation of the contract;
- payment schedules;
- delays in delivery schedules;
- completion schedules;
- independent laboratory test results;
- design issues; and
- condition of the condoms upon arrival in-country or at some time after delivery.

It is essential that the procurement contract specifies a process for the resolution of any disputes that might arise over contract or product quality issues. This chapter only deals with disputes over product quality.

2. DISPUTES OVER LABORATORY RESULTS

Disputes over product acceptance most often arise when independent testing determines that the product does not conform to the required specification or standard. It is also possible for a manufacturer to dispute a decision made by the sampling agency regarding product packaging or appearance.

In most cases, manufacturers accept the results of independent laboratories and replace lots that have been rejected. When they question the results they usually present their own test results or other evidence to suggest that the independent tests are incorrect and do not accurately represent the quality of the product tested.

3. SOURCES OF DISPUTES ARISING FROM LABORATORY TESTING

Laboratory testing is always done on a sample from the production lot. There are generally two main sources of uncertainty in test results:

- **The uncertainty arising due to sampling.** There is always an intrinsic level of uncertainty in estimating the properties of any population based on testing of a sample. This uncertainty decreases as the sample size is increased. The sampling plans specified in *ISO 4074* generally provide a 95% to 99% probability that a lot that is just within specification will be accepted. (For sampling plans with acceptance numbers of zero, the probability of acceptance can be as low as 90%.) There is therefore a small risk that lots of acceptable quality will be occasionally rejected.

- **Testing or reporting mistakes due to operator error, equipment malfunction, drifts in calibration, transcription errors and other causes.** These types of mistakes are, in principle, preventable and should be minimized by application of the quality management system and procedures outlined in *ISO 17025*. In addition, there is also the normal uncertainty associated with measurement.

There are a number of important consequences that have to be considered because of the inherent limitations in the sampling plans. These are:

- In any shipment of condoms there is always a risk that some lots will be rejected even though the process averages may be at or even below relevant AQL. This risk is most severe with sampling schemes with an accept on zero, reject on one decision rule and with process averages that approach the AQL. Manufacturers can minimize such risks by ensuring that the process averages are maintained well below the AQL. For example, by operating with process averages that are half of the relevant AQLs, manufacturers can cut the risk of rejecting lots that actually conform to freedom from holes, package seal and inflation requirements to less than 1%.

- Manufacturers and purchasing agencies should plan on the assumption that some lots, possibly up to 5% in extreme cases, will be rejected. Estimates of volume requirements and pricing should take into account the impact of possible lot failures. Again, manufacturers can keep down the percentage of lots rejected by maintaining process averages well below the relevant AQLs.

- Lots with defect levels slightly above the AQL have a high and significant chance of being accepted. Lots that significantly exceed the AQL still have a reasonable chance of being accepted. It is only when the defect levels are several times the AQL that the probability of rejection becomes very high.

As a general rule, when the level of lot failures exceeds 5% over a large number of lots, i.e. 50 or more, then doubts can be raised about the quality of the manufacturer's production. Similarly, if the percentage of lots rejected exceeds 10% in the short term (e.g. between 5 and 50 lots), then again doubts can be raised about the quality of the products. Finally, if any two lots in a sequence of five lots are rejected, there is a significant risk that the process average may exceed the AQL; further investigations of quality should be undertaken according to the techniques described in Annex 2.

4. REVIEW OF INFORMATION

If a result is disputed, the laboratory and the manufacturer should be asked to verify basic issues, as follows:

4.1 Independent testing laboratory

- Verify that testing was performed as prescribed in the test method applicable to the order concerned;
- Verify that test equipment was in proper working order and in calibration at the time of testing;
- Check on staff performance by looking at the relevant tester's results on other products tested at about the same time;
- Verify by checking records and any retained samples the identity of the test samples and that the normal precautions were taken not to damage the samples prior to testing; and
- Verify that the appropriate uncertainty estimates have been applied for the individual non complying condoms when deciding on the pass fail decision for marginal lots. This is to see if disputed differences can be explained by uncertainty of measurement.

If the laboratory has any doubts about any of these issues, it should re-test the products free of charge.

4.2. Manufacturer

- Review manufacturing and test documents for completeness and for anomalies that may indicate problems; and
- Review all the items above that the independent testing laboratory is required to verify.

When the lot concerned is part of an ongoing order and there is historical or concurrent data on at least 10 lots, the process average can be estimated by one or more of the techniques given in Annex 2. If this process average is within the AQL, it strengthens the case for a re-test. Data sets from both the test laboratory and the manufacturer should be available.

5. DECISIONS ON RE-TESTING

If an agreement cannot be reached between the parties and retesting is undertaken, this should be done by independent third party laboratory accredited to *ISO 17025* for male latex condom testing.

Before a re-test is considered, all available data should be reviewed and discussed with the independent laboratory. If a manufacturer disputes a test result, the following issues should be considered in deciding whether to allow a re-test:

- What is the margin by which the product has failed to comply?
- Is the manufacturer's history of production for the client a good one?
- What is the nature of the difference between the manufacturer's and the laboratory's test results?

In particular, if an estimate of the process average for the test concerned over the last 10 lots is available, it should be taken into account.

The amount of information available for review depends on the type of test. With inflation testing, for example, data on the number of non-compliers will be available as well as the individual volumes and pressures. In this case, a detailed comparison of the data from the manufacturer and the test laboratory can be conducted and it may be possible to identify the cause of disagreement. If, however, the dispute relates to freedom from holes, then the manufacturer must provide detailed and credible pre-release and in-process test results to support the claim for a re-test. In general, a manufacturer requesting a re-test should be prepared to make in-process test data for the lot concerned available for review.

Re-testing should be undertaken only when:

1. There is considerable evidence that the laboratory has made a mistake.

Examples of considerable evidence could be failure to produce evidence that the equipment had been calibrated properly, lack of training records and proficiency test results for the technicians conducting the tests, failure of a critical piece of equipment, evidence of data tampering, loss or mistakes, results completely out of line with other lots manufactured and/or tested at the same time, etc.

Or:

2. There is considerable evidence that the test result is not representative of the population from which the lot sample is taken.

The evidence for a retest in most cases will be the results for similar lots made at the same time on the same equipment.

Therefore, re-testing should be undertaken only when there is strong evidence that an error has been made. More information on the statistical issues associated with sampling is given in Annex 2.

Before a re-test is considered, all available data should be reviewed and discussed with the independent laboratory. If a manufacturer disputes a test result, the following issues should be considered in deciding whether to allow a re-test:

- What is the margin by which the product has failed to comply?
- Is the manufacturer's history of production for the client a good one?
- What is the nature of the difference between the manufacturer's and the laboratory's test results?

The amount of information available for review depends on the type of test. With inflation testing, for example, data on the number of non-compliers will be available as well as the individual volumes and pressures. In this case, a detailed comparison of the data from the manufacturer and the test laboratory can be conducted and it may be possible to identify the cause of disagreement. If, however, the dispute relates to freedom from holes, then the manufacturer must provide detailed and credible pre-release and in-process test results to support the claim for a re-test.

When a lot is rejected, in case there is a dispute over a lot or shipment of condoms, then the laboratory should keep the non-conforming condoms in respect to freedom from holes, visible defects and dimensions until the results have been accepted or until the dispute is resolved.

When the lot concerned is part of an ongoing order and there is historical or concurrent data on at least 10 lots, the process average can be estimated by one or more of the techniques given in Annex 2. If this process average is within the AQL, a re-test may be allowed.

6. RE-TESTING

Where re-testing is done, the second test should give additional confidence about the result, compared with the first test. Re-testing may be done using the next higher inspection level defined in *ISO 2859-1* than the one used for the first sample (e.g. G-II instead of G-I).

Because of the operating characteristics of the sampling plans specified in *ISO 4074*, which are primarily intended for the routine testing of a continuing series of lots, there can be a significant probability that a rejected lot will be accepted on re-test even if the lot does not conform to the relevant AQLs. This means that, in many cases, re-testing will lead to conflicting results. Therefore, re-testing should be undertaken only when there is strong evidence that an error has been made. More information on the statistical issues associated with sampling is given in Annex 2.

Where possible, the re-tested sample should be taken from the laboratory's retained sample taken at the time of sampling. If this is insufficient, or if the sample is suspect, a new sample will need to be taken.

If disputes cannot be resolved, it is recommended that retesting be undertaken by independent third laboratory accredited for male latex condom testing.

Annex 1

Sampling Procedures for Condoms

1. ACRONYMS

EOI: Expression of Interest
ISO: International Organization for Standardization
PSB: Procurement Services Branch
QA: Quality Assurance
SO: Super Office
SOP: Standard Operating Procedure
UNFPA: United Nations Population Fund

2. DEFINITION

This Standard Operating Procedure (SOP) describes the process to be followed when sampling consignments of male condoms and female condoms.

3. PURPOSE

The purpose of this SOP is to provide guidance for the process to be followed when preparing for sampling; and sampling of male and female condoms.

4. SCOPE AND APPLICABILITY

This SOP is intended to be used by inspecting and sampling agencies, as designated by the United Nations Population Fund (UNFPA) and UNFPA/World Health Organization (WHO) prequalification inspections, and for the QA of MC/FC procurement.

5. PROCESS

The required number of individual condoms for the sample is taken in whole bulk (inner) boxes, each of which typically contains 144 or 100 condoms. The number of boxes required should be calculated based on the sample size required and the number of condoms in the bulk boxes. The individual boxes should not be opened. If any are opened, for example to confirm the number of condoms in a box, they should be re-sealed under the supervision of the inspector or sampling agent.

a. Determine the number of pallets in each batch of the consignment.

b. Calculate how many exterior cartons are to be checked visually, as specified in the summary of the requirements of Lot-by-Lot pre-shipment testing. The pallets that the exterior cartons are in should also be checked visually.

c. Check the condition and integrity of the outer packing material and the pallets. Amongst the verification of the conditions, the sampler (inspector) should document via a written statement, as well as photographic evidence, the conditions and integrity of the outer packaging.

d. Check the general cleanliness of the outside of the goods on the pallets.

e. Check that the overall labelling of the pallets matches the packing list.

f. Record any defects. The record should include a written statement as well as photographic evidence of the defects.

g. Count the total number of transport packs (cartons) on the pallets and verify the total against the packing list. Record the total on the inspection report.

h. Calculate the number of cartons to be sampled using the formula $n = \sqrt{N} + 1$, where n is the number of cartons to be sampled and N is the total number of cartons.

i. Round up n to a whole number if necessary.

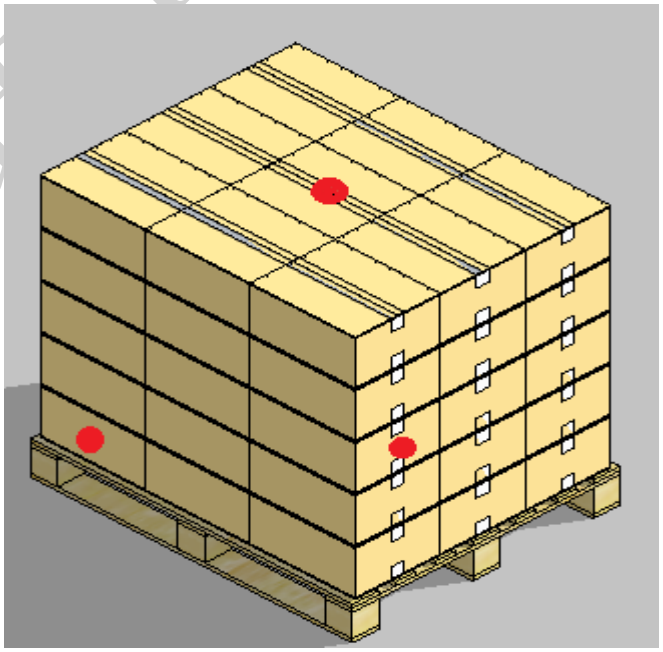
ii. If N is less than, say, 15, then sample all of the cartons.

iii. Sample the N cartons, using a random sampling plan, as described below, and place the samples in a separate container.

i. Randomly select the cartons to be sampled from each pallet, using one of the two methods below:

i. Option 1. Obtain the total number of cartons in the consignment from the manufacturer in advance and select the cartons to be sampled using a random number generator (e.g. by computer software or on a smartphone) or random number tables. To maintain independence, DO NOT inform the manufacturer about the actual cartons to be sampled.

ii. Option 2. Draw the samples equally (as far as possible) from each pallet. For example, if there are ten cartons to be sampled from three pallets, sample three cartons from two of the pallets and four cartons from the remaining pallet. Cartons should be randomly selected from the top, middle and bottom of the pallets, for example as shown in figure 1.



iii. Take pictures of the pallets/lots before retrieving sample boxes so UNFPA can see the total quantities available for sample dispatch.

iv. Take individual pictures of each pallet so UNFPA can monitor how the selection of boxes within the different pallets has been performed.

v. Record the number of cartons sampled and the carton number from which the samples were drawn.

j. Check the condition of the cartons for the integrity of the packing material.

k. Check the cartons for cleanliness.

l. Confirm the labels on the cartons are undamaged.

m. Confirm that the cartons are undamaged.

n. Check the labels for spelling mistakes.

o. Confirm that the expiry date is present and legible (and the date of manufacture, if required). Products should be recently manufactured and, unless specifically authorized in writing, have at least 75% of the shelf life remaining at the time of the delivery to country of destination.

p. Check and verify the requirements in the inspection templates (Annex II and/or Annex III).

q. Record any defects and discrepancies. (Include the Lot number and Carton number of where the defect was found.)

r. Numbers of condoms to be selected from the sampled cartons. The condoms shall be selected in their bulk pack – usually as boxes of 1 gross (144 units) but occasionally as boxes of 100 units. **Note**: Samples should be taken, taking into account the actual Lot size, irrespective of pieces ordered.

i. Standard pre-shipment testing for male condoms (no oven conditioning required). See table 1.

ii. Exceptional pre-shipment testing for male condoms – oven conditioning required. See table 2.

iii. Female condoms (note that female condoms are not usually packed in boxes of 1 gross). See table 3.

iv. Sample the condoms based on the Lot size, not the order quantities.

v. Take the condom boxes from the cartons selected for sampling. Randomly select the boxes from the top, middle and bottom of the cartons and spread the sampling across the cartons as evenly as possible.

s. Check the condom boxes for integrity of the packing material.

t. Check the condom boxes for cleanliness.

u. Check the condom boxes for distortion or discolouration.

v. Confirm that the labelling of the condom boxes is undamaged.

w. Check if there is any special artwork that may have been proposed from the country of destination is appropriately added.

x. Check the condom boxes for overall damage.

y. Check the labelling on the condom boxes for spelling mistakes.

z. Confirm that the labels on the condom boxes carry the name of the manufacturer, expiry date and date of manufacture (if required).

aa. Check the instructions for use.

bb. Record the defects. (Include the Lot number and Carton number of where the defect

was found.)

6. REPORTING RESULTS

a. A summary of the inspection should be included in the report.

b. In addition to the standard content of the report, the report should include the following:

i. Full details of goods and packaging;
ii. Total number of cartons opened for collection of the samples;
iii. Serial number of the cartons opened;
iv. Number of grosses sampled per carton;
v. Record all Lot/Batch numbers sampled;
vi. Number of grosses per batch sampled;
vii. Description of sealing procedure : describe how the samples were sealed in a tamper proof manner (for example, box was taped and dated).
viii. Seal numbers, if applicable.

References

ISO 4074:2015 Natural rubber latex male condoms – Requirements and test methods.

ISO 25841:2014 Female condoms – Requirements and test methods.

Male Latex Condom: Specification, Procurement and Guidelines for Procurement 2013.

Female Condom: Generic Specification, Procurement and Guidelines for Procurement 2012.

Annex 2

Methods for Assessing Quality of Suppliers

There are a number of methods for assessing the quality of manufacturers. Because of the uncertainty in estimating the quality of a LOT by testing a sample, as discussed in Section 1, Chapters 1 and 4, it is only by monitoring quality across many LOTS that a reliable picture can be established about the quality of a specific manufacturer. Decisions based on information from a small number of LOTS—for example, in the case of short-term or small-volume contracts—can be misleading when considered in isolation. In general, it is most important to monitor the performance related to the Performance Requirements.

Based on an analysis of data from a number of manufacturers, individual lot average values should not vary by more than ± 20% from the overall average across all lots tested. Any lot exhibiting a shift from the overall mean that is larger than 20% should be rejected, and any long-term shift in the lot averages should be investigated. Monitoring is best achieved by using a control chart (e.g. a Shewhart chart).

Unless there is specific concern about an individual supplier's ability to comply with the design-related requirements, it is probably not worth monitoring these properties.

The methods that can be used to monitor quality are as follows.

1. PROCESS AVERAGE

The process average is the percentage of condoms that are non-conforming over a defined time period or quantity of production. It is calculated for each requirement detailed in the WHO/UNFPA Specification by dividing the number of non-conforming condoms by the total number of condoms tested. Ideally, the process average for a specific attribute should be not greater than half the specified AQL.

2. CONTROL CHARTS (SHEWHART CHART)

Control charts provide a very convenient and simple way of monitoring quality over time and observing trends in process averages. They can provide early warning of any change in quality, alerting both manufacturers and purchasers to potential problems. They can be used retrospectively to assess how stable a process is. They provide a means of correlating changes in process average with process operating conditions or change in raw material batch. Their use is strongly recommended to confirm that a manufacturer has production under control and is capable of achieving the quality levels specified.

To construct a control chart, the percentage defects for each LOT is plotted against LOT number or any other appropriate parameter such as date of manufacture.

Control charts can also be constructed for variable data, such as average burst volumes and burst pressures, and for standard deviations. Warning and control limits are usually added to the control chart to allow changes in quality to be assessed quickly. Typically, warning limits are set at the overall mean ±2 standard errors of the means. If the warning limits are approached, it implies that changes are occurring that could lead to problems with product quality and action should be taken to restore the process to normal operation.

Action limits are set at the overall mean ±3 standard errors of the means. If the action limits are approached, then it is most probable that a statistically significant change to product quality has occurred and immediate action must be taken to address the problem. The standard error of the means is determined by calculating the standard deviation of a sequence of LOT means when the process is considered to be operating in statistical control. It is recommended that data from between 20 and 30 individual LOTS be used when computing the standard error of the means.

Typically, for latex condom production the standard error of the means, expressed as a percentage of the overall means, for burst volume and burst pressure data is in the region of 6%.

Any shift in the average burst pressure or volume of a LOT or LOTS by more than 18% to 20% almost certainly signals that there has been a highly statistically significant change in the manufacturing process and/or the materials used. If this occurs, further investigation is urgently required.

Monitoring changes in average burst volumes and pressures using control charts is an excellent method of detecting significant changes in the quality of production. This procedure can be implemented as an alternative to testing oven-conditioned condoms for bursting volume and pressure on a LOT-by-LOT basis.

Cumulative sum (cusum) control charts can also be used. In these charts, the cumulative difference between the actual result and the target or expected result is plotted in place of the process average. Cusum charts have advantage of being able to detect changes in underlying quality more rapidly than standard charts based on the process average, but they are more complex to construct and not quite so intuitive to understand.

Refer to a standard textbook on quality control procedures or statistics for more information on control charts. Procedures for producing these charts are also given in a series of ISO standards: *ISO 7870* is a general guide and introduction to control charts; *ISO 8245* describes Shewhart charts and includes techniques for charting attribute data; and *ISO 7966* describes acceptance charts. Cusum charts are described in parts 1–4 of *BS 5703*.

3. AGGREGATE ANALYSIS

On occasion, it might be useful to determine whether a shipment consisting of a number of LOTS is in compliance based on an aggregate assessment of the results taken across all the LOTS tested. In order to do this, the acceptance number for the total sample size may be calculated using the table below. The acceptance numbers (D) can be calculated from the following equations for any specific AQL and aggregated sample size (N). For additional advice on calculating and using these acceptance numbers, please contact the Help-Line.

When using the aggregate analysis method, it is also necessary to take into account the results for individual LOTS and the process average before reaching a decision about the capability of the manufacturer.

4. NUMBER OF LOTS REJECTED

Another approach is to review the number of LOTS rejected over the long term. If this number significantly exceeds 5%, there is a high probability that the manufacturer's process average is greater than the stipulated AQL. A problem with this approach is that the number of LOTS that may fail in the short run will vary considerably and may exceed 5% because of the same type of sampling errors that apply to individual LOTS.

Therefore, this rule can only be applied to large numbers of LOTS. The sampling plans given in *ISO 2859–1* do, however, contain a useful guide that can be used to identify potential problems with quality in the short term.

These plans are primarily intended to be used with the switching rules which alter the probability of acceptance of LOTS on the basis of history. The switching rules are not generally used in the condom sector, but the rule for switching to tightened inspection is a very useful indicator of potential problems. This switch is triggered whenever there are two LOT rejections in any continuous sequence of five or fewer LOTS. If this occurs, the quality of all further LOTS from the manufacturer should be closely monitored and the procedures described in this annex should be used to determine the process average. Discontinuation of supply may be appropriate if this investigation confirms a serious quality problem. Contact the Help-Line for further information:

qa-team-group@unfpa.org

AQL 0.25 D = 0.01(0.25N + 8N 0.55)
AQL 1.0 D = 0.01(1.0N + 17N 0.55)
AQL 1.5 D = 0.01(1.5N + 22N 0.55)
AQL 2.5 D = 0.01(2.5N + 30N 0.55)

1132 AQL 4.0 $D = 0.01(4.0N + 36N\ 0.55\ )$

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Annex 3

Glossary of Terms and Abbreviations

Acceptance number	The highest number of non-compliers (failures) allowed in a specific test from a selected sample.
AQL	Acceptable Quality Limit. The quality level that is the worst tolerable process average when a continuing series of LOTS is submitted for acceptance sampling (*ISO 2859–1*). N.B. Manufacturers should be consistently achieving a process average that is better than the AQL.
Batch	Sometimes used in place of "LOT" (see definition of LOT). (WHO recommends that "LOT" be used when referring to condoms.) Can also refer to a homogenous quantity of latex that has been compounded and is ready for dipping from which several LOTS will be made. Or, to describe a quantity of individual raw materials.
Bioburden	The population of micro-organisms on a raw material, component, product, packaging or equipment.
CE mark	On condom packaging, a mark certifying that the product conforms to the essential requirements of the European medical device directive 93/42/EEC.
Compliance testing	A regime of testing to verify that a LOT complies with the specification.
Condom	Medical device that is intended to be worn on the penis during sexual activity for purposes of contraception and to prevent the spread of sexually transmitted infections. Condoms are usually made from natural rubber latex but may also be made from synthetic materials, such as polyurethane.
Confirmatory testing	Testing carried out on receipt of a product in country.

Design Requirements	Characteristics of the condom that are specified according to the procurer's requirements.
Expiry date	The date at which the product is no longer considered acceptable for use.
Inspection level	The degree of examination of the LOT, as specified in *ISO 2859–1*. The higher the inspection level, the more samples will be tested and, hence, the lower the risk of faulty products reaching the end user.
ISO	International Organization for Standardization.
ISO/TC 157	International Organization for Standardization, Technical Committee 157 for Non-Systemic Contraceptives and STI Barrier Prophylactics.
Length	The length of the condom measured from the open end to the tip, excluding any reservoir.
LOT	A quantity of condoms of a single grade, class, size and composition, manufactured under essentially the same conditions. With certain exceptions, all the condoms comprising a LOT will have identical formulation; the same dimension, colour, shape, and surface texture; be manufactured on the same production line; and be vulcanized under the same conditions.
National Regulatory Authority	A regulatory body with authority in a specific country to control the importation and distribution of medical products. See also *Regulatory authority.*
Package	The foil sachet in which the condom is sealed after manufacture.
Performance Requirements	The critical tests of quality that all LOTS must pass in order to provide adequate consumer protection.

Prequalification	The steps taken by the procurer to verify a manufacturer's suitability to provide condoms of the required quality. The WHO/UNFPA Prequalification Scheme includes periodic assessment of manufacturing dossiers, testing of samples and factory inspection.
Pre-shipment compliance testing	A regimen of compliance tests carried out before a shipment leaves the supplier's factory.
Process average	The percentage of condoms that is non-conforming over a defined time period or quantity of production. It is calculated for each requirement detailed in the *WHO/UNFPA Specification* by dividing the number of non-conforming condoms by the total number of condoms tested. Ideally, the process average for a specific attribute should be not greater than half the specified AQL.
Random sample	A sample of condoms drawn randomly from a LOT for testing purposes.
Regulatory authority	A national or international body set up to oversee the safety, efficacy and quality of medical devices, including condoms, imported and distributed within a country or region.
Sampling plan	A specific plan that indicates the number of units (condoms) from each LOT that are to be inspected (sample size) and the associated criteria for determining the acceptability of the LOT (acceptance and rejection numbers).
Shelf-life	The period of time after manufacture that the product is considered acceptable for use.
Specification	A detailed statement of a product's requirements as established by the procurer. Usually, a specification is based on an established standard.
Standard	A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority.
Total Viable Count (TVC)	The number of living micro-organisms in a given sample.

UNFPA	United Nations Population Fund.
USFDA	United States Food and Drug Administration.
Width	The dimension measured 30 mm from the open end, at a right angle to the length of the condom when it is unrolled and laid flat without any creases.
WHO	World Health Organization.
WHO/RHR	World Health Organization, Department of Reproductive Health and Research.

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