# Male Latex Condom:

## Specification, Prequalification and Guidelines for Procurement, 2010

revised April 2013

World Health Organization

UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
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The following organizations support the use of the WHO/UNFPA Male Latex Condom Specification and Prequalification Scheme.

The Global Fund to Fight AIDS, Tuberculosis and Malaria

Family Health International (FHI)

International Planned Parenthood Federation/International CONtraceptive & SRH Marketing Ltd. (IPPF/ICON)

Marie Stopes International (MSI)

John Snow, Inc. (JSI)

Joint United Nations Programme on HIV/AIDS (UNAIDS)

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Population Action International (PAI)

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Reproductive Health Supplies Coalition (RHSC)

United Nations Population Fund (UNFPA)

World Health Organization, Department of Reproductive Health and Research (WHO/RHR)

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Department of Reproductive Health and Research
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# ACKNOWLEDGEMENTS

This manual is a result of a review of the latest available evidence and an extensive consultative consensus-building process with individuals who represent the condom manufacturing industry, the International Organization for Standardization (ISO), testing laboratories, national regulatory authorities, research institutes, bulk procurement agencies, social marketing companies, international agencies, nongovernmental organizations, consumer groups, and family planning and HIV/AIDS prevention policy-makers and programme managers.

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**Co-authors**

William Potter, Consultant/WHO Technical Adviser, and Margaret Usher-Patel, Scientist/Secretariat, Implementing Best Practices Consortium, WHO/RHR, led the development of this document in close collaboration with Eli Carter, FHI; John Gerofi, Enersol Laboratories; Lorna Wilcox, microbiologist; Paul Hayes, Kingsway Management Services Ltd.; Morten Sorensen, UNFPA; and Jakub Srebro, APOTEKET.

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# FOREWORD

The *2009 AIDS Epidemic Update,* published by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO) states that the number of people living with HIV continued to grow in 2008, reaching an estimated 33.4 million, with 2.7 million new infections that year (*1*). For several years women have accounted for around 50% of those infected with HIV, while young people, between the ages of 15 and 24, now account for 45% of new HIV infections. *2008 Report on the Global AIDS Epidemic,* published by UNAIDS and WHO, states that this is mainly because young people lack access to condoms and accurate and complete information on how to avoid exposure to the virus (*2*).

The World Health Organization estimates that 340 million new cases of curable sexually transmitted infections (STIs), namely syphilis, gonorrhoea, *Chlamydia trachomatis* and *Trichomonas vaginalis,* occur every year throughout the world in men and women ages 15–49 years. In addition, millions of sexually transmitted viral infections occur annually, attributable not only to HIV but also to human herpes viruses, human papillomavirus and the hepatitis B virus. Globally, these infections inflict a huge health and economic burden, especially in developing countries (*3*).

**Condoms, as a proven effective barrier method,** can be used as a dual-purpose method for both prevention of pregnancy and protection against HIV and other STIs. For maximum effect any barrier method for contraception or infection prevention has to be used correctly and consistently.

Laboratory *(in-vitro)* testing shows that intact latex condoms are highly effective barriers to sexually transmitted pathogens, including HIV (*4, 5*). Condoms therefore protect against many STIs, although the level of protection has not been quantified for each specific STI (*6*). Male latex condoms may be less effective in protecting against STIs that are transmitted by skin-to-skin contact than those transmitted in fluids, since the condom may not cover all of the infected skin areas (*7*).

> The male latex condom is the single most efficient, available technology to reduce the sexual transmission of HIV and other sexually transmitted infections and offer dual protection for the prevention of unintended pregnancy.
>
> Source: *WHO/UNFPA/UNAIDS position statement—condoms and HIV prevention.* 2004, updated 2009.

A natural rubber latex condom is a simple, low-cost device that has to meet demanding performance requirements. The basic process used to manufacture natural latex condoms has not changed significantly over the last 20 years. The quality of the product has been considerably improved, however, by better process control and more stringent standards of production.

Natural rubber latex condoms are made in large quantities—many billions per year. Latex rubber, being a natural material, can be subject to variations in quality, depending upon a number of factors including the location of the plantation and the effects of seasonal and climatic changes. Furthermore, the manufacturing process is complex. Because of these factors, stringent process and quality control procedures are required to manufacture quality natural latex condoms. If the correct quality control procedures are followed, the latex is converted into a condom that offers an excellent combination of sensitivity, strength and elasticity.

The purchase of poor-quality condoms will adversely affect every aspect of condom promotion and programming. Not only is it a waste of limited budgetary resources, but also it damages the credibility of the one inexpensive device that has been proven to help prevent the transmission of HIV/STIs and unintended pregnancy.

Therefore, it is important for policy-makers, programme managers, bulk procurement agencies, social marketing programmes, logistic/procurement officers and national regulatory authorities to know how to apply the essential elements of condom quality assurance to guarantee that a quality product is purchased, promoted and distributed to the end user. The condom is an important medical device and needs to be regulated and controlled as such.

**Roles of the World Health Organization (WHO), the United Nations Population Fund (UNFPA) and the Joint United Nations Programme on HIV/AIDS (UNAIDS)**

UNAIDS recommends condoms in all the interventions it cites to prevent sexually transmitted HIV. It mentions condoms, directly or indirectly, as part of *each* HIV prevention measure for key audiences (*8*).

UNFPA is working with WHO, UNAIDS and many other partners to generate stronger global commitment, increased financing and collective action to support a strategic approach to Comprehensive Condom Programming (CCP) to prevent unintended pregnancy and the transmission of STIs including HIV. To help strengthen this approach, UNFPA developed two interrelated tools: the *Comprehensive Condom Programming Framework*, which describes the work areas that need to be addressed in an effective CCP response, and the *Ten-Step Strategic Approach to Scale Up CCP*, which describes a process that country programme managers and their development partners can follow to move CCP from concept to reality. Together, they provide national managers with a structural framework and a process to operationalize this vital HIV prevention intervention.

WHO has worked for more than 15 years in collaboration with UNFPA, UNAIDS and the United States Agency for International Development (USAID) to see that the issue of condom quality assurance is taken very seriously. WHO has also worked with partners from donor agencies, international and nongovernmental organizations, research institutions, the private sector including the manufacturing community, testing laboratories and consumer groups, and the International Organization for Standardization (ISO) to advocate and support the development of rigorous international standards and the establishment of purchase specifications and a Prequalification Scheme for the production, procurement and distribution of good-quality natural rubber latex condoms.

The manufacturing community has developed improved technologies, and research has generated more awareness of the type of quality assurance systems and laboratory tests needed to ensure that a quality product is manufactured and distributed. In February 2002 the current version of the International Standard *ISO 4074* for the manufacture of the natural rubber male latex condom was published. It is now under revision. An updated edition may be published in 2011.

Establishing standards and product specifications is a dynamic process that must be responsive to the outcome of research and to new information. WHO first published *Male Latex Condom: Specification and Guidelines for Condom Procurement* in 1989. It was updated and republished in 2003.

In 2008 the WHO Department of Reproductive Health and Research, in collaboration with Family Health International (FHI), UNFPA and all key public- and private-sector stakeholders, initiated a technical review process to ensure that the latest available evidence and information were considered prior to updating and republishing this manual.

The technical review process undertaken to prepare and update this manual is summarized in Section 4, Annex I along with a review of the technical basis that underpins the revision of the natural rubber male latex condom specification detailed in Section 1, Chapter 2 of this manual.

These activities have led to the revision and publication of this manual, *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010.*

This guideline will help policy-makers, procurement officers, logistics and programme managers, national regulatory authorities and testing laboratories make the right decisions to procure, receive, distribute, test and promote a quality product.

To request documents, contact the Help-Line (HELPLINEcondomquality@fhi360.org) or:

**World Health Organization**
Documentation Centre
Avenue Appia
CH-1211 Geneva 27, Switzerland

This document is available on the web sites of WHO (http://www.WHO.int/reproductive health) and UNFPA (bookorders@who.int).

**Family Health International**
P.O. Box 13950
Research Triangle Park, NC 27709, USA
http://www.fhi.org/en/publications/index.htm
publications@fhi.org

**PATH**
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P.O. Box 900922
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http://www.path.org/publications/
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**UNFPA**
United Nations Population Fund
220 East 42nd Street
New York, NY 10017, USA
http://www.unfpa.org/public/procurement

**World Bank**
Publications
1818 H Street, N.W.
Washington, DC 20433, USA
http://publications.worldbank.org/ecommerce/books@worldbank.org

**HELP-LINE**

Do you have a question or problem?

Contact our team of experts at:

**HELPLINEcondomquality@fhi360.org**

We will help you find the right answer to your question.

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# INTRODUCTION

Consistent and correct use of condoms is vital to achieve the level of protection required to prevent unintended pregnancy and the transmission of HIV and other STIs. Another vital factor is the quality of the product. If condoms leak or break, they cannot offer adequate protection.

In many programmes attention tends to be focused on the condom user and the promotion of condoms. Often, inadequate attention is paid to ensuring, as a key component of a comprehensive condom programming strategy, that a quality product is manufactured, purchased, stored, distributed and handled properly[1].

The male latex condom is an important medical device, and its manufacture needs to be regulated and controlled as such. This publication, *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010,* provides the essential information required to achieve the procurement and distribution of a quality product.

### For whom is this document intended?

This document is intended primarily for any policy-maker, manager or procurement officer who has the responsibility for procuring, supplying and promoting natural latex male condoms.

Individuals working in reproductive health care programmes, particularly STI/HIV/AIDS prevention and family planning programmes, should also review this document to understand why it is vitally important to establish systems that ensure that a quality product is manufactured, procured and promoted.

Bulk procurement agencies, testing laboratories and national regulatory authorities will also need to study this document in preparation for the manufacture, procurement and supply of condoms.

In addition to these primary users, the document will be useful to manufacturers, social marketing programmes, nongovernmental agencies and policy-makers as they work to improve the acceptability and use of condoms in their target populations.

### Purpose of the document

This document describes a technically sound, systematic process to support the manufacture, prequalification, procurement and distribution of a quality product that can meet the needs of different populations in a broad spectrum of challenging environmental conditions.

WHO/RHR has worked in collaboration with many partners from the private and public sectors to generate the evidence and gain the consensus needed to recommend the procedures detailed in this manual.

The importance of using the *WHO/UNFPA Specification for Male Latex Condoms* and supporting the Prequalification Scheme and procurement procedures detailed in this manual cannot be overemphasized, as they address issues related to:

- ensuring the procurement of a quality product;
- improving levels of competence in procurement;
- improving levels of confidence in the performance of the product;
- ensuring the health and safety of the end user.

1 *Prevent HIV now—strategic framework for Comprehensive Condom Programming strategy.* Geneva, UNFPA, 2006.

# CHAPTER 1

# Condom Quality Assurance

# SECTION ONE
# CHAPTER 1: CONDOM QUALITY ASSURANCE

Chapter 1 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 the minimum safety, performance and quality requirements for a wide range of products including medical devices such as condoms. Standards may be generic or product-specific. Many different types of organizations and bodies participate in the development of these standards, including manufacturers, national regulatory authorities, researchers, consumer groups, international agencies and testing laboratories.

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 appropriate national or international standards before it can be marketed. Compliance can be voluntary, but in many cases government or regulatory authorities have made compliance mandatory.

In addition to specifying safety, performance and quality requirements, standards also specify test methods that can be used to verify that products comply with 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. A second corrigendum to *ISO 4074* was published in April 2008, and the current edition of *ISO 4074* is undergoing revision. A summary of the second corrigendum and the expected changes to *ISO 4074* are given in Annex I. The date of publication of the revised standard is difficult to estimate but will not be before 2011.

World Health Organization Department of Reproductive Health and Research (WHO/RHR), UNFPA 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 2002 edition of *ISO 4074* can be purchased from national standards organizations or from:

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

Copies of the standard can also be downloaded (for a fee) from the ISO web site (http://www.iso.org) and the web sites of other national standards organizations. *ISO 4074:2002 Corrigendum 1:2003* and *ISO 4074:2002 Corrigendum 2:2008* can be downloaded free of charge from the ISO web site (http://www.iso.org/iso/iso_catalogue.htm).

## 2 Specifications

A specification is a statement of the buyer's requirements and covers all of the product attributes necessary for buyer 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; refer to Section 1, Chapter 2 of this document.

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 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 protect both the buyer and the end user.

It is recommended that purchasers buy only from manufacturers that are prequalified under the WHO/UNFPA Prequalification Scheme.

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 is 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 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. Full details of the WHO/UNFPA Prequalification Scheme for male latex condoms are given in Section 2 of this document.

UNFPA maintains a list of prequalified manufacturers. This list is available on the WHO and UNFPA prequalification web sites. It is strongly recommended that only prequalified manufacturers be used for the procurement of condoms for public-sector distribution.

## 4 Procurement

This document also describes the procurement procedure for male latex condoms. Full details of the procurement process are given in Section 3 of this document. The procedure, when used in conjunction with the WHO/UNFPA Prequalification Scheme and the *WHO/UNFPA Specification,* ensures that good-quality condoms will be procured.

The *WHO/UNFPA Specification,* Prequalification Scheme and procurement procedures detailed in this manual are necessary because:

- They specify quality assurance measures designed to protect both the procuring agency and the end user, since there may be substantial differences in the quality of condoms produced by different manufacturers.
- Condoms are likely to degrade unless they are appropriately formulated and packaged.
- Stringent quality control procedures are necessary to ensure LOT-to-LOT consistency and to reduce the risk that quality may vary between production runs.
- A poor-quality product fails to provide adequate protection.

- A poor-quality product will quickly create negative publicity and destroy the credibility of any condom promotion programme.
- A poor-quality product can cause a logistical, political, financial or social crisis since funds would have to be found to replace the poor-quality condoms, and, if funds cannot be found, those condoms would potentially be unavailable for use.

## 5 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.

Review and comply with national regulatory policies before importing condoms into a country.

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 Section 3 of this document, "Guidelines for Procurement".

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.

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 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 and 2007/47/EC. Manufacturers are required to follow specific conformity assessment procedures that include submitting a dossier to a European Notified Body. Compliance with *EN ISO 4074* (European designation for the standard) can be taken as evidence of compliance with the essential requirements of the medical device directive. Manufacturing facilities are required to be certified to *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.

## 6 Manufacturing quality management

A well-run factory will have an audited, documented and effective quality management system. ISO has created a quality management scheme specifically for medical device manufacture; this scheme is described in *ISO 13485.* This standard prescribes

the documentation, procedures and structures to be followed in all types of establishments to facilitate the production of medical devices of a consistent standard.

The essential components of these systems are documented:

- quality objectives;
- management responsibilities;
- training procedures;
- process and quality assurance procedures;
- systematic record-keeping;
- remedial action in case of product quality problems.

Factories should 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 there is no contamination and that bioburden levels are maintained within acceptable limits.

A number of organizations offer certification to *ISO 13485* by audit. In most countries these organizations are private companies, although in some cases there 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. Some organizations offer more comprehensive national accreditation systems that include product testing, such as NF mark in France and BSI Kitemark in the United Kingdom.

## 7 LOTS[1]

A LOT 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;
- 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.

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 controlled temperature conditions consistent with the manufacturer's recommended storage conditions for the duration of the shelf-life of the product.

> The date of manufacture (MFD) is the date the LOT was dipped, regardless of when packaging was completed.

1 The word "LOT" is capitalized to emphasize that it is the technical term for a batch of condoms and to distinguish it from "a lot", meaning "many".

## 8 LOT-by-LOT Pre-shipment compliance testing

The manufacture of condoms is complex and can be influenced by a variety of 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,* before the condoms are accepted for shipment to the purchaser.

The methods of sampling the condoms for Pre-shipment compliance testing and the relative merits of testing prior to delivery are discussed in Section 3, Guidelines for Procurement. Either a 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 Section 1, Chapter 1, 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.

## 9 Sampling

The quality of each LOT is estimated by testing a randomly selected sample of condoms from that LOT. The sample sizes are defined 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 either an independent accredited laboratory or by an independent sampling organization 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);
- 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.

> An example of an acceptable sampling procedure is the "Square Root + 1" plan, in which the number of cases from which to take samples is determined by calculating the square root of the total number of cases in the LOT (i.e. SqR of 100 = 10), plus one additional case. The total number of samples required for testing is then randomly selected equally among the cases.

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 buyer reference at receipt.

## 10 Acceptable 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 Acceptable Quality Limits (AQLs). The technical definition of an AQL is given in the glossary in Annex V.

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.

Compliance 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 accuracy 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 IV.

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 defective 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 in compliance with the relevant AQL. More information on AQLs and sampling is given in Annex IV. If you need assistance, contact the Help-Line: HELPLINEcondomquality@fhi360.org.

## 11 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 or 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 IV for details.

## 12 Testing laboratories

Laboratories may be:

- manufacturers' laboratories;
- independent accredited test laboratories;
- 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.*

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. Telephone: +61 2 9736 8222; Fax: +61 2 9745 5311. http://www.ilac.org.

It is recommended that all laboratories—national, independent and manufacturers—confirm their competence by participation in condom inter-laboratory proficiency trials. In such trials laboratories test samples of condoms supplied by the trial organizers. The

results of the tests are returned to the organizers, who analyze 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;
- the reputation of the laboratory among large-volume purchasers.

## 13 Testing costs

Some buyers 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. Buyers who have experimented with it have found that the savings were a false economy.

## 14 Confirmatory testing

In many countries national regulatory authorities confine their role to reviewing the data and conclusions reached by the accredited independent laboratory that has been contracted to undertake the Pre-shipment compliance testing. In some countries, in contrast, the national regulatory authority may require in-country confirmatory testing. Where feasible, the confirmatory testing should be undertaken by the same laboratory that undertook the Pre-shipment compliance testing. Where possible, confirmatory 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.*

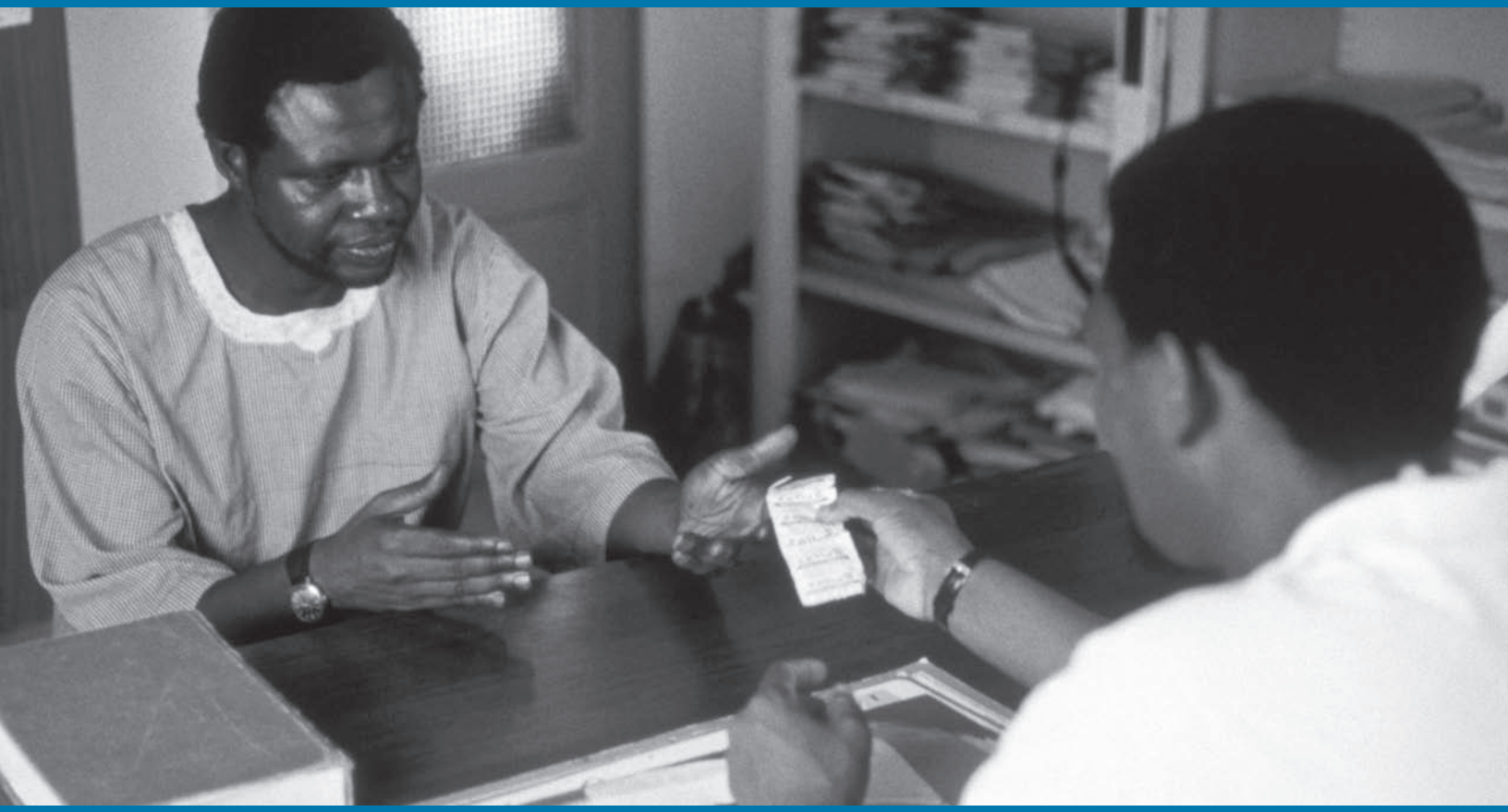
**If Pre-shipment compliance testing and confirmatory testing are undertaken by different laboratories, there is a risk of contradictory results.**

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.

Local regulatory authorities must 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 LOTS 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 1, Chapter 4, Resolution of Disputes.



# CHAPTER 2

# WHO/UNFPA Specification for Male Latex Condoms

# SECTION ONE
# CHAPTER 2: WHO/UNFPA SPECIFICATION FOR MALE LATEX CONDOMS

## 1 Introduction

This section contains the *WHO/UNFPA Specification,* which is suitable for the bulk procurement of male latex condoms for use in social marketing and public-sector programmes for STI/HIV prevention and family planning. A summary of the technical basis for the *WHO/UNFPA Specification* is given in Annex I and Annex II.

A specification is a statement of the buyer's requirements and covers all the attributes and features of the product. Many of these requirements, particularly the design features, may be unique to the buyer and not specified in *ISO 4074.* The buyer's specification must be a detailed and unambiguous statement of the buyer's requirements and describe the means by which those requirements can be measured and assessed. The specification is generally attached to the Bidding Documents and forms part of the supply contract.

The *WHO/UNFPA Specification* is based on the minimum performance requirements for male latex condoms given in the *International Standard ISO 4074 Natural Latex Rubber Condoms—Requirements and Test Methods.* This standard specifies the essential performance requirements that latex condoms are expected to meet and the test methods that are used to assess compliance with these requirements. This standard is based on extensive research and an ongoing consultation process involving leading experts from around the world in all aspects of condom manufacturing, testing, research and use. The *WHO/UNFPA Specification* described here incorporates the performance requirements of *ISO 4074.*

This specification can be used unchanged or adapted to the specific requirements of a programme in accordance with the guidance detailed in this chapter.

The *WHO/UNFPA Specification* has been developed by consensus and is based on available evidence, details of which are given in Annex I and Annex II. The *WHO/UNFPA Specification* describes the general, design, performance, and packaging requirements for the product and the methods of verification. It can be used unchanged or adapted to the specific requirements of programmes. It is important to understand, however, that:

- **General Requirements** specify the safety of constituent materials and other characteristics, such as shelf-life. These properties should not vary from LOT to LOT and therefore do not need testing on a regular basis. Re-testing is required following any significant change to the formulation, manufacturing process, equipment used and packaging. The General Requirements detailed in the *WHO/UNFPA Specification* should not be changed. They are listed in Clause 2.1 of this chapter.
- **Performance Requirements** specify the essential performance attributes of the condoms, established in accordance with *ISO 4074.* These must be tested on a LOT-by-LOT basis since the quality of these attributes may vary due to the manufacturing process. Laboratory tests are carried out to assess the barrier properties of the package, the integrity of the product and its ability to resist breakage. Performance requirements detailed in the *WHO/UNFPA Specification* should not be changed. The only exception is the optional requirement for bursting volume and pressure testing after oven conditioning (see box, page 26). The Performance Requirements are listed in Clause 2.2 of this chapter.
- **Design Requirements** are mainly concerned with the acceptability of the product to the end user. These can be varied within certain limits to meet specific programmatic requirements. Special boxes have been provided in the *WHO/UNFPA Specification* for changes to such design requirements as colour, length and width. For each design requirement there is a means of verification. These are listed in Clause 2.3 of this chapter.
- **Packaging Requirements** are detailed in the *WHO/UNFPA Specification* and should not be changed. If consumer packaging is required, it is important to include detailed instructions in the specification and to discuss the design requirements with the manufacturer. The

Packaging Requirements are listed in Clause 2.4 of this chapter.

The *WHO/UNFPA Specification* is based on:

- the International Standard *ISO 4074;*
- a literature review of the available evidence;
- the recommendations of the WHO/UNFPA/UNAIDS/FHI Male Latex Condom Technical Review Committee (May 2002, August 2007 and July 2008);
- recommendations made by delegates at the 25th annual ISO Technical Committee 157 meeting in Montreux, Switzerland, October 2008. This committee is undertaking the revision of the *ISO 4074* standard;
- feedback from participants attending the WHO/UNFPA workshops to introduce the male latex condom specification, prequalification and procurement procedures, conducted between November 2007 and March 2008 in Belgium, Botswana, China, India, Indonesia, South Africa, Thailand and Viet Nam.

Where appropriate, reference is made to the current edition and corrigenda of the published International Standard, *ISO 4074 Natural Latex Rubber Condoms.*

This *WHO/UNFPA Specification* should not be considered nor used as a standard for regulatory purposes.

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

**Optional test: bursting volume and pressure after oven conditioning**

The requirement for testing oven-conditioned (seven days at 70 °C) condoms for airburst properties was deleted from *ISO 4074* with the publication of Corrigendum 2 in 2008. During the internal and external review of this Specification, however, consensus could not be reached on whether to follow the ISO lead and remove this requirement from the *WHO/UNFPA Specification.* It is generally accepted that oven conditioning for seven days at 70 °C does not provide useful information about the shelf-life of a product, but some experts contend that the test may provide a warning of a significant variability in formulation or process.

As an interim measure pending the production of definitive evidence supporting the benefits of testing oven-conditioned condoms on a LOT-by-LOT basis, it has been decided to make this an optional requirement within the Specification. It is at the discretion of the purchaser to decide whether or not to include this requirement in any contract. Purchasers may, for example, decide to include the testing of oven-conditioned condoms from a new manufacturer either until a track record of supplying quality products has been established or if there are any concerns over quality from a specific manufacturer.

Purchasers electing not to include the requirement for testing oven-conditioned condoms in a contract may decide to use methods of assessing whether significant variability in formulation or process is occurring. For example, purchasers may develop systems to monitor the variability in LOT-to-LOT average burst pressures and volumes for untreated condoms (i.e. condoms not subjected to oven conditioning).

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). Further information on methods of monitoring quality using this type of procedure is given is Annex IV.

## 2 WHO/UNFPA Specification

### 2.1 General Requirements

Manufacturers shall include in their Site Master File summary and Product Dossier documentary evidence to confirm that the condoms comply with the following General Requirements. Verification of conformance to these requirements is assessed during prequalification and if the purchaser has doubts whether the product complies with the specification.

General Requirements cover the selection and safety of materials and the shelf-life of the product. Further information relating to the safety of materials can be found in Annexes I and II.

Condoms shall comply with the Performance Requirements of this *WHO/UNFPA Specification* throughout the stated shelf-life of the condom. Manufacturers shall determine the shelf-life by real-time studies conducted at (30 $^{+5}_{-2}$) °C. Pending the outcome of real-time studies, manufacturers may use accelerated studies at (50 ± 2) °C to estimate a provisional shelf-life.

*ISO 4074* describes minimum stability requirements for condoms. These are considered the minimum requirements before placing condoms on the market. It can be assumed that condoms meeting these requirements have a minimum shelf-life of two years. Details of these requirements are also included in the General Requirements of the *WHO/UNFPA Specification.* Data supporting compliance with the Minimum Stability Requirements can be extracted from accelerated ageing (stability) studies. Manufacturers may wish to use the minimum stability test as a screening procedure during product or process development. Purchasers may request that minimum stability studies be completed if there is concern about the shelf-life of a product.

UNFPA requires confirmation that condoms comply with the minimum stability requirements specified in ISO 4074 during prequalification by testing condoms that have been oven conditioned for (168 ± 5) hours at (70 ± 2) °C.

| **General Requirements (to be verified during prequalification)** | |
|---|---|
| **Materials** | |
| | The condoms shall be made of natural rubber latex.<br><br>The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use. |
| **Biocompatibility** | Biocompatibility assessments shall be conducted in accordance with ***ISO 10993–1.*** Specifically, tests shall be conducted for cytotoxicity according to ***ISO 10993–5*** and for irritation and sensitization according to ***ISO 10993–10.*** Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert.<br><br>Expert reports should be available for review.<br><br>*Manufacturers and/or the purchasers are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed.* In accordance with *ISO 10993–1*, manufacturers may provide data on equivalent products. |
| **Water-extractable protein levels** | ***It is recommended* that manufacturers determine the water-extractable levels of proteins in their products.**<br><br>The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than **200 µg/g.** Manufacturers should take steps not to exceed this level and should monitor production periodically.<br><br>There is no specific standard for determining the protein levels in condoms. The methods described in *ISO 12243*, *EN 455–3* and *ASTM D5172* for determining the protein levels in medical gloves can be modified for condoms[1].<br><br>Documentation recording protein levels should be available for review. |

1 For further information about latex allergy and protein levels, refer to Annex I.

| General Requirements (to be verified during prequalification) | |
|---|---|
| **Bioburden levels** | Condoms are not sterile devices, but nevertheless manufacturers should take steps to minimize the risk of contamination of the products with micro-organisms.<br><br>***It is recommended*** **that bioburden levels on packed condoms be maintained below 100 cfu and not be allowed to exceed 500 cfu.** There should be an absence of *Staphylococcus aureus* and *Enterobacteriaceae* including *Escherichia coli* and *Pseudomonas aeruginosa*.<br><br>***It is recommended*** **that bioburden levels be determined periodically,** e.g. at least quarterly, by extracting the condoms with a neutralizing medium and determining the total viable aerobic count using appropriate test methods. Further information on the rationale for the bioburden limits, methods of determining bioburden levels and general guidelines on controlling bioburden contamination during manufacture is given in Annex II. |
| **Nitrosamines** | ***It is recommended*** **that manufacturers take steps to minimize the formation of nitrosamines.** This can be done by ensuring that condoms are adequately leached and washed, by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile[2]. |
| **Dusting powder** | A suitable dusting powder (e.g. cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and to allow them to unroll easily.<br><br>Manufacturers may use other dusting powders with the agreement of the purchaser. In such cases the purchaser may require the manufacturer to justify the choice of dusting powder.<br><br>Talc or lycopodium spores shall not be used.<br><br>***It is recommended*** **that manufacturers not use excess powder** (maximum recommended is **50 mg** per condom). |
| **Shelf-life and stability** | |
| ***Shelf-life*** | Condoms shall comply with the performance requirements of this *WHO/UNFPA Specification* throughout the stated shelf-life of the condom.<br><br>The manufacturer shall determine the shelf-life based on the outcome of stability studies and measured from the date of manufacture. *The date of manufacture is the date that the condoms were dipped.*<br><br>**The claimed shelf-life shall be not less than three years and not more than five years.**<br><br>Shelf-life shall be determined on condoms that have been stored for the maximum period of time between dipping and foiling that is permitted in the standard operating procedures of the manufacturer.<br><br>Shelf-life shall be confirmed by real-time stability studies conducted at (30 $^{+5}_{-2}$) °C [3] according to the relevant clause in *ISO 4074*.<br><br>If results from such studies are not available prior to the prequalification stage, then manufacturers must initiate the studies immediately.<br><br>Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study[4]. |
| **Sampling** | Sample condoms from three manufacturing LOTS in accordance with Annex B of *ISO 4074*. |
| **Conditioning** | Condition condoms at (30 $^{+5}_{-2}$) °C in accordance with the relevant annex of *ISO 4074*. |
| **Testing requirement** | Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074* at least annually for the full shelf-life of the product.<br><br>All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074* for the duration of the stability study.<br><br>If at any time during the real-time studies the manufacturer becomes aware that the shelf-life estimates made using the accelerated studies are incorrect, the manufacturer must notify the purchasers immediately. |

2 Tinkler J et al. Risk assessment of dithiocarbamate accelerator residues in latex-based medical devices: genotoxicity considerations. *Journal of Food Chemistry and Toxicology*, 1998, 36(9–10):849–866. For further details regarding nitrosamines, refer to Annex I.

3 That is, in the temperature range of 28 °C to 35 °C.

4 As described in *ISO 4074*.

| General Requirements (to be verified during prequalification) | |
|---|---|
| ***Provisional shelf-life*** | Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study[5]. |
| **Sampling** | Sample condoms from three manufacturing LOTS in accordance with Annex B of *ISO 4074*. |
| **Conditioning** | Condition condoms at (50 ± 2) °C for 120 days or 180 days in accordance with the relevant annex of *ISO 4074*. |
| **Testing requirement** | Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074*.<br><br>If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **120 days** at (50 ± 2) °C, *a provisional shelf-life of **three years** may be assigned.*<br><br>If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **180 days** at (50 ± 2) °C, *a provisional shelf-life of **five years** may be assigned.* |
| ***Minimum stability requirements*** | Condoms shall comply with the minimum stability requirements defined in the relevant clause of *ISO 4074*. Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of two years. |
| **Sampling** | Three LOTS sampled in accordance with *ISO 2859–1* and Annex B of *ISO 4074*. |
| **Conditioning** | Incubate samples in their individual sealed containers according to the relevant annex of *ISO 4074:*<br>• One set for 168 ± 2 hours at (70 ± 2) °C, and another set for (90 ± 1) days at (50 ± 2) °C.<br>• At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal.<br>• The incubation period at (50 ± 2) °C can be extended to 120 or 180 days in order to estimate a provisional shelf-life by accelerated ageing, in which case testing at 90 days is not necessary. |
| **Testing requirement** | All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074*. |

### 2.2 Performance Requirements

The performance requirements specified here are based on the requirements of *ISO 4074*. These requirements cannot be altered. Verification of compliance with these requirements must be done as part of prequalification and the LOT-by-LOT Pre-shipment compliance testing of the product. For prequalification purposes the sampling plans specified in Annex B of *ISO 4074* shall be used. For LOT-by-LOT Pre-shipment compliance testing the sampling plans specified in Annex A of *ISO 4074* shall be used.

| Performance Requirements | |
|---|---|
| **Bursting volume and pressure** | |
| **Sampling** | In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used. |
| **Testing** | In accordance with test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*. |
| **Requirement** | **Minimum bursting requirements as listed below:**<br><br>**AQL 1.5**<br><br>**Volume:**<br><br>16.0 $dm^3$ for condoms with widths less than 50.0 mm<br><br>18.0 $dm^3$ for condoms with widths from 50.0 mm up to 55.5 mm<br><br>22.0 $dm^3$ for condoms with widths greater than or equal to 56.0 mm<br><br>**Pressure:** 1.0 kPa (for all widths)<br><br>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm. |

5 As described in *ISO 4074*.

| Performance Requirements | |
|---|---|
| **Bursting volume and pressure after oven conditioning (optional: see Annex I[6])** | |
| **Sampling** | In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used. |
| **Testing** | Condition the samples in accordance with the relevant annex of *ISO 4074* for (168 ± 2) hours at 70 °C. Remove from oven and keep the packages at (25 ± 5) °C until tested. Within 96 hours but no sooner than 12 hours after removal from the oven, determine the bursting volume and pressure in accordance with the test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*. |
| **Requirement** | **Minimum bursting requirements as listed below:**<br>**AQL 1.5**<br>**Volume:**<br>16.0 $dm^3$ for condoms with widths less than 50.0 mm<br>18.0 $dm^3$ for condoms with widths from 50.0 mm up to 55.5 mm<br>22.0 $dm^3$ for condoms with widths greater than or equal to 56.0 mm<br>**Pressure:** 1.0 kPa (for all widths)<br>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm. |
| **Freedom from holes and visible defects** | |
| **Sampling** | *ISO 2859–1* General Inspection Level I, but at least Code Letter M.<br>For prequalification testing at least Code Letter N as specified in Annex B of *ISO 4074* shall be used. |
| **Testing** | In accordance with the relevant annex of *ISO 4074*. |
| **Requirement** | In accordance with test method in the relevant annex of *ISO 4074*.<br>Freedom from holes: **AQL 0.25**<br>Critical visible defects: **AQL 0.4**<br>Non-critical visible defects: **AQL 2.5**<br>*ISO 4074* describes a limited number of critical visible defects. WHO specifies an extended list of critical visible defects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2.<br>**Exact definitions of critical and non-critical defects should be reviewed and agreed upon during the contractual process.** |
| **Package seal integrity** | |
| **Sampling** | *ISO 2859–1* Inspection Level S-3. |
| **Testing** | In accordance with the package integrity test method in the relevant annex of *ISO 4074*. |
| **Requirement** | **AQL 2.5** |

6 As an interim measure pending the production of definitive evidence supporting the benefits of testing oven-conditioned condoms on a LOT-by-LOT basis, it has been decided to make this an optional requirement within the *WHO/UNFPA Specification.* Purchasers may wish to include this requirement in specific contracts depending upon the level of confidence in the supplier.

### 2.3 Design Requirements

The design properties listed below may be adapted, where appropriately indicated, to reflect the specific needs of the programme and population of intended users. Modification should be based on information about the target population. Verification of compliance with these requirements is to be done as part of the LOT-by-LOT compliance testing of the product.

If specific design changes are agreed between manufacturer and purchaser, then any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed. Changes in condom design, such as different shapes or the inclusion of pigments, can affect airburst properties and, in some circumstances, freedom from holes.

*It is recommended* that, where changes to the specification are made, dimensional requirements and design features should be subject to *ISO 2859-1* Inspection Level S-2 with an **AQL of 1.0.**

Appropriate reference samples should be maintained by the manufacturer and testing laboratory. The purchaser and/or national regulatory authority may also retain reference samples.

| **Design Requirements** | |
|---|---|
| **Shape and texture** | |
| **Verify by visual inspection** | The surface of the condoms can be textured or non-textured. Texturing typically consists of a number of ribs or dots formed onto the surface of the condom.<br>Condoms may be of any shape consistent with normal commercial practice and client requirements.<br>*If the condom is not parallel-sided and smooth, attach a dimensioned drawing with detailed description, and check here:* ☐ |
| **Integral bead** | |
| **Verify by visual inspection** | The open end of the condom shall have a rolled ring of latex, called an integral bead. |
| **Colour** | |
| **Verify by visual inspection** | Condoms can be translucent or coloured.<br>**Pigments used with coloured condoms shall be suitable for use in medical devices.**<br>If a pigment is required, indicate the colour here and provide full details of the pigment, including a Material Safety Data Sheet (MSDS). ☐ |
| **Odour, fragrance and flavour** | |
| **Verify by visual inspection and smell** | The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf-life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened. A mild odour that dissipates quickly is acceptable.)<br>It is suggested that appropriate reference samples be retained by the testing laboratory to help resolve disputes over odour. It is recommended that the retained samples be kept for the duration of the shelf-life of the condom.<br>Purchasers may specify the addition of a suitable fragrance and/or flavour. Such fragrances and flavours must be non-toxic, non-irritant and not degrade the rubber.<br>If a fragrance is desired, describe here (specify fragrance and amount added) and provide full details of the fragrance, including a Material Safety Data Sheet (MSDS). ☐ |

| Design Requirements | |
|---|---|
| | If a flavour is desired, describe here (specify flavour and amount added) and provide full details of the flavour including a Material Safety Data Sheet (MSDS). |
| **Testing** | See Annex III for guidance on odour testing. If a masking agent or flavour is used, odour testing should become part of the LOT-by-LOT Pre-shipment compliance testing. Odour testing should be included in ageing studies. |
| **Width** | |
| **Sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **Testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **Requirement** | Standard widths within the public sector are 49 mm and 53 mm, with a tolerance of ± 2 mm.<br>**AQL 1.0**<br>Other widths are available and may be more appropriate for specific target populations described in Annex I. Users should select the appropriate width based on the best available data on the target population.<br>Indicate the width here: |
| **Length** | |
| **Sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **Testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **Requirement** | A minimum of 165 mm for condoms with widths less than 50.0 mm.<br>A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm.<br>A minimum of 190 mm for condoms with widths equal to or greater than 56.0 mm.<br>**AQL 1.0**<br>Length may be specified based on the best available data on the target population.<br>Indicate the length here:<br>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (35 ± 15) mm from the open end, rounded to the nearest 0.5 mm. |
| **Thickness** | |
| **Sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **Testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **Requirement** | The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.<br>For partially textured condoms the thickness shall be measured at points closest to those specified above where the surface is smooth. The locations of the points of measurement shall be noted.<br>If it is not possible to locate a smooth region on the condom where thickness can be measured, then thickness shall be measured at the points specified above and the specification should be adjusted to allow for the effect of the texturing—for example, by reference to the manufacturer's specification.<br>**AQL 1.0**<br>The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 + 0.015 mm – 0.020 mm.<br>*Condoms thicker than 0.080 mm are usually considered to be extra thick, whereas condoms that are thinner than 0.060 mm are usually considered to be thin.* There is no evidence that extra thick condoms (sometimes called extra strong) provide additional protection. |

| Design Requirements | |
|---|---|
| **Quantity of lubricant including powder** | |
| **Sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **Testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **Requirement** | The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.<br><br>*Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants* ***should NOT*** *be used.*<br><br>If an alternative lubricant is required, specify the type here and provide full details of the lubricant including a Material Safety Data Sheet (MSDS). ☐<br><br>The quantity of lubricant, including powder, in the package should be (550 ± 150) mg.<br><br>**AQL 4.0**<br><br>*If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.*<br><br>If the lubricant quantity is less than (550 ± 150) mg, indicate here: ☐ |
| **Individual package materials and markings** | |
| **Sampling** | In accordance with *ISO 2859* Inspection Level S-3. |
| **Testing** | The sample of condom packages is visually inspected to verify the required aspects of package quality. |
| **Requirement** | The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to this specification.<br><br>The individual package shall have the following markings:<br>• manufacturer's name;<br>• LOT number or LOT identification code (printed at the time of packaging, not pre-printed);<br>• expiry date: month and year labelled expiry date;<br>• date in a language to be specified by the purchaser.<br><br>*Manufacturing date: Month-and-year manufacturing date can be added if required by purchaser.*<br><br>**AQL 2.5** |
| **Verified by visual inspection** | Individual packages shall be square or circular and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultraviolet and visible light. |
| **Verified by supplier's data or independent test** | The recommended packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminium foil (recommended minimum thickness of 8 micrometres) and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. |

| Design Requirements | |
|---|---|
| **Alternate package materials** | *Alternative package materials can be accepted if they have barrier and strength properties comparable to those of the packaging recommended above or if there are real-time stability data to show that the condom in its pack has adequate shelf-life.*<br><br>If an alternative material is required, append the full specification and mark here: ☐<br>The LOT numbers on packages must be printed at the time of packaging.<br><br>In addition, the following shall apply:<br>• There shall be no evidence of leakage.<br>• The outside surface of the package shall be clean.<br>• There shall be no separation of the layers of laminate.<br>• If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals.<br>• The package must be easy to open without damaging the condom. |

### 2.4 Packaging for shipment

Inspections or verifications in this section will generally be carried out during LOT-by-LOT Pre-shipment compliance testing and periodic inspections.

Information included on all packaging shall be in accordance with the language specified by the purchaser.

| Packaging Requirements | |
|---|---|
| **Consumer packs** | No consumer packs are included in the *WHO/UNFPA Specification*.<br><br>If required, the full design of the consumer pack should be specified in accordance with the requirements of the programme. |
| **Inner boxes** | The inner boxes shall be constructed of cardboard. A suitable moisture-resistant barrier on its inner or outer surfaces may be specified by the purchaser. The boxes shall be of sufficient strength and rigidity to retain their shape through every stage of the distribution chain.<br><br>The inner boxes will be marked in a legible manner to describe the contents and to facilitate identification in case of subsequent query.<br><br>**The following information shall be included in the inner box marking:**<br>• LOT identification number;<br>• month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in language(s) to be specified by the purchaser. The year will be written as a four-digit number and the month as a two-digit number;<br>• month and year of expiry (including the words *Expiry Date, Month, Year*) in language(s) to be specified by the purchaser. The year will be written as a four-digit number and the month as a two-digit number;<br>• manufacturer's name and registered address;<br>• nominal width of the condom, expressed in millimetres;<br>• number of condoms in box;<br>• instructions for storage.<br><br>**Note: All markings must be legible.**<br><br>Inner box markings can be specified in accordance with programme requirements. |

| Packaging Requirements | |
|---|---|
| **Information** | If, in accordance with local regulations or programme requirements, information is to be provided with the condom, then the following instructions should be considered for inclusion:<br>• to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.;<br>• how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body, to assist in the prevention of sexually transmitted infections and pregnancy;<br>• to stop and check if the user feels the condom slipping, as it may fall off the penis;<br>• to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage;<br>• to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;<br>• if an additional lubricant is desired, to use the correct type of lubricant, one that is recommended for use with condoms, and the need to avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom;<br>• to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;<br>• to seek medical assistance at soon as possible within five days, should a condom leak or burst during use;<br>• if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package;<br>• instructions on how to dispose of the used condom;<br>• a statement that the condom is for single use;<br>• the number of the International Standard, i.e. *ISO 4074*.<br>***It is recommended* that the following statement relating to the safety and effectiveness of the condom be included:**<br>**"When used correctly every time you have sex, condoms greatly reduce the risk of unintended pregnancy, HIV/AIDS and some other sexually transmitted infections. Use a new condom every time you have sex and follow the instructions carefully."** |
| **Exterior shipping cartons** | The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fibreboard with a bursting test strength of not less than 1900 kPa.<br>The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps, or with 75 mm wide water-resistant tape applied to the full length of the centre seams and extending over the ends by not less than 75 mm.<br>The cartons may be secured by plastic strapping at not less than two positions.<br>Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.<br>The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.<br>In some countries the three-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases an inner carton of two-walled corrugated fibreboard shall be inserted into the shipping carton before packing the condoms. |

| Packaging Requirements | |
|---|---|
| | The exterior shipping carton, like the inner box, shall be marked with information about the contents in a clearly legible manner. The information shall include:<br>• LOT identification number;<br>• month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in language(s) to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number;<br>• month and year of expiry (including the words *Expiry Date, Month, Year*) in language(s) to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number;<br>• name and address of supplier;<br>• nominal width;<br>• number contained in the carton;<br>• instructions for storage and handling.<br>To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together. |
| **LOT traceability** | Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.<br><br>These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel. |

### Summary tables

The following tables summarize the testing methods and requirements for packaging defects, general requirements, performance requirements and design requirements for prequalification and LOT-by-LOT compliance testing.

| Table 1. Classification of defects in packaging and marking of packaging for delivery | |
|---|---|
| **Examine** | **Defects** |
| **Contents** | Number of condoms not as specified; packages or strips not as specified. |
| **Marking** | Omitted; incorrect; illegible; of an improper size (exterior, interior), incorrect location, sequences, or method of application. |
| **Materials** | Packaging/packing materials not as specified, missing, damaged or non-serviceable. |
| **Workmanship** | Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages. |

The following tables summarize the different requirements for prequalification and pre-shipment testing. For pre-shipment testing, which is required prior to the consignment of condoms, samples sizes will be selected in accordance with *ISO 4074: 2002* Annex A and will be inspected and tested against technical specifications that govern the respective agreement or purchase orders. All testing activities will be conducted under *ISO 17025* accreditation.

For prequalification testing, UNFPA requires that three lots of condoms be randomly selected for testing. At the time of the prequalification inspection, the inspected factory may not be producing condoms against the *WHO/UNFPA Male Latex Condom Specification, 2010*. Thus, the manufacturer may not be producing condoms that comply with the full requirements of the *WHO/UNFPA Male Latex Condom Specification, 2010*. This applies in particular to requirements for package marking and labelling, but may apply to other properties such as dimensions. Inspectors and/or inspection companies shall select condom lots for testing that comply as closely as possible with the requirements of the *WHO/UNFPA Male Latex Condom Specification 2010*. The selected sample must comply with and will be tested against the requirements of *ISO 4074: 2002*.

UNFPA includes testing condoms that have been oven conditioning for (168 ± 5) hours at (70 ± 2) °C for bursting pressure and volume during prequalification testing to confirm that the condoms comply with the minimum stability requirements specified in Clause 7.2 of *ISO 4074: 2002*. In anticipation of changes in the next edition of *ISO 4074* (which is expected to be published later in 2013) UNFPA also requires testing for freedom from holes and visible defects, and package integrity after oven conditioning for (168 ± 5) hours at (70 ± 2) °C for prequalification testing.

**Table 2. Summary of prequalification tests and requirements**

| **Sample according to Annex B of *ISO 4074* for "isolated LOTS" and *ISO 2859–1*** | | |
|---|---|---|
| **Test** | **Sampling** | **Requirements** |
| Verification of constituent materials | NA | Manufacturer's documentation |
| Verification of shelf-life | NA | Manufacturer's documentation |
| Minimum stability (if required) | As listed below for burst volume, burst pressure, freedom from holes and package integrity | As listed below for burst volume, burst pressure, freedom from holes and package integrity |
| Bursting volume (before and after oven conditioning) | Level G-I<br>Minimum Code Letter M | Minimum volumes:<br>1. **16.0** $dm^3$ for condoms with widths less than 50 mm<br>2. **18.0** $dm^3$ for condoms with widths from 50 mm to 55.5 mm<br>3. **22** $dm^3$ for condoms with widths greater than 56 mm<br>AQL 1.5 |
| Bursting pressure (before and after oven conditioning) | Level G-I<br>Minimum Code Letter M | Minimum pressure: 1.0 kPa<br>AQL 1.5 |
| Freedom from holes (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C) | Level G-I<br>Minimum Code Letter N | AQL 0.25 |
| Visible defects (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C) | Level G-I<br>Minimum Code Letter N | Critical defects: AQL 0.4<br>Non-critical defects: AQL 2.5 |
| Shape and texture | Agreed between manufacturer and buyer | Visual inspection |
| Package integrity (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C | Level S-3<br>Minimum Code Letter H | AQL 2.5 |
| Integral bead | Agreed between manufacturer and buyer | Visual inspection |
| Colour | Agreed between manufacturer and buyer | Visual inspection |
| Fragrance and flavouring | Agreed between manufacturer and buyer | Sensory inspection |
| Width | Level S-2 | ± 2 mm of claimed width<br>AQL 1.0 |
| Length | Level S-2 | 1. **165** mm for widths less than 50 mm<br>2. **180** mm for widths between 50 mm and 55.5 mm<br>3. **190** mm for widths of 56.0 and above<br>AQL 1.0 |
| Thickness | Level S-2 | 0.045–0.080 mm<br>AQL 1.0 |
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes<br>Qty: 400–700 mg/condom<br>AQL 4.0 |
| Odour (if necessary) | Agreed between manufacturer and buyer | Sensory inspection |
| Inner box | Level S-3 | Compliant with procurement specifications |
| Exterior shipping cartons | Level S-2 | Compliant with procurement specifications |

| Table 3. Summary of LOT-by-LOT Pre-shipment compliance testing and requirements | | |
|---|---|---|
| **Sample according to Annex A in *ISO 4074* for "continuous LOTS" and *ISO 2859–1*** | | |
| **Test** | **Sampling** | **Requirements** |
| Bursting volume (before and after oven conditioning) | Level G-I | Minimum volumes:<br>1. **16.0** $dm^3$ for condoms with widths less than 50 mm<br>2. **18.0** $dm^3$ for condoms with widths from 50 mm to 55.5 mm<br>3. **22** $dm^3$ for condoms with widths greater than 56 mm<br>AQL 1.5 |
| Bursting pressure (before and after oven conditioning) | Level G-I | Minimum pressure: 1.0 kPa<br>AQL 1.5 |
| Freedom from holes | Level G-I<br>Minimum Code Letter M | AQL 0.25 |
| Visible defects | Level G-I<br>Minimum Code Letter M | Critical defects: AQL 0.4<br>Non-critical defects: AQL 2.5 |
| Shape and texture | Agreed between manufacturer and buyer | Visual inspection |
| Package integrity | Level S-3 | AQL 2.5 |
| Integral bead | Agreed between manufacturer and buyer | Visual inspection |
| Colour | Agreed between manufacturer and buyer | Visual inspection |
| Fragrance and flavouring | Agreed between manufacturer and buyer | Sensory inspection |
| Width | Level S-2 | ± 2 mm of claimed width<br>AQL 1.0 |
| Length | Level S-2 | 1. **165** mm for widths less than 50 mm<br>2. **180** mm for widths between 50 mm and 55.5 mm<br>3. **190** mm for widths of 56.0 and above<br>AQL 1.0 |
| Thickness | Level S-2 | 0.045–0.080 mm<br>AQL 1.0 |
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes<br>Qty: 400–700 mg/condom<br>AQL 4.0 |
| Odour (if necessary) | Agreed between manufacturer and buyer | Sensory inspection |
| Inner box | Level S-3 | Compliant with procurement specifications |
| Exterior shipping cartons | Level S-2 | Compliant with procurement specifications |
| Individual package materials and markings | Level S-3 | Compliant with procurement specifications<br>AQL 2.5 |

# CHAPTER 3

# Workmanship and Visible Defects

# CHAPTER 3: WORKMANSHIP AND VISIBLE DEFECTS

## 1 Introduction

All condoms in the sample are inspected for workmanship as part of the test for freedom from holes prior to mounting on the test equipment. The number of condoms exhibiting a visible defect is recorded, and defects are classified either according to the type of defect listed below or as specified in the contract.

Visible defects are divided into (a) critical visible defects and (b) non-critical visible defects.

The condom packs in the sample also are inspected for visual defects before the samples are removed for testing.

## 2 Types of visible defects

It is not possible to define all critical and non-critical visible defects, and it may be necessary to exercise some judgement about whether a particular visible defect is critical. (If you need assistance, contact the Help-Line: HELPLINEcondomquality@fhi360.org.)

If the visible defect may affect the performance of the condom, the defect is considered critical. If a defect not listed below is considered critical by any party, then the purchaser, test laboratory and manufacturer must consult with each other to agree on the classification of the defect concerned.

### 2.1 Critical visible defects

Critical visible defects may adversely affect the performance of the condom. Condoms having critical visible defects are therefore non-conforming.

The most common critical visible defects are covered by *ISO 4074*. These defects include broken, missing or severely distorted beads and permanent creases with adhesion of the film. They are evaluated by visual inspection as part of the procedure for testing for freedom from holes. An AQL of 0.4 is applied to these defects.

Other types of critical visual defects are occasionally seen, and they should be assessed for their potential effect on the performance and acceptability of the condom.

Some of the more common critical visible defects are described in Table 4.

**Table 4. Critical visible defects**

| AQL 0.4 | |
|---|---|
| **Defect** | **Description** |
| Pleat/crease | The film sticks to itself, and the pleat/crease cannot be removed by gentle stretching of the adjacent film. |
| Blister/bubble | An obvious circular or teardrop-shaped thin area with a well-defined border in the film. (Such defects may break under pressure.) |
| Coagulum (large) | Rubber particles with any dimension greater than 1 mm. These may cause the condom to fail in use. |
| Embedded and surface particles | Any particle with any dimension of 1 mm or greater. These may be dirt, hair, insects, powder granules, etc. |
| Bead defects | Faulty, missing or severely distorted beads (as in *ISO 4074*). |
| Crack marks | Lines that penetrate the surface of the film, formed by shrinkage of the latex during drying. These do not include flow lines or marks from the mould. |
| Delamination | Areas where the individual layers of latex separate. (Condoms are formed by two or more dips in the liquid latex.) |
| Thin areas | Small areas of the condom (including the teat) that are visibly thin. These can show up as bulges with well-defined edges on the freedom-from-holes test. Condoms that look asymmetrical when filled with water are not necessarily in this category (see Table 6). |

### 2.2 Non-critical visible defects

Non-critical visible defects are considered minor defects, as they may not cause the condom to fail the specification. Nevertheless, they are undesirable from the user's standpoint. If non-critical visible defects are specified in a purchase specification, then an AQL of 2.5 is recommended.

Depending upon the requirements of the specific user population, the purchaser may wish to include in the specification specific non-critical visible defects, including the most common ones, as listed in Table 5. Detailed descriptions of the non-critical visible defects should be discussed with the manufacturer and included in the contract.

**Table 5. Non-critical visible defects**

| AQL 2.5 | |
|---|---|
| **Defect** | **Description** |
| Embedded and surface particles (small) | Particles with dimensions less than 1 mm that are visible to the naked or corrected eye. |
| Faulty bead (minor) | Uneven and partially distorted beads. |
| Uneven colour | Minor streaking |

Other types of non-critical defects should be assessed to determine if they will affect the acceptability of the product.

### 2.3 Imperfections

Occasionally, imperfections can be seen in condoms that do not affect the performance or acceptability of the condom. A list of the more common imperfections that fall into this category is given in Table 6. No action should be taken when these imperfections are seen.

## 3 Packaging defects

The main packaging defects are listed in the *WHO/UNFPA Specification.* Additional defects are sometimes detected only after shipment. This section summarizes common types of packaging defects, including those detailed in the *WHO/UNFPA Specification.*

*Individual packages*

The quality of the individual foil packages shall be assessed by visual inspection, using a sampling plan in accordance with *ISO 2859–1* Inspection Level S-3. An AQL of 2.5 shall be applied to these defects collectively. Packaging defects are summarized in Table 7.

**Table 6. Imperfections that are not regarded as defects**

| AQL 0.4 | |
|---|---|
| **Phenomenon** | **Description** |
| Micro-coagulum | Particles of rubber with dimensions less than 1 mm. |
| Flow lines | Lines of denser material in the film. |
| Concave spot at end of teat | An apparent indentation caused during the withdrawal of the former (dipping mould) from the latex. |
| Distortion due to rolling | Apparent variations in condom width due to stretching during rolling. |
| Bulges | Large bulges or distortion of the condom during the freedom-from-holes test that are due to differences in thickness around the wall of the condom caused by relative movement of the latex and the former (dipping mould) during dipping. (These may or may not have well-defined edges.) |
| Uneven lubricant | The open end of the condom may appear dry, especially on new condoms. The lubricant penetrates the roll slowly. |

Note: Any visible hole anywhere in the condom, including under the bead, is not acceptable. These defects are counted as holes if they can be seen before water is added to the condom, even if they are within 25 mm of the open end.

*Consumer packs*

There are no requirements for consumer packs included in the *WHO/UNFPA Specification.* Purchasers should fully specify requirements in accordance with programme needs. Compliance should be assessed by visual inspection, using a sampling plan in accordance with *ISO 2859–1* Inspection Level S-3. It is recommended that an AQL of 2.5 be applied to consumer pack requirements.

*Cartons and marking*

Purchasers should fully specify requirements in accordance with programme needs. Compliance should be assessed by visual inspection, using a sampling plan in accordance with *ISO 2859–1* Inspection Level S-3. It is recommended that an AQL of 4.0 be applied to carton requirements.

**Table 7. Packaging defects**

| | |
|---|---|
| **Individual foil packaging defects** | |
| Empty package | Missing manufacturer's name |
| No lubricant | Incorrect/missing LOT number |
| Lubricant leakage | Incorrect/missing manufacture date |
| Delamination of the packaging film | Incorrect/missing expiry date |
| Discoloured film and labels | |
| **Consumer packs** | |
| Missing manufacturer's name | Empty or partially filled packs |
| Incorrect/missing LOT number | Discoloration |
| Incorrect/missing manufacturer date | Delamination |
| Incorrect/missing expiry date | |
| **Cartons and markings** | |
| Missing manufacturer's name | Non-permanent marking |
| Incorrect/missing LOT number | Empty or partially filled cartons |
| Incorrect/missing manufacture date | Damaged cartons that may affect the integrity or quality of the condoms inside |
| Incorrect/missing expiry date | |

# CHAPTER 4

# Resolution of Disputes

# CHAPTER 4: 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;
- condition of the condoms on arrival in-country or at some time after delivery.

It is essential that the procurement contract specify a process for the resolution of any disputes that might arise over contract or product quality issues.

## 2 Disputes over laboratory results

Disputes over product acceptance most often arise when independent testing determines that the product is not in compliance with 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 errors.** 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 they are in compliance with the relevant AQLs. Manufacturers can minimize this risk 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 are actually in compliance to less than 1%.
- Manufacturers and purchasing agencies should plan on the assumption that some LOTS, possibly up to 5%, will be rejected. Estimates of volume requirements and pricing should take into account the impact of 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 significant chance of being accepted.

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 IV.

It is because of these issues that WHO/UNFPA recommends that only one accredited laboratory undertake the Pre-shipment compliance testing.

## 4 Decisions on re-testing

Re-testing should be undertaken only when:

1. There is considerable evidence that the laboratory has made a mistake.
2. There is considerable evidence that the test result is not representative of the population from which the LOT is taken.

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 is not in compliance with 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 IV.

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.

If there is a dispute over a LOT or shipment of condoms, then the laboratory should keep non-conforming condoms 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 IV. If this process average is within the AQL, a re-test may be allowed.

## 5 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* than the one used for the first sample (e.g. G-II instead of G-I).

Where possible the re-tested sample should be taken from the laboratory's retained sample or the duplicate 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 a result is disputed, the laboratory and the manufacturer should be asked to verify basic issues, including:

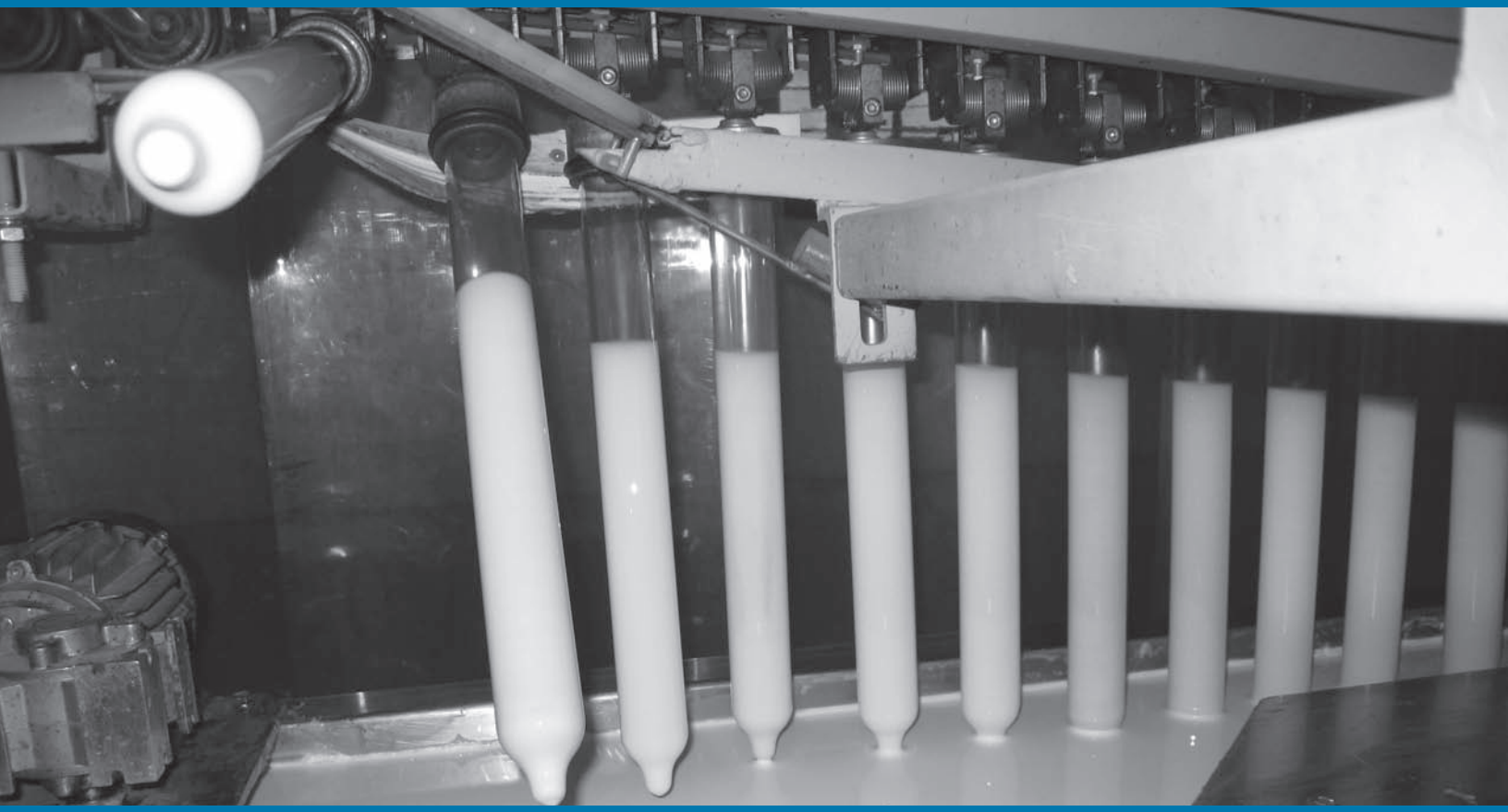
### 5.1 Independent testing laboratory

- 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 the identity of the test samples and that the normal precautions were taken not to damage the samples prior to testing;
- verify the uncertainty estimates being applied to the measurements.

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

### 5.2 Manufacturer

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



# CHAPTER 5

# Male Latex Condom Prequalification Scheme

# SECTION TWO
# CHAPTER 5: MALE LATEX CONDOM PREQUALIFICATION SCHEME

## 1 Introduction

### 1.1 Background

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.

Until 2002 the World Health Organization (WHO) undertook the procurement of condoms. In 2002 this responsibility was transferred to the United Nations Population Fund (UNFPA). WHO, however, continued its normative work and, together with key partners, developed recommended international specifications for condoms and technical and procurement guidelines. The guidelines were published in 2004 as *The Male Latex Condom: Specification and Guidelines for Condom Procurement.* They include an update of the specifications and recommended procedures for the prequalification, procurement and Pre-shipment compliance testing of condoms.

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 the Selection and Use of Essential Medicines.* From this list and based on the recommendations of members of the Reproductive Health Supplies Coalition (RHSC), it was agreed that WHO would include a core group of reproductive health essential medicines in its Prequalification Scheme, implementation of which began in 2006. It was agreed that, as part of this activity, UNFPA would take the responsibility for the prequalification of intrauterine devices (IUDs) and male latex condoms and that the Prequalification Scheme for IUDs and condoms would be harmonized with the WHO Prequalification Scheme for Essential Medicines[1].

This chapter describes the implementation of the Prequalification Scheme for the male latex condom. The Prequalification Scheme is supported by a specific UNFPA management system with detailed standard operating procedures (SOPs).

### 1.2 Objectives

The overall objective is to implement a scheme to prequalify manufacturers of male latex condoms 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 male latex condoms from manufacturing sites that have been judged to have the capacity to produce good-quality products;
- establish a system that promotes the procurement of good-quality products that conform to the latest edition of the international standard *ISO 4074*[2] and the *WHO/UNFPA Specification* for the male latex condom, as detailed in this document, and that retain their effectiveness throughout their stated shelf-life;
- broaden the base of suppliers for male latex condoms that are deemed acceptable, in principle, for procurement by United Nations agencies and other bulk procurement agencies;
- maintain and publish a list of prequalified suppliers.

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

## 2 The Prequalification Scheme for male latex condoms

### 2.1 Eligibility to participate

The Prequalification Scheme is intended for manufacturers of male latex condoms who undertake the processes of formulation, compounding and dipping, as well as for manufacturers using pre-vulcanized latex, as specified

1 *Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies*. WHO Technical Report Series, No. 948, May 2008.

2 ISO documents are available from: International Organization for Standardization, ISO Secretariat, 1, ch. de la Voie-Creuse, CP 56, 1211 Geneva 20, Switzerland (http://www.iso.org).

by UNFPA in the call for Expressions of Interest (EOI) referred to in Clause 2.2, below. An agent may respond to the EOI on behalf of a manufacturer who undertakes the manufacturing process described above.

## 2.2 Expression of Interest

### *2.2.1 Calls for and submission of Expressions of Interest*

Invitations to interested parties to submit Expressions of Interest (EOI) are published at regular intervals on the web sites of the United Nations Global Marketplace (UNGM) (http://www.ungm.org), UNFPA (http://www.unfpa.org/public/procurement) and WHO (http://www.who.int/prequal/).

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, such as male latex condoms. The applicants or manufacturers should submit their EOIs to the UNFPA focal point with the relevant information requested in the invitation. The applicants or 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 2.11, Language).

UNFPA will receive and record the EOI from each applicant/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 (see Chapter 6).

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

- a covering letter expressing interest in participating in the WHO/UNFPA Prequalification Scheme and confirming that the information submitted in the Product Dossier and Site Master File summary is complete and correct;
- a Product Dossier in the format specified in the WHO/UNFPA guidance documents for submitting product data and information (see Chapter 6);
- ten product samples, as examples of products produced;
- a Site Master File summary for each manufacturing site listed in the Product Dossier in the requisite format specified in the WHO/UNFPA guidance documents for submitting a Site Master File summary (see Chapter 6, Clause 3).

The Quality Manual information 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 applicants that are corporations); specific certification/licences required in the country for manufacturing and exporting; and other legal documents, such as trading certificates. Contact information of bankers, including all appropriate banking account references and codes, shall also be included.

The documentation should be submitted in English and sent by courier or registered mail (see Clause 2.11, Language). Manufacturer must provide an electronic version (CD or USB) of this material. The electronic version must be in addition to, and not in place of, the hard copy of the documentation.

### *2.2.2 Assessment of documents submitted*

The aim of the assessment of the submitted documentation will be to determine whether the applicant/manufacturer meets the minimum requirements detailed in the relevant ISO standards and *WHO/UNFPA Specification* with respect to product quality and safety, production and quality management, regulatory approvals and capacity of production.

*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 it contains all the required information.

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

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

UNFPA will exchange letters with the applicant/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 Product Dossier and the Site Master File summary*
UNFPA aims to convene a team of experts acting as assessors to complete the assessment of the Product Dossier and the Site Master File summary within a specified time period (90 days) of the closing date for receipt of responses.

The submissions will be evaluated by assessors with documented qualifications and relevant experience. The selection of assessors and the assessment will be carried out in accordance with existing United Nations procedures for the selection of consultants and experts. The team of assessors may include one or more inspectors responsible for subsequent inspections of the manufacturing sites. The assessors must comply with the confidentiality and conflict of interest rules of UNFPA, as laid down in Clauses 3 and 4 of this chapter.

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.

In making its assessment, UNFPA may take into account information submitted by the applicant during previous applications that may be in UNFPA's possession, including results from previous site inspections and laboratory test results on 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 Chapter 6 and on the WHO and UNFPA web sites, the manufacturing site will be scheduled for inspection.

## 2.3 Site inspection

UNFPA will plan and coordinate inspections at the manufacturing sites to assess the manufacturing process and the product and quality management systems for compliance with general and performance requirements of the *WHO/UNFPA Specification* and good management practice, including in particular the following international standards:

- *ISO 4074 Natural Latex Rubber Condoms—Requirements and Test Methods;*
- *ISO 13485 Medical Devices—Quality Management Systems: Requirements for Regulatory Purposes;*
- *ISO 10993–1 Biological Evaluation of Medical Devices. Part 1.* Evaluation and Testing and other relevant parts of this standard.

### *2.3.1 Inspection team*

The inspection will be performed by a team of inspectors consisting of experts appointed by UNFPA, who will act as temporary advisers to UNFPA. The inspectors must have documented qualifications, detailed knowledge of male latex condom manufacturing processes, expertise in auditing and quality management systems, and specific experience in inspecting condom 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 chapter. 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 the coordination of 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 and will provide their curricula vitae. The manufacturer then 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. In the event of such an objection, UNFPA may cancel all or part of its agreement with, and the activities to be undertaken by, that inspector.

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 Part 3 and 4 of the procedure.

#### *2.3.2 Scope and scheduling*

Prior to the inspection the applicant/manufacturer will be informed of the scope of the inspectors' planned activities. The key components of the inspection are described in Section 2, Chapter 6 of this document and on the WHO and UNFPA web sites under the heading *"Scope of manufacturing site inspection: male latex condoms"*. 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 applicant 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 applicant/manufacturer that the inspectors may request copies of documents presented as evidence during inspection and may request permission to make a photographic record of the inspection, subject always to considerations of confidential information, as referred to in Clauses 2.5 and 3 of this chapter.

#### *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 to and from the airport or station and 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 applicants or manufacturers do not make any offers of gifts of whatever value to the inspectors and/or UNFPA staff.

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

- any of the facilities that are in any way involved in the production of the product(s) concerned;
- 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 will lead to termination of the site inspection.

### 2.4 Product testing

Products will be sampled for independent testing, prior or subsequent to the inspection, by an independent sampler appointed by UNFPA or by the inspectors at an appropriate point during the inspection. Further sampling may be requested before completion of specific supply contracts, particularly in response to tenders issued more than a year after a manufacturer has been prequalified. Again, sampling will be undertaken by an independent sampler under the direction of UNFPA.

The samples will be packed and sealed by the inspectors or the independent sampler, as may be appropriate. The inspectors may take the samples with them or arrange for the manufacturer to have the sealed boxes sent to the selected laboratory by courier at UNFPA's expense.

The sample size is taken in accordance with the current international standard for male latex condoms, *ISO 4074* Annex B. The range of tests to be conducted will be in accordance with the *WHO/UNFPA Specification;* refer to Chapter 2. All product testing will be undertaken by independent, accredited test laboratories selected by UNFPA. Such test laboratories must possess defined and documented competence and experience as demonstrated by accreditation to the current *ISO 17025* standard.

A copy of the test report will be provided to the applicant/manufacturer.

### 2.5 Reporting and communication of the results of the site inspection

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.

In addition, the inspection team will finalize its main report according to the established UNFPA SOP and format, describing the findings, evidence and recommendations. The report will be submitted to UNFPA.

The inspection report will be communicated by UNFPA to the applicant and/or manufacturer. If any additional information is required, or corrective action has to be taken by the applicant/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 UNFPA inspectors.

UNFPA reserves the right to terminate the procedure of quality assessment of a specific manufacturing site/product if the applicant/manufacturer is either not able to provide the required information or not able to implement the corrective actions within a specified time period, or if the information supplied is inadequate to complete the quality assessment process.

In the event of any disagreement between an applicant and UNFPA, an SOP established by UNFPA for the handling of appeals and complaints will be followed to discuss and resolve the issue.

The ownership of any of the reports produced in 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 to the protection of any commercially confidential information of the applicant and/or manufacturer. Confidential information may include:

- confidential intellectual property, "know-how" and trade secrets (e.g. formulas, programmes, process or information contained or embodied in a product, unpublished aspects of trademarks, patents);
- 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 Product Dossier or inspection of the manufacturing site(s), between UNFPA and each applicant/manufacturer.

Notwithstanding the foregoing, UNFPA and WHO reserve the right to 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.

### 2.6 Decision to prequalify

It is UNFPA's responsibility to compile the information submitted in response to the invitation for EOI, the assessment report, the inspection report and the test report. A UNFPA staff member with appropriate experience and training will assess the information about each applicant/manufacturer and, in consultation with the assessors and inspectors, will make a final decision about the outcome of the prequalification process.

Based on this assessment, UNFPA will either:

- Prequalify male latex condoms manufactured at a specific site without conditions. This will only be the case when no evidence that corrective action should be taken is submitted to UNFPA.

  **or**

- Require the manufacturer, where deemed necessary, to undertake specified corrective action(s). The inspectors may also recommend further inspection[3] and/or product testing once the corrective actions have been completed. The manufacturer must carry out the corrective action within an agreed time period and provide UNFPA with evidence, where required, showing that the corrective action has been taken. If UNFPA is satisfied with this additional information, the manufacturing site will be added to the list of prequalified condom manufacturers.

  **or**

- Determine that a manufacturing site is ineligible for prequalification (without any requirement for corrective action being offered). This will not, however, preclude the applicant/manufacturer from resubmitting an application in response to future invitations for EOIs.

Where the inspectors recommend corrective action requiring a subsequent inspection, 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. After review of the evidence, UNFPA will decide whether or not to schedule a further inspection.

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 chapter. Any re-inspection may be at the expense of the manufacturer.

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

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

The findings of the inspection may include non-mandatory observations aimed at highlighting potential for improved manufacturing and quality management practices.

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 in light of the specified international standards, as detailed in the list of relevant standards on page 61 of this chapter.

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

Each applicant 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.

### 2.7 Listing of prequalified male latex condoms and manufacturing sites

Once UNFPA is satisfied that the quality assessment process is complete and where the Product Dossier and corresponding manufacturing site have been found to meet the prequalification requirements, the

3 In accordance with SOPs, UNFPA may require the manufacturer to pay for a re-inspection.

product produced at the specified manufacturing site(s) will be listed on the WHO and UNFPA prequalification web sites.

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

### 2.8 Maintenance of prequalification status

Once the product is included in the list of prequalified male latex condoms and corresponding manufacturing sites, the applicant/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 condom design;
- change in suppliers of latex not previously listed in the Site Master File summary;
- change in specification of raw materials;
- change in packaging;
- new information about shelf-life.

It is the applicant's responsibility to provide UNFPA with the appropriate documentation (referring to relevant parts of the Dossier) 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 the applicant. Compliance with the requirement to report changes will be checked during the inspections carried out by UNFPA.

### 2.9 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 male latex condoms 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 male latex condoms *ISO 4074* Annex B. The range of tests to be conducted will be in accordance with LOT-by-LOT Pre-shipment compliance testing as detailed in the *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010.*

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 applicant, 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 male latex condoms.

Complaints communicated to UNFPA concerning male latex condoms procured through this Prequalification Scheme 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 applicant/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, subject always to considerations of commercially confidential information, as referred to in

Clause 2.5, above. 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 summary report and/or recommendations for action with WHO and relevant authorities of interested Member States of WHO.

### 2.10 Reassessment

UNFPA aims to undertake a reassessment of male latex condoms manufactured at a specific site at intervals of no more than three years. Such reassessments will consist of a comprehensive evaluation of documentation, site inspection and product testing similar to the initial prequalification assessment.

Reassessment may also be required in the following situations:

- if the male latex condoms 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, as detailed in *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010;*
- if a complaint considered serious in nature has been received by UNFPA or one or more of the other United Nations agencies or organizations;
- if there is a significant change in the manufacturing process in respect to one or more of the items listed in Clause 2.8, 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 male latex condom and its manufacturing site on the list of prequalified products without need for corrective actions;

  **or**

- maintain the prequalification status of the male latex condom 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 prequalified status.

UNFPA aims to advise the applicant/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.

### 2.11 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 applicant 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 an interpreter is required for the inspection.

### 2.12 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 Scheme.

Currently, the process is conducted by UNFPA free of charge. UNFPA reserves the right, however, to charge a fee on a cost-reimbursement basis.

### 2.13 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;
- 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.

## List of relevant international standards

**(The latest edition of each standard should be applied.)**

*ISO 4074. Natural Latex Rubber Condoms—Requirements and Test Methods.* International Organization for Standardization.

*ISO 16038. Rubber Condom—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms.* International Organization for Standardization.

*ISO 13485. Medical Devices—Quality Management Systems: Requirements for Regulatory Purposes.* International Organization for Standardization.

*ISO 10993–1. Biological Evaluation of Medical Devices. Part 1. Evaluation and Testing.* International Organization for Standardization.

*ISO 10993–5. Biological Evaluation of Medical Devices. Part 5. Tests for in vitro Cytotoxicity.* International Organization for Standardization.

*ISO 10993–10. Biological Evaluation of Medical Devices. Part 10. Tests for Irritation and Skin Sensitization.* International Organization for Standardization.

*ISO 17025. General Requirements for the Competence of Testing and Calibration Laboratories.* International Organization for Standardization.

The latest editions of all international standards are available from:

**International Organization for Standardization (ISO)**
ISO Central Secretariat
1, ch. de la Voie-Creuse
CP 56
1211 Geneva 20, Switzerland
Telephone: +41 22 749 0111
Fax: +41 22 733 3430
E-mail: central@iso.org
http://www.iso.org

# CHAPTER 6

# Operational Guidance—Male Latex Condoms WHO/UNFPA Prequalification Scheme

## SECTION TWO

# CHAPTER 6: OPERATIONAL GUIDANCE—MALE LATEX CONDOMS WHO/UNFPA PREQUALIFICATION SCHEME

## 1 Introduction

The manufacturers on the list of prequalified male latex condom manufacturing sites offer products that, as part of the WHO/UNFPA Prequalification Scheme, have been found to be acceptable, in principle, for procurement by United Nations agencies.

The aim of the WHO/UNFPA Prequalification Scheme is to determine whether the applicant/manufacturer meets the minimum requirements detailed in the relevant ISO standards[1] and the *WHO/UNFPA Specification* in respect of product quality and safety, production and quality management, regulatory approvals and capacity of production.

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

- evaluation of documents submitted in response to an invitation for an Expression of Interest (EOI);
- manufacturing site inspection;
- product testing;
- review of testing and inspection reports to inform a decision about the acceptability of each applicant;
- publication and periodic updating of a list of prequalified products and manufacturing sites on WHO and UNFPA web sites.

Periodic reassessment of the prequalification status of the product and manufacturing site will be undertaken at intervals of every three years or less.

The Prequalification Scheme was approved for publication by the 42nd WHO Expert Committee on Specifications for Pharmaceutical Preparations, October 2007, and published as WHO Technical Report, No. 948, May 2008[2].

**The purpose of this document is to outline the procedures required by WHO/UNFPA to:**

- respond to an invitation for Expression of Interest;
- prepare a Product Dossier;
- prepare a Site Master File (SMF) summary;
- support a manufacturing site inspection.

### 1.1 Invitation for Expression of Interest

Invitations to interested parties to submit an Expression of Interest (EOI) are published at regular intervals on the web sites of the United Nations Global Market Place (UNGM) (http://www.ungm.org), UNFPA (http://www.unfpa.org/public/procurement) and WHO (http://www.who.int/prequal/) and possibly through other media, such as the international press.

Each invitation will be open and transparent, inviting all relevant parties to submit EOIs for the product listed. The applicant/manufacturer will be given a specified period to submit the responses from the time of publication of the advertisement.

In situations of high public health concern, as determined by WHO, UNFPA may also directly invite relevant parties to submit their product for assessment by UNFPA under this procedure without publication of an invitation for EOIs.

Manufacturers/applicants should submit their EOIs to the UNFPA focal point with the relevant information requested in the invitation. UNFPA will receive and record the EOI from each manufacturer and issue an acknowledgement of receipt.

The official language of the Prequalification Scheme 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 copy of the translation into English. Manufacturer must provide an electronic version (CD or USB) of this material. The CD-ROM must be in addition to, and not in place of, the hard copy of the documentation.

1 ISO documents are available from: International Organization for Standardization, ISO Secretariat, 1, ch. de la Voie-Creuse, CP 56, 1211 Geneva 20, Switzerland (http://www.iso.org).

2 *Procedure for assessing the acceptability, in principle, of male latex condoms for procurement by United Nations agencies.* WHO Technical Report Series, No. 948, May 2008.

All correspondence between UNFPA and the applicant will be in English. All reports on the inspections issued by the inspectors and by UNFPA will be in English.

**The Prequalification Scheme does not apply to agents, distributors or suppliers engaged only with testing, lubricating and packaging.**

The Prequalification Scheme is intended for male latex condom manufacturers who undertake the processes of formulation, compounding and dipping, as well as for manufacturers using pre-vulcanized latex, as specified by UNFPA in the call for EOIs. An agent may respond to the request for EOI on behalf of a manufacturer who undertakes the processes described above.

### 1.2 Data and information to be submitted

Interested applicants must submit to the UNFPA focal person the following documentation in hard copy:

- covering letter, expressing interest in participating in the UNFPA prequalification procedure and confirming that the information submitted in the Product Dossier and Site Master File summary is complete and correct;
- Product Dossier, in the format specified in the WHO/UNFPA guidance documents for submitting product data and information;
- product samples as examples of products produced;
- a Site Master File summary, for each manufacturing site listed in the Product Dossier, in the format specified in the WHO/UNFPA guidance documents for submitting a Site Master File summary;
- copies of all current certifications/accreditations, all manufacturing licences/registrations held, and a copy of the company registration;
- copies of certificates and relevant documentation as applicable in the country where the site is located, such as:
  - the certificate stating the principal place of incorporation (for applicants that are corporations)
  - specific certification/licences required in the country for:
    - manufacturing
    - exporting
  - other legal documents, such as Trading Certificates;
- contact information of bankers, including all appropriate banking account references and codes.

### 1.3 Process for submitting documentation

- Hard copies of all documents must be submitted with the letter of application.
- Documentation, in English, should be submitted by courier or registered mail.
- The letter of application must clearly state: **"Request for prequalification for male latex condoms".**
- Applications for prequalification with supporting documents should be submitted in sealed envelopes not later than the date specified in the invitation for EOIs, clearly marked **"Application to prequalify for male latex condoms"** and delivered to:

  Attention: *[insert name of UNFPA representative]*
  United Nations Population Fund
  Midtermolen 3, P.O. Box 2530
  DK 2100 Copenhagen 0, Denmark
  Tel: +45 35 46 7162, Fax: +45 35 46 7018

- The back of the envelope should display the information shown in the box below.

**Invitation for Expression of Interest**

**Managed by:** UNFPA PROCUREMENT SECTION, COPENHAGEN, DENMARK

**Invitation for Prequalification**
**Country:** UNFPA Headquarters
Midtermolen 3, P.O. Box 2530
DK 2100, Copenhagen 0, Denmark
**Sector:** Reproductive Health Commodities Security

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

UNFPA reserves the right to accept or reject late applications.

**Further information may be obtained regarding prequalification from the UNFPA web site: http://www.unfpa.org/procurement/ or by sending a written request to the Officer in Charge, Prequalification, United Nations Population Fund, Midtermolen 3, P.O. Box 2530, DK 2100 Copenhagen 0, Denmark.**

### 1.4 Sample of the letter of application

**PREQUALIFICATION OF MALE LATEX CONDOM MANUFACTURING SITES**

Date ……..

To: United Nations Population Fund

Midtermolen 3, P.O. Box 2530

DK 2100 Copenhagen 0, Denmark

Sir/Madam,

Being duly authorized to represent and act on behalf of *[insert name of manufacturer]* (hereinafter referred to as the "Applicant"), and having reviewed and fully understood all the prequalification information provided, the undersigned hereby applies to be prequalified by UNFPA as potential suppliers of male latex condoms.

Attached to this letter are copies of original documents defining:

- The Applicant's legal status;
- Product Dossier;
- Summary of the Site Master File;
- Sample products.

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 information to provide such information deemed necessary and requested by UNFPA 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_____ _____

### 1.5 Assessment of documents submitted

The aim of the assessment of the submitted documentation will be to determine whether the applicant/manufacturer meets the minimum requirements detailed in the relevant ISO standards and *WHO/UNFPA Specification* in respect of product quality and safety, production and quality management, regulatory approvals and capacity of production.

UNFPA will aim to screen the documentation within 30 days of the closing date for responses to ascertain whether it contains all the required information. If the submission is incomplete, the manufacturer will be informed and requested to complete the dossier within a specified time period. If the dossier remains incomplete, it may be rejected and returned to the applicant. Dossiers that are considered complete as the result of the administrative screening will be retained by UNFPA for evaluation.

UNFPA will exchange letters with the applicant/manufacturer covering provisions of confidentiality and the process of assessment of submitted information and, if all documentation is correct, scheduling of site inspection. For further information, refer to Section 2, Chapter 5.

## 2 Preparation of a Product Dossier

The Product Dossier follows the requirements included in the *WHO/UNFPA Specification* described in this publication, *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010.*

This document is intended to provide guidance on the format and content of a prequalification application for male latex condom manufacturing sites.

The text in this chapter is intended to be explanatory and illustrative only. The content of these sections includes relevant information described in existing guidelines of the World Health Organization and the International Organization for Standardization.

Each section including attachments should be clearly referenced in the table of contents and in the product file. The table of contents should list the sections, sub-sections and titles in numerical order with the corresponding page numbers. All pages should be consecutively numbered throughout the document.

### 2.1 Characteristics of the products

Provide the following information on the design of condoms produced at this manufacturing site.

| Product characteristics | |
|---|---|
| Widths | |
| Thickness range | |
| Lengths | |
| Shapes | |
| Textures | |
| Lubricant(s) | |
| Flavours | |
| Finishing powders | |
| Colours | |
| Other relevant information | |

### 2.2 Samples

Provide samples of the condoms (at least 10 foiled condoms of each design) produced at this manufacturing site.

### 2.3 Local, country and regional regulatory approvals for the products

Provide copies of relevant certificates related to the product including local product/marketing approvals, CE marking, etc.

List the countries in which:

- the products have been registered and granted a marketing authorization;
- an application for marketing authorization is currently pending;
- any marketing approvals that have been revoked within the last five years.

### 2.4 Raw materials

List all raw materials, including lubricants. Use the following table as an example.

Add additional explanatory information if required and modify the table as necessary.

| **Compounding** | | | |
|---|---|---|---|
| **Chemical name** | **Brand name** | **Manufacturer** | **Function** |
| | | | |
| | | | |
| | | | |
| **Other** | | | |
| **Chemical name** | **Brand name** | **Manufacturer** | **Function** |
| | | | |
| | | | |
| | | | |

### 2.5 Supplier(s)

State the name, street address and country of each facility from which latex is obtained.

### 2.6 Sites of manufacture

State the name and street address of each facility where any aspect of manufacture occurs, including production, packaging and quality control. Indicate the activity performed at each site.

Provide telephone number(s), fax number(s) and e-mail addresses of all manufacturing sites associated with condom production.

### 2.7 Risk management of the product

Provide the Risk Management Plan according to *ISO 14971* and *ISO 13485.*

### 2.8 Specifications for the finished products

Answer the following questions:

- Do the condoms that you currently manufacture meet the requirements of *ISO 4074?*
- Do you currently manufacture any condoms meeting the requirements of the *WHO/UNFPA Specification?*
- If not, describe the differences between the condoms you currently manufacture and condoms that will be produced to meet the WHO/UNFPA requirements.

### 2.9 Evidence of compliance with WHO/UNFPA's General Requirements

Provide the following information:

- confirmation that condoms are made of natural rubber latex;
- verification that biocompatibility testing has been carried out in accordance with *ISO 10993* Sections 1, 5 and 10;

- summary reports of biocompatibility testing including, if available, toxicologists' reports;
- confirmation that neither lycopodium nor talc is used;
- confirmation whether or not protein levels on finished products are periodically monitored; if so, provide summary data as appropriate;
- confirmation whether or not bioburden levels on finished products are periodically monitored; if so, provide summary data. If bioburden levels are not monitored, state whether or not you are prepared to do so in accordance with requirements included in the *WHO/UNFPA Specification*.

### 2.10 Stability data

Data supporting the stated shelf-life of the product shall be presented. This should include data demonstrating compliance with the minimum stability requirements of *ISO 4074* and real-time data from stability studies conducted at 30 °C (range 28 °C to 35 °C) according to *ISO 4074*.

If results from real-time studies are not available prior to the prequalification stage, manufacturers must initiate the studies immediately. Pending the outcome of the real-time studies, manufacturers may use data from accelerated ageing studies conducted according to the relevant annex of *ISO 4074* to support their shelf-life claims. Procedures for conducting these studies are summarised in Chapter 2, Clause 2.1.

### 2.11 Labelling and additional information

Provide examples of the labelling that will be used for the:

- individual packages;
- inner boxes;
- exterior shipping cartons.

Provide an example of the additional information that will be supplied with the condoms, including the instructions for use.

All labelling and additional information, including the instructions for use, shall comply with the requirements specified in the *WHO/UNFPA Specification*. Manufacturers that do not produce condoms to the *WHO/UNFPA Specification* at the time of prequalification may supply draft copy or print proofs for review. Actual examples of printed foil, if necessary for current products, should be supplied to allow assessment of the quality of the print used for LOT number, manufacturing date and expiry date.

Manufacturers should note that requirements for labelling and additional information may be subject to specific contractual requirements, depending upon the requirements of the purchaser.

## 3 Preparation of a Site Master File summary

A Site Master File (SMF) summary for each manufacturing site must be prepared and sent with the letter of application.

A SMF summary should be succinct and, as far as possible, not exceed 25 A4-sized pages.

A SMF summary is a document prepared by the manufacturer from the documented quality management system. It should include the following:

- specific factual information about the manufacturing operations;
- quality assurance procedures carried out at the named site;
- description of any closely integrated operations at adjacent or nearby buildings.

If only part of a manufacturing operation is carried out on the site, the SMF summary needs to describe only the operations carried out at the site. The layout of the SMF summary should include a title page and table of contents.

Clauses 3.1 through 3.12, which follow, describe the required contents of the SMF summary.

### 3.1 General information

1. name and exact address of the site, including fax number, e-mail, and 24-hour telephone numbers;

2. brief information about the corporate structure, including information about holding or parent company, affiliates, subsidiaries and partners;
3. total manufacturing capacity of the site, including:
   - dipping capacity
   - electronic testing capacity
   - packaging capacity;
4. length of time manufacturing condoms at this manufacturing site. Length of time manufacturing condoms at other sites;
5. what other, if any, manufacturing activities take place at this site;
6. summary of type of condoms manufactured at this site.

### 3.2 Manufacturing certifications

A list and copies of all relevant certifications, including *ISO 13485* and *ISO 9000* series if applicable.

### 3.3 Personnel

1. total number of persons employed in condom manufacturing;
2. numbers employed, divided into the following categories: senior management, production management, quality assurance, quality control, maintenance, and administration;
3. an organization chart showing all management and supervisory positions, including the arrangements for quality assurance and quality control;
4. the qualifications, experience and responsibilities of key personnel, senior managers, and directors, quality assurance supervisors, production manager/directors and laboratory manager/director, if appropriate;
5. a summary of policy and procedure for health requirements for personnel engaged in production;
6. a brief description of the staff training scheme and the structure and maintenance of training records;
7. a brief summary of personnel hygiene and safety requirements, including protective clothing;
8. confirmation that there is a written health and safety policy and a summary of the key components of this policy;
9. information on the use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis.

### 3.4 Premises and equipment

1. a simple plan or description of manufacturing areas with indication of scale (architectural or engineering drawings not required);
2. the nature of construction of the building and finishes of floors, ceilings and walls;
3. a brief description of ventilation systems, including steps taken to prevent product contamination and excessive exposure of staff to ammonia and dust;
4. a brief description of the areas for handling compounding ingredients;
5. a brief description of procedures and arrangements for storing quarantined materials, work in progress and finished products;
6. a description of water systems, including sanitation and effluent treatment; schematic drawings of the systems are desirable;
7. a summary of planned preventive maintenance programmes for manufacturing and testing equipment;
8. a brief description of major equipment used in production and control laboratories, including major computer systems used for production and quality control (a full list of equipment is not required);
9. qualification and calibration arrangements, including the recording system, for computerized systems validation, and external calibration laboratory accreditations for those laboratories providing traceable calibrations;

10. availability of written specifications and procedures for cleaning manufacturing areas and equipment;

11. a brief summary of the procedures for monitoring and controlling microbiological contamination in production areas and of the product, and procedures for controlling the purity of the air and water.

### 3.5 Documentation

Arrangements for the preparation, revision and distribution of all necessary management system documentation.

### 3.6 Records

Arrangements for safe storage, access and retrieval of records.

### 3.7 Production

1. a brief description of production operations, using, wherever possible, flow sheets and charts and specifying important parameters; include brief details of the scale of production; identify equipment by type (e.g. dipping machines, electronic testing machines); and state working capacity where relevant;

2. summary of the procedures for the handling of starting materials, work in progress, packaging materials and finished products, including product release and storage;

3. a brief description of the general policy for process validation and a summary of the validation plan.

### 3.8 Risk management plan

A summary of the risk management assessment of the manufacturing process undertaken in accordance with ISO 14971

### 3.9 Quality control

1. brief details of the quality control system and of the activities of the quality control department;

2. brief details of the sampling and testing procedures for in-process testing and final product release, including pass/fail criteria.

### 3.10 Distribution, complaints and product recall

1. a brief description of procedures and arrangements for LOT traceability;

2. a brief description of the arrangements for managing and recording complaints and product recalls.

### 3.11 Self-inspection (internal audits)

A short description of the self-inspection (internal audit) system.

### 3.12 Corrective and preventive action

A brief description of procedures and arrangements for identifying the need for and implementing corrective and preventive action.

### 3.13 Design and development

A brief description of procedures used to control design and development.

## 4 Scope of manufacturing site inspections

The objective of the manufacturing site inspection is to:

- determine if male latex condoms are consistently manufactured to the required specifications;
- verify whether the production processes occur as described in the Product Dossier and Site Master File summary.

UNFPA will plan and coordinate inspections at manufacturing sites to assess the manufacturing process, the product and the quality management systems for compliance with requirements specified in the *WHO/UNFPA Specification* and relevant current editions of international standards including:

- *ISO 4074. Natural Latex Rubber Condoms—Requirements and Test Methods*.
- *ISO 16038. Rubber Condoms—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms*.
- *ISO 13485. Medical Devices—Quality Management Systems: Requirements for Regulatory Purposes*.

- *ISO 14971. Medical Devices—Application of Risk Management to Medical Devices*.
- *ISO 10993–1. Biological Evaluation of Medical Devices. Part 1. Evaluation and Testing*.
- *ISO 10993–5. Biological Evaluation of Medical Devices. Part 5: Tests for in vitro Cytotoxicity*.
- *ISO 10993–10. Biological Evaluation of Medical Devices. Part 10: Tests for Irritation and Sensitization*.
- *ISO/IEC 17025. General Requirements for the Competence of Testing and Calibration Laboratories*.

The inspection will be performed by a team of inspectors, consisting of experts appointed by UNFPA, who will act as temporary advisers to UNFPA. The inspectors must have documented qualifications; expertise in male latex condom manufacturing, auditing and quality management systems; and specific experience with inspecting condom manufacturing sites. The inspectors must comply with the confidentiality and conflict of interest rules of UNFPA, as detailed in Section 2, Chapter 5, Clauses 3 and 4.

The following checklist forms a guide for the manufacturing sites inspection and details the key areas to be reviewed during the inspection.

Condom manufacturing sites vary widely in size, scale, manufacturing equipment and processes employed. Inspectors will need to use their expertise and knowledge of condom manufacturing to tailor the inspection checklist to the specific situation presented at each inspection site.

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 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 Section 2, Chapter 5, Clauses 3 and 4.

### Table 8. Inspection guide

Areas listed below will typically be covered during the inspection, which may be varied for different process flows and use of different materials.

Inspectors will require access to all documents and records related to the manufacture of specific male latex condoms as indicated in *ISO 4074* and the *WHO/UNFPA Specification.*

| Areas under inspection | Comments |
|---|---|
| **1. General company detail** | |
| Address and contact detail | |
| Condom designs manufactured | |
| Independent certifications of systems and products, including regulatory approvals | |
| Markets served | |
| Operating hours and shifts | |

| Areas under inspection | Comments |
|---|---|
| **2. Management team and key staff** | |
| Detail of management and key staff, including authority and responsibilities | |
| Organizational chart | |
| Out-of-office hours, responsibilities and authority | |
| **3. Human resources** | |
| Staff numbers and areas of deployment | |
| Staff selection, induction and training systems | |
| Records | |
| **4. Production capacities throughout the operation** | |
| Number and type of machines | |
| Quoted output and yields | |
| Actual sales for past three years | |
| **5. Latex and other raw materials** | |
| Latex and other raw materials selection, storage and quality | |
| Latex and other material vendor evaluation/validation | |
| Security of latex supplies | |
| Quality assurance and storage procedures | |
| Status indication, labelling and documentation | |
| Environment | |
| **6. Preparation of dispersions and compounds** | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Environment | |
| **7. Latex pre-vulcanization and maturation process and controls** | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Equipment and process validation | |
| Environment | |

| Areas under inspection | Comments |
|---|---|
| **8. Dipping** | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Equipment and process validation | |
| Environment | |
| **9. Processing (washing and powdering)** | |
| Materials used | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Equipment and process validation | |
| Environment | |
| **10. Electronic testing** | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Equipment and process validation | |
| Environment | |
| **11. Foiling** | |
| Materials used | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| LOT coding | |
| Equipment and process validation | |
| Environment | |

| Areas under inspection | Comments |
|---|---|
| **12. Consumer/customer packing** | |
| Materials used | |
| Process | |
| Adequacy of equipment | |
| Testing and controls | |
| Documentation and labelling | |
| Understanding of LOT coding | |
| Environment | |
| **13. Warehousing** | |
| Adequacy | |
| Segregation | |
| Labelling | |
| Stock control/rotation | |
| Presence of aged or non-conforming goods | |
| **14. Distribution procedures** | |
| Agreements | |
| Records | |
| **15. Quality control plan** | |
| Detail of product testing throughout each stage of the manufacturing process, including LOT release | |
| Process yields throughout each stage of manufacture | |
| **16. Provisions for storage and control of work in progress** | |
| Segregation | |
| Labelling | |
| Status identification | |
| Environment | |
| Security | |
| **17. Outgoing product quality** | |
| Review of process averages | |
| Verification of complying product and process capabilities | |
| **18. Quality system and documentation** | |
| Quality policy and objectives | |
| Quality manual | |

| Areas under inspection | Comments |
|---|---|
| Documentation and structure | |
| SOPs and work instructions | |
| Documented versus actual practices | |
| Document control | |
| Process approach | |
| Records | |
| Contract review | |
| Risk review assessment and management | |
| Complaints, recall, vigilance and advisory notices | |
| Post-market surveillance | |
| Internal audit | |
| Control of non-conforming product (corrective and preventive action) | |
| LOT traceability | |
| Statistical analysis of collected data | |
| Product Dossier | |
| Site Master File summary | |
| Management review and improvement | |
| **19. Maintenance** | |
| Documented programme, including schedule | |
| Detail of maintenance for key areas | |
| Records of maintenance | |
| Adequacy of maintenance programme | |
| **20. Laboratory facilities, competence and calibration** | |
| Routine activities of each lab | |
| Equipment and methods | |
| Reporting of results | |
| Documentation | |
| Calibration system | |
| Certifications | |
| Participation in inter-laboratory trials | |
| Research and development activities | |
| Understanding and competence | |

| Areas under inspection | Comments |
|---|---|
| **21. Shelf-life stability** | |
| Detail of studies conducted | |
| Programme for retention of samples | |
| **22. Building, grounds and services** | |
| Overall fabrication and condition of premises | |
| Pest and rodent control | |
| Compressed air | |
| Process water quality | |
| Effluent treatment | |
| Electricity | |
| **23 Prequalification independent testing** | |
| Sampling | |
| Results summary | |

The reports from each site visit will be structured in accordance with UNFPA's SOPs.

## 5 Product testing

Products will be sampled for testing, either prior to the inspection by an independent sampler or by the inspectors during the site inspection.

The sample size is taken in accordance with the current international standard for male latex condom, *ISO 4074* Annex B. The range of tests to be conducted will be in accordance with this document, *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010.* 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.

The sample will be packed and sealed by the inspectors 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 receive a copy of the test report.***

# CHAPTER 7

# Guidelines for Procurement

## SECTION THREE
# CHAPTER 7: GUIDELINES FOR PROCUREMENT

### 1 Introduction

An effective supply chain ensures that the right quality product, in the right quantities, and in the right condition is delivered to the right place at the right time, for a reasonable cost. To accomplish this purpose, the customary supply cycle has four major components: product selection, product procurement, product distribution and product use. Section 3 of this manual addresses the procurement component of the supply chain cycle, identifying the key procurement steps used to enable reproductive health care programmes to receive good-quality condoms that meet the needs of their clients.

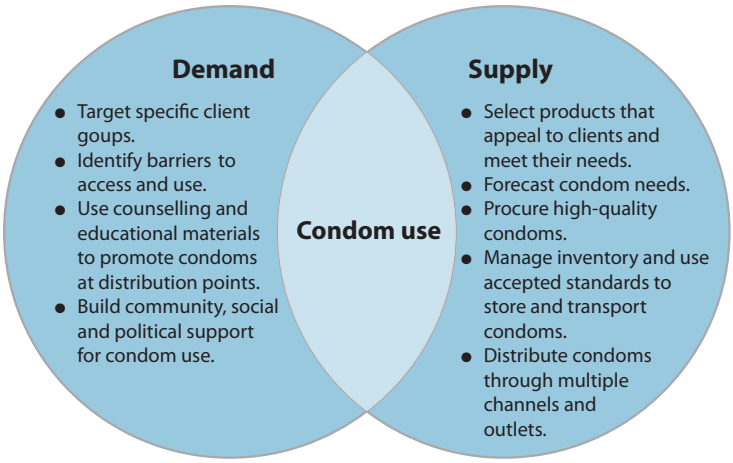
Before addressing the details of the procurement process, however, it is important to understand the broad context and ultimate objective of effectively procuring quality condoms, which is to support a country's efforts to achieve its goal of Comprehensive Condom Programming.

The goal of Comprehensive Condom Programming is to develop strategies and programmes through which every sexually active person at risk of unintended pregnancy, HIV and other sexually transmitted infections, regardless of age, culture, economic situation, gender, marital status, religion or sexual orientation, has access to good-quality condoms when and where he or she needs them, is motivated to use male or female condoms as appropriate, and has the information and knowledge to use them consistently and correctly. The overall aim is to decrease the number of sex acts that go unprotected, thereby reducing the incidence of unwanted pregnancy and sexually transmitted infections, including HIV.

#### 1.1 Comprehensive Condom Programming

Comprehensive Condom Programming links and integrates a number of activities, including leadership and coordination, male and female condom promotion, communication for behaviour change, market research, segmentation of messages, optimized use of entry points (in both reproductive health clinics and HIV prevention/management venues), advocacy and coordinated management of procurement, distribution and supply[1]. Figure 1 illustrates the key demand and supply elements that must be addressed in condom programming.

**Figure 1. Elements of condom programming**




Source: *Condom programming for HIV prevention—an operations manual for programme managers.* UNFPA, PATH, WHO, 2006.

Systems must be established to support the procurement of good-quality products, as detailed in this manual, but at the same time effective procurement processes must be part of a strategic and co-coordinated effort to improve access to and the use of condoms to prevent unwanted pregnancy and the transmission of sexually transmitted infections including HIV. For further information on Comprehensive Condom Programming, refer to: http://www.unfpa.org/hiv/programming.htm.

#### 1.2 Procurement

These guidelines outline the steps required in the procurement process to enable country programmes to receive good-quality condoms in the right quantities, in the right condition, delivered to the right place, at the right time, for a reasonable cost.

Detailed methodologies for conducting the public-sector procurement process and managing the supply

1 *Condoms and HIV prevention: position statement by UNAIDS, UNFPA and WHO.* March 2009.

chain have been developed by a number of international agencies working in the field of contraceptive procurement and logistics management[2].

To ensure that the procurement steps outlined in this manual are harmonized with the latest guidance on Comprehensive Condom Programming, two key manuals have been used as reference documents:

- *Condom Programming for HIV Prevention—An Operations Manual for Programme Managers.* UNFPA, PATH, WHO, 2006;
- *Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies.* PATH, 2009.

The 10-step approach to procurement outlined in this document is based on the *Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies* (PATH, 2009). This toolkit synthesizes the public-sector supply process for reproductive health commodities into three phases: programme planning, procurement process, and performance. Within these three phases 10 customary steps are identified that are designed to support the purchaser in obtaining a good-quality product at a reasonable cost at the needed time.

The three phases and 10 steps of public-sector health care procurement are identified in Table 9.

**It should be noted that:**

a) The steps outlined in this manual define effective practice, but the actual procurement process that a purchaser follows will vary slightly, depending on such factors as government procurement regulations, source of funding, whether qualified manufacturers exist in-country, and the purchaser's own procurement procedures and requirements.

b) Although the procurement steps have been presented in a sequential format, it is often necessary to implement several steps at the same time.

c) Procurement steps may vary from country to country, but, to be undertaken effectively, each step requires:
   - leadership;
   - adequate human and financial resources;
   - willingness to collaborate and coordinate with the different parties involved in each step of the procurement process;
   - timely decision-making.

## Ten steps in the procurement process

### Phase 1: Programme planning

#### 1 Step 1: Define supply requirements[3]

Assessing and defining programme requirements depends on several factors that should be discussed with all parties involved in condom usage, promotion, procurement and distribution.

***1.1 Define programme context***

Before forecasting and quantifying condom requirements, it is important to understand the needs of the intended end users and the history of condom procurement and use in the country.

This information can be obtained through a desk search of available information and by meeting with all parties involved in the programming, procurement, distribution and promotion of condoms.

There is a need to determine:

- Which agencies, donors, nongovernmental organizations, social marketing agencies, commercial enterprises and different public-sector ministries are involved in the procurement, distribution and promotion of condoms?

2 John Snow, Inc., Family Health International (FHI), Crown Agents, Population Services International (PSI), UNFPA, PATH, and the World Bank have developed technical resource materials on establishing and strengthening the various components of the supply chain and ensuring product quality assurance. See Annex VII for contact information for these agencies.

3 For additional information, see Module 1 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

**Table 9. Three phases and 10 steps of procurement**

| Phases | Ten steps of procurement |
|---|---|
| **1 Programme planning** | 1. Defining supply requirements<br>2. Customize the specification<br>3. Assessment of procurement options<br>4. Budget, funding and procurement requisition |
| **Critical link: funded procurement requisition** | |
| **2 Procurement process** | 5. Procurement planning<br>6. Developing Bidding Documents and inviting offers<br>7. Selecting suppliers<br>8. Contract negotiation/award |
| **Critical link: signed contract and payment guarantee** | |
| **3 Performance** | 9. Contract performance and monitoring<br>10. Delivery of goods |
| **Critical conclusion: delivery and acceptance of good-quality products** | |

**The rest of this chapter on procurement is organized according to these 10 steps.**

- What are their roles?
- What are the sources of funding?
- What sources of supply are used?
- How are the condoms procured and in what quantity?

It is important to create a broad picture of what is happening in the field of condom programming and procurement and in the country to ensure that all stakeholders who need to be involved in the process are identified.

### *1.2 Forecast programme requirements*

Before the actual procurement process can begin, it is important to know the quantity of condoms and the desired delivery schedule. Questions that need to be answered by the procurer and the programme managers are:

*Users and use*

- Who are the intended end users?
- What research, if any, has been undertaken to determine the population's current needs and unmet need?

- What are the trends in condom use?
- Are there expected policy, programmatic or other changes that will affect this trend?

*Current programming and supplies*

- Which programmes will this procurement supply? Combining several programme procurement requirements, such as those from HIV/AIDS and Reproductive Health, can offer potential savings through price discounts. Also, combining procurements reduces the purchaser's administrative costs that would be associated with processing multiple orders.
- What is the current stock of condoms at those programmes?
- When will the products reach their expiry date?
- Are there any products that may not be distributed before they reach expiry?
- Are losses or transfers in or out of programmes expected?
- How many months will supplies last?
- What is the annual consumption?
- Are orders or shipments already planned or in transit for the programme?
- What is the desired buffer stock level that the programmes want to maintain?
- What is the storage capacity for condoms? Limited storage capacity could require that the procurement of condoms be phased in smaller shipment increments over time rather than arriving as one large consignment.
- Are the storage facilities secure and adequate for the long-term storage of condoms?
- Does the storage facility provide adequate protection against excessive temperature rises and other environmental issues?
- Is there a Logistic Management Information System (LMIS) in place that captures stock levels and distribution to users?

*Current procurement process*

- What are the requirements of the national regulatory authority (or authorities) regarding the procurement and importation of condoms?
- How are condoms imported into the country? Airfreight is generally very expensive, and so condoms are usually shipped by sea to the nearest port of entry.
- What is the history of previous shipments?
- What problems, if any, have been encountered with the procurement and distribution of condoms over the last two years?
- What is the average length of time involved in the procurement cycle? This may vary according to the source of funds, but it is important to consider this issue when forecasting condom requirements, as it can take between 12 and 18 months to complete a condom procurement cycle.

Information gathered by undertaking this assessment will enable the purchaser to identify the total quantity of condoms required to support programme needs.

Different methods can be used to estimate requirements, depending on the time frame to be projected, the geographic area covered, the purpose of the forecast, and the availability of data to develop the forecast. Forecasting methods use logistics data (including consumption data, service statistics and population data)[4]. Forecasts are usually made using more than one method and then compared and reconciled. This is done because usually data are not adequate to rely on one method alone and because different methods have different advantages. Consolidating forecasts from different data sources improves the accuracy of the overall forecast.

For additional information on forecasting, see also: *The Contraceptive Forecasting Handbook for Family Planning and HIV/AIDS Prevention Programs* (JSI, Family Planning Logistics Management Project, 2000). This is a reference book for forecasting commodity needs

4 Summary information on these methods can be found in Module 1 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

for family planning and HIV/AIDS prevention programmes. Topics range from general methodological considerations to special considerations when forecasting for HIV/AIDS prevention programmes.

## 2 Step 2: Customize the specification

### *2.1 Review the WHO/UNFPA Specification (see Section 1, Chapter 2)*

A specification is a statement of a buyer's requirements. One of the more important responsibilities of a purchaser is to ensure that the condom specification is accurate, detailed, clear and consistent. The purchaser should review the *WHO/UNFPA Specification* to fully understand the different levels of requirements called out in the specification and to identify which requirements can be adapted by the purchaser to address specific programme needs and which requirements must be left unaltered so as not to jeopardize the integrity and quality of the product. The *WHO/UNFPA Specification* can be copied from this document or the WHO web site (http://www.WHO.int/reproductivehealth).

### *2.2 General Requirements*

The General Requirements section of the *WHO/UNFPA Specification* covers those qualities of the condom that should be assessed by the manufacturer before the product is put on the market. The General Requirements define the purity and safety of the constituent materials used to make the latex rubber condoms and the safety of the powders and lubricants applied to the condom. Also included in this section are recommendations for requirements relating to the periodic monitoring of levels of bioburden and to establishing shelf-life. The General Requirements are not to be altered by the purchaser.

> Use the *WHO/UNFPA Specification.*
>
> Do not alter General Requirements or Performance Requirements.

### *2.3 Performance Requirements*

The Performance Requirements specified in the *WHO/UNFPA Specification* are based on the requirements of *ISO 4074.* The specification includes testing requirements for freedom from holes, airburst properties and package integrity. These requirements cannot be altered. Verification of compliance with these requirements is to be done as part of the LOT-by-LOT Pre-shipment compliance testing of the product, as detailed in the *WHO/UNFPA Specification* (refer to Section 1, Chapter 2).

### *2.4 Design Requirements*

The Design Requirements may be adapted, where appropriately indicated, to reflect the specific needs of the programme and population of intended users. Programme managers should review the design requirements in the *WHO/UNFPA Specification* and determine what alternative requirements might better meet their programme and target population needs. Modification should be based on information about the target population. It is, however, important to remember that changes in design may increase the cost of the product and limit the number of possible suppliers.

If specific design changes are agreed upon by the manufacturer and purchaser, any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed upon.

> Use the *WHO/UNFPA Specification.*
>
> Modify Design Requirements according to programmatic needs.

Verification of compliance with the Design Requirements is to be done as part of the LOT-by-LOT Pre-shipment compliance testing of the product.

### *2.5 Packaging Requirements*

The *WHO/UNFPA Specification* specifies stringent requirements for condom packaging to protect the condom during transportation, storage and distribution.

### *2.6 Consumer packs or additional requirements*

Other packaging, such as consumer packs for delivery, will depend on individual requirements of the programme and are not included in the *WHO/UNFPA Specification.* For example:

- If the buyer wants a particular consumer package, such as a box or wallet, it is important to specify in detail these requirements and the means by which the buyer will verify the quality.
- If the purchaser requires flavoured, scented or coloured condoms, it is important to discuss and agree upon the flavour, scent or colour with the manufacturer before the condoms are produced. If condoms are to be coloured, only one colour should be included in a box or strip.
- If the buyer wants a design, logo or writing on the packaging or carton, it is important to specify and agree with the manufacturer on the type font (face and size), style and colour (by Pantone number).

## 3 Step 3. Assessment of procurement options[5]

In preparing for the procurement of condoms, the purchaser must determine which option, or procurement method, would be most appropriate for the particular circumstances. The process of assessing the options, or methods, is intended to:

- identify the procurement options that are possible;
- consider what is practical under the circumstances;
- look at who can/will do the work;
- examine cost implications;
- evaluate the options and select the most appropriate option, or procurement method, for the procurement.

The assessment process must be objective and must look to answer questions such as:

- Are there any issues that might affect the purchaser's ability to perform a specific procurement method?
- Does the purchaser have staff with the knowledge and skills required for implementing a more complex procurement method such as international competitive bidding?
- What is the value of the order, and is it large enough to attract bids from major international suppliers?
- What method is most cost-effective for the purchaser?
- Does the purchaser have suitable infrastructure, such as access to foreign currency, international banking and Internet services?
- Is sufficient time available to conduct a more complex procurement method such as international competitive bidding?
- Are there funder's requirements specifying that a certain procurement method be used?

### *3.1 Select a procurement method*

Upon completion of the assessment process, the purchaser should have sufficient information to determine which procurement method would be most appropriate for the particular circumstances that have been identified. In principle, there are four common procurement methods that the purchaser could choose from.

#### *3.1.1 Procure directly from a manufacturer through a competitive bidding process*

This is a satisfactory method for fairly large orders. When undertaking this method of procurement, it is important that procurement staff have the technical skills needed to follow the procedures detailed in these guidelines.

Competitive bidding, including international competitive bidding, is the most complex of the procurement methods used. It is the method preferred by some international lending organizations, such as the World Bank. The purchaser must (a) develop the specification and Bidding Documents; (b) either select prequalified potential suppliers from the WHO/UNFPA list or undertake a comparable prequalification process; (c) implement the bidding process; (d) select the supplier(s) and (e) arrange for Pre-shipment compliance testing and shipping.

5 For additional information, see Module 3 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

Unless the purchasing entity has existing procurement capacity with competitive bidding experience, this method may not adequately support the needs of the programmes.

In addition, the time required to complete an international competitive bidding process (from identification of requirements to delivery of product) can be quite lengthy, possibly ranging from 12 to 18 months.

Purchasing entities that select this method must ensure that they comply with and perform every required step in the process as identified by both national procurement policies and donor requirements. If the procurement is donor-funded, the purchasing entity should secure an agreement with the donor to use WHO/UNFPA prequalified suppliers. The WHO/UNFPA Prequalification Scheme is harmonized with the WHO Essential Medicine Prequalification Scheme, and a list of prequalified manufacturers is available for use by any procuring entity (refer to http://www.unfpa.org/webdav/site/global/shared/procurement/Prequalified_Condom_Factories_Sept09.pdf).

LOT-by-LOT Pre-shipment compliance testing is still recommended when procuring from WHO/UNFPA prequalified suppliers.

*3.1.2 Source from a procurement agency*

Procurement agencies undertake sourcing for organizations and national programmes that do not have their own procurement department and/or staff with expertise in condom procurement and/or the time to develop the needed capabilities to conduct competitive bidding.

Although independent procurement agencies exist in most cities worldwide, very few of them have extensive knowledge of and experience with the special requirements for buying condoms. It is, therefore, important to select a procurement agent with a track record of procuring good-quality condoms.

The procurement agent takes responsibility for procurement and quality assurance of the product. The purchaser has to identify or develop the specification using the *WHO/UNFPA Specification* and issue a suitable contract to the procurement agent. The agent will be responsible for ensuring that potential suppliers are prequalified by WHO/UNFPA, selecting the supplier, awarding the manufacturing contract, and arranging for Pre-shipment compliance testing and shipping. It is recommended that all procurement agents use the WHO/UNFPA prequalification process and prequalified suppliers.

Some procurement agents may have existing supply contracts with condom manufacturers and may be able to offer a purchaser a shorter delivery time. For small orders, arrangements can be made with an agent to purchase the quantity required as part of a larger bulk order. This can reduce procurement costs.

If the agency does not have experience with condoms, it is advisable to use an international procurement agency that does (see Clause 3.1.3, below). For example, UNFPA, International Planned Parenthood Federation, International CONtraceptives Sexual and Reproductive Health, (IPPF/ICON), Marie Stopes International (MSI), Crown Agents and Population Services International (PSI) all act as international procurement agents. They will undertake the procurement process and/or, if funds are available, may provide technical assistance to support the procurement process.

*3.1.3 Source from an international procurement agency/organization*

International agencies such as UNFPA, USAID, IPPF/ICON, MSI, PSI and others provide condoms for sale or donation to country programmes. Unique programme requirements can be considered if the quantity ordered is significant and there is sufficient time for a manufacturer to process the order.

Procurement should not be through a non-specialized commercial agency or importer because the condoms may not be traceable to their manufacturer and quality issues will prove more difficult to resolve.

WHO recommends the use of an experienced procurement agency and that the source of the condoms be a WHO/UNFPA prequalified primary condom manufacturer.

This is an option for organizations and national programmes that do not have the procurement capacity required to implement more complex procurement methods, such as sourcing directly from a condom manufacturer through a competitive bidding process or using a procurement agency. Depending on the quantity of condoms needed, this option can also offer a shorter delivery time than the other options.

Certain international organizations, such as UNFPA and USAID, maintain stocks of condoms to respond quickly to stock-outs and emergency situations. These organizations can draw upon supplies either held in stock or from manufacturers, based on its pre-existing supply contracts, and will either sell or donate to programmes for distribution in-country.

*3.1.4 Buy from a social marketing organization*

Social marketing organizations, such as PSI, DKT and MSI, operate much like commercial retail companies. They buy products and promote and sell them in the market at subsidized prices. Occasionally, a programme may approach a social marketing organization in a country, requesting condoms. If the social marketing organization has sufficient stock, it may sell or donate some to the requesting programme.

**Table 10. Comparison of four procurement methods**

| Method | Experience and capacity of programme staff | Size of procurement | Advantages/disadvantages |
|---|---|---|---|
| **Direct from manufacturer** (do not use a non-specialized commercial agent) | Programme must have adequate staff with appropriate skills, particularly an experienced procurement manager.<br>Alternatively, expert technical assistance should be sought to help develop local capacity of the logistics management chain. | Better for larger procurement cycles. | Good control of supply and quality assurance.<br>Requires reliable staff and experienced management. |
| **Procurement agency** | Valuable where capacity of the in-country logistics management requires support or further development. | Good option for large, more complex procurements.<br>May be expensive for smaller quantities. It may be possible for the purchase of smaller quantities to be combined with an existing supply contract. This would reduce costs. | Important to collaborate with the procurement agent to ensure procurement to the correct specification and within an agreed-upon time frame. Can be used to develop the capacity of the logistics management chain.<br>Important to select a procurement agent with a reputation for following quality assurance measures in a timely fashion.<br>The procurement agent charges a fee for its services. |
| **International agency** | No experience required. | Good option for large volumes. | Quality management and control over supply chain assured. Very competitive prices. Long-term agreement with suppliers (quality monitored over time). Capacity to respond to requests quickly. Assistance can be provided to develop the capacity of the logistics management chain.<br>The international procurement agency charges a fee for its services. |
| **Social marketing organization** | Complete procurement and marketing and distribution service. | More suitable for working in larger markets. | All details of procurement handled by outside agency. |

Source: *World bank condom procurement guide.* November 2001.

While not a common source of procurement, this is another avenue that country programmes can explore.

Table 10 compares the advantages and disadvantages of the four basic procurement methods. Once the procurement method is decided, it should become a routine practice to then inform the budget and/or finance committee of the method selected.

## 4 Step 4: Budget, funding and procurement requisition[6]

Given the often limited financial resources that are available for funding reproductive health commodities, it is important that the process of estimating product costs, developing budgets and securing funding be conducted in as effective a manner as possible. Accurately estimating procurement costs is an important first step in this process.

### *4.1 Estimating procurement costs to determine a budget*

There are several cost factors that must be considered when developing a budget estimate for condom procurement that is then used to secure funding. The key procurement cost factors include:

- *Unit price.* The unit price charged by the manufacturer or supplier constitutes the largest component of the condom procurement cost. There are several methods that a purchaser can use to estimate the unit price. Direct inquiry to the manufacturer or supplier and previous contract invoices are useful sources for price information. Since the quantity procured can influence unit price, it is important, when contacting manufacturers or reviewing previous invoices, to factor in the estimate of programme quantity developed in the preceding step. It is also important to make clear to the manufacturer or supplier that the information requested is for a budget estimate only and there is no commitment being made by either party.

  Another resource for price information is the Management Sciences for Health (MSH) *International Drug Price Indicator Guide,* available online at: http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=Dmp&language=English. This guide provides prices from suppliers and procurement agencies as well as prices paid by government agencies. It is important for the purchaser to review the "Data Notes" page, which provides information about the sources and how prices were calculated.

- *Freight cost and insurance.* The estimated costs to ship the condoms and insure them during transit must also be included in the budget estimate for condom procurement. These costs are often included in the unit cost. Therefore, it is important for the purchaser, when directly enquiring from a manufacturer, reviewing previous contract invoices or conducting web research, to review the stated INCOTERMS (shipping terms) to determine the extent to which freight costs and insurance are included in the unit price.

  If the unit price does not include freight and insurance costs, the purchaser can request an estimate of these costs from a freight shipping agency. This would require providing the weight and dimensions of the shipment, the mode of transportation (ocean, air or ground) and the value of the shipment. When this information is not readily available, purchasers will often add a standard percentage to the value of the goods. For example, for shipping and insurance costs, UN agencies estimate 15% of the value of the goods purchased.

- *Sampling and testing.* Pre-shipment compliance testing is recommended for every condom LOT, and these costs should be included in the budget estimate for condom procurement. For general budgeting purposes, the purchaser should estimate approximately 7% to 11% of the cost of the product to cover costs for these services.

  **Note:** UNFPA should be able to confirm a reasonable percentage estimate to include for these activities, based on their experience with the prequalification of suppliers.

6 For additional information on budgeting and funding, see Module 4 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

- *Import/customs clearance costs.* These vary from country to country and port to port, so the purchaser must enquire locally to establish reasonable cost estimates for import licence fees, customs broker fees and port clearing fees.
- *Post-shipment confirmatory testing.* If national regulations call for confirmatory testing of condom LOTS, then these costs should also be included in the budget estimate for condom procurement. The purchaser must enquire locally to find out whether there is a specific country regulatory requirement. ***WHO recommends that only one laboratory carry out the LOT-by-LOT Pre-shipment compliance testing.*** If the national laboratory is functioning at internationally accredited standards, then the purchaser can arrange for this laboratory to undertake the Pre-shipment compliance testing and, if required, post shipment confirmatory testing (refer to Phase 3, Clauses 9.1 and 10.1, below).
- *Taxes.* Most public-sector health commodities are exempt from tax. This is not always the case, however, and sometimes value-added tax is applied uniformly to all products. The purchaser must enquire locally to determine if there are any taxes that should be included in the budget estimate for condom procurement.

The above costs are directly associated with condom procurement and the related activities required to test, ship and clear the product through customs. They become the budget estimate that is used to secure funding.

There are, however, additional costs that are associated with the condom programme that are not directly related to condom procurement. Programme staff must be fully aware of these other costs to ensure that they are adequately addressed in their overall condom programme budget. These in-country programme costs would include:

- promotion costs;
- warehouse and storage costs;
- distribution and transportation costs.

Establishing and maintaining an open communication channel between the purchaser and the condom programme staff will help ensure that condom procurement costs and condom programme costs are accounted for and appropriately budgeted.

### *4.2 Funding*

Funding for health care commodities, including contraceptives, for public-sector programmes in low-resource countries has historically been limited and insufficient to meet full health care programme requirements. This shortfall has been addressed primarily through funding support and donations from multilateral organizations such as the Global Fund for AIDS, TB and Malaria; UNFPA; and the World Bank and through bilateral donors such as USAID, the UK Department for International Development (DFID), Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and other agencies.

In the last decade, however, there has been a trend towards providing donor funding through arrangements such as Sector-Wide Approaches (SWAps) and basket funding, in which the international agencies pool their financial resources and transfer funds to the government to use to implement the health care programme that has been negotiated between the partnering international agencies and the host national government. In many of these financial arrangements, the partnering international agencies will require the host national government to establish a national budget line for reproductive health essential medicines and commodities as a first step towards the government eventually taking full responsibility for funding these items from the national budget. Additionally, under SWAp arrangements the national government is often assigned responsibility, with review, oversight and technical support provided by the SWAp partners as appropriate, for procuring the health care commodities funded under the programme.

In most cases the programme supply requirements under a SWAp or basket-funded approach are negotiated between Ministry of Health and Finance managers and representatives of the international agencies and donor countries. The purchasing entity's role, in consultation with other condom programming experts, is to

provide the budgetary information and programmatic justification to inform the negotiations. As part of the negotiation, each party must agree on the terms and conditions that govern the procurement, quality control, importation and distribution of these condoms.

Bi-lateral donor funding for condom procurement is usually initiated by senior ministry personnel contacting the donor's country mission with a request for support. Many countries may already have arrangements in place that are renewed on an annual basis. For bi-lateral donor funding requests, the purchasing entity's role is generally limited to providing senior government personnel with specific programme and cost information.

For condom procurement funded through the national government, the purchaser must submit accurate estimates of the condom procurement budget for government approval.

In each of the above funding scenarios, it is important to make allowances for the length of time it will take to secure funding. It is also important to determine what kind of payment mechanism will be used.

The completion of the budget and funding process should result in an official procurement requisition that identifies the products to be procured, the quantities, the amount of funds authorized for the procurement and other important details necessary to implement final planning for the procurement.

## Phase 2: Procurement process

### 5 Step 5: Procurement planning[7]

The procurement planning and scheduling process is an important step because it:

- provides a framework for guiding procurement activities and monitoring progress;
- provides an opportunity to anticipate problems and solve them before they happen;
- establishes expectations for a delivery date that other parties will use for their own planning purposes;
- establishes a time frame for payment obligations.

For a procuring entity to be able to successfully implement a procurement plan, it needs a defined chain of authority to support and validate its actions, a clear definition of where its responsibility begins and ends and an understanding of the supply chain process to know whom to contact for information on activities in the supply chain that are outside its mandated performance area.

The procuring entity also must be authorized to contract and commit funds on behalf of the organization it represents. A formal delegation of financial powers is used for this purpose in some government structures.

As part of the process to develop a procurement plan, the procuring entity should:

- confirm budget allocations and timing for availability of funds by direct contact with the appropriate funding authority;
- review technical specifications to make sure that they are complete and in a format consistent with international standards for the industry, making sure that:
  - the general, performance and design description is complete
  - regulatory and testing requirements are clearly stated
  - packing, labelling and marking requirements are included
  - sampling, inspection and testing protocols are included;
- confirm that the date, delivery location and mode of transport are appropriate;
- confirm that the date of delivery is realistic;

7 For additional information on procurement planning, see Module 5 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

- confirm that specific country requirements and national regulatory procedures have been taken into consideration. These issues are discussed in more detail in country requirements, Clause 5.1.

### *5.1 Country requirements*

Since condoms are medical devices, many countries have special regulations covering importation and distribution. Any procuring entity involved in the procurement of condoms for a particular country must be aware of these rules and regulations. Questions concerning specific requirements that should be answered include:

- Is there a mandatory national quality standard with which all condoms must comply?
- How are the standards applied?
- Is there a requirement to undertake LOT-by-LOT Pre-shipment compliance testing of condoms before they are allowed into the country?
- Is there a competent, accredited laboratory in-country to handle the testing? If not, is there an accredited regional laboratory?
- Is it possible to work with this laboratory to undertake the Pre-shipment compliance testing?
- What other entry requirements are there, such as import duties and certification?
- Is there a requirement for registration prior to importation?
- Is there an in-country requirement for confirmatory testing as well as Pre-shipment compliance testing?

Familiarity with these regulations will help to ensure compliance with national requirements, ensure the smooth clearance of the condoms through customs and reduce frustrating delays that can hold up delivery after the products have arrived in country. Information on current regulatory requirements for condoms can be obtained from the National Regulatory Authority of each country. The role and responsibilities of a National Regulatory Authority are briefly discussed in the following section.

### *5.2 National Regulatory Authority*

The National Regulatory Authority (NRA), or Drug Regulatory Authority (DRA), in every country undertakes some type of licensing or registration process to protect the population from unsafe or ineffective pharmaceuticals, contraceptives and medical devices. NRAs bar unlicensed products from entering their countries and look to national customs services for enforcement. Many countries do regulate the importation of condoms, and it is important to check the local regulations. Regulatory licensing procedures can be complex, lengthy and expensive for the manufacturer, so those without an existing presence in a country are reluctant to begin the process until and unless a contract is assured. Given the time that it can take for licensing, this issue threatens timely delivery and limits competition.

> Always meet with representatives from the national regulatory authority and customs to discuss their requirements early in the procurement process.

Procurement officers must be able to communicate with NRA personnel in order to obtain accurate information about registration requirements that should be included in Bidding Documents. They also need to stay current on products that are registered in-country and ensure that procurement specifications reflect current regulatory requirements.

If procurement personnel know from experience that there may be problems and/or delays due to budget deficits, mode of transportation or importation challenges, these issues should be discussed and solutions should be sought during the procurement planning phase.

After gathering the necessary information described above, the procuring entity develops a detailed procurement plan, with clear timelines and delegation of responsibility for each activity identified in the plan, along with a clear process for monitoring implementation of the plan.

## 6 Step 6: Developing Bidding Documents and inviting offers[8]

In public-sector competitive procurement, the purchasing entity prepares and provides detailed Bidding Documents to potential suppliers. These documents explain all the requirements of what is to be supplied, all rules and procedures for bidding, and specific criteria that will be used to choose a winning bid. Some sections of the Bidding Document become part of the future contract between the supplier and the purchaser.

Well-prepared Bidding Documents and process:

- vastly reduce problems during the procurement process regarding bidding, evaluation, and contract award;
- provide a key opportunity to protect against counterfeit, fake, and possibly unsafe products;
- set up rules and expectations for contract performance, including timely delivery of the product;
- define responsibilities of the purchaser and the eventual supplier.

> Make sure Bidding Documents are correct and complete in every way. Under the rules of public procurement, nothing can be changed after bids are opened, even if a mistake is discovered.

Six major challenges that must be taken into consideration when preparing Bidding Documents are:

- finding or developing a model Bidding Document that is appropriate for this specific purchase;
- reaching decisions on details that must be included in the Bidding Documents;
- thinking through potential problems and addressing them in the Bidding Documents;
- using clear wording and assuring consistency across different sections of the document;
- building in product quality protections;
- making sure that the purchaser's responsibility (commitment) as outlined in the Bidding Documents is what will actually happen, thus reducing the chance of bidder protest, which often leads to delayed delivery.

### *6.1 Identify information required for the Bidding Documents*

The Bidding Documents should include all essential information and requirements, both technical and contractual, that the manufacturer must know in order to be able to submit a responsive bid. Some of the important information that should be provided to the manufacturer includes:

- instructions, rules and procedures for bidding;
- where and when bids will be opened;
- how bids will be evaluated and how the purchaser will select the winning bid;
- any factors in addition to price that the purchaser will consider;
- technical specifications and compliance requirements;
- quantity, delivery schedule and delay clauses (requirements);
- national regulatory requirements;
- terms and conditions for the future contract between the purchaser and the winning bidder;
- request for documentary evidence of manufacturing quality assurance measures;
- procedure for resolution of disputes;
- procedures for Pre-shipment compliance testing and, if required by national bodies, confirmatory testing procedures;

8 For additional information on the preparation of Bidding Documents, see Module 6 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

- shipping arrangements;
- payment arrangements;
- sample forms containing necessary wording for the bidder to use.

It is recommended that purchasers use only WHO/UNFPA prequalified manufacturers.

***6.2 Decide on the prequalification procedures***

The purchaser decides on the prequalification procedures that will be used for procurement. ***It is recommended that only WHO/UNFPA prequalified suppliers be included in this bidding process.*** If, however, the purchaser does not choose to use only WHO/UNFPA prequalified condom suppliers, it is recommended that a prequalification process be conducted in accordance with the procedure described in Section 2 of this document.

The overall objective of the WHO/UNFPA Prequalification Scheme is to prequalify manufacturers of male latex condoms of assured quality, at specific manufacturing sites, for procurement by United Nations agencies and other bulk procurement agencies.

Specific objectives of the WHO/UNFPA Prequalification Scheme are to:

- promote the procurement of male latex condoms from manufacturing sites that have been assessed as having the capacity to produce good-quality products;
- establish a system that promotes the procurement of condoms that conform to the international standard *ISO 4074*[9] and the *WHO/UNFPA Specification* for the male latex condom, as described in this document, and that retain their effectiveness throughout their stated shelf-life;
- broaden the supplier base for male latex condoms that are deemed acceptable, in principle, for procurement by United Nations agencies and other bulk procurement agencies;
- maintain and publish a list of prequalified suppliers.

***6.3 Verify suppliers' manufacturing capacity***

The Bidding Documents should include a request to suppliers to provide the following documentary information:

- evidence that they are a primary manufacturer (i.e. that the formulation, dipping, testing and packaging of condoms is conducted on their own premises);
- production history and products currently manufactured;
- at least two references with postal and e-mail addresses and telefax and telephone numbers;
- production capacity of the factory, available production capacity for this order and standard LOT size;
- regulatory compliance credentials and applicable national regulatory code;
- other quality management certifications;
- data to support compliance with the general and performance requirements specified in the *WHO/UNFPA Specification;*
- statement of the ability to comply with the specification attached (this statement may be incorporated into the bid form);
- explanation of the manufacturer's codes and markings.

***6.4 Seek information about potential suppliers***

The purchaser should request information on the potential supplier's financial situation, years in business and list of key clients. This will establish that there is adequate working capital available to ensure the timely supply of raw materials and that all necessary factory maintenance can be carried out. The purchaser should always request references from the potential supplier

9 ISO documents are available from: International Organization for Standardization, ISO Secretariat, 1, ch. de la Voie-Creuse, CP 56, 1211 Geneva 20, Switzerland (http://www.iso.org).

so that the purchasing entity can contact the references and request feedback on the supplier's performance and reputation.

### *6.5 Select an independent testing laboratory and choose a sampling agent*

The purchasing entity must select an accredited testing laboratory to test the condom samples and must choose a sampling agent qualified to conduct random sampling of condoms in accordance with ISO requirements. The purchaser should request written confirmation from the supplier that the supplier will accept the results of the testing laboratory chosen for Pre-shipment compliance testing. If a country has an internationally accredited national laboratory, then arrangements can be made for the national laboratory to undertake Pre-shipment compliance testing and, if required by the national authorities, this laboratory can conduct confirmatory testing as well.

### *6.6 Prepare the Bidding Document package*

The information and documents discussed above are assembled into a Bidding Document package. The names of Bidding Document sections and their precise contents will vary depending upon donor, national and purchasing entity requirements, but the following list represents the essence of a good public-sector Bidding Document:

- general instructions to bidders;
- special instructions to bidders;
- eligible/ineligible countries and suppliers;
- general terms and conditions of the contract;
- special terms and conditions of the contract;
- technical specifications;
- schedule of requirements and delivery dates;
- evaluation criteria;
- qualification criteria;
- bid and contract forms, which include:
  - price schedule
  - bid security form
  - performance security form
  - contract agreement form.

Many organizations, funders, and government entities wish to review and approve draft Bidding Documents before they are made available to the public. Changes or corrections may be required as a result of this review. These should be undertaken with great care, as it is easy to forget to make corresponding changes in other sections.

For more information on preparing Bidding Documents and the details and specific information that is found under each of the above Bidding Document package headings, see Module 6 of the *Procurement Capacity Toolkit* (PATH, 2009).

### *6.7 Invite bids*

When the documents are ready for issue, the procuring entity can begin soliciting bids by extending a public invitation to bid to all interested firms and parties. Alternatively, they may restrict the bids to the WHO/UNFPA list of prequalified suppliers.

### *6.8 Receive and manage bids*

Basic rules for receiving and managing bids:

- Bids must be held unopened in a secure location until the stated day and time of bid opening.
- Bid envelopes should be stamped with the date and time that they are received.
- No one associated with the procurement is permitted to communicate with bidders from the time the advertisement appears until after an award has been made, except for written communication directly related to clarifying minor deviations in the bid.
- Procedures must be in place and adhered to for opening and reviewing the bids.

## 7 Step 7: Selecting suppliers[10]

Potential suppliers will submit Bidding Documents in response to the advertised invitation to bid. The purchasing entity convenes a committee and opens the

10 For additional information on evaluating bids and selecting suppliers, see Module 7 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

bids at the time designated in the Bidding Documents and then begins the evaluation process to determine which supplier should be awarded the contract.

The committee evaluating the suppliers' Bidding Documents should include procurement specialists and also condom quality experts with the technical expertise to help evaluate the documentation and certification submitted by suppliers. The evaluation committee also should check to see that the suppliers have confirmed that:

- they are capable of providing the quantities required within the desired time frame;
- they have a proven record of manufacturing products that conform to the *WHO/UNFPA Specification,* the purchaser's specification, or similar requirements;

The supplier is chosen on the basis of:

- WHO/UNFPA prequalified supplier;
- quality of the product;
- capacity to supply;
- price;
- ability to meet the requirements of the contract.

It is important to consider all five factors.

**Selection should not be based on price alone.**

Select the most economically advantageous bid that meets the selection criteria.

- they are WHO/UNFPA prequalified suppliers, if that qualification has been identified in the Bidding Documents as a requirement for bidding;
- they will permit a sampling agency to perform random sampling of condoms at the manufacturing facility;
- they will accept Pre-shipment compliance testing and, if required, confirmatory testing;
- they will accept the test results of an independent laboratory agreed to by both parties;
- they will accept the procedure for the resolution of disputes;
- they will accept the general and specific conditions of the contract.

Any supplier that has not submitted the required documentation and certification, has not adequately responded to the requests of the bidding package or is found for other reasons to be non-responsive by the evaluation committee is removed from consideration for the contract award.

***Non-specialized procurement agents and importers should be eliminated from the list of potential suppliers.***

The supplier should be chosen based on:

- being listed as a WHO/UNFPA prequalified supplier (if that qualification has been identified in the Bidding Document);
- proven supplier of quality products;
- demonstrated capacity to supply;
- price;
- ability to meet the requirements of the contract.

***Suppliers should not be selected based on price alone.***

Once the committee has identified and qualified the winning bidder, the committee makes a recommendation to the contracting authority for contract award. Upon approval or endorsement of the recommendation by the contracting authority, a contract can be awarded to the winning supplier.

### 8 Step 8: Contract negotiation/award

After the supplier has been selected and the contracting authority has approved the supplier recommendation, the contract needs to be prepared, signed, and awarded. Often, there is a time limit for obtaining contract signatures. This activity also includes deciding on payment methods.

The first responsibility for contract execution lies with the purchaser, who provides some type of payment guarantee to the supplier. Particularly in trade with developing countries, manufacturers usually do not enter an order into production until this payment guarantee is in place.

Manufacturers frequently have a backlog of orders for products in high demand (e.g. condoms), so quickly establishing the payment guarantee keeps the delivery date on track. The most prevalent payment guarantee is a commercial letter of credit (L/C) opened at a reputable international bank by the purchaser in favour of the seller. The purchaser deposits money in the bank to "collateralize" the L/C; the bank then holds it until the seller provides documentary evidence that it has complied with its terms and conditions. This process completes the series of events required to secure performance commitment of both the purchaser and the supplier and begins the performance stage of the supply process.

## Phase 3: Performance

### 9 Step 9: Contract performance and monitoring[11]

Once both parties sign a contract and payment arrangements are in place, the purchaser is responsible for monitoring the supplier's performance of its contract obligations.

Proactive contract management and performance monitoring that engage the supplier's support allow the purchaser to obtain information on supplier production and performance problems at an early stage in their development. Early identification improves the chances of resolving a problem before it significantly affects the product delivery schedule. It can also be more cost-effective, since early problem identification allows the purchaser and supplier to consider a broader range of options, thereby minimizing the need to resort to more costly solutions such as delaying shipments.

11 For additional information see Modules 8 and 9 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

#### *9.1 Pre-shipment compliance testing*

There is reasonable assurance that WHO/UNFPA prequalified suppliers will deliver a product that is of consistently good quality.

Given, however, the intrinsic variability of latex, which is a naturally occurring material, and the complexity of the manufacturing process, even the most conscientious manufacturers can occasionally suffer quality problems. For this reason it is important to verify that every LOT manufactured complies with the requirements of the *WHO/UNFPA Specification* before it is accepted for shipment. This is called LOT-by-LOT Pre-shipment compliance testing.

LOT-by-LOT Pre-shipment compliance testing ensures that a quality product is prepared for shipment in accordance with the contract issued by the procurement agency. This is an internationally accepted practice that is highly recommended for all condom procurement, as it ensures the integrity of the product before it is shipped from the manufacturer.

***WHO recommends that every LOT be tested for compliance with the WHO/UNFPA Specification before it is accepted for shipment by the purchaser.***

When a consignment (or manageable portion of a consignment) is complete and ready for shipment, the supplier will inform the purchaser that the consignment is ready for testing. The purchaser then instructs a sampling agency to visit the supplier's factory to draw samples from the LOTS that have been produced for the order, in accordance with sampling guidelines provided in *ISO 2859–1,* as described in Section 1,

If the condoms do not meet the performance requirements, they should not be shipped.

If there are any problems or doubts about the quality of the product, follow the procedure detailed in Section 1, Chapter 4, Resolution of Disputes.

| Table 11. Summary of LOT-by-LOT Pre-shipment compliance testing and requirements | | |
|---|---|---|
| **Sample according to the relevant annex in *ISO 4074* for "continuous LOTS" and *ISO 2859–1*** | | |
| **Test** | **Sampling** | **Requirements** |
| Bursting volume (before and after oven conditioning) | Level G-I | Minimum volumes:<br>1. **16.0** $dm^3$ for condoms with widths less than 50 mm<br>2. **18.0** $dm^3$ for condoms with widths from 50 mm to 55.5 mm<br>3. **22** $dm^3$ for condoms with widths greater than 56 mm<br>AQL 1.5 |
| Bursting pressure (before and after oven conditioning) | Level G-I | Minimum pressure: 1.0 kPa<br>AQL 1.5 |
| Freedom from holes | Level G-I<br>Minimum Code Letter M | AQL 0.25 |
| Visible defects | Level G-I<br>Minimum Code Letter M | Critical defects: AQL 0.4<br>Non-critical defects: AQL 2.5 |
| Shape and texture | Agreed between manufacturer and buyer | Visual inspection |
| Package integrity | Level S-2 | AQL 2.5 |
| Integral bead | Agreed between manufacturer and buyer | Visual inspection |
| Colour | Agreed between manufacturer and buyer | Visual inspection |
| Fragrance and flavouring | Agreed between manufacturer and buyer | Sensory inspection |
| Width | Level S-2 | ± 2 mm of claimed width<br>AQL 1.0 |
| Length | Level S-2 | 1. **165** mm for widths less than 50 mm<br>2. **180** mm for widths between 50 mm and 55.5 mm<br>3. **190** mm for widths of 56.0 and above<br>AQL 1.0 |
| Thickness | Level S-2 | 0.045–0.085 mm<br>AQL 1.0 |
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes<br>Qty: 400–700 mg<br>AQL 4.0 |
| Odour (if necessary) | Agreed between manufacturer and buyer | Sensory inspection |
| Inner box | Level S-3 | Compliant with procurement specifications |
| Exterior shipping cartons | Level S-2 | Compliant with procurement specifications |

Chapter 2, Table 3 and as reproduced here for convenience as Table 11. The table lists the tests and gives the sample sizes and acceptance limits for Pre-shipment compliance testing.

The sampling agency sends the samples directly to the internationally accredited testing laboratory chosen by the purchaser, where they are subjected to the quality tests detailed in Table 11. All Pre-shipment compliance testing must be undertaken by an experienced, internationally accredited laboratory.

If the National Regulatory Authority has the technical expertise and appropriate laboratory equipment and is internationally accredited, arrangements can be made for this laboratory to undertake the Pre-shipment compliance testing of condoms prior to shipping. This arrangement would be identified in the contract with the supplier.

The Pre-shipment compliance testing reports are sent to the purchaser, who will approve the consignment for shipment. It is recommended that a certificate of compliance and a summary of the results of compliance testing be sent to the appropriate consignee and national regulatory authority to comply with any national regulatory requirements that may exist. It is also recommended that a summary of the test results of compliance testing is sent to the manufacturer irrespective of the results to give the manufacturer clear evidence of the outcome of the tests.

The shipping agent and manufacturer should ensure that all required documentation for the shipment is forwarded to the appropriate national authority as specified in the contract.

## 10 Step 10: Delivery of goods[12]

Public-sector contraceptives are normally shipped via ocean freight unless the supply source is close enough for trucking. Both of these options are far less expensive than air freight, which is usually reserved for emergency situations.

12 For additional information, see Module 10 of the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies* (PATH, 2009).

The contract between the supplier and the client will include a clear statement, known as an "INCOTERM", which defines when the ownership, responsibility and liability for a shipment is transferred from the supplier to the client and/or receiving country.

### *10.1 Customs clearance*

It is advisable to know the procedures for customs clearance before a contract is awarded to the supplier. The purchase contract should identify all customs documentation requirements that the supplier needs to provide for the shipment to clear customs. Being well prepared can reduce the time condoms are left sitting on the dock, which not only incurs demurrage (storage) charges but also can damage the condoms if they are not stored properly.

At the port of entry the regulatory licensing status of imported goods, including contraceptives and pharmaceuticals, is appraised. The purchasing entity may hire a customs clearing agent to complete necessary paperwork and obtain a release from customs. When this is not accomplished within a few days, the port authority applies demurrage charges, which can add up to significant sums of money.

Upon release from customs, it is up to the purchasing entity to transport the goods to its own warehouse. Some customs clearing agents will make this arrangement, and sometimes a local representative of the supplier will do it. In most cases the purchaser sends its own trucks or hires private transport.

Once the condoms are delivered to the initial warehouse, personnel perform a receiving inspection, to confirm that: a) all goods are present according to the accompanying packing slips; b) goods are in good condition; and, c) product names and expiry dates are clearly marked.

If the products pass receiving inspection, they are accepted; inventory records are updated to reflect receipt; and the product is officially placed in warehouse storage for distribution to and use by the programme.

If the product does not pass receiving inspection, a receiving report documenting the discrepancy is prepared and submitted to the purchasing entity, who

has responsibility for following up with the supplier to establish the cause of the discrepancy. If appropriate, recourse can then be obtained in accordance with the conditions of the contract.

### *10.2 Confirmatory testing*

Some national regulatory authorities may insist on undertaking confirmatory testing upon receipt of the shipment to ensure that the condoms have not been damaged during shipping. Where feasible, the confirmatory testing should be undertaken by the same laboratory that undertook the Pre-shipment compliance testing. Where possible, confirmatory 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.*

At no time should Pre-shipment compliance testing and confirmatory testing be undertaken by different laboratories, as this may risk contradictory results.

Confirmatory testing should be restricted to LOTS selected at random from a full shipment or consignment. It is recommended that priority be given to critical performance parameters: freedom from holes, airburst properties and package integrity.

The risk of statistical LOT failures due to sampling error should be considered when interpreting the results of such tests. If there are any problems or doubts about the quality of the product, then the procedure detailed in Section 1, Chapter 4, Resolution of Disputes, should be followed.

For additional information, the DELIVER Project (supported by USAID) has "Frequently Asked Questions" on post-shipment of condoms (http://pdf.usaid.gov/pdf_docs/PNADN675.pdf).


# CHAPTER 8

# Condom Storage

## SECTION THREE
# CHAPTER 8: CONDOM STORAGE

Condom factories prequalified by UNFPA will have provided evidence to verify the claimed shelf-life of the product. The shelf-life is determined by a real-time study, conducted at a specific temperature (30 $^{+5}_{-2}$°C), because this is the mean kinetic temperature of the most extreme climate in climatic zones III and IV. Research has demonstrated that properly packaged good-quality condoms stored at average temperatures in tropical climates do not deteriorate during storage. More information about the rationale for choosing 30 $^{+5}_{-2}$°C as the storage temperature for stability studies is given in the Technical Basis Paper in Annex I.

Since the shelf-life of the condoms will have been determined at 30 $^{+5}_{-2}$°C, air-conditioned storage is not necessary, but it would be an advantage in hot climates if available. In hot climates it is important that condoms are stored in a well-ventilated environment away from direct sunlight and other sources of heat in order to minimize the exposure of the condoms to high temperatures. Similar precautions should be taken during transportation and delivery. Condoms stored outdoors in shipping containers are particularly vulnerable, as the temperatures inside containers can be substantially above ambient temperatures, resulting in faster deterioration. Storage time in containers should be minimized.

The condoms are sealed in individual foil packages, which are themselves packed in cardboard. The cardboard storage containers are vulnerable to moisture and should be stored in a dry storeroom away from walls and placed on pallets to protect against rising damp. Cartons should be stored at least 10 cm off the floor, 30 cm away from the walls and stacked no more than 2.4 metres high.

Condoms are fully protected by the individual foil package. However, cosmetic damage to the foil and damage to the outer packaging can make the product appear damaged and therefore less acceptable to the user. Contaminants of any sort (e.g. powders or liquids) should be avoided.

Condoms should be left in their original cartons and inner boxes until needed for distribution. The cartons should be positioned so that the LOT number and expiry date are visible. The cartons should be identified and their locations recorded to ensure that specific LOTS can be located. LOTS should be released on a *first expiry—first out basis* (FEFO).

Damaged or expired condoms should be kept separately and disposed of in accordance with local procedures for the disposal of damaged medical devices.

For additional information in chart format on condom storage, refer to: http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidPropStor_Char.pdf.

For detailed information on the in-country management of storage and distribution, refer to the UNFPA-published *Condom Programming for HIV Prevention—An Operations Manual for Programme Managers* and PATH's *Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies.*

# CHAPTER 9

# Specification and Procurement Checklists

# SECTION THREE
# CHAPTER 9: SPECIFICATION AND PROCUREMENT CHECKLISTS

## 1 Introduction

These checklists are designed as useful tools to ensure that every step in the preparation of a specification and in the procurement process has been effectively addressed. They may be photocopied and/or downloaded from the following web sites: **http://www.who.int/rhem/** and **http://www.who.int/reproductivehealth/publications/family_planning/9789241599900/en/index.html.**

## 2 WHO/UNFPA Specification Checklist

Refer to Section 1, Chapter 2. Check the cycle of procurement, as it can take between 12 and 18 months to procure condoms.

| WHO/UNFPA Specification Checklist | | | |
|---|---|---|---|
| **Step** | **Checklist** | **Action** | **Comments/notes** |
| **1** | Are the condoms for:<br>• Social marketing programmes<br>• Public sector<br>• Both | | |
| **2** | Target population:<br>• Family planning programmes<br>• STI/HIV/AIDS prevention programmes<br>• Specific population groups | | |
| **3** | What are the regulatory requirements? (Refer to Procurement Checklist) | | |
| | What are the customs clearance requirements?<br>• Clearance<br>• Exemptions/waivers<br>• Documentation required | | |
| | What are the programmatic requirements? | | |
| **4** | Where are stocks of condoms held? | | |
| | How long will existing stocks last? | | |
| | Are high-priority areas or populations identified? | | |
| | What is the delivery schedule? | | |
| | What quantity is needed over what period? | | |
| | What is the storage capacity—where and what quantity? | | |
| | Is a distribution system in place? | | |
| **5** | Sampling agency and testing laboratory selected | | |
| | Prequalified suppliers reviewed | | |
| | Testing regimes for Pre-shipment compliance testing—testing laboratories selected | | |
| | Is confirmatory testing required? | | |

| WHO/UNFPA Specification Checklist | | | |
|---|---|---|---|
| **Step** | **Checklist** | **Action** | **Comments/notes** |
| **6** | Prepare specification | | |
| | General Requirements specified as detailed in the *WHO/UNFPA Specification* | | |
| | Performance Requirements specified as detailed in the *WHO/UNFPA Specification* | | |
| | Check Design Requirements:<br>• Colour: Indicate pigment and discuss with manufacturer<br>• Scent and flavouring: If fragrance is required, add to specification and discuss with manufacturer<br>• Shape and texture:<br>m State width<br>m State length<br>• Thickness as recommended in the *WHO/UNFPA Specification*<br>• Lubricant as recommended in the *WHO/UNFPA Specification* | | |
| | Check Packaging Requirements:<br>• Individual packaging and packaging markings according to the *WHO/UNFPA Specification*<br>• Language agreed to by manufacturer<br>• Individual package foil markings:<br>m Manufacturer's name and address<br>m Expiry date and date of manufacture<br>m LOT number<br>• Other references required by regulatory authority<br>• Shelf-life (not less than 3 and not more than 5 years) | | |
| | What additional foil markings are required?<br>• AIDS Help-Line<br>• Licence number<br>• "Not for sale"<br>• Instructions for use and disposal | | |

| WHO/UNFPA Specification Checklist | | | |
|---|---|---|---|
| **Step** | **Checklist** | **Action** | **Comments/notes** |
| **7** | Specify packaging | | |
| | Check packaging foil design:<br>• Colour (Pantone number)<br>• Font<br>• Logo<br>• Style<br>• Foil colour<br>• Foil shape<br>Foil approval: What procedure to follow? | | |
| **8** | Check Packaging Requirements: | | |
| | • Inner boxes and outer cartons according to the *WHO/UNFPA Specification*<br>• Markings of inner boxes and cartons according to the *WHO/UNFPA Specification*<br>• Inner pack quantity—any additional requirements:<br>• Logo?<br>• Address of procuring agency?<br>• Donor logo? | | |
| **9** | Consumer packs specified by purchaser:<br>• Wallet size and design<br>• Number per strip | | |

## 3 Procurement Checklist

Check the cycle of procurement, as it can take between 12 and 18 months to procure condoms.

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| **Step 1: Define supply requirements** | | | |
| *1.1 Define programme context* | | | |
| Which donor agencies, nongovernmental agencies, social marketing agencies, commercial enterprises and different public-sector ministries are involved in the procurement, distribution and promotion of condoms? | | | |
| What are the sources of funding? | | | |
| What sources of supply are used? | | | |
| History of condom procurement over the last three years | | | |
| *1.2 Forecast programme requirements* | | | |
| Research population's current needs and unmet needs | | | |
| History of previous shipments? | | | |
| Trends in condom use and procurement? | | | |
| What is the desired buffer stock level? | | | |
| Is there a Logistic Management Information System in place that captures stock level and distribution? | | | |
| What are the requirements of National Regulatory Authorities regarding procurement and importation? | | | |
| How are condoms imported into the country? | | | |
| Problems encountered in past procurement of condoms? | | | |
| Length of previous procurement cycles? | | | |
| Current stock levels and where condoms are stored?<br>What is the annual consumption?<br>How many months will current supplies last?<br>Any products that may not be distributed before expiry date? | | | |
| Projected time-scale for distribution? | | | |
| Projected requirements? | | | |
| Time-scale for delivery? | | | |
| Storage and distribution system in place? | | | |

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| **Step 2: Customize the specification** | | | |
| Refer to *WHO/UNFPA Specification* | | | |
| General Requirements should not be modified | | | |
| Performance Requirements should not be modified | | | |
| Design Requirements can be modified | | | |
| Packaging Requirements should not be modified | | | |
| Consumer pack designed and approved | | | |
| Specification of consumer pack prepared for discussion with manufacturer | | | |
| Other issues | | | |
| **Step 3: Assessment of procurement options** | | | |
| Select one method:<br>i) Procure directly from a manufacturer through competitive bidding process | | | |
| ii) Source from a procurement agency | | | |
| iii) Source from an international procurement agency/ organization | | | |
| iv) Buy from a social marketing organization | | | |
| **Step 4: Budget, funding and procurement requisition** | | | |
| Estimate procurement costs to determine budget:<br>• unit price;<br>• freight cost and insurance;<br>• sampling and testing;<br>• import/customs clearance costs;<br>• post-shipment confirmatory testing;<br>• taxes. | | | |
| Also consider:<br>• warehouse and storage costs;<br>• distribution costs;<br>• promotion costs. | | | |
| Funding: Identify and secure funding | | | |
| Identify key challenges and how you are going to deal with them | | | |

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| **Step 5: Procurement planning** | | | |
| Obtain authorization to contract and commit funds | | | |
| Confirm budget allocations and timing for availability of funds | | | |
| Review technical specifications to ensure that they are complete and in a format consistent with international standards | | | |
| Confirm the date, delivery location and mode of transport | | | |
| Visit customs authorities and discuss procedures | | | |
| Review regulations covering national regulatory procedures, importation and distribution of condoms | | | |
| Confirm specific country requirements and national regulatory procedures:<br>• Is there a mandatory national quality standard?<br>• How are the standards applied?<br>• Is there a requirement to test every LOT of condoms before it is shipped to the country?<br>• Is there a competent accredited laboratory in-country? If not, is there an accredited regional laboratory?<br>• What other entry requirements are there?<br>• Is there a registration requirement prior to importation? | | | |
| Visit National Regulatory Authority and review and understand procedures | | | |
| **Step 6: Developing Bidding Documents and inviting offers** | | | |
| Identify information required for Bidding Documents:<br>• instructions, rules, and procedures for bidding;<br>• information about where and when bids will be opened;<br>• information about how bids will be evaluated and how the purchaser will select the winning bid;<br>• information about any factors in addition to price that the purchaser will consider;<br>• technical specifications and compliance requirements;<br>• quantity, delivery schedule and delay clauses (requirements);<br>• national regulatory requirements;<br>• terms and conditions for the future contract between the purchaser and the winning bidder; | | | |

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| • request for documentary evidence of manufacturing quality assurance measures;<br>• procedure for resolution of disputes;<br>• procedures for Pre-shipment compliance testing and, if required by national bodies, confirmatory testing procedures;<br>• shipping arrangements;<br>• payment arrangements;<br>• sample forms containing necessary wording for the bidder to use. | | | |
| Any other issues? | | | |
| Use WHO/UNFPA prequalified suppliers:<br>• verify manufacturing capacity;<br>• seek information on potential suppliers;<br>• select an independent testing laboratory;<br>• select an independent sampling agency. | | | |
| Prepare Bidding Document package:<br>• general instructions to bidders;<br>• special instructions to bidders;<br>• eligible/ineligible countries and suppliers;<br>• general conditions of contract;<br>• special conditions of contract;<br>• technical specifications;<br>• schedule of requirements and delivery dates;<br>• evaluation criteria;<br>• qualification criteria;<br>• bid and contract forms, which include:<br>m price schedule<br>m bid security form<br>m performance security form<br>m contract agreement form. | | | |
| Invitation to bid:<br>Media for advertising bid invitation known? | | | |
| Receiving and managing bids:<br>• Bids must be held unopened until the stated day and time of bid opening.<br>• Bid envelopes should stamped with the date and time received. | | | |

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| **Step 7: Selecting suppliers** | | | |
| Agree on criteria for evaluating bids | | | |
| Is assistance required to review and interpret documentary evidence supplied by manufacturers? | | | |
| Check to see if the suppliers have confirmed that they:<br>• are capable of providing the quantities required within the desired time frame;<br>• have a proven record of manufacturing products that conform to the *WHO/UNFPA Specification*, the purchaser's specification, or similar requirements;<br>• are WHO/UNFPA prequalified suppliers, if that qualification has been identified in the Bidding Documents as a requirement for bidding;<br>• will permit a sampling agency to perform random sampling of condoms at the site of the manufacturing facility;<br>• will accept Pre-shipment compliance testing and, if required, confirmatory testing;<br>• will accept the test results of an independent laboratory agreed to by both parties;<br>• will accept the procedure for the resolution of disputes;<br>• will accept the general and specific conditions of the contract. | | | |
| Eliminate non-specialized procurement agents and importers from the list of potential suppliers. | | | |
| **Step 8: Contract negotiation/award** | | | |
| Is the supplier chosen on the basis of:<br>• WHO/UNFPA prequalified supplier;<br>• quality of the product;<br>• capacity to supply;<br>• price;<br>• ability to meet the requirements of the contract. | | | |
| Payment guarantee in place? | | | |
| **Step 9: Contract performance and monitoring** | | | |
| System to proactively manage contract in place? | | | |
| LOT-by-LOT Pre-shipment compliance testing organized? | | | |

| Procurement Checklist | | | |
|---|---|---|---|
| **Step and checklist** | **Yes** | **Date completed** | **Comments/notes** |
| **Step 10: Delivery of goods** | | | |
| Are procedures for customs clearance known and implemented? | | | |
| Is storage organized? | | | |
| Are arrangements made for every LOT manufactured to be sampled and tested for compliance with the specification prior to shipping? | | | |
| Are regulatory requirements met? | | | |
| Is assistance to interpret the results of the laboratory tests required? (Discuss with laboratory or contact Help-Line.) | | | |
| Is there an established procedure for the resolution of disputes? | | | |
| Do you know the delivery schedule? | | | |
| Do you know the customs clearance procedures?<br>Do you have all the appropriate information and forms required for customs clearance? | | | |
| Does the regulatory authority require confirmatory testing?<br>If yes, have sampling procedures and testing regime been agreed upon? | | | |
| Is the regulatory authority familiar with the process for resolving disputes? | | | |
| Has the delivery schedule been reconfirmed? | | | |
| Is the customs clearance procedure known? | | | |
| Has all of the customs documentation been received? | | | |
| Do you need to deal with any factors that could delay receipt of the shipment? | | | |
| Are storage facilities ready and prepared to receive the shipment of condoms? | | | |
| Has transportation been organized? | | | |
| *Storage* | | | |
| Clean, dry, well-ventilated environment? | | | |
| No contact with oil, petrol, water, ultraviolet light? | | | |
| In original packaging with manufacturing markings? | | | |
| Stored on the basis of first in—first expiry out? | | | |

# SECTION FOUR

## Annexes

# ANNEX I
# TECHNICAL BASIS FOR THE WHO/UNFPA SPECIFICATION, 2003–2010

## 1 Review of the technical process to publish the Male Latex Condom: Specification and Guidelines for Procurement (WHO, 2004)

The *Male Latex Condom: Specification and Guidelines for Condom Procurement* was updated and published by the World Health Organization (WHO) in January 2004. Included in that document was the *Model Specification for Male Latex Condoms.* The 2004 publication was based on an extensive review and technical consultative process to ensure that it reflected the latest available information. WHO, in collaboration with Family Health International, UNFPA and UNAIDS, undertook the following activities:

- Supported the preparation of a technical background paper for the meeting by Dr William Potter, reviewing the evidence base for the *Specification and Guidelines for Condom Procurement.*
- Supported the preparation of a technical background paper by Dr John Gerofi, reviewing the available information on whether two sizes of condoms meet the needs of all potential users.
- Supported the preparation of a review of the literature to collate the latest available evidence on the efficacy and effectiveness of the male latex condom to prevent the transmission of STIs/HIV.
- Convened an Informal Technical Consultation, held in Johannesburg, South Africa, in May 2002, in collaboration with the WHO Africa Regional Office (WHO/AFRO); the Reproductive Health Research Unit, Department of Obstetrics and Gynaecology, University of the Witwatersrand; and Chris Hani Baragwanath Hospital in Soweto, South Africa. This meeting involved 32 participants, including representatives from bulk procurement agencies; international organizations and nongovernmental agencies; manufacturers; testing laboratories and programme managers from China, Ghana, Nigeria, South Africa, Thailand and Zimbabwe; and the national bureaus of standards of South Africa and Tanzania. The purpose of the meeting was to review the 1998 WHO publication *Specification and Guidelines for Condom Procurement* against the latest available information, programmatic experience and the newly published *ISO 4074:2002* standard. A report of the meeting is available from the documentation centre of WHO, Department of Reproductive Health and Research (WHO/RHR) by e-mail (rhrpublication@who.int). It will also be published on the WHO/RHR web site (http://www.WHO.int/reproductivehealth).
- Convened a meeting with delegates to the International Organization for Standardization Technical Committee 157 (ISO/TC 157), which is responsible for the revision and publication of *ISO 4074 Natural Latex Rubber Condoms.* This meeting took place during the 19th annual meeting of the delegates to ISO/TC 157, with support from the Malaysia Department of Standards and the Secretariat to ISO. The meeting was held on 12 July 2002 in Kuala Lumpur, Malaysia, and involved 67 delegates representing manufacturers, testing laboratories, scientists and consumer groups from 19 countries. The purpose of this meeting was to review and receive comments on the revised *Model Specification* for the male latex condom in order to foster consensus and commitment to support the use of the *Model Specification* and recommended procurement procedures.
- Conducted an external review of the revised *Male Latex Condom: Specification and Guidelines for Condom Procurement* between January and March 2003. The document was sent to 120 reviewers who represented the interests of bulk procurement agencies, international organizations and nongovernmental agencies, manufacturers, testing laboratories and programme managers. The response rate was 60%. Comments were collated and reviewed by a small team of technical experts prior to the final revision of this document.
- Reviewed the *Model Specification* in June 2003 against the conclusions and recommendations made at the 20th annual meeting, in Denver, Colorado, USA, of delegates to ISO/TC 157, who were responsible for the revision and publication of *ISO 4074 Natural Latex Rubber Condoms.*

All papers and consultations were used as a basis for formulating the WHO/UNFPA/UNAIDS/FHI publication, *Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO 2004).

References from these papers have been included in the bibliography of this annex.

## 2 WHO/UNFPA Prequalification Scheme for Male Latex Condoms

In 2001 WHO established a Prequalification Scheme as a service to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. From the outset, the Prequalification Scheme was supported by UNAIDS, UNICEF, UNFPA and the World Bank as a concrete contribution to the United Nations priority goal of addressing widespread diseases in countries with limited access to quality medicines. Prequalification was originally intended to give United Nations procurement agencies, such as UNICEF, the choice of a range of quality medicines. With time, the growing list of products that have been found to meet the set requirements has come to be seen as a useful tool for anyone bulk-purchasing medicines, including countries themselves and other organizations.

Since 2002 the prequalification of manufacturers of male latex condoms has been recommended by WHO and incorporated into the guidelines for procurement in the *Male Latex Condom: Specification and Guidelines for Procurement* (WHO, 2004). UNFPA and other agencies independently implemented Prequalification Schemes based on these recommendations.

In 2006 it was agreed that WHO would work with UNFPA to formulate a Prequalification Scheme for male latex condoms and intrauterine devices (IUDs) that would be harmonized with the WHO Prequalification Scheme for Essential Medicines. The Prequalification Scheme would support a rigorous process of assessment, and all manufacturers successfully completing this process would be listed on the WHO and UNFPA web sites as prequalified suppliers. This list would then be available to all bulk procurement agencies and national authorities that wish to purchase these medical devices.

In order to achieve this objective, WHO set up a series of meetings engaging a team of technical experts and has published Prequalification Schemes for male latex condoms and the TCu-380A IUD. These schemes are harmonized with the WHO Prequalification Scheme for Essential Medicines, recognizing of course that both the condom and the IUD are classified as medical devices rather than medicines. The schemes were presented to and approved by the 42nd WHO Expert Committee on Specifications for Pharmaceutical Preparations, October 2007, and approved for publication subject to external review.

The Prequalification Scheme for male latex condoms was then reviewed by programme managers and representatives from the condom manufacturing industry, regulatory authorities and national testing laboratories at three prequalification workshops—held in Beijing, China; Delhi, India; and Bangkok, Thailand—in January and February 2008. The Prequalification Scheme was revised based on feedback received and published by WHO/UNFPA in May 2008[1]. As a result of feedback from the participants in these workshops, a guidance document on how to implement the Prequalification Scheme was prepared and has since been reviewed by participants in prequalification workshops undertaken in Botswana, Indonesia, South Africa, and Viet Nam, from January to March 2009. Both the Prequalification Scheme and the Prequalification Operational Guidance document have been included in Section 2 of this manual.

## 3 Technical basis for updating the WHO/UNFPA Specification, 2008–2009

In 2008 ISO published a second technical corrigendum to *ISO 4074* and, as of late 2009, following a periodic review, ISO is updating the standard. A committee draft of the proposed revised standard was published for review in 2008 by national standards organizations and other agencies represented at the international standard committee for non-systemic contraceptives and STI-barrier prophylactics, ISO/TC 157. The date of publication of the revised *ISO 4074* standard is difficult to estimate since the timing depends upon achieving consensus, but it is unlikely to be before 2011.

1 *Forty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.* Geneva, WHO, May 2008 (WHO Technical Report Series, No. 948).

Since the publication of the 2003 Model Specification, manufacturers, laboratories, agencies and other bodies have gained considerable experience with applying the procedures for determining the shelf-life of condoms. As a consequence, it has now been recognized that some of the procedures and requirements for shelf-life determination that are specified in *ISO 4074:2002* and cross-referenced in the 2003 Model Specification are inappropriate and required review.

With the introduction of the WHO/UNFPA Prequalification Scheme, the publication of the second technical corrigendum to *ISO 4074* and the pending revision of *ISO 4074,* it was recognized that the 2003 publication needed updating. A technical basis paper for the revision of the Model Specification was developed by Dr William Potter, reviewing the implications of the publication of the second technical corrigendum to *ISO 4074,* the proposed changes to *ISO 4074* and feedback from the prequalification workshops.

WHO, UNFPA and FHI convened a meeting of the Male Condom Technical Review Committee on 14–18 July 2008 to update the specification and procurement guidelines, taking into account the recommendations and information in the technical basis paper. Experts from a broad range of interested parties, including donors, international agencies, bulk procurement agencies, non-governmental agencies, national regulatory authorities and testing laboratories, were invited along with independent experts to participate in the technical review process. The recommendations from this meeting formed the basis for a core team of technical experts to revise the specification and procurement guidelines for male latex condoms. The revised specification was reviewed by all members of ISO/TC 157 during the 25th annual meeting, hosted by WHO/UNFPA/FHI/PATH, 13–18 October 2008, in Montreux, Switzerland, and again at the 26th annual meeting in October 2009 in Shanghai, China.

Reports of the Male Condom Technical Review Committee meetings are available from the WHO Department of Reproductive Health and Research.

This annex is designed to explain the technical basis for the updated *WHO/UNFPA Specification.* It includes, where appropriate, the rationale for changes that have been made to the *WHO/UNFPA Specification.*

## 3.1 Requirements

### *3.1.1 General Requirements*

General Requirements are those properties of the condom that are not expected to change from LOT to LOT. Manufacturers are expected to include evidence that the products comply with the General Requirements in their Product Dossiers and Site Master File summaries.

### *3.1.2 Materials*

Many of the materials used in latex formulations are irritating and sensitizing if used in excess. Manufacturers are required to demonstrate that their products are safe, using the appropriate sections of *ISO 10993 Biological Evaluation of Medical Devices.* In response to feedback from manufacturers, more details about the type of biological evaluations required and the specified parts of *ISO 10993* that apply to condoms are given in the *WHO/UNFPA Specification.* The safety assessment must include any dusting powder, colourant, lubricant and any other material that is added to the condom as well as any biocides added to the slurry, leach or washing solutions. A dossier containing the safety assessment, including expert reports interpreting the outcome of the studies, shall be made available to prospective purchasers. Summary reports must be included in the Product Dossier.

Manufacturers may rely upon regulatory clearance from internationally recognized regulatory authorities to substantiate the safety of their products. Examples of acceptable approvals include a 510(k) premarket clearance to market the product from the U.S. Food and Drug Administration (USFDA) and approval for CE marking from a European Notified Body. When reliance upon such regulatory documentation is made, the manufacturer shall be required to supply all supporting documentation used in making the submission.

*Allergic reaction*

Two types of potential allergic reaction to latex condoms are possible. The first, more common potential risk is of a Type IV reaction. This type of reaction, also known as delayed hypersensitivity, most usually causes a skin rash (contact dermatitis). It is caused primarily by accelerator residues remaining in the condom. Manufacturers are encouraged to minimize accelerator residues by using the minimum amount of these chemicals in their formulations, effectively leaching and washing the condoms

and choosing accelerators with a good safety profile such as zinc dibutyldithiocarbamate (*1*).

The second type of allergic reaction is a Type I hypersensitivity to some of the naturally occurring water-soluble proteins found in latex. This type of allergic reaction to condoms is extremely rare. One report cites the incidence of latex protein allergy amongst condom users as 0.08% (*2*). Type I allergic reactions tends to affect the respiratory system and can, in extreme circumstances, lead to anaphylaxis.

*Protein levels*
Manufacturers shall take every precaution through effective leaching and washing of the product to maintain low levels of residual extractable proteins and shall periodically determine the residual protein levels to confirm the effectiveness of the washing and leaching procedures.

Feedback from manufacturers indicated that guidance on maximum permissible protein levels in condoms would be useful. Accordingly, a guideline limit of not more than 200 μg of water-soluble protein, as determined by the modified Lowry method, per gram of condom is recommended. There is no specific standard for determining the protein levels in condoms; the methods described in *ISO 12243, EN 455-3* and *ASTM D5172* for determining the protein levels in medical gloves can be modified for condoms.

*Nitrosamines*
Chemicals known as nitrosamines can be formed in condoms in very small quantities, typically below 500 μg/kg, by the interaction of accelerator residues in the condom with nitrogen oxides from the air. These chemicals are potentially carcinogenic. The levels of nitrosamines typically found in condoms constitute only a small proportion of normal nitrosamine exposure (*3*). Nevertheless, manufacturers should try to minimize the amounts of nitrosamines formed by using minimum amounts of accelerator, choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile and ensuring that the condom is well leached.

*Bioburden level*
Condoms are not sterile products and, given their mode of use, there is no need for them to be sterile. Nevertheless, manufacturers are required to minimize the risks of microbial contamination during manufacture and packaging. In response to requests from the manufacturers, recommendations for the maximum recommended microbial bioburden on condoms prior to packaging are now included in the *WHO/UNFPA Specification.* The technical basis for recommending these limits has been reviewed and is given in Annex II.

### *3.1.3 Shelf-life*
Manufacturers are required to verify the shelf-life of their products using real-time stability studies. Critical to conducting these studies is the choice of a reference temperature appropriate to the expected storage conditions for the condoms in the destination countries.

The International Conference on Harmonization (ICH) guidelines on pharmaceutical stability studies[2] define the concept of mean kinetic temperature as "a single derived temperature which if maintained over a defined period would afford the same thermal challenge to a pharmaceutical product as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period". In other words, the mean kinetic temperature is a single temperature that will result in the same degree of thermal challenge to a product as storage in a particular climatic zone, taking into account the normal variation in temperature over the storage period. It also takes into account the changes in rates of chemical reactions that occur as the temperature increases.

The concept of dividing the world into four climatic zones to facilitate the stability testing of pharmaceutical products was proposed by Paul Schumacher in 1972 (*4*) and Wolfgang Grimm in 1986 (*5*), 1993 (*6*) and 1998 (*7*). The proposal was accepted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 1996, following extensive consultations (*8*). The mean kinetic temperature of the two most extreme climatic zones, Zone III (hot/dry) and Zone IV

2 *Guidance on stability testing: stability testing of new drug substances and products.* (CPMP/ICH/2736/99). Geneva, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), 2003 (http://www.emea.europa.eu/pdfs/human/ich/273699en.pdf).

(hot/humid), was established as 30 °C. Proposals are at an advanced stage to divide Zone IV further on the basis of humidity, but this will not affect the choice of 30 °C as the mean kinetic temperature.

Given that the mean kinetic temperature for the two most extreme climatic zones is 30 °C, this temperature is specified as the reference temperature for condom stability studies. A tolerance of -2 °C has been allowed, based on conventional practice. The upper tolerance was increased to +5 °C to simplify temperature control requirements when conducting real-time stability studies in countries where ambient temperatures may periodically exceed 32 °C. Real-time studies shall therefore be conducted at a temperature of ($30\ ^{+5}_{-2}$) °C.

Methods of assessing the shelf-life of latex condoms have been researched in considerable detail by a working group, ISO/TC 157 WG 13, a subcommittee of ISO/TC 157. Since the publication of *ISO 4074:2002,* manufacturers have been required to complete both accelerated and real-time studies to determine the shelf-lives of their condoms. In addition, a number of independent researchers have undertaken comparative real-time and accelerated studies, most notably Dr M.C. Bo of the Instituto Nacional de Tecnologia, Rio de Janeiro, Brazil (*9*). Much, but not necessarily all, of this information has been made available to ISO/TC 157 WG 13. In the data supplied, the following general trends are usually seen in the way in which the burst properties of condoms change under accelerated and real-time storage conditions:

1. At higher temperatures, i.e. above approximately 50 °C, the burst pressure properties of the condom tend to decline more rapidly than the burst volume. Estimates of shelf-life are most likely to be limited by failure of the condoms to achieve the minimum AQL requirements for burst pressure. Burst volume behaviour can vary considerably depending upon manufacturer, but often the burst volume remains relatively constant or even increases initially before slowly declining.
2. At lower temperatures, particularly at 30 °C, which is the reference temperature for real-time stability studies, burst volumes tend to decline more rapidly than burst pressure. The shelf-life of the product is more likely to be constrained by failing to achieve the AQL requirements for burst volume than for pressure.
3. The early phases of stability studies can be misleading since fresh condoms can undergo changes in burst properties resulting from maturation of the network structure within the latex film. Often, this can result in an initial fall in burst volume and a rise in burst pressure.
4. The Arrhenius relationship, which correlates changes in the rate of chemical reactions with temperature, can often be applied to burst pressure changes but not necessarily to burst volume changes. Even when the Arrhenius relationship is found to apply to burst volume data, the activation energy differs from that determined using burst pressure data. These factors, coupled with the different behaviour patterns observed in burst property trends at low and high temperatures, make application of the methods described in Annex K of *ISO 4074:2002* difficult and potentially unreliable.

Given this new information, ISO/TC 157 WG 13 agreed to recommend to ISO/TC 157 a number of changes to the procedures and requirements for determining the shelf-life of the condoms by accelerated studies. These changes are being considered for inclusion in the next edition of *ISO 4074.* They apply only to accelerated studies. The requirement to confirm the shelf-life of the product through real-time studies at ($30\ ^{+5}_{-2}$) °C will remain unaltered in the next edition of *ISO 4074.* The proposed changes are:

1. To retain the requirement to conduct a minimum stability assessment on any new or modified condom as described in the relevant clause of *ISO 4074.* This requires the manufacturer to demonstrate that condoms remain in compliance with the minimum airburst requirements of the relevant clause after conditioning for (168 ± 2) hours at (70 ± 2) °C and (90 ± 1) days at (50 ± 2) °C. A provisional shelf-life of two years may be assigned to products that meet this requirement.
2. To amend Annex K, which describes procedures for conducting accelerated studies, to allow a provisional shelf-life of three years to be assigned

to a product if it remains in compliance with the airburst requirements of the relevant clause of *ISO 4074* for a period of 120 days at (50 ± 2) °C or a provisional shelf-life of five years if it remains in compliance after 180 days at (50 ± 2) °C. An alternative procedure is also being proposed that would allow a new or modified product to be compared with a control product in a parallel stability study, providing the shelf-life of the control product has already been validated by a real-time study.

After considering the proposals made by ISO/TC 157 WG 13, the experts present at the WHO/UNFPA/FHI Technical Review Committee Meeting, in July 2008, agreed to adopt the following requirements for shelf-life in the *WHO/UNFPA Specification:*

1. Manufacturers shall confirm, using real-time studies at ($30\ ^{+5}_{-2}$) °C, that the condoms comply with the performance requirements of the *WHO/UNFPA Specification* throughout the stated shelf-life. Manufacturers shall stipulate a shelf-life based on the outcome of stability studies and measured from the date of manufacture, which for the purposes of the *WHO/UNFPA Specification* is defined as the date of dipping. The stated shelf-life shall be not less than three years and not more than five years from the date of manufacture.
2. Pending the outcome of real-time studies, manufacturers may claim a provisional shelf-life based on demonstrating compliance with the performance requirements of this *WHO/UNFPA Specification* on the basis of accelerated studies conducted at (50 ± 2) °C.
    a. A provisional shelf-life of three years may be claimed after an ageing period of 120 days.
    b. A provisional shelf-life of five years may be claimed after a period of 180 days.

It is emphasized that manufacturers are required to demonstrate that the condoms comply with all the performance requirements of the *WHO/UNFPA Specification* throughout the shelf-life of the product. This means that, as part of any stability study, changes in burst properties, freedom from holes and pack integrity will have to be monitored.

#### *3.1.4 Minimum stability requirements*

ISO/TC 157 has determined that all condoms shall meet minimum stability requirements before being placed on the market. This allows manufacturers and purchasers to assess the stability of a product relatively quickly. Additionally, it has been agreed that products meeting these requirements may be assigned a provisional shelf-life of two years. These requirements are specified in Clause 7.2 of *ISO 4074:2002* and will most probably be retained in the next edition of the standard.

The test for minimum stability includes accelerated conditioning regimens at (50 ± 2) °C for 90 days and (70 ± 2) °C for 7 days. The temperatures and times have been selected on the basis of practical experience with stability studies on condoms. Meeting these requirements does not imply that the condoms will have any specific shelf-life. In practice, it is anticipated that manufacturers will continue the study at (50 ± 2) °C for 120 and/or 180 days to estimate a provisional shelf-life for the product.

The minimum stability test can be commenced as part of the prequalification stage of the procurement procedure and must be completed before any contract is confirmed.

### 3.2 Performance requirements

#### *3.2.1 Bursting volume and pressure*

The inflation test was adopted by ISO for condom testing in 1990 and has always been a part of the WHO specifications. The condom is inflated with air until it bursts. The test challenges a large part of the surface area of the condom, and flaws in the latex film will reduce the burst volume and pressure of the condom. The 2003 *Model Specification* requires that samples from every LOT of condoms are inflation-tested without oven treatment and with oven treatment at (70 ± 2) °C for (168 ± 2) hours.

Two corrigenda to *ISO 4074* have been published. The first, published in December 2002, corrected a number of errors in the original text of *ISO 4074:2002* and increased the upper limit of the temperature tolerance for conducting real-time stability studies to 35 °C from 32 °C. Relevant amendments to *ISO 4074:2002* resulting from Corrigendum 1 were incorporated into the 2003 *Model Specification and Procurement Guidelines.*

The second corrigendum, published in April 2008, eliminated the requirement specified in Clause 6.2 and other related parts of *ISO 4074:2002* for LOT testing of oven-treated condoms. Clause 6.2 specified that condoms conditioned for (168 ± 2) hours at (70 ± 2) °C shall meet the minimum airburst requirements specified in clause 6.1. It is expected that the next edition of *ISO 4074* will not include requirements for LOT testing of oven-treated condoms.

The implications of eliminating the need for inflation testing after oven treatment were reviewed at the WHO/UNFPA/FHI Male Condom Technical Review Committee meeting. There was some reluctance to drop the requirement to test oven-treated condoms completely from the *WHO/UNFPA Specification* since the test can, on occasions, provide potential warning of shelf-life problems when condoms are stored in hot climates. It was originally agreed to retain the test on an intermittent sampling basis and recommend that samples be drawn from every fifth LOT for inflation testing after oven treatment.

Following an external review, consensus could not be reached on the need for this requirement. As an interim measure, pending the production of definitive evidence supporting the benefits of testing oven-conditioned condoms on a LOT-by-LOT basis, this requirement has been made optional in the *WHO/UNFPA Specification.* Purchasers may wish to include this requirement in specific contracts depending upon their level of confidence in the supplier.

It is recommended as an alternative that purchasers develop systems to monitor the variability in LOT-to-LOT average burst pressures and volumes for untreated condoms. Individual LOT average values should not vary by more than ± 20% of the overall average across all LOTS tested. Any LOT exhibiting a shift from the overall mean that is larger than 20% should be quarantined until further investigations are carried out, and any long-term shift in the LOT average should be investigated. Monitoring is best achieved by using a control chart. Further information on methods of monitoring quality using control charts is given in Annex IV.

The test methods and minimum burst volume and pressure requirements in this section are identical to those in *ISO 4074.* The pass/fail criterion is based on constraining the number of condoms bursting below the limits stated. ISO/TC 157 is currently considering introducing requirements for humidity control during burst testing. The proposed limits are (55 ± 15)% relative humidity. If humidity control is adopted and incorporated into a future edition of *ISO 4074,* then by reference to this standard the same limits will apply to the test method specified in the *WHO/UNFPA Specification.*

The relevance of inflation testing to the performance of the condom in use has been explored in many articles (*10–14*). Inflation testing is currently regarded as a reliable and effective method of assessing the strength and consistency of condoms.

### *3.2.2 Freedom from holes and visible defects*

A condom with a hole in it is clearly defective. The methods for testing for freedom from holes in the *WHO/UNFPA Specification* are identical to those in *ISO 4074,* as are the requirements. These test methods have been used for condoms for many years.

There are two alternative tests. The first is a visual test, in which the condom is filled with water and inspected for leakage. The second is a conductivity test, in which the condom is filled with a salt solution and immersed in a tank containing salt solution. An electrical voltage is applied across the film. If there is a hole in the condom, it is detected by a flow of current. Any holes detected by the electrical conductivity test are confirmed by the water test. The equivalence of the two tests has been verified by a study funded by the European Commission (*15*).

Some modifications to the electrical test for freedom from holes are being considered by ISO/TC 157 based on recommendations from working group ISO/TC 157 WG 19. The proposed changes are intended to address possible issues with the sensitivity of the electrical test with certain types of condoms. The proposed changes include increasing the amount of electrolyte to 300 ml, filling the condoms with electrolyte before immersing them in the electrolyte bath, and applying the voltage between the condom and the electrolyte bath before the start of immersion. If these changes are adopted and incorporated into a future edition of *ISO 4074,* then by reference to this standard the same

changes will also apply to the test method specified in the *WHO/UNFPA Specification.*

Several studies have investigated the viral barrier properties of condoms that pass the tests for freedom from holes (*16–20*). These studies have demonstrated that intact condoms are, for all practical purposes, an effective barrier to the smallest viruses.

*ISO 4074* also requires that, at the time that testing for freedom from holes is being done, the condoms are examined visually for specified visible defects that may render the condom likely to fail in use. Such defects include a broken, missing or severely distorted bead or permanent creases with adhesion of the film (see Section 1, Chapter 3, Workmanship and Visible Defects).

#### *3.2.3 Package seal integrity*

The purpose of the package is to protect the condom from mechanical damage, oxygen, ozone and light and to prevent lubricant from leaking. Exposure to oxygen, ozone and ultraviolet and visible light increases the risk of degradation of the condom.

The test adopted is identical to that in *ISO 4074.* It involves putting the packs under water in a transparent container and then drawing a vacuum on the container. The packs are observed for signs of rising bubbles while under vacuum. The vacuum is then removed and the packs are opened for evidence of ingress of any water. The presence of rising bubbles while under vacuum or the ingress of water into the pack after removing the vacuum indicates a leaking pack.

### 3.3 Design requirements

The recommended design features are specified, but they may be modified by the purchaser to suit local conditions and preferences. They are modified in the appropriate clause by mutual agreement among the purchaser, manufacturer and recipients. It is recommended that only well-established commercial designs be used.

The differences in manufacturing costs for established designs are generally marginal, but it is expensive for a manufacturer to change a design or introduce a new one.

#### *3.3.1 Shape and texture*

The conventional parallel-sided (cylindrical) condom shape has been in the WHO specification since it was first published. In the commercial sector a variety of other shapes are available. There are few studies on the relative acceptability and efficacy of condom shapes. Two of these studies (*21, 22*) indicate that approximately equal proportions of people preferred each of the variants covered in the trials.

The design details of shaped condoms are specific to particular manufacturers who have the appropriate formers and testing mandrels. Selecting a particular non-parallel profile may thus reduce the range of possible suppliers.

Textured condoms can be more difficult to manufacture. Depending upon the type and location of the texturing, it may be difficult to measure the thickness of textured condoms. Members of the Male Latex Condom Technical Review Committee agreed to make this version of the *WHO/UNFPA Specification* more flexible regarding the shape and texture of condoms that could be ordered for bulk procurement.

#### *3.3.2 Integral bead*

The integral bead (or rim) is a ring of rubber at the open end of the condom.

#### *3.3.3 Colour*

Pigments may be added to the latex formulation. They need to be selected so that they are not harmful to the users as demonstrated by biocompatibility studies conducted according to *ISO 10993.*

Some pigments may affect the physical properties of the rubber and increase the incidence of holes. Such pigments should not be used.

Appropriate methods of defining the colours shall be agreed upon between the manufacturer and purchaser. The use of Pantone colour charts may be useful. Strips that mix different coloured condoms are not recommended because they require the mixing of condoms from different LOTS. This complicates sampling for quality assurance as well as the tracing of defects.

#### *3.3.4 Odour and flavouring*

Rubber products generally have some odour. Inadequate washing of the product during manufacture and excess of some chemicals may cause a smell that is stronger than normal. Only subjective assessments of smell are practical at this stage.

It is possible to mask the smell of rubber or provide a pleasant smell using some flavours or fragrances. It is, however, preferable to eliminate the odour as far as possible by selection of formulation and processing conditions. Condoms often smell most strongly when the pack is first opened. Odours can disperse relatively quickly.

Flavouring can be used on condoms, especially if they may be used for oral sex. It is usual to add flavouring and fragrances to the lubricant.

Fragrance and flavouring must be discussed and agreed on by the manufacturer and purchaser. They need to be selected so that they are not harmful to the users as demonstrated by biocompatibility studies conducted according to *ISO 10993.*

More details on assessing odour using a panel of testers are given in Annex III.

### *3.3.5 Width*

Condom width is defined as the width when the condom is laid flat; it is half the circumference.

The relative circumferences of the condom and penis determine how well the condom fits. Excessively large or small condoms relative to penis size appear to increase the risk of failure. It appears from the limited information available that three widths of condoms will meet the needs of most of the population[3]. Condoms of a width of 49 mm are readily available from many manufacturers, and this is therefore the preferred size for a narrower condom. The standard width for condoms is usually 52 to 53 mm (WHO/UNFPA specify 53 mm ± 2 mm). There is no recognized size for larger condoms. Some manufacturers produce condoms of 56 mm width or more.

### *3.3.6 Length*

Based on the information available in the literature and anecdotally, there is a weak correlation between mean penis circumference and mean penis length. As far as it is possible to ascertain from the limited data available at the country level, the narrower condoms should be shorter. Therefore, it is recommended that the minimum length of the condom depend upon the chosen width.

### *3.3.7 Thickness*

The thickness range has been chosen to avoid both very thin and very thick condoms. The very thin products are likely to fail inflation requirements, while the very thick ones appear to offer no added efficacy (*23*) and are likely to be less acceptable to users. The normal thickness range for condoms is between 0.060 and 0.080 mm. Condoms thinner than 0.060 mm are normally classified as thin, and those thicker than 0.080 mm are normally classified as thick.

The method of determining thickness follows *ISO 4074* and involves weighing a known area of the condom, then dividing by the density. Alternatively, the thickness may be determined using a micrometre with a foot diameter of (5 ± 2) mm and a foot pressure of (22 ± 4) kPa. It is expected that more details of the micrometre method will be included in the next edition of *ISO 4074.* The micrometre method can give different results than the weight method because of partial compression of the film during the micrometre test. Therefore, care should be taken in a contract to specify the referee method to be used. It is expected that the weight method will remain the preferred method in the next edition of *ISO 4074.*

The Male Latex Condom Technical Review Committee agreed to retain measuring at the three specified locations along the condom length irrespective of the decision to be made by ISO/TC 157. *ISO 4074* currently specifies that the thickness shall be measured at three points along the length of the condom—at 30 mm from the open end, at the midpoint and at 30 mm from the closed end.

### *3.3.8 Extra strong condoms*

There is currently no published evidence to verify claims that extra strong condoms, which tend to be thicker than standard condoms, break less often in use. There is evidence, however, that using an additional lubricant, supplied separately and applied to the condom at the time of use, can reduce the rate of breakage during anal intercourse (*23*).

3 Review paper prepared by J Gerofi, to be published on the WHO/RHR web site.

### *3.3.9 Lubricant*

Silicone fluid is the most commonly used lubricant for condoms and is therefore recommended. It is inert and has minimal effect on the properties of the latex film. The quantity used has been selected to provide as high a level of lubrication as practical without creating package sealing problems in the factory.

Other lubricants, especially glycols and water-based lubricants, can be used. If the lubricant used is water-based, preservatives may be needed to prevent microbial growth.

Powders are added to condoms to facilitate manufacturing and allow them to unroll easily. Acceptable powders include starch and calcium carbonate. Talc and mica should not be used. Manufacturers may use other powders by agreement with the purchaser. In such cases the choice of powder may need to be justified.

Some manufacturers add biocides to the powder slurry to prevent bacterial growth. The choice of biocide and the amount used require careful consideration to achieve an acceptable level of bacterial control without increasing the risk of irritation or sensitization to end users and manufacturing personnel. A full risk assessment is required to justify the use of any biocide.

Lubricant quantity is measured by weighing the condom and pack before and after washing and drying. The difference between these values is taken as the quantity of lubricant and powder added.

Additional lubricants, supplied separately and applied to the condom at the time of use, are sometimes used to improve lubrication and comfort. Research suggests that this is particularly important for anal intercourse (*23*), where breakage rates might be reduced by using additional lubricants.

Any additional lubricant that is used must not have a deleterious effect on the properties of the condoms, such that the risk of breakage is increased. Methods of testing additional lubricants for compatibility with condoms are being developed by working group ISO/TC 157 WG 15, but poor inter-laboratory reproducibility has delayed the development of a widely acceptable procedure. Usually, these additional lubricants are water-based, but glycol-based lubricants are becoming more common. Household products are also sometimes used as sexual lubricants. Some have a highly damaging effect on latex and should not be used with condoms (see box).

### *3.3.10 Spermicidal additives*

Spermicidal additives to the lubricant have been used in some commercial products. Recent summaries of research findings suggest that these spermicides (predominantly nonoxynol-9) have significant irritant effects, and, overall, their use is not recommended (*24*).

**Household products that should not be used with condoms:**

- Baby oil
- Burn ointments
- Cooking oil
- Dairy butter
- Fish oil
- Haemorrhoid ointment
- Insect repellent
- Mineral oils
- Palm oil
- Petroleum jelly
- Rubbing alcohol
- Suntan oil

### *3.3.11 Addition of medicinal substances to condom lubricants*

In the commercial sector there is increasing availability of condoms containing medicinal substances. Many manufacturers incorporate the medicinal substance into a viscous gel or paste to localize it within the closed end of the condom. This is done to ensure that only the male partner is exposed to the active ingredients. If a medicinal substance is added to a condom, it is recommended that it is not added directly to the lubricant, as both partners will then be exposed to it. The most common example of a medicinal substance added to a condom is a local anaesthetic such as benzocaine.

Condoms containing medicinal substances are subject to local regulatory requirements for medicines, and there may be legal issues with their distribution. **The inclusion of such products in bulk procurement programmes is therefore not recommended in this *WHO/UNFPA Specification.*** It is suggested that individual bulk procurement agencies should consider all the issues before procuring this type of condom.

## 4 Individual package materials and labelling

Aluminium foil laminates are the most commonly used packaging material. It is important that the packaging protect the condom from oxygen, ozone and ultraviolet and visible light; be easy to open; and not leak lubricant.

There are requirements for labelling individual packs to provide the minimum essential information for the end user. The labelling also helps to track the storage, supply and distribution of the condoms and can be used to locate LOTS if there are ever any questions about the quality of the product.

In addition, it is a requirement of *ISO 4074* to include essential information for the condom user, which includes instructions for use, advice on disposal of the product after use, a statement that the condom is for single use only and the number of the international standard, *ISO 4074.* The Male Latex Condom Technical Review Committee recommended that, in addition, the *WHO/UNFPA Specification* include a requirement for a statement about the effectiveness of the condom.

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# ANNEX II
# BIOBURDEN AND MICROBIAL CONTROL[1]

## 1 Introduction

This annex is intended to provide information concerning bioburden in condom manufacturing, to recommend bioburden limits for foiled product and to give guidance for manufacturers in controlling and monitoring bioburden.

This annex has also been prepared to provide an accurate explanation regarding bioburden and microbial control for male latex condoms for national regulatory authorities, programme managers, procurement bodies and other interested parties.

## 2 Bioburden, limits and rationale

### 2.1 Bioburden

Control of microbial contamination on medical devices is essential to ensure the consistency and safety of the product. The total population of viable aerobic micro-organisms on the product and inner foil is termed the bioburden. Micro-organisms normally associated with contamination during manufacturing are bacteria, yeasts and fungi. Although some viruses can survive for varying times, they cannot multiply outside the body and are therefore not normally included in bioburden counts.

A number of sources, such as raw materials, process water, manufacturing equipment, packaging materials, personnel and the environment, can contribute to the total bioburden count of a final foiled product. In order to control and minimize bioburden, regular monitoring of these sources should be maintained.

Because bioburden control is a requirement of Good Manufacturing Practice (GMP) (*1–3*) of medical device manufacture, this monitoring may also be used as part of the quality control system to ensure adequate environmental control, efficacy of cleaning procedures, efficacy of monitoring and adherence to GMP.

It is recommended that bioburden levels be determined periodically—for example, at quarterly or, ideally, weekly intervals.

Standard operating procedures (SOPs) for bioburden monitoring should include limits for each stage of the manufacturing process and should include equipment and the environment.

### 2.2 Condom bioburden limits

Searches of the scientific literature have failed to identify any reports of genito-urinary infections linked to use of condoms that may have been contaminated during manufacture. Nevertheless, limits for bioburden levels on final foiled product are recommended in order to ensure product quality and user safety.

Final foiled product should have a bioburden maintained at less than 100 colony forming units (cfu) per item. Occasional excursion above this recommended limit may occur but, if so, should not be allowed to exceed 500 cfu per item. If the higher end of the limit is exceeded, immediate action should be taken to reduce the bioburden, for example, by undertaking cleaning and sanitizing procedures.

There should be an absence of all pathogenic organisms and in particular of *Staphylococcus aureus, Pseudomonas aeruginosa* and *Enterobacteriaceae,* including *Escherichia coli.* There should also be no growth of fungi and yeasts.

Routine testing of condoms may be conducted using the Total Viable Count (TVC) methods (*4–6*) and the Specified Organism Test (*7, 8*).

### 2.3 Rationale

*Staphylococcus aureus* organisms, which are carried by 25% to 32% of the general population (*9, 10*), may be pathogenic and can cause severe infections of skin, wounds, respiratory tract, and the urinary tract as well as septicaemia (*11–13*). Some specific *Staphylococci* produce an enterotoxin (*14, 15*) that, if ingested, causes gastric upset and food poisoning.

*Staphylococci* may also produce a toxin (TSST) (*16*) that causes toxic shock syndrome (*17*). This has never been implicated in condom use, however. It was classically associated with prolonged insertion of highly absorbent tampons, but it is now known that other medical conditions are related to the syndrome (*18*).

1 Author: Lorna M. Willcox, FIBMS (January 2009).

Poor GMP may facilitate cross-contamination with *Staphylococci* from manufacturing operators to the product.

*Pseudomonas* species are opportunistic pathogens that are often resistant to many of the commonly used antibiotics. They may cause a range of infections, particularly in people whose immune systems are compromised. They have been known to cause lung, ear, eye, and urinary tract infection and septicaemia (*19–21*). This organism is frequently found in water supplies. Therefore, strict contamination control of all process water is required.

*Enterobacteriaceae* including *Escherichia coli,* may cause infections of many sites including the genital and urinary tracts, brain, blood and gastrointestinal tract (*22, 23*). Specific *Escherichia coli* strains produce an enterotoxin that causes food poisoning and may lead to kidney and liver failure (*24*). Poor personal hygiene, especially inadequate hand-washing after using the toilet, will cause cross-infection with *Escherichia coli* by transfer between people touching surfaces, materials and products.

Some fungal species have been shown to cause slow deterioration of latex products and should therefore be absent from the final packed product (*25–27*). Yeast species may cause infections of skin, mouth and genital areas. Therefore, these also should be absent from final foiled product (*28, 29*).

## 3 Test methods

Bioburden testing should be conducted at regular intervals—for example, quarterly, but preferably weekly. It is recommended that results are regularly monitored so that bioburden trends may be analysed in order to validate microbiological control measures and to monitor environment and product for significant changes. Regular monitoring of results will also enable any necessary remedial actions to be completed as soon as possible.

Bioburden testing should be conducted in accordance with written procedures. The methods used must be adequate to extract bioburden from the test sample, including surfaces, and must maintain the viability of the organisms extracted. The culture media used must support growth of the extracted bioburden. To allow comparisons over time, sampling systems should be consistent.

Some of the samples tested may contain materials that might inhibit growth of micro-organisms. It is recommended that culture media used contain additives that will neutralize these antimicrobial effects (*30–32*).

When tests are conducted, care must be taken to avoid contamination of samples, culture media and test equipment. Careful control and good aseptic technique will ensure that there is no inadvertent external contamination.

All methods utilized must be validated in order to ensure that test requirements are met. Dilution factors and recovery factors will be calculated from these validation studies and must be incorporated into the test calculations (*33*).

It may be possible to utilize rapid methods both for routine monitoring of the environment, equipment and materials and for testing of condoms. There will be interference, however, from chemicals and powder used in the manufacturing process. Therefore, an extensive validation programme will be required, particularly if used for condom Total Viable Counts.

When micro-organisms are isolated, some additional testing must be completed to ensure that the isolates are none of the prohibited organisms.

### 3.1 Routine monitoring

Routine monitoring procedures for the manufacturing environment and equipment may involve the following methods.

#### *3.1.1 Surface testing*

Testing of surfaces may be carried out using swabs, contact plates, contact slides or the rapid bioluminescence test.

Contact plates and slides are designed so that the surface of the solid media may be directly applied to the test surface and then incubated. Such tests are quick

and easy to use, and results are directly related to the contact area. The disadvantage is that possibly not all organisms will adhere to the media, and the plates or slides can be used only on flat surfaces (*34, 35*).

Determining bioburden by use of swabs is particularly useful for monitoring irregularly shaped equipment and difficult-to-access surfaces. Swabs are normally moistened in a liquid medium and then rubbed across a predetermined area. The swab may be directly applied to agar medium, or the swab may be immersed in liquid media, agitated to remove organisms and the TVC completed as for liquid testing. Direct application of the swab to the agar may not remove all organisms from the swab, whereas using an intermediate liquid stage will improve recovery of the organisms (*34*).

Bioluminescence testing (*36, 37*) is especially helpful for examining surface bioburden because results are rapidly obtained and will confirm whether cleaning procedures have been carried out correctly. This will enable a quick response to any problem areas identified, thereby preventing product contamination. The test method utilizes the reaction that occurs between bacterial adenosine triphosphate (ATP) and firefly luciferin/luciferase, resulting in emission of light.

### *3.1.2 Powders and liquids*

Microbiological testing of powders and liquids can be achieved utilizing pour plates, spiral plating/spread plates, membrane filtration or the dilution droplet technique of Miles and Misra. In the case of water testing, the Most Probable Number (MPN) method can also be considered (*30, 38–41*).

A measured amount of powder can be dissolved in either a suitable solvent or in liquid culture media. Testing then proceeds as for liquid samples. Solvents and powder samples may have an inhibitory effect, however. Therefore, suitable dilutions or neutralizing agents should be used.

For the pour plate method, samples of liquid are added to cooled molten agar and mixed, and plates are poured. When set, plates are incubated at appropriate temperatures and times, and colonies are counted.

Alternatively, a liquid sample may be directly applied to the agar surface, spread and then incubated. A smaller sample may be required in order to ensure that discrete colonies are cultured and so enable accurate counting. Samples may be delivered and spread using spiral plating equipment. The number of colonies can be related to the volume of suspension delivered and the total count calculated.

For the Miles and Misra method, a series of dilutions are made from the samples. Then measured drops are placed on the agar surface. A minimum of five separated drops from each dilution is required. Plates are allowed to dry and are incubated, and counts are made.

When large sample volumes are available, particularly as in the case of water testing, the MPN method may be used. A range of dilutions is made in liquid growth medium. The range must be selected so that the lowest dilutions do not show microbial growth. Tables have been produced, such as those by DeMan, using statistical assessments to determine the MPNs of organisms present in the initial sample.

In tests of chlorinated water, any residual antimicrobial effect of the chlorine may be neutralized with sodium thiosulphate.

The membrane filtration technique utilizes a membrane with a sub-micron pore size, large enough to enable large volumes to pass under pressure, but small enough to retain bacteria. The membrane is then placed onto an agar plate and incubated, and colonies are counted. This technique is particularly useful when there are low numbers of microbes or when there may be interfering substances in the liquid sample being tested.

### *3.1.3 Air sampling*

Microbiological testing of air samples may be achieved by using settle plates or by active air sampling (*42–44*). Agar plates are left exposed for a defined period of time in the area under test. They are then incubated and colonies are counted. Whyte has established that, for a bioburden of 100 cfu per $m^3$, a 90 mm diameter plate exposed for an hour will show 10 or 11 cfu (*42*).

Active sampling systems are also available (*45, 46*). Air is drawn into a device for a measured period of time. The micro-organisms are deposited onto agar, which is then incubated. Types of active air samplers available are slit

samplers, centrifugal samplers and impaction samplers. The cost of equipment and consumables may be high.

Membrane filtration may also be used. Air samples are passed through a sub-micron membrane filter pad for a designated time. The membrane is subsequently placed on an agar surface and then cultured to determine bacterial numbers present in the air sample.

In the case of all air sampling techniques, loss of viability may occur due to desiccation of the organisms. Hence, prolonged sampling times should be avoided.

#### *3.1.4 Identification of micro-organisms*

On completion of the primary testing, additional tests may be required to identify any organisms isolated, in order to confirm that none of the prohibited organisms are present. A gram stain, coagulase test and oxidase test will indicate whether species identification is required. Biochemical profiles may be used to identify organisms to species level.

#### *3.1.5 Rapid test methods*

There are rapid test methods available that may be considered for testing materials and product and for environmental testing. Rapid test technology obtains bioburden measurement by utilizing turbidity, bioluminescence, conductance or impedance (*35, 36, 47, 48*).

The advantage of using rapid methods for routine monitoring is that any increase in bioburden will be detected early, thus allowing action to be taken quickly to prevent continuing contamination of product.

The disadvantage of using rapid methods is that there may be interference from some samples that could nullify the use of these techniques. There must be extensive validation programmes, and initial outlay for equipment will be high. Dependant on the particular rapid test method used, ongoing supplies of consumables may also be expensive.

## 4 Guidance for controlling microbial contamination

Cleaning and sanitizing procedures and bioburden limits should be established for all manufacturing procedures and for environmental monitoring. A period of preliminary testing will determine baseline counts to enable routine test limits to be established.

When defined, the recommended limits must be at a level that will ensure product safety. After bioburden limits have been established, routine testing programmes can be installed for all stages of the manufacturing process.

### 4.1 Equipment

All manufacturing equipment, including tote bins, should be cleaned and sanitized at regular intervals to a written schedule. Cleaning should be microbiologically validated using surface test methods to ensure the efficacy of the cleaning procedures and to ensure that there is no cross-contamination onto product.

### 4.2 Environment

The manufacturing environment should be controlled to minimize microbial contamination and to ensure that pests such as rodents, birds and insects do not gain access to any manufacturing areas. This is especially important in the manufacturing stages after final drying. It is recommended that air sampling be regularly conducted, particularly in areas where the condoms are most vulnerable to microbial contamination, until product has been foiled.

### 4.3 Personnel

Microbial contamination may also arise from personnel. When standing still, a person will normally shed 100,000 particles per minute. Moving may increase this to more than one million particles per minute. These particles will contain microbes normally present on skin. Coughing, sneezing and touching product or equipment will also greatly add to the bioburden. Suitable protective clothing and gloved hands will give a measure of protection against this contamination. GMP training will help to enforce correct handling procedures to ensure that contact and cross-contamination between personnel and product are minimized.

### 4.4 Raw materials

All raw materials, including water and packaging materials, should be tested at regular intervals. Some materials may have an inherent antimicrobial effect. If this

has been confirmed, then monitoring may continue at a much reduced rate on these particular materials.

#### *4.4.1 Water*

Water is a major material used during manufacturing, and so it must be controlled microbiologically and chemically.

Some incoming water supplies may contain extremely high bioburden levels, particularly in adverse local weather conditions such as very heavy rainfall or drought, and must be treated before storage. Treatment methods may include filtration, reverse osmosis (RO) (*49, 50*), ultraviolet irradiation (UV) or chemical treatment. It should be noted that chemical treatment may interfere with production processes and, depending on the chemicals used, may also cause adverse reactions in personnel.

After initial treatment the stored water should be kept under controlled conditions to minimize any further contamination or growth of micro-organisms.

Additional treatment of water may be necessary to produce deionised (DI) or softened water. Many micro-organisms find favourable conditions for growth on the DI resin beds and on RO membranes. It is essential, therefore, that the servicing protocols be followed rigorously to prevent colonization of the equipment with microbes.

If UV irradiation is used, monitoring of the system to confirm correct UV emission is essential in order to ensure that the UV lamps have not become partially obscured and therefore ineffective.

### 4.5 Dipping, stripping and drying

Dipping lines utilize large volumes of process water, which is sometimes recirculated at certain points of the process. It is recommended that there is no recirculation, but, if recirculation is necessary, it should be kept to a minimum and only recirculated for short periods of time or for a single re-use. Microbiological testing will confirm whether bioburden is being properly controlled under these circumstances.

All equipment should be regularly monitored, using surface testing methods that will confirm the efficacy of cleaning.

Handling of condoms should always be carried out with gloved hands. Whenever necessary, gloves should be either sanitized with antimicrobial wipes or else replaced. Any antimicrobial materials used for sanitizing must not interfere with process or product or adversely affect personnel.

It is recognized that heat and drying will inactivate many micro-organisms. Nevertheless, there are species that can survive such treatment, and, therefore, dryers should be cleaned and sanitized at intervals and included in the monitoring programme.

### 4.6 Slurry treatment

The slurry is a rich medium normally stored at a temperature that is optimal for microbial growth. Therefore, great care must be taken firstly in the cleaning and sanitizing of the mixing vessels, the reservoir tanks and the processors, and secondly in the choice of materials used to make the slurry. The water quality used in this process is particularly important. Ideally, slurry should not be recycled. Bioburden should be regularly monitored using TVC tests for liquids.

If necessary, consideration may be given to antimicrobial treatment of the slurry. Depending on the biocide used, it is possible that this may interfere with processing, cause skin reactions in operators and users and possibly be ineffective at the pH of the slurry. If a biocide is used, a full risk assessment must be completed.

### 4.7 Electronic testing, lubrication and foiling

After drying, condoms will be electronically tested by either wet or dry methods and will then be rolled, ready for lubrication and foiling. Bioburden of the liquids, the water in the testing baths in the case of wet testing and the lubricant and the lubricating and foiling equipment should be frequently monitored.

These processes should be maintained in a controlled environment. Personnel in these manufacturing areas should wear protective clothing and gloves and maintain a high standard of GMP.

All batches of foil should be microbiologically tested before release for use.

Once the condoms are sealed in their individual packs, they are protected from contamination, and any further operations do not necessarily have to be carried out in controlled environments. If any further operations are carried out where un-foiled condoms are stored, however, appropriate controls remain necessary.

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40 Tests for Microbial Enumeration, *European Pharmacopoeia,* 2002, Suppl. 4.2:133–612.
41 DeMan JC. Most Probable Number (MPN) tables. *European Journal for Applied Microbiology,* 1983, 17:301–305. (See also *British Pharmacopoeia* 2010, IV, Appendix XVIB:418.)
42 Whyte W et al. Airborne bacteria sampling. *Journal of Parenteral Science & Technology,* 1986, 40(5):182–187.
43 Andon BM. Active air versus passive air (settle plate) monitoring in routine environment monitoring programmes. *Journal of Pharmaceutical Science and Technology,* 2006, 60(6):350–355.
44 Whyte W. In support of settle plates. *Journal of Pharmaceutical Science and Technology,* 1996, 50(4):201–204.
45 Temprano G et al. Comparative study of airborne particles: assessment methods in microbiological environmental monitoring. *Journal of Pharmaceutical Science and Technology,* 2004, 58(4):215–221.
46 *BS EN 13098:2001,* Workplace atmosphere—guidelines for measurement of airborne micro-organisms and endotoxin.
47 Waweria M et al. Impedance microbiology: applications in food hygiene. *Journal of Food Protection,* 1999, 62(2):1469–1488.
48 Edmondson AS. New approaches to bioburden estimation. *Conference Proceedings. Bioburden in Medical Device and Surgical Dressing Manufacture,* March 1992:127–139.
49 Treating the water we drink. *Water Review Technical Brief,* 1994, 9(4) (http://www.wqa.org/sitelogic.cfm?ID=475).
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## ANNEX II, Appendix 1

### Method 1. Enumeration of total population of micro-organisms on foiled condoms

1. Using sterile forceps and scissors, aseptically remove a condom from the foil, cut the bead in two places, unroll the condom with sterile forceps and place in 10 ml of peptone water with added 0.3% lecithin and 3% polysorbate (Tween 80). Lecithin and polysorbate are added to neutralize any residual inhibitory effects from the condoms. Letheen broth may be used as an alternative extraction medium.

2. In order to remove the bioburden from the condom, mix the contents with a shaker, stomacher or vortex mixer for the time previously determined from validation studies. Care must be taken not to mix too vigorously, as this may kill some microbes.

3. Using a sterile pipette, transfer 1 ml of the extraction fluid into 20 ml of molten Sabourauds Dextrose Agar (SDA) kept at 40 °C. Mix gently to disperse the sample throughout the media and pour into a sterile Petri dish. Allow to set.

4. Repeat with another SDA and with 2x 20 ml of Tryptone Soya Agar (TSA).

5. Incubate the SDA plates at 20 °C for five days and incubate TSA plates at 30 °C for three days.

6. Inspect the TSA plates at three days and count colonies. Re-incubate and count at five days.

7. Count the number of colonies on each TSA plate and find the average of the two counts. Examine the SDA plates and count fungal and yeast colonies. Calculate the average count as above. Make corrections for dilution and recovery factors (previously determined by the validation tests).

   The total viable aerobic count is determined by adding together the corrected averages of the fungal and bacterial counts.

8. Some identification of bacteria is required in order to confirm the absence of the specified organisms. Gram stain and colonial morphology will identify gram positive cocci and gram negative

bacilli. A positive coagulase test will indicate probable *Staphylococcus aureus,* whilst the oxidase test will indicate possible *Pseudomonas* species. Results from these short tests will determine if further identification is required. Biochemical profiling will identify organisms to species level.

**Method 2. Enumeration of total viable aerobic microbial population and tests for specified micro-organisms on foiled condoms**

1. Using aseptic technique, remove 13 condoms from packaging with sterile forceps into a large sterile dish, and cut up the condoms using sterile scissors.
2. Weigh 10 grams of material and place it in 100 ml of extraction media in either a 150 ml bottle or a stomacher bag. The extraction media should be capable of neutralizing any residual antimicrobial effect from the condoms. Suggested media is peptone water with the addition of 3% polysorbate (Tween 80) and 0.3% lecithin.
3. Stomach or mix the sample for the time required to remove the bioburden, as previously determined by validation testing.
4. Using a sterile pipette, transfer 10 ml of the condom extraction fluid into 100 ml of Soya casein digest broth and gently mix.
5. Proceed using the methods described in *United States Pharmacopeia,* 31 Microbiological tests <61> and <62> or in the *German Pharmacopoeia* (DAB) V2.1.8.1 and V.2.1.8.2 in order to determine Total Viable Count and absence of *Escherichia coli, Staphylococcus aureus* and *Pseudomonas aeruginosa.*

# ANNEX III
# GUIDELINES ON THE ASSESSMENT OF ODOUR

Odour can be assessed by a panel. There are certain guidelines that apply when assessing the odour of condoms. Following these guidelines should help provide a more consistent level of odour assessment. Recommendations include:

- The panel should consist of between 6 and 10 individuals.
- Panellists should not wear perfume, smoke or be exposed to strong odours on assessment days.
- Panellists should be trained and may be required to undergo periodic assessments.
- Odour assessments should not be carried out in a factory or other environments where there may be strong background odours present.
- Odour assessments should be done blind and in a random order without the panellists being aware of the source of the samples.
- Adequate time should be allowed between samples for the panellists' olfactory sense to recover.
- To prevent fatigue, the number of samples evaluated in one session should be limited.
- An appropriate grading system should be developed to quantify the intensity, acceptability and type of odour. For example, odour intensity can be rated on a balanced scale from 0 (no perceptible odour) to 6 (extremely strong odour).
- Control samples should be included to allow comparisons to be made between different panels and different sessions.
- The time delay between opening a condom pack and smelling the condom can be critical. This time should be standardized.

It is recommended that manufacturers retain samples for reference purposes and to help resolve disputes. Retained samples should be kept for the duration of the shelf-life of the product.

# ANNEX IV
# METHODS FOR ASSESSING THE 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. 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

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

the 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).

| | |
|---|---|
| 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 | $D = 0.01(2.5N + 30N^{0.55})$ |
| AQL 4.0 | $D = 0.01(4.0N + 36N^{0.55})$ |

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: HELPLIFEcondomquality@fhi360.org

# ANNEX V
# GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| **Acceptance number** | The highest number of non-compliers (failures) allowed in a specific test from a selected sample. |
| **AFRO** | WHO Regional Office for Africa. |
| **Aggregate analysis** | A retrospective method of assessing whether the total number of defective condoms found in a series of LOTS is within the normal statistical bounds of the specific sampling plans being used. It helps determine accept/reject numbers for the total sample size obtained by aggregating the results from a number of LOTS for any specific AQL and aggregated sample size (N). |
| **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. |
| **Aseptic technique** | Precautionary measures taken to prevent external contamination of materials, samples, and culture media; employed during testing. |
| **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. |
| **Bead** | The thickened ring formed at the open end of the condom. |
| **Bid security** | A guarantee from a bank that the bidder will perform its obligations in regard to the bid. |
| **Bioburden** | The population of micro-organisms on a raw material, component, product, packaging or equipment. |
| **Bioluminescence** | When bacterial adenosine triphosphate (ATP) reacts with firefly luciferin and luciferase, light is emitted. Bioluminescence tests are designed to measure the amount of light produced, which will be related to the number of micro-organisms present in the sample. |
| **CCP** | Comprehensive Condom Programming. |
| **CDC** | U.S. Centers for Disease Control and Prevention. |
| **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. |

| | |
|---|---|
| **cfu** | Colony forming units—a unit of measure of the level of microbial contamination of a product. |
| **C/L** | Commercial letter of credit. |
| **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. |
| **Condom procurement cycle** | The time taken from making the initial forecast to the completion of the final shipment. |
| **Comprehensive Condom Programming** | A strategic approach to create the demand for and ensure the supply of good-quality male and female condoms. |
| **Confirmatory testing** | Testing carried out on receipt of a product in country. |
| **Consumer pack** | A wallet or carton into which one or more foil packages are inserted for marketing purposes. |
| **DFID** | U.K. Department for International Development. |
| **Design Requirements** | Characteristics of the condom that are specified according to the buyer's requirements. |
| **DKT** | A social marketing company. |
| **DRA** | Drug regulatory authority. |
| **EOI** | Expression of Interest. |
| **Expiry date** | The date at which the product is no longer considered acceptable for use. |
| **Exterior shipping carton** | The container into which a number of inner boxes are packed. |
| **FEFO** | First expiry, first out. |
| **FHI** | Family Health International. |
| **Forecast** | An assessment of the future requirements of a programme, based on historical trends, research, or feedback from field workers on current needs. |

| | |
|---|---|
| **General Requirements** | The general quality characteristics of condoms that are verified before supply commences and that are not expected to vary from LOT to LOT. |
| **GMP** | Good manufacturing practice is a code of practice aimed at ensuring that product is consistently manufactured to the required standard. |
| **GTZ** | Deutsche Gesellschaft für Technische Zusammenarbeit. |
| **HIV** | Human immunodeficiency virus. |
| **ICH** | International Conference on Harmonization. |
| **INCOTERMS** | Defines when the ownership, responsibility and liability for a shipment is transferred from the supplier to the client and/or receiving country. |
| **Inner box** | A box used to contain a convenient number of condoms in packages or consumer packs. Inner boxes typically contain 100–200 condoms; where a gross (144 condoms) is used as the unit of purchase, inner boxes are usually specified to contain one gross. |
| **Inspection level** | The degree of examination of the LOT, as specified in *ISO 2859–1.*<br><br>The higher the inspection level, the more samples will be tested and, hence, the lower the risk of faulty products reaching the end user. |
| **IPPF** | International Planned Parenthood Federation. |
| **IPPF/ICON** | International Planned Parenthood Federation, International CONtraceptives Sexual and Reproductive Health. |
| **IUD** | Intrauterine device. |
| **ISO** | International Organization for Standardization. |
| **ISO/TC 157** | International Organization for Standardization, Technical Committee 157 for Non-Systemic Contraceptives and STI Barrier Prophylactics. |
| **JSI** | John Snow, Inc. |
| **Length** | The length of the condom measured from the open end to the tip, excluding any reservoir. |

| | |
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| **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. |
| **LOT number or code** | A unique identifying alphanumeric code assigned to a LOT. |
| **Lowry method (modified)** | A method for determining the water-extractable protein levels in latex products. |
| **Manufacture date** | The date on which the condoms were dipped. |
| **MPN** | Most Probable Number. |
| **MSDS** | Material Safety Data Sheet. |
| **MSH** | Management Sciences for Health. |
| **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.* |
| **Opportunistic pathogen** | An organism that does not normally cause disease but becomes pathogenic under certain circumstances. |
| **Package** | The foil sachet in which the condom is sealed after manufacture. |
| **PATH** | Program for Appropriate Technology in Health. |
| **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 buyer 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. |

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|---|---|
| **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. |
| **PSI** | Population Services International. |
| **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. |
| **Rejection number** | The number of non-compliers (failures) in a test sample that will cause a LOT to be rejected. |
| **RHSC** | Reproductive Health Supplies Coalition. |
| **Reservoir** | A narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat. |
| **Reverse osmosis (RO)** | A process used to provide pure water by removing unwanted salts and micro-organisms by applying pressure in the opposite direction of natural osmotic flow across a semi-permeable membrane. |
| **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). |
| **SDA** | Sabourauds Dextrose Aga. |
| **SMF** | Site Master File summary. |
| **Shelf-life** | The period of time after manufacture that the product is considered acceptable for use. |
| **Social marketing** | The use of commercial marketing techniques to distribute, promote and sell products and services of social importance, often at a subsidized price. |
| **SOP** | Standard operating procedure. |

| | |
|---|---|
| **Specification** | A detailed statement of a product's requirements as established by the buyer. 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. |
| **STIs** | Sexually transmitted infections. |
| **SWAp** | Sector-wide approach. |
| **TSA** | Travel subsistence allowance. |
| **Total Viable Count (TVC)** | The number of living micro-organisms in a given sample. |
| **UN** | United Nations. |
| **UNAIDS** | Joint United Nations Programme on HIV/AIDS. |
| **UNFPA** | United Nations Population Fund. |
| **UNICEF** | United Nations Children's Fund. |
| **USAID** | United States Agency for International Development. |
| **USFDA** | United States Food and Drug Administration. |
| **Ultraviolet irradiation (UV)** | Normally emitted at a wavelength of 254 nm; may be used to diminish or eliminate bioburden in process water. |
| **Viscosity** | The resistance to flow of a fluid. |
| **Wall thickness** | The thickness of the latex film. |
| **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. |

# ANNEX VI
# APPLICABLE DOCUMENTS

Various external documents form part of the *WHO/UNFPA Specification,* and the buyer may wish to mention them in any Invitation to Bid or order sent to the supplier. In every case the edition of the document is the one in force on the date of the Invitation to Bid.

## 1 International Standards

These are standards published by the International Organization for Standardization (ISO). Copies can be obtained from the national standardization organization in the buyer's country or:

**International Organization for Standardization**
ISO Central Secretariat
1, ch. de la Voie-Creuse
CP 56
1211 Geneva 20, Switzerland
Telephone: +41 22 749 0111
E-mail: central@iso.org
Web site: http://www.iso.org

**Latex condoms**

| | |
|---|---|
| *ISO 4074:2002*<br>*Cor 1:2003*<br>*Cor 2:2008* | Natural Latex Rubber Condoms Requirements and Test Methods |

**Testing methods**[1]

| | |
|---|---|
| *ISO 4074:2002 Annex A* | Sampling Plans Intended for Assessing Compliance of a Continuing Series of LOTS of Sufficient Number to Allow the Switching Rules to Be Applied |
| *ISO 4074:2002 Annex B* | Sampling Plans Intended for Assessing Compliance of Isolated LOTS |
| *ISO 4074:2002 Annex C* | Determination of Total Lubricant in Condoms in Individual Containers |
| *ISO 4074:2002 Annex D* | Determination of Length |
| *ISO 4074:2002 Annex E* | Determination of Width |
| *ISO 4074:2002 Annex F* | Determination of Thickness |
| *ISO 4074:2002 Annex G* | Determination of Bursting Volume and Pressure |
| *ISO 4074:2002 Annex H* | Oven Treatment of Condoms |
| *ISO 4074:2002 Annex I* | Determination of Force and Elongation at Break |
| *ISO 4074:2002 Annex J* | Determination of Shelf-Life by Real-Time Stability Studies |
| *ISO 4074:2002 Annex K* | Guidance on Conducting and Analysing Accelerated Ageing Studies |
| *ISO 4074:2002 Annex L* | Testing for Holes |
| *ISO 4074:2002 Annex M* | Tests for Package Integrity |
| *ISO 12243:2003* | Medical Gloves Made from Natural Rubber Latex Determination of Water-Extractable Protein Using the Modified Lowry Method |
| *ISO 2859–1* | Sampling Procedures and Tables for Inspection by Attributes |

1 Please note that date of publication of standards are accurate at the time of publication of this document. With international standards always check the date of the latest edition.

**Labelling of shipping cartons**

| | |
|---|---|
| *ISO 780* | Packaging Pictorial Marking for Handling of Goods |

**Quality management**

| | |
|---|---|
| *ISO 9000:2005* | Quality Management Systems Fundamentals and Vocabulary |
| *ISO 9001:2008* | Quality Management Systems Requirements |
| *ISO 9004:2000* | Quality Management Systems Guidelines for Performance Improvements |
| *ISO 13485:2003* | Medical Devices Quality Management Systems Requirements for Regulatory Purposes |
| *ISO/IEC 17025:2005* | General Requirements for the Competence of Testing and Calibration Laboratories |
| *ISO/IEC 1725:2005 Cor 1:2006* | |

**Biocompatibility**

| | |
|---|---|
| *ISO 10993 1:2003* | Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing |
| *ISO 10993 5:1999* | Biological Evaluation of Medical Devices. Part 5: Tests for in vitro Cytotoxicity |
| *ISO 10993 10:2002* | Biological Evaluation of Medical Devices. Part 10: Tests for Irritation and Delayed-Type Hypersensitivity |

## 2 Other publications

The following additional documents form part of the *WHO/UNFPA Specification* and may be cited in an Invitation to Bid or an order issued by a buyer.

- regulations on toxicity and tissue irritation (e.g. *U.S. Code of Federal Regulations* Title 21);
- freight classification;
- regulations for medical devices (if applicable);
- any other documents that are relevant under the law or regulations of the purchaser's or the destination country;
- *ASTM D3492 08* Standard Specification for Rubber Contraceptives (Male Condoms).

# ANNEX VII
# LIST OF RESOURCE AGENCIES

**Centers for Disease Control and Prevention**
Programme Services and Evaluation Division of Reproductive Health
1600 Clifton Road N.E. (Mailstop K-22)
Atlanta, Georgia 30030, USA
http://www.cdc.gov/health/diseases.htm

**Crown Agents Services, Ltd.**
St. Nicolas House, St. Nicolas Road
Sutton, Surrey SM1 1EL, UK
http://www.crownagents.com/
enquiries@crownagents.co.uk

**Family Health International**
P.O. Box 13950
Research Triangle Park, NC 27709, USA
http://www.fhi.org
publications@fhi.org

**International Laboratory Accreditation Cooperation (ILAC)**
NATA 7 Leeds Street
Rhodes, NSW, Australia
http://www.nata.asn.au

**International Organization for Standardization (ISO)**
ISO Central Secretariat
1, ch. de la Voie-Creuse
CP 56
1211 Geneva 20, Switzerland
http://www.iso.org
central@iso.org

**John Snow, Inc.**
1616 North Fort Myer Drive
Arlington, Virginia 22209, USA
http://deliver.jsi.com/dhome

**Partners in Population and Development**
P.O. Box 6020
Gulshan 1, Dhaka 1212
Bangladesh
http://www.partners-popdev.org/abtppd/abtppd_secretariat_contact.asp

**Population Action International**
1300 19th Street N.W., Second Floor
Washington, DC 20036, USA
http://www.populationaction.org
pai@popact.org

**Population Services International**
Procurement and Logistics
1120 19th Street N.W., Suite 600
Washington, DC 20036, USA
http://www.psi.org
publications@psi.org

**Program for Appropriate Technology in Health (PATH)**
Publications
P.O. Box 900922
Seattle, WA 98109, USA
http://www.path.org
publications@path.org

**Reproductive Health Supplies Coalition**
Coalition Secretariat
Rue Marie-Thérèse 21
1000 Brussels, Belgium
http://www.rhsupplies.org/
secretariat@rhsupplies.org

**UNAIDS**
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
http://www.unaids.org
unaids@unaids.org

**UNFPA**
Technical and Evaluation Division, Reproductive Health Branch
220 East 42nd Street
New York, NY 10017, USA
http://www.unfpa.org/procurement
http://www.unfpa.org/publications

**World Bank**
Publications
1818 H Street N.W.
Washington, DC 20433, USA
books@worldbank.org
pic@worldbank.org

**World Health Organization**
Documentation Centre, Department of Reproductive
Health and Research
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
http://www.who.int/reproductive-health

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