The Male Latex Condom

Specification and Guidelines for Condom Procurement

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RHR

Department of Reproductive Health and Research
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Contact our team of experts at:

HELPLINEcondomquality@fhi.org

We will help you find the right answer.

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These guidelines are a result of review of the latest available evidence and an extensive consultative consensus-building process with individuals that represent the interests of manufacturing industries, the International Organization for Standardization (ISO), testing laboratories, national regulatory boards, research institutes, bulk procurement agencies, social marketing companies, international agencies and nongovernmental organizations, consumer groups, and family planning and HIV/AIDS prevention programme managers.

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FOREWORD

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that every day approximately 14,000 people become infected with the human immunodeficiency virus (HIV) that causes AIDS, and the vast majority are infected through sexual intercourse[1]. In 2002, over 40 million people were living with HIV or AIDS. Of these individuals, nearly 50% are women and one-third are between 15 and 24 years of age. The World Health Organization (WHO) estimates that globally there are 340 million preventable and curable sexually transmitted infections (STIs) annually[2]. The number of people infected with STIs grows larger every year.

Yet there is compelling evidence that male latex condoms, when used consistently and correctly, protect against unwanted pregnancy and the transmission of HIV[3]. Condoms also protect against several other STIs, although the level of protection has not been quantified for each specific STI[4]. Male latex condoms may be less effective in protecting against STIs that are transmitted by skin-to-skin contact, since the infected areas may not be covered by the condom[4].

> "There is compelling evidence that male latex condoms, when used consistently and correctly, protect against unwanted pregnancy and the transmission of HIV, the virus that causes AIDS."
>
> UNAIDS. *Making Condoms Work for HIV Prevention: Cutting Edge Perspectives*. Draft, 2004.

Promotion of condom use is an essential component of any HIV/STI prevention and care programme. Evidence confirms that the successful promotion of condom use as part of a comprehensive HIV prevention programme focused on behaviour change is effective in reducing HIV[5].

A condom is a simple, low-cost device, but it has to meet demanding performance requirements. The technology used to manufacture condoms has not changed significantly over the last ten years. However, the quality of the product has been considerably improved by better process control and more stringent standards of production.

Natural rubber latex condoms are made in large quantities (many billions per year). Rubber latex is a raw material that can be subject to variable quality depending upon a number of factors including the location of the plantation, seasonal and climatic changes, and the procedures used to concentrate the latex. The manufacturing process is complex, requiring strict process-control procedures and quality assurance measures. If the correct quality and quality control procedures are followed, the latex is converted into a condom that offers an excellent combination of thinness, 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 prevent the transmission of HIV. It is therefore important for policy-makers, programme managers, providers, and procurement officers to know how to apply the essential elements of condom quality assurance to guarantee that a quality product is manufactured, purchased, promoted and distributed to the consumer. The same arguments apply equally to national regulatory bodies. The condom is an important medical device and needs to be regulated and controlled as such.

For more than 12 years, WHO, the United Nations Population Fund (UNFPA) and UNAIDS have taken the issue of condom quality very seriously. WHO, UNFPA and UNAIDS have worked with partners from donor, international and nongovernmental organizations; research institutions; the private sector, including the manufacturing community; testing laboratories; consumer groups; and the International Organization for Standardization (ISO) to advocate for the development of a new and rigorous quality assurance for the production, procurement

and distribution of 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 latest version of the International Standard *ISO 4074:2002* for the manufacture of the natural rubber male latex condom was published.

The *Specification and Guidelines for Condom Procurement* was first published by WHO in 1989. It has been periodically updated to provide the latest information both on the capability of the condom industry to manufacture high-quality male latex condoms and the quality assurance procedures that must be followed to manufacture, procure and promote such a product.

Establishing standards and product specifications is a dynamic process that must be responsive to the outcome of research and new information. To ensure that this document reflects the latest available information, WHO, in collaboration with Family Health International, UNFPA and UNAIDS, has:

- Commissioned a review of the literature to determine the technical basis for the male latex condom specification.
- Commissioned 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.
- Commissioned a review of the literature on available evidence on determining whether two sizes of condoms are sufficient for all potential needs.
- Convened an Informal Technical Consultation in collaboration with the WHO Africa Regional Office (WHO/AFRO) and the Reproductive Health Research Unit, Department of Obstetrics and Gynaecology, University of the Witwatersrand, Chris Hani Baragwanath Hospital, in Soweto, Johannesburg, South Africa, in May 2002. This meeting involved 32 participants, including representatives from bulk procurement agencies; international organizations and nongovernmental agencies; manufacturers; testing laboratories; programme managers from Thailand, China, South Africa, Ghana, Nigeria and Zimbabwe; and the national bureaus of standards of Tanzania and South Africa. 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), (e-mail: rhrpublication@who.int) and will be published on the WHO/RHR web site (http://www.WHO.int/reproductive-health).
- Convened a meeting with delegates to the International Standardization Organization Technical Committee 157 (ISO/TC/157), who were responsible for the revision and publication of *ISO 4074 — Male Natural Latex Condom*. This meeting took place during the 19th annual meeting of the delegates to the ISO/TC/157 with support from the Malaysia Board Standards and Secretariat to the 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 *The Male Latex Condom — Specification and Guidelines for Condom Procurement* between January and March 2003. The document was sent to 120 reviewers who represent 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 undertaking the final revision of this document.

- Reviewed the *Model Specification* in June 2003 against the conclusions and recommendations made at the 20th annual meeting of delegates to the ISO/TC/157, who were responsible for the revision and publication of *ISO 4074 — Male Natural Latex Condom*, in Denver, Colorado, June 2003.

The Male Latex Condom — Specification and Guidelines for Condom Procurement is designed to provide a set of purchase specifications and procurement guidelines that ensures the highest level of safety consistent with high-volume purchases, the needs of different populations, harsh environmental conditions and the probability of less than ideal storage conditions. It is a guide to help policy-makers, and procurement and programme managers make the right decisions to procure, distribute and promote a quality product.

UNFPA will also publish jointly with WHO a complementary manual: *Condom Programming for HIV Prevention — An Operations Manual for Programme Managers*. This manual is designed to give programme managers a practical and specific seven-step approach to improve the effectiveness of existing condom programmes or create a new condom programme. An essential step in this process is obviously the logistics management cycle. The operations manual refers to the logistic management after condoms have been procured and arrive in-country. *The Male Latex Condom — Specification and Guidelines for Condom Procurement* details the application of the quality assurance measures required to manufacture, procure and receive in-country quality condoms.

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

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This document will be available on the Web (http://www.WHO.int/reproductive-health) in early 2004.

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WHO has worked with many partners to generate the evidence and gain the consensus needed to recommend these procedures. The importance of following these guidelines cannot be overemphasized, as it addresses the issues related to the performance of condoms, the comfort and confidence of the user, and the health and safety of the population at large.

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3 Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission (Cochrane Review). *Cochrane Library,* 2002, 3.

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5 HIV/AIDS make dual protection a must. In: *Progress in Reproductive Health Research*, No. 59. Geneva, WHO/UNFPA/UNAIDS/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), 2002. Available: http://www.who.int/reproductive-health/hrp/progress/59/news/95.pdfh.

INTRODUCTION

There is compelling evidence that condoms, when used consistently and correctly, protect against unwanted pregnancy and the transmission of HIV, the virus that causes AIDS. Condoms also protect against several other STIs, although the level of protection has not been quantified for each specific STI. Male condoms may be less effective in protecting against STIs that are transmitted by skin-to-skin contact, since the infected areas may not be covered by the condom.

Consistent and correct use of the condom is vital for achieving the level of protection required to prevent unwanted pregnancy and the transmission of HIV. 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. Inadequate attention is often paid to ensuring that a quality product is manufactured, purchased, stored, distributed and handled properly.

Therefore, it is important for policy-makers, programme managers, providers and procurement officers to be aware of condom quality. They need 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 consumer. The same argument applies equally to national regulatory bodies. The condom is an important medical device and needs to be regulated and controlled as such. This publication, *The Male Latex Condom — Specification and Guidelines for Procurement,* provides the essential information required to achieve these objectives.

For Whom Is This Document Intended?

This document is intended primarily for any manager or procurement officer who has the responsibility of 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, manufacturers, testing laboratories and national regulatory authorities will also need to study this document in preparation for the supply of condoms and the quality management services to programmes using the *Specification and Guidelines for Procurement* procedures.

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

Structure of the Document

There are three main sections to the document:

Section One **The Male Latex Condom: Quality Assurance**
Includes:
- Chapter One — Essential Elements of Condom Quality Assurance
- Chapter Two — Model Specification for Male Latex Condoms
- Chapter Three — Workmanship and Visible Defects
- Chapter Four — Resolution of Disputes

This section details the essential components of a *Model Specification*, which has been prepared to support the bulk procurement of male latex condoms. The *Model Specification* can be copied or adapted according to individual country requirements. It defines:

The **general and performance requirements** and the tests by which they can be verified. These requirements address the fundamental aspects of safety and efficacy and should not be changed.

The **design requirements** and the tests by which these requirements may be verified. These requirements may be changed, within reasonable limits, to meet the special needs of users and programmes.

The **packaging requirements** and the tests by which they can be verified. These requirements should not be changed. External consumer packaging is, of course, made in accordance with the purchaser's requirements.

This section also includes chapters on the essential components of quality assurance, workmanship, and resolution of disputes.

Section Two **The Male Latex Condom: Guidelines for Procurement**

Includes:
- Chapter Five — Guidelines for Procurement
- Chapter Six — Procurement Checklist
- Chapter Seven — Specification Checklist

This section describes a step-by-step guide to the procurement process recommended by WHO and partner agencies and outlines the quality assurance measures required to procure a quality product. This section includes a chart of the procurement procedure steps and checklists for the procurement procedure and the preparation of a specification.

Section Three **Annexes**

Includes:
- Annex I — Technical Basis for the Model Specification
- Annex II — Glossary of Terms and Acronyms
- Annex III — Methods for Assessing the Quality of Suppliers
- Annex IV — Applicable Documents
- Annex V — Selected Methods for Reducing Testing Costs
- Annex VI — List of Resource Agencies
- Annex VII — List of Manufacturers and Testing Laboratories
- Annex VIII — Bibliography

Annex I — Technical Basis for the Model Specification provides essential background information and explains the rationale behind the requirements detailed in the *Model Specification*.

SECTION ONE
Quality Assurance

CHAPTER ONE
Essential Elements of Condom Quality Assurance

1 Quality Management Systems

1.1 Standards

Safety and performance standards are published by national and international regulatory authorities or standards bodies to establish the minimum quality for products that are made, imported and sold within a particular country or region. Standards are developed by voluntary standards committees in collaboration with manufacturers, national regulatory boards, researchers, consumer groups, international agencies and testing laboratories. Compliance with some standards is voluntary, but in many cases, government or regulatory bodies have made compliance mandatory.

A standard only addresses the safety and performance of the product produced. Design features that are a matter of choice and discretion are not normally included in a standard. Standards also generally specify methods to use when carrying out basic tests for quality verification.

The principal international standards authority is the **International Organization for Standardization (ISO)**, a worldwide federation of national standards bodies responsible for drafting international standards based on the best available evidence and practice. Standards may be generic or product-specific. Standards are developed by technical committees, whose members are experts in the relevant fields.

ISO Technical Committee 157 (ISO/TC/157) is responsible for developing the international standard for male latex rubber condoms: *ISO 4074:2002 — Requirements and Test Methods*. The committee has a membership of approximately 25 countries with representatives drawn from a wide range of interested parties including manufacturers, test laboratories, regulatory bodies and consumers' representatives. For the last five years, it has been debating issues and generating the evidence to revise this international standard. WHO and other partner agencies have worked with this committee to broaden the standard to provide for situations in which economic and social circumstances dictate a limited choice of products and the need for:

- Adequate protection against harsh environmental conditions
- 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 stated shelf-life and expiry dates
- Allowance for inadequate systems of storage and distribution
- Appropriate packaging and information on how to use condoms

The revised standard *ISO 4074:2002* was published in February 2002 and can be obtained from national standards organizations or purchased from:

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central@iso.org
http://www.iso.org

1.2 Specification

A specification is a statement of the buyer's requirements and covers all the product attributes necessary for buyer acceptance. These include the essential general and performance requirements as well as discretionary design requirements. A specification states how to verify the quality of a product and may demand a higher level of quality than a published standard requires.

The *Model Specification* is based, where appropriate, upon the *ISO 4074:2002*. The *Model Specification,* if used in conjunction with the procurement procedure (see Section 2), will ensure that a quality product is manufactured, purchased and distributed to the consumer.

1.3 The Male Latex Condom — Specification and Guidelines for Condom Procurement

This document focuses on procurement issues related to condom quality assurance, as they differ significantly from those used to procure other health care products. The purchaser must provide a specification that details the characteristics and quality of the product to be manufactured and specify the tests by which the quality can be verified. WHO and partners have prepared a specification that is internationally accepted for the bulk procurement of male latex condoms.

The procurement of quality condoms goes beyond the production of a specification. There is a specific procurement procedure, which if ignored may result in the procurement of a less than adequate product. The contract to manufacture should not be awarded based only on the price of the product. Prior to issuing a contract, it is recommended that the purchaser pre-qualify the suppliers with a procedure to verify that the manufacturers have the potential capacity, capability and quality infrastructure to produce the required products in the specified time-frame. A contract should only be awarded to suppliers who are able to comply with the above requirements. Prior to accepting the shipment of the condoms, procurement officers should verify the quality of the product through a process of compliance testing. Once shipped the condoms become the property of the procuring agency, so it is advisable to know the quality of the product before it is received.

These procedures are necessary because:

- The quality assurance measures in this process are designed to protect both the procuring agency and consumer since there may be substantial differences in the quality of condoms produced by different manufacturers. Quality can also vary over time or at different times of manufacture.
- Condoms will degrade unless they are appropriately formulated and packaged.
- Condom quality can be affected by a number of factors, some of which may not be directly under the control of the manufacturer. Stringent quality control procedures are necessary to ensure LOT-to-LOT consistency, but there is always a risk that quality may vary between production runs.
- A poor-quality product fails to provide adequate protection.
- A poor-quality product will quickly destroy the credibility of any condom promotion programme.
- A poor-quality product will create negative publicity and cause endless logistical problems.
- A poor-quality product can cause a political, financial and social crisis since funds would have to be found to replace the poor-quality condoms, potentially making condoms unavailable for use.

1.4 Regulatory Authorities

Condoms are classified as medical devices and as such are regulated by various regulatory agencies 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 audits and product testing. They generally have the power to refuse to license, recall products and close factories in the event of continued noncompliance with their regulations.

It is important 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. If the regulatory authority requires in-country testing, then the local laboratory should be capable of testing to internationally recognized standards. The testing should form part of the compliance testing regime recommended in the Guidelines for Procurement (see Section 2, Chapter 5). The national regulatory body may also undertake confirmatory testing and periodic audits of the product to ensure that it has not deteriorated during shipping, handling and storage.

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

- **USFDA 510(k) pre-market clearance:** The manufacturer has submitted documentation stating that the product is equivalent to one

that is already on the market. A 510(k) clearance to market a product usually means that the manufacturer has submitted acceptable safety data on the product and promises to comply with USFDA requirements for the manufacture and distribution of the product.

- **USFDA audit reports:** As part of USFDA compliance, inspectors audit manufacturers at random to verify USFDA compliance. The USFDA may provide audit reports or Form 483 observations. This process can provide additional evidence that a manufacturer is consistently maintaining an acceptable quality system.
- **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. Manufacturers are required to follow specific conformity assessment procedures that include submitting a dossier to a European notified body.

Most countries have their own regulatory procedures, which should be updated in accordance with the published standard. It is always advisable to review national regulatory policy and guidelines before importing condoms into a country.

Review national regulatory policy and guidelines before importing condoms.

2 Manufacturing Quality Assurance

2.1 Good Manufacturing Practice (GMP)

A well-run factory will have an audited, well-documented quality management system. ISO has created a number of model standards for quality management systems, perhaps the best known of which is the internationally recognized *ISO 9000* series. Additional requirements specific to medical devices are given in *ISO 13485*. These standards prescribe the documentation, procedures and structures to be followed in all types of establishments to facilitate the production of a consistent standard in the output of services and products. Most factories, regardless of the product they manufacture, can use this system of quality management.

The essential components of these systems are:

- Documented quality objectives
- Documented management responsibilities
- Documented training procedures
- Documented process and quality assurance procedures
- Documented record-keeping
- Remedial action in case of product quality problems

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

A number of organizations offer certification to these standards 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 factory's documentation. They do not regulate the quality of the product and do not necessarily ensure that the factory follows best manufacturing practices. The certifying organization should be registered with the national standards body of the country where the manufacturer is located. Some organizations offer more comprehensive national accreditation systems that include product testing such as NF mark and BSI kite mark.

2.2 LOTS

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, in the same type of individual container. 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

LOT size should be selected from one of two recommended ranges: 35,001 to 150,000 and 150,001 to 500,000. This is to ensure compatibility with the sampling plans given in *ISO 2859-1*. LOT sizes over 500,000 are not recommended due to the risk that the LOT may not be homogeneous.

Any interruption in production must result in a new LOT being started. LOTS must not be comprised of separate interrupted runs.

The date of manufacture (MFD) is considered to be the date the LOT was dipped, regardless of whether packaging has been completed.

2.3 LOT-by-LOT Testing

The existence of a quality management system does not necessarily guarantee uniformly high-quality product. The manufacture of condoms is complex and can be influenced by a variety of different manufacturing and raw material factors. For this reason WHO recommends that independent LOT-by-LOT 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.

Bulk purchasers who conduct LOT-by-LOT testing in accordance with recommendations in this document can base acceptance of each LOT on test results and additionally have access to detailed information about the quality of the product submitted for testing. Use of this accumulated data can provide a good indication of the quality of the manufacturer's product. Significant (in excess of 5%) levels of LOT failures are indicative of marginal or poor quality.

In principle, manufacturers should submit a finished product for sampling and testing only after they have satisfied themselves that the product meets this specification.

2.4 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 2859-1 — Sampling Procedures for Inspection by Attributes*. These are the most widely used sampling schemes using attribute criteria to check multiple LOTS (that is, passing or failing an individual product based on a specification requirement such as freedom from holes).

Sampling for independent testing should be done by the *independent laboratory* or by an *independent sampling organization* and not by the factory producing the condoms. Such sampling is required for pre-qualification, compliance testing and confirmatory testing.

The sampler must verify LOT integrity during sampling.

Samples must be:

- Taken in accordance with a pre-agreed sampling plan using *ISO 2859-1* or other agreed-upon method between buyer and seller
- 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 despatched under the sampler's supervision.

At the request of the manufacturer, a duplicate sample may be taken for use in case of disputes. The sampling agency must issue a report on the sampling process, indicating the sampling process, identification of the cases from which the sample was 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.

2.5 Acceptable Quality Level (AQL)

It is accepted that with current manufacturing technology a small number of condoms in any LOT may be defective. Limits have been set for the maximum percentage of defective condoms allowed. For important performance properties, such as freedom from holes, this limit is set very low (0.25%) to ensure that the consumer is protected. For properties that are less important and do not affect the performance of the condom, such as non-critical visible defects, slightly higher limits are recommended.

Compliance with the limits for the maximum percentage of defective condoms in a LOT is determined by testing a sample. Testing a sample only gives an estimate of the percentage of defective products in a LOT. The accuracy of this estimate increases with the size of the sample. If the process is stable, then the average percentage of defective products — the process average — can be estimated by pooling the results of testing from many LOTS.

In *ISO 4074:2002* and the WHO *Model Specification*, the limits for the maximum percentage of defective condoms are specified in terms of acceptable quality levels (AQLs). AQL is a statistical term for the upper limit of the process average of the percentage of defective products at which the majority of LOTS (usually more than 95%) will be accepted. The full definition of AQL is given in the glossary.

Testing is conducted according to sampling plans given 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. This means there is a high probability that a very bad LOT will be rejected, but the plans are less discriminating when the quality is just below the AQL.

As stated above, the AQL is the upper limit for the process average of defective condoms. WHO does not, therefore, regard the AQL as a target but as an upper limit. Manufacturers should set a target for their process average below this limit, ideally at not more than half the AQL.

In the long run 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. Because of the inherent errors associated with estimating quality by testing samples, it is possible that in the short term more than 5% of LOTS can fail even when the manufacturer is in compliance with the relevant AQLs. If, however, the number of LOTS rejected in any sequence of five LOTS exceeds two, then there is a real risk that the manufacturer is not in compliance. In such circumstances it is recommended that a full analysis of the manufacturer be undertaken as described in Annex III. Any such analysis should include an investigation into the process average of defective products. If you need assistance, contact the Help-Line.

3 Monitoring Quality

3.1 Testing Laboratories

Laboratories may be:

- Manufacturers' laboratories
- Independent test laboratories
- National regulatory laboratories

A number of issues are common to all. Laboratories that test condoms need to have systems in place to ensure reliability of their results. Internal management arrangements should provide a quality system generally in accordance with *ISO 9000*. In addition, the laboratory should conduct regular calibration of its measuring equipment and have an adequate maintenance system. There is a special ISO standard for the management of testing laboratories (*ISO 17025*). It covers the essential elements of *ISO 9000* as well as laboratory-specific issues.

Laboratories should confirm their competence by participation in **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 compare them and provide feedback to each participant. The test results are reported anonymously to all the test laboratories, allowing participants to have the opportunity to investigate any tests in which their results disagree with those of other participants.

It is also important that laboratories train staff and monitor staff proficiency; conducting internal trials to ensure uniformity of methods among staff is generally necessary.

Laboratory accreditation is a system of verifying the performance of testing laboratories. It is available to all laboratories and is recommended especially for independent and national regulatory laboratories. Accreditation involves a systems audit similar to *ISO 9000*, as well as a detailed technical audit. The

accreditation body will also impose a number of technical requirements for equipment, calibration and technical competency of the staff.

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)
NATA, 7 Leeds Street
Rhodes, NSW
Australia
telephone: (+61 2) 9736 8222
telefax: (+61 2) 9745 5311
http://www.nata.asn.au

Evaluation of a potential testing laboratory would include:

- Accreditation by an internationally recognized body
- Participation in inter-laboratory proficiency trials
- Reputation among large purchasers

Some countries have medical device regulations that require local testing of imported condoms by an approved laboratory. Where a procurement agency has a system involving sampling from the factory, it may be possible for the agency to have the test results from internationally accredited laboratories accepted in lieu of local testing. Alternatively, if the national regulatory laboratory functions to an accredited standard, it can undertake the compliance testing of condoms. WHO recommends that only laboratories that are accredited or that participate in inter-laboratory proficiency trials should be used for condom testing.

3.2 Testing Costs

Some buyers question the cost of independent LOT-by-LOT 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 a whole shipment as a single LOT. The trouble with this method is that it is unlikely that the whole shipment has been manufactured under uniform conditions, with identical properties, at the same time, as required for a LOT (see Section 1, Chapter 1, Part 2.3 and Annex II). The homogeneity of the shipment is in doubt, and the method is statistically compromised. Furthermore, it is difficult to detect problems that may be present in individual LOTS.

The use of this method increases the risk to the consumer beyond an acceptable level, and buyers who have experimented with it have found that the savings they made were a false economy.

The sole purpose of the strict testing regime recommended by WHO is to protect users who are not in a position to check the quality of the product themselves. The cost of testing, at approximately 6% to 10% of the manufacturers' selling price of the actual condoms, might be considered a relatively inexpensive method of insuring against the delivery of poor-quality condoms to a programme.

Any reduction in the number of condoms tested reduces the amount and accuracy of information available about the LOTS being supplied to the purchaser. There are, however, certain ways in which these costs can be contained and even reduced, while still maintaining effective vigilance against defective goods.

WHO has reviewed various methods that have been proposed by buyers for reducing quality assurance costs. These are described and commented upon in Annex V. If you need assistance, contact the Help-Line.

It should be stressed that any cost-saving regimes should be introduced only after fully proving the reliability of the suppliers by an extended period of full LOT-by-LOT testing and a detailed analysis of the performance of these suppliers.

3.3 Pre-qualification of Suppliers

Pre-qualification is a procedure designed to test the ability of the supplier to provide a quality product before a contract is awarded. Pre-qualification reduces the risk of awarding a contract to a manufacturer who is unable to meet the quality requirements defined in this *Specification*. The purpose of pre-qualification is to protect both the buyer and the consumer. An effective pre-qualification scheme:

- Excludes manufacturers that do not have the capability of producing condoms that meet the performance requirements of the *Specification*
- Maximizes the likelihood that the product quality will be consistent throughout the order
- Verifies that the manufacturer has the quality assurance and management system to control the properties and parameters stated in the general requirements of the *Specification* that cannot be practically checked on the finished product
- Verifies that the manufacturing process produces products in compliance with *ISO 4074:2002*
- Ensures that the manufacturer has the physical capacity to make the goods according to the *Specification* and the delivery schedule
- Saves time and expense when dealing with orders and deliveries later on
- Eliminates the least competent and least reliable suppliers

There are several approaches that can be used to pre-qualify suppliers, as detailed in Section 2, Chapter 5 — Guidelines for Procurement, Step 9. Samples from three LOTS of condoms, selected by a sampling agency or the test laboratory, are submitted for testing to a test laboratory designated by the purchaser. Increased sample sizes as described in Annex B of *ISO 4074:2002* are specified to increase the reliability of the results. The test laboratory should be selected in line with the recommendations given in Section 1, Chapter 1, Part 3.1.

3.4 Compliance Testing

WHO recommends that every LOT of condoms be tested for compliance with this *Specification* by an independent test laboratory before it leaves the factory and is shipped to the purchaser. This is known as **compliance testing**. The methods of sampling the condoms and the relative merits of testing prior to delivery are discussed in Section 2, Chapter 5 — Guidelines for Procurement, Step 11. 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, Part 3.1. Whenever possible, it is recommended that only one set of compliance testing be carried out.

3.5 Confirmatory Testing

In some circumstances local regulatory bodies or government agencies may require testing when the condoms are received in-country. Whenever possible, this should form part of the compliance testing. Local regulatory bodies must take into account the results of compliance testing before reaching any conclusions about quality. Confirmatory testing may also be done to confirm that the product has not undergone any deterioration in properties during shipment.

Confirmatory testing can be restricted to selected LOTS, chosen at random, from a shipment or consignment. It is essential that the samples taken are representative of the whole shipment and not just one or two boxes. It is recommended that priority be given to the critical performance parameters of airburst properties and pack integrity when such testing is undertaken. The risk of statistical LOT failures due to sampling error should be considered when interpreting such tests. Occasional differences between the compliance tests and the confirmatory tests must be expected. Guidance on action to take in such circumstances is given in Section 2, Chapter 7 — Resolution of Disputes.

CHAPTER TWO
Model Specification for Male Latex Condoms

1 Introduction

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

The minimum performance requirements for male latex condoms are given in the recently revised *ISO 4074:2002 — Natural Latex Rubber Condoms; Requirements and Test Methods*. This standard specifies the essential performance requirements that latex condoms are expected to achieve and the test methods that are used to assess compliance with these requirements. This latest revision of *ISO 4074:2002* was based on an extensive research and consultation process started in 1996, involving leading experts from around the world in all aspects of condom manufacturing, testing, research and use. The *Model Specification* described here incorporates the performance requirements of *ISO 4074:2002*.

A specification is a statement of the buyer's requirements and must cover all the attributes and features of the product. Many of these requirements, particularly the design features, may be unique to the buyer and are not specified in *ISO 4074:2002*. The buyer's specification must be a detailed and unambiguous statement of the buyer's requirements and must 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.

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

The *Model Specification* has been generated by consensus and is based on the outcome of a great deal of research, details of which are given in Annex I. The *Model Specification* details all the attributes required of the product and the means of verification. It can be used unchanged or adapted to the specific requirements of programmes. It is, however, important to understand that:

- **General requirements** specify the safety of constituent materials and other characteristics, such as shelf-life. These properties are difficult to assess on a regular basis and should not vary from LOT to LOT. ***The general requirements detailed in the* Model Specification *should not be changed and are listed in Section 1, Chapter 2, Part 3.1.***
- **Performance requirements** specify the essential performance attributes of the condoms established in accordance with *ISO 4074:2002* and 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 the ability to resist breakage. ***Performance requirements detailed in the* Model Specification *should not be changed and are listed in Section 1, Chapter 2, Part 3.2.***
- **Design requirements** are mainly concerned with the acceptability of the product, and these can be varied within certain parameters to meet specific programmatic requirements. Special boxes have been provided in the *Model Specification* for changes to the design requirements, such as colour, length and width. For each design requirement, there is a means of verification. These are listed in Section 1, Chapter 2, Part 3.3.
- **Packaging requirements** are detailed in the *Model Specification* and ***should not be changed***. If consumer packaging is required, it is important to include detailed instructions in the specification and discuss the design requirements with the manufacturer. These are listed in Section 1, Chapter 2, Part 3.4.

The *Model Specification* is based on:

- Recently finalized *ISO 4074:2002*

- A literature review of the available evidence
- The recommendations of a WHO/UNFPA/UNAIDS/FHI-led Informal Technical Consultation (May 2002)
- Recommendations made by delegates to the ISO/TC/157 working on the revised *ISO 4074:2002* (July 2002 and June 2003)

Where appropriate, reference is made to *ISO 4074:2002*.

2 Background to the *Model Specification*

This chapter provides a sample of a *Model Specification* for the male latex condom. A specification is an unambiguous statement of the buyer's requirements and covers all the attributes of the product and the means by which they can be verified.

The *Model Specification* is based, where appropriate, on the *ISO 4074:2002* standard for the male latex rubber condom. If used in conjunction with the procurement procedure (see Section 2), the *Model Specification* will ensure that a quality product is purchased and distributed to the consumer.

Table 2 (see page 25) indicates which of the tests should be done at pre-qualification, and Table 3 (see page 26) indicates which tests should form part of LOT-by-LOT compliance testing.

3 Requirements

3.1 General Requirements

Manufacturers shall provide documentary evidence to confirm that the condoms comply with the following general requirements. Verification of conformance to these requirements is to be done at the pre-qualification stage, during occasional random checks and if the purchaser has doubts whether the product complies with the specification.

General Requirements	
Materials	
	The condoms shall be made of natural rubber latex.
	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.
	Safety assessments shall be conducted in accordance with *ISO 10993* or equivalent methods.
	Manufacturers shall take steps to minimize the level of water-extractable proteins in the condoms.
	A suitable dusting powder (e.g., cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and allow them to unroll easily.
	Talc or lycopodium spores shall not be used.
	Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).
Shelf-life	
Expiry date	Condoms shall comply with the performance requirements of this *Model Specification* throughout the stated shelf-life of the condom.
	The manufacturer shall stipulate a shelf-life based on the outcome of stability studies and measured from the date of manufacture. This shelf-life shall be not less than three years and not more than five years.

General Requirements

Shelf-life (continued)

Shelf-life

Shelf-life shall be confirmed by real-time stability studies conducted at (30_{-2}^{+5}) °C[i] according *ISO 4074:2002,* Section 7.3. If results from such studies are not available prior to the pre-qualification stage, manufacturers must initiate the studies immediately.

Pending the outcome of the real-time studies, manufacturers may rely upon:

- Accelerated stability studies at elevated temperatures to estimate the shelf-life of their products
- Their own established and validated procedures for establishing shelf-life estimates

Advice on conducting and analysing stability studies is in *ISO 4074:2002,* Section 7.4, Annex K[ii]. Data from such studies should be reviewed as part of the pre-qualification procedure.

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 purchasers must be notified immediately.

Minimum Stability Requirements

Condoms shall comply with the minimum stability requirements defined in *ISO 4074:2002*, Section 7.2.

Sampling

Three LOTS sampled in accordance with *ISO 2859-1,* Inspection Level G-I but at least Code Letter M.

Conditioning

Incubate samples in their individual, sealed containers according to Annex H of *ISO 4074:2002*; one set for 168 ± 2 hours at 70 ± 2 °C and the other set for 90 ± 1 days at 50 ± 2 °C. At the end of the incubation periods, withdraw the condoms and test for airburst properties.

Testing

In accordance with test method in *ISO 4074:2002*, Annex G.

Requirement

Minimum bursting requirements:

- AQL 1.5
- **Volume**
  - -- **16.0 dm³** for condoms with widths less than 50.0 mm
  - -- **18.0 dm³** for condoms with widths 50.0 mm up to 56.0 mm
  - -- **22.0 dm³** for condoms with widths greater than 56.0 mm
- **Pressure**
  - -- **1.0 kPa** (for all widths)

The width is defined as the mean lay flat width of 13 condoms measured in accordance with Annex E of *ISO 4074: 2002* at a point (75 ± 5) mm from the closed end.

[i] That is, in the temperature range 28 °C to 35 °C.

[ii] Recent studies have shown that changes in the physical properties of condoms that occur at temperatures in excess of 50 °C to 60 °C may differ significantly from those observed in ageing studies conducted at 30 °C. Therefore, caution should be exercised when extrapolating shelf-life estimates from accelerated ageing studies conducted at elevated temperatures, particularly if these studies include results obtained at temperatures above 60 °C.

3.2 Performance Requirements

The performance requirements specified here are based on the requirements of *ISO 4074:2002*. These requirements cannot be altered. Verification of compliance with these requirements is to be done as part of pre-qualification and the LOT-by-LOT compliance testing of the product.

Performance Requirements

Bursting Volume and Pressure

Sampling In accordance with *ISO 2859-1,* Inspection Level G-I.

Testing In accordance with test method in *ISO 4074:2002*, Annex G, clauses 6.1 (before oven conditioning) and 6.2 (after oven conditioning) for (168 ± 2) hours at (70 ± 2) °C.

Requirement Minimum bursting requirements:

- AQL 1.5
- **Volume**
  -- **16.0 dm³** for condoms with widths less than 50.0 mm
  -- **18.0 dm³** for condoms with widths 50.0 mm up to 56.0 mm
  -- **22.0 dm³** for condoms with widths greater than 56.0 mm
- **Pressure**
  -- **1.0 kPa** (for all widths)

The width is defined as the mean lay flat width of 13 condoms measured in accordance with *ISO 4074:2002,* Annex E at a point (75 ± 5) mm from the closed end.

Freedom from Holes and Visible Defects

Sampling In accordance with *ISO 2859-1*, Inspection Level G-I but at least Code Letter M.

Testing In accordance with test method in *ISO 4074:2002*, Annex L.

Requirement

- Freedom from holes: AQL 0.25
- Visible defects: AQL 0.4

There is a more detailed discussion on critical and non-critical visible defects in Section 1, Chapter 3.

Package Integrity (seal integrity)

Sampling In accordance with *ISO 2859-1*, Inspection Level S-3.

Testing In accordance with test method in *ISO 4074:2002,* Annex M.

Requirement AQL 2.5

3.3 Design Requirements

The design properties listed below may be adapted, where 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 upon between manufacturer and purchaser, any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed upon. 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 should be subject to *ISO 2859-1,* Inspection Level S-2 with an AQL of 1.0 and other design features should be subject to *ISO 2859-1,* Inspection Level S-3 with an AQL of 2.5.

Appropriate reference samples should be maintained by the purchaser, the manufacturer and the testing laboratory.

Design Requirements	
Shape and Texture	
Verify by visual inspection	The surface of the condoms shall be non-textured throughout. The recommended condom should have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir tip. Shape may be modified in line with normal commercial condom designs. *If the shape is other than above, attach a dimensioned drawing with detailed description and check here.* ☐
Integral Bead	
	The open end of the condom shall have a rolled ring of latex, called an integral bead.
Colour	
Verify by visual inspection	The recommended condom should be translucent and without added colouring. **If coloured condoms are desired, pigments must be suitable for use in medical devices.** If a pigment is required, indicate the colour here. ☐
Scents and Flavouring	
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.) Appropriate reference samples should be retained by the testing laboratory and can be used to resolve disputes over odour. The recommended condom should be free from added fragrance and flavouring agents.

Design Requirements

Scents and Flavouring (continued)

Verify by visual inspection and smell

Users may specify the addition of a suitable fragrance or flavour to mask the characteristic rubber odour. Such fragrances and flavours must be non-toxic and non-irritating and must not degrade the rubber as demonstrated by biocompatibility studies conducted according to *ISO 10993*.

If a fragrance is desired, describe here. ☐

If a flavour is desired, describe here. ☐

Width

Sampling In accordance with *ISO 2859-1,* Inspection Level S-2.

Testing In accordance with test method in *ISO 4074:2002*, Annex E.

Requirement A width of 53 mm, with a tolerance of ± 2 mm is allowed for individual condoms with a tolerance of ± 1 mm for the mean of the LOT.

AQL 1.0

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.

If the width is not (53 ± 2) mm, indicate the width here. ☐

Length

Sampling In accordance with *ISO 2859-1,* Inspection Level S-2.

Testing In accordance with test method in *ISO 4074:2002,* Annex D.

Requirement A minimum of 170 mm for condoms with widths less than 50.0 mm.

A minimum of 180 mm for condoms with widths of 50.0 mm up to 56.0 mm.

A minimum of 190 mm for condoms with widths greater than 56.0 mm.

AQL 1.0

Other lengths may be specified based on the best available data on the target population.

Length ☐

Thickness

Sampling In accordance with *ISO 2859-1,* Inspection Level S-2.

Testing In accordance with test method in *ISO 4074:2002,* Annex F.

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.

AQL 1.0

The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm.

Design Requirements

Thickness (continued)

Note: Extra-strength condoms are normally thicker and less elastic, and extra lubricant is recommended. For further requirements, see *ISO 4074:2002*, Section 6.3.

Quantity of Lubricant Including Powder

Sampling In accordance with *ISO 2859-1,* Inspection Level S-2.

Testing In accordance with test method in *ISO 4074:2002*, Annex C.

Requirement The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.

Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants should NOT be used.

If an alternative lubricant is required, specify the type here. ☐

The quantity of lubricant, including powder, in the package should be 550 ± 150 mg.

AQL 4.0

If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.

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 attached to this specification.

Verified by visual inspection Individual packages shall be square 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.

Alternative packaging materials can be accepted if their impermeability and strength are comparable to the recommended packaging above, or if there is real-time stability data to show the condom in its pack has adequate shelf-life.

If an alternative material is required, attach the full specification and mark here. ☐

The LOT numbers on packages must be printed at the time of packaging.

Design Requirements

Individual Package Materials and Markings (continued)

In addition, the following shall apply:

- There shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- 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.
- The package must be easy to open without damaging the condom.

Requirement

The individual package shall be individually marked as follows:

- Manufacturer's name
- LOT number or LOT identification code (printed at the time of packaging, not pre-printed)
- **Manufacturing date (dip date):** Month and year — labelled *Manufacturing Date*
- **Expiry date:** Month and year — labelled *Expiry Date*
- **Date** in a language to be specified by the purchaser

AQL 2.5

3.4 Packaging for Shipment

Inspections or verifications in this section will generally be carried out at the pre-qualification stage and during periodic audits.

Packaging for Shipment

Consumer Packs

No consumer packs are included in the *Model Specification*.

Specify in accordance with the requirements of the programme.

Inner Boxes

The inner boxes shall be constructed of board plasticized on its inner surface and of sufficient strength and rigidity that the box will retain its shape through every stage of the distribution chain.

The inner boxes will be marked in a legible manner to show the contents and to facilitate identification in case of subsequent query.

The following information shall be included in the inner box marking:

- Lot identification number
- 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.

Packaging for Shipment

Inner Boxes (continued)

- 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.
- Manufacturer's name and registered address
- Nominal width, expressed in millimetres
- Number of condoms in box
- Instructions for storage

Note: All markings must be legible. Can be specified in accordance with programme requirements.

Exterior Shipping Cartons

The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-walled corrugated fibreboard cartons made from weather-resistant fibreboard with a bursting test strength of not less than 1900 kPa.

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 not less than 75 mm.

The cartons will be secured by plastic strapping at not less than two positions.

Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.

The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.

In some countries, the three-walled 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.

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:

- LOT identification number
- 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.
- 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.
- Name and address of supplier
- Nominal width
- Number contained in the carton
- Instructions for storage and handling

Packaging for Shipment

LOT Traceability

To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together.

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.

These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons, colour coding and palleting of discrete LOTS. Instructions to this effect shall be issued to shipping and warehouse personnel.

Table 1: Defects in Packaging and Marking 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), location, sequence, 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

Table 2: Pre-qualification Requirements

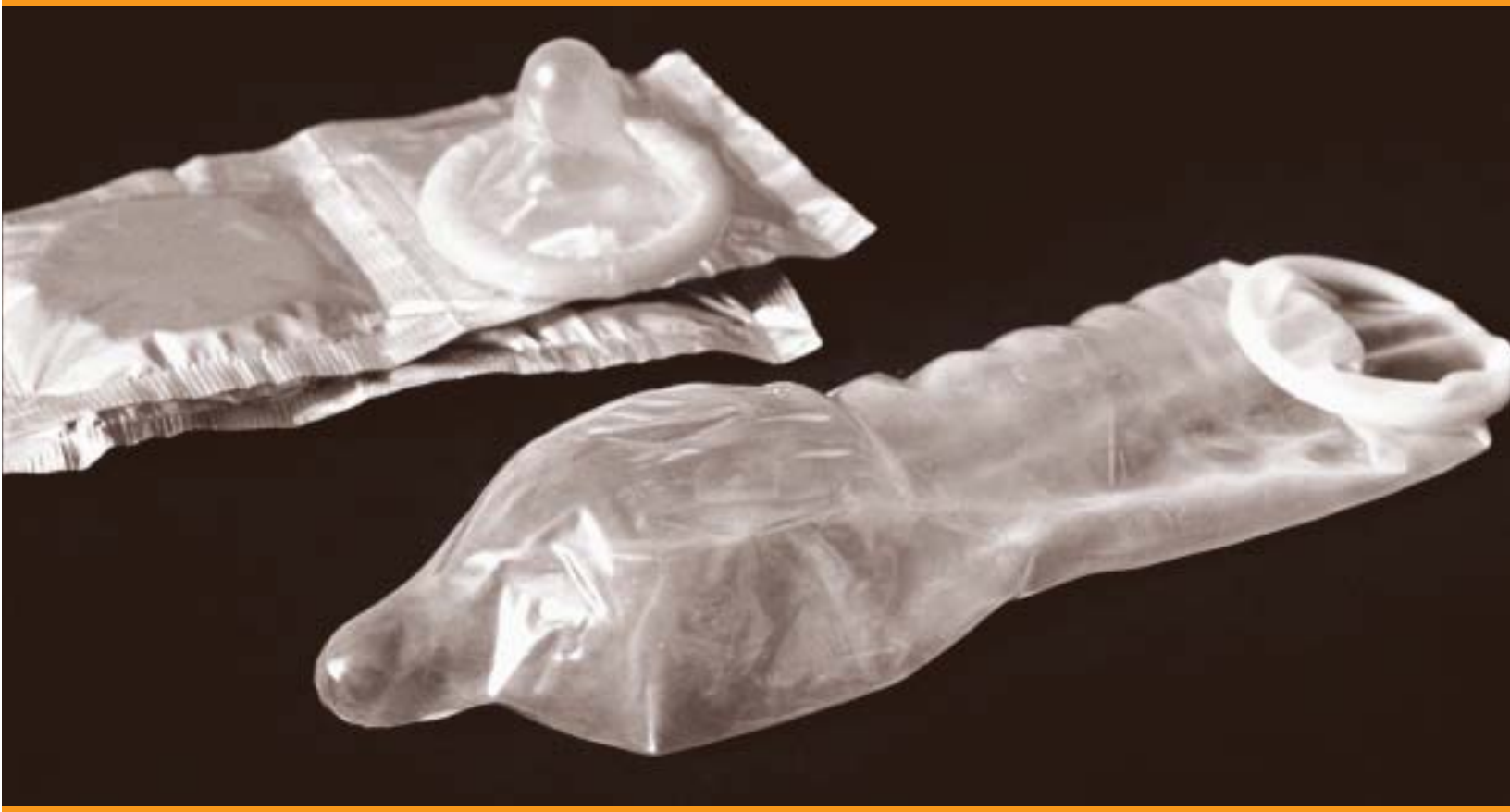
Tests that should be applied for pre-qualification purposes.

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
General Requirements			
Constituent materials	3.1		Manufacturers' documentation
Shelf-life (minimum stability) (ISO 4074: 2002, Section 7.2)	3.1	*ISO 2859-1*, Level G-I, minimum Code Letter M	Manufacturers' documentation Laboratory testing AQL 1.5
Performance Requirements			
Burst volume before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 1.5
Burst pressure before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 1.5
Freedom from holes	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter N	Laboratory testing AQL 0.25
Visible defects	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter N	Laboratory testing AQL 0.4
Package integrity	3.2	*ISO 2859-1*, Level S-3, minimum Code Letter H	Laboratory testing AQL 2.5

Table 3: Compliance Test Requirements

Tests required for LOT-by-LOT compliance testing.

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
Performance Requirements			
Burst volume before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I	Laboratory testing AQL 1.5
Burst pressure before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I	Laboratory testing AQL 1.5
Freedom from holes	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 0.25
Visible defects	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 0.4
Package integrity	3.2	*ISO 2859-1*, Level S-3	Laboratory testing AQL 2.5
Design Requirements			
Shape and texture	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Integral bead	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Colour	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Scents and flavouring	3.3	Agreed upon between manufacturer and buyer	Sensory inspection
Width	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Length	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Thickness	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Lubricant quality (including powder)	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 4.0
Packaging Requirements			
Individual package	3.3	*ISO 2859-1*, Level S-3	Visual inspection AQL 2.5
Inner boxes and exterior shipping cartons	3.4	*ISO 2859-1*, Level S-3	Visual inspection



CHAPTER THREE
Workmanship and Visible Defects

1 Introduction

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 defect is critical (if you need assistance, contact the Help-Line). If the defect will affect the performance of the condom, the defect is critical.

2 Types of Defects

2.1 Critical Visible Defects

The most common critical visible defects are covered by *ISO 4074:2002*. These defects include broken, missing or severely distorted rim (bead), and permanent creases with adhesion of the film. These defects are evaluated by visual inspection as part of the procedure for testing for freedom from holes. AQL 0.4 applies to these defects. Based on practical experience, other types of critical visual defects are occasionally seen. Some of the more common defects are described in Table 4 (see page 30).

2.2 Non-critical Defects

Non-critical visible defects may not cause the condom to fail the specification but nevertheless are undesirable from the user standpoint. Depending upon the requirements of the specific user population, the purchaser may wish to establish limits for these types of defects in the final specification. Consideration should be given to the establishment of realistic AQLs for these defects, and agreement should be reached with manufacturers before implementing them.

The most common types of **non-critical defects** and their causes are described in Table 5 (see page 31). Appropriate guidance is given when specific types of defects should be regarded as critical, in which case they should be treated as visible defects under *ISO 4072:2002* and an AQL of 0.4 should be applied. An AQL of 2.5 is recommended for non-critical defects.

Condoms should be inspected for workmanship as part of the test for freedom from holes. As the samples are inspected prior to mounting on the testing equipment, any that exhibit the following defects should be noted as **non-critical failures**. The condoms should then be mounted on the testing equipment and tested for freedom from holes.

3 Packaging Defects

The quality of the individual packs shall be assessed by visual inspection using a sampling plan in accordance with *ISO 2859*, Inspection Level S-3. An AQL of 2.5 shall be applied to these defects collectively. Defects are summarized in Table 6 (see page 32).

Consumer Packs

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

Cartons and Marking

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

Table 4: Critical Condom Defects

DEFECT	DESCRIPTION
Pleat/Crease	An area of the condom where the film sticks to itself and the pleat or crease cannot be removed by gently stretching the film. If the pleat or crease cannot be removed, it is considered a permanent visible defect under *ISO 4074:2002*.
Visible Holes under the Bead	Visible holes immediately beneath the bead are critical defects and are treated as visible holes under *ISO 4074:2002*.
Blister/Bubble	A small circular or teardrop-shaped thin area in the film, which may break under pressure. If, in the opinion of the testing laboratory and the purchaser, there is a risk that this type of defect will cause failure in use, it should be treated as a visible defect under *ISO 4074:2002*.
Coagulum	Particles greater than 0.2 mm located towards the closed end of the condom may cause failure of the condom in use and should be regarded as a visible defect under *ISO 4074:2002*.
Embedded Particle(s)	Particles such as dirt and hair trapped in the film. Larger particles (greater than 1 mm) may affect the performance of the condom and should be treated as a visible defect under *ISO 4074:2002*.
Faulty Bead (Rim)	Missing, broken or severely distorted beads are visible defects under *ISO 4074:2002*.
Crack Marks	Lines left in the latex film formed as the latex dries. A crack mark that penetrates the surface of the condom, which could affect the performance of the condom.
Delamination	Separation of the layers of the latex film.
Thin Spots	Area(s) of the condom that are visibly thin. In many instances, thin spots will lead to failure of the condom during testing for freedom from holes or airburst testing. If, in the opinion of the test laboratory and the purchaser, the defect, because of its nature and location, could lead to failure in use, it shall be considered a visible defect under *ISO 4074:2002*.

Table 5: Non-critical Condom Defects

DEFECT	DESCRIPTION/CAUSE
Coagulum	Particles of solid rubber trapped in the film. Small particles of coagulum (less than 0.2 mm) are unlikely to affect the performance of the condom and should be regarded as non-critical defects.
Embedded Particle(s)	Particles such as dirt and hair trapped in the film. Small particles (less than 0.1 mm) are unlikely to affect the performance of the condom and should be regarded as non-critical defects.
Faulty Bead (Rim)	Minor bead defects such as unevenness and partial distortion will not affect the performance of the condom and should be regarded as non-critical defects.
Crack Marks	Crack marks on the surface of the condom are unlikely to affect the performance of the condom and should be regarded as non-critical defects.
Irregularly Formed Teat	Minor distortions of the teat not caused by one of the defects described in the critical defects table are unlikely to affect the performance of the condom and should be regarded as non-critical defects.
Surface Discoloration/Streaks	Surface discoloration and minor streaking on colored condoms should be regarded as non-critical defects.

Table 6: Packaging Defects

Individual Foil Packaging Defects

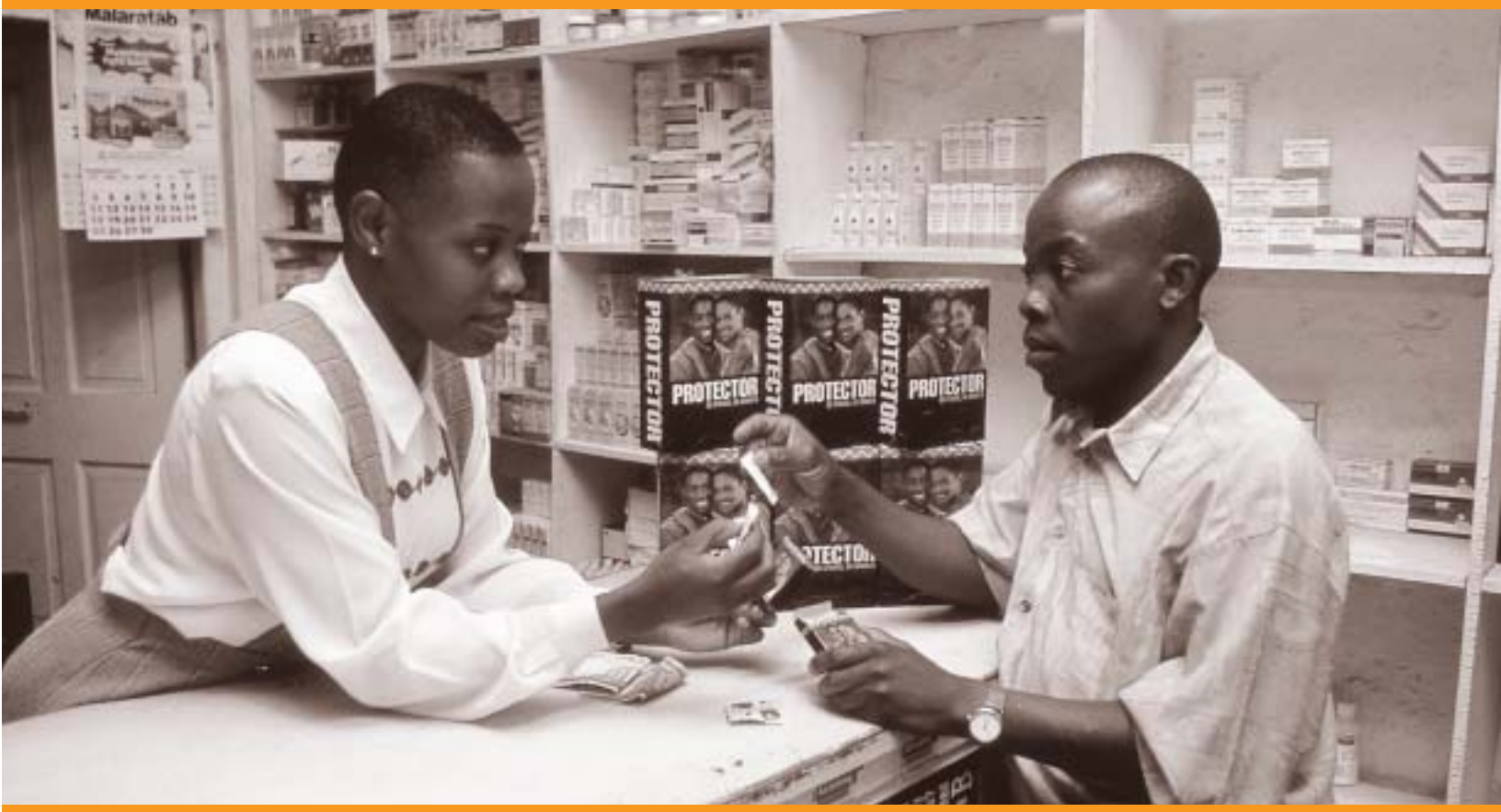
- Empty package
- No lubricant
- Lubricant leakage
- Delamination of the packaging film
- Discoloured film and labels
- Missing manufacturer's name
- Incorrect/missing LOT number
- Incorrect/missing manufacture date
- Incorrect/missing expiry date

Consumer Packs

- Missing manufacturer's name
- Incorrect/missing LOT number
- Incorrect/missing manufacturer date
- Incorrect/missing expiry date
- Empty or partially filled packs
- Discoloration
- Delamination

Cartons and Markings

- Missing manufacturer's name
- Incorrect/missing LOT number
- Incorrect/missing manufacture date
- Incorrect/missing expiry date
- Non-permanent marking
- Empty or partially filled cartons
- Damaged cartons that may affect the integrity or quality of the condoms inside



CHAPTER FOUR
Resolution of Disputes

1 Introduction

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

1) Interpretation of the contract
2) Payment schedules — delays in delivery schedules
3) Completion schedules
4) Independent laboratory test results
5) Design issues
6) Condition of the condoms on arrival in-country or some time after delivery

Items 1 to 3 are principally commercial matters and **will not** be considered in this section.

Items 4 to 6 are principally manufacturing issues and are discussed in this chapter.

It is essential that the procurement contract specify a process for the settlement of disputes.

2 Disputes over Laboratory Results

Disputes over product acceptance usually 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 test results or other evidence to suggest that the independent tests are incorrect and do not accurately represent the quality of the product tested. Procedures for dealing with such disputes should be covered in the contract.

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 reasons for questioning the results:

- Because of the level of uncertainty in estimating the percentage of defective condoms in a LOT by testing a sample
- Because of testing or reporting mistakes due to operator error, equipment malfunction, drifts in calibration, transcription errors and others

It is often very difficult to distinguish between these two sources of error. When disputes arise, it is strongly recommended that independent assistance be sought (such as calling the Help-Line) to resolve the issue. Some guidance on resolving disputes and deciding when a re-test is appropriate is given in the remainder of this chapter.

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

- In any shipment of condoms there is always a risk that some LOTS will be rejected even if 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 lot rejection to less than 1%.
- Manufacturers and purchasing agencies should plan on the basis 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 rejected LOTS by maintaining process averages well below the relevant AQLs.
- As a general rule, when the level of LOT failures exceeds 5% over a large number of LOTS, doubts can be raised about the quality of a specific manufacturer. In the shorter term, if any two LOTS in a sequence of five LOTS are rejected, there is a risk that the process average may exceed the AQL and further investigations of quality should be undertaken according to Annex III.

4 Decisions on Re-testing

Re-testing should only be undertaken when there is considerable evidence that the laboratory has made a mistake. Before considering a re-test all the available data should be reviewed. 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? Where appropriate, the laboratory should keep the failed condoms so the manufacturer can examine them.

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 test laboratory can be conducted, and it may be possible to identify the cause of any disagreement. If 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. The laboratory must keep the condoms with holes for further investigation.

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 III. If this process average is within the AQL, a re-test should be allowed. If it is not, the purchaser can still use discretion to allow a re-test if a good case is made for it.

In all cases, the manufacturer should bear the cost of a re-test, unless it can be demonstrated that it is likely that the laboratory has made a mistake.

> LOTS found non-compliant with more than one performance requirement, regardless of possible statistical error, shall not be considered for re-test unless probable causes related to the sample treatment or testing can be established.

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 by drawing a new sample using the next higher inspection level defined in *ISO 2859* than the one used for the first sample (e.g., GII instead of GI).

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

Independent Testing Laboratory

- Verify testing was performed as prescribed in the test method applicable to the order concerned
- Verify 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

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

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

6 Defects

The requirements in the *Model Specification* may be divided into two categories:

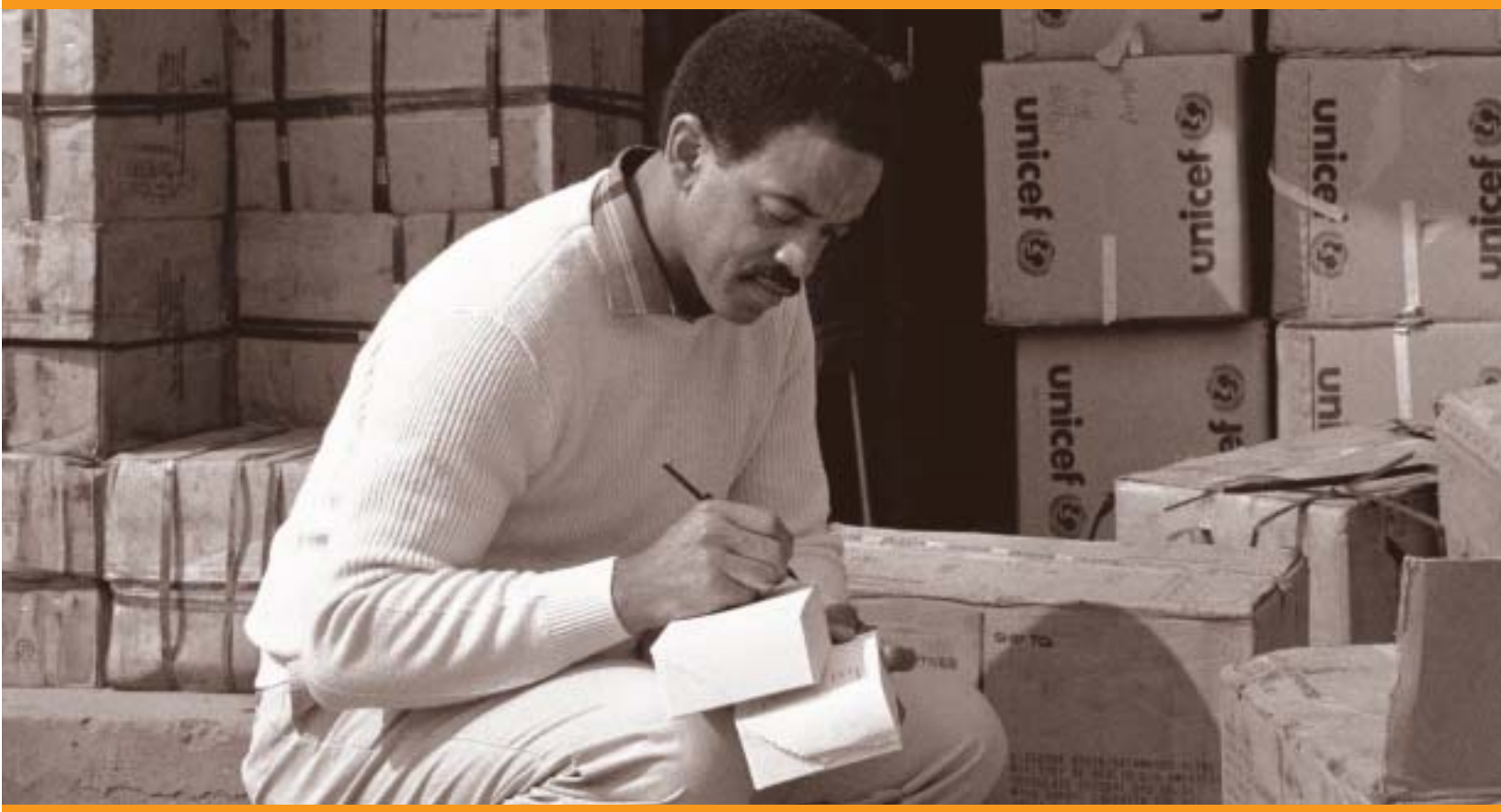
- Design requirements — define the physical characteristics of the condom and in most cases do not directly affect the performance of the product
- Performance requirements — include freedom from holes, inflation and package seal

Minor transgressions in the design requirements may not be serious, and non-complying product could be accepted under some circumstances at the purchaser's discretion. For example, if some condoms were 179 mm long instead of 180 mm as specified, it is unlikely that they would be markedly less fit for use. On the other hand, if they were measured at 120 mm, there would be no grounds for acceptance. Similarly condoms containing excess lubricant would still be fit for use unless the lubricant levels were such that pack integrity was compromised.

Failures on performance requirements are not acceptable, but the test results should, as far as possible, be representative of the LOT in question.

Manufacturers should agree with the purchaser on any design variations to the specification and should not attempt to supply designs that are not specifically agreed upon in the contract.

SECTION TWO
Guidelines for Procurement



CHAPTER FIVE
Guidelines for Procurement

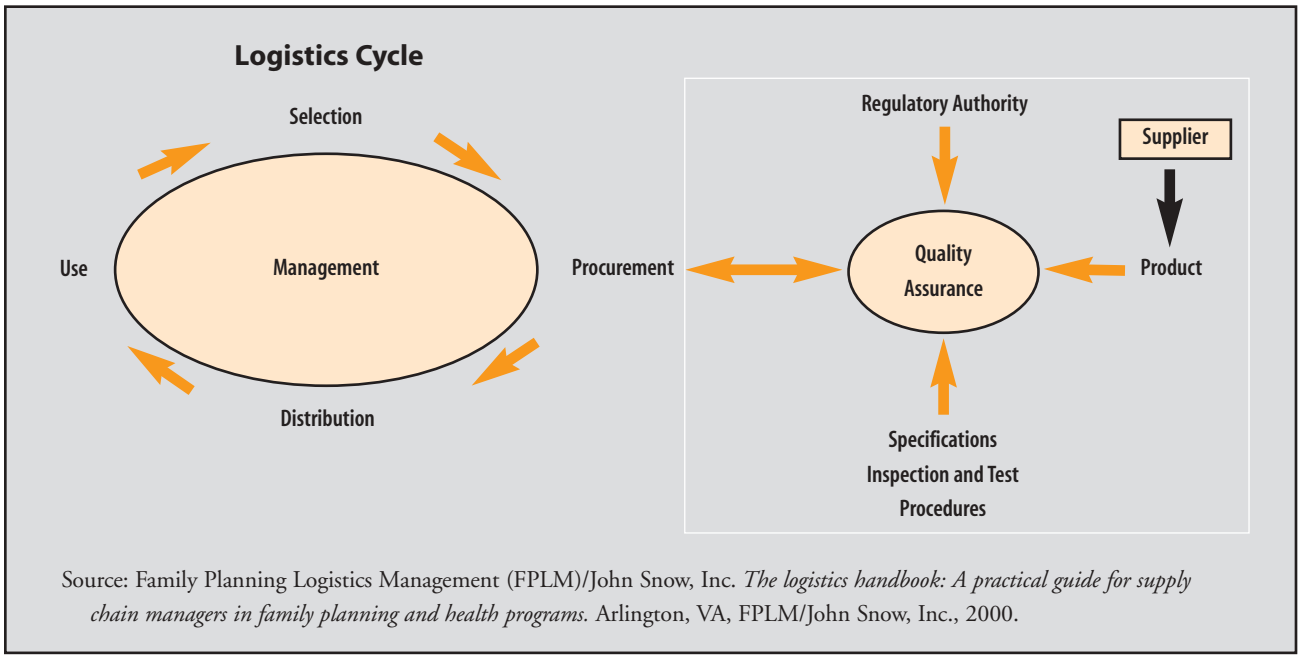
1 Introduction

Procurement is a component of the logistic management cycle detailed in Figure 1 (see below). The steps outlined in these guidelines deal only with one of the four components of logistics management — the steps required in the procurement process to receive a quality product in-country. More detailed methodologies for the procurement process and managing the supply chain have been developed by a number of international agencies working in the field of contraceptive procurement and logistics management.[i] Technical resource materials on establishing or strengthening the various functions of the condom management system are available from each of these agencies (refer to Annex VI for contact details).

UNFPA, PATH, WHO, and UNAIDS will publish *Condom Programming for HIV Prevention — An Operations Manual for Programme Managers.* This manual is designed to give programme managers a practical and specific seven-step approach to improve the effectiveness of existing condom programmes or create a new condom programme. An essential step in this process is obviously the application of the quality assurance measures, required to manufacture, procure and receive quality condoms in-country as detailed in *The Male Latex Condom — Specification and Guidelines for Condom Procurement.*

In condom sector procurement there are several traditional steps to ensure the purchaser obtains a quality product at a reasonable cost at the needed time. This section reviews the principle steps of the condom procurement process and identifies at each step essential quality assurance issues and stakeholders the purchaser may need to work with to obtain additional critical information. While the steps in the procedure outlined here should be followed, the actual procurement procedure a purchaser follows will depend on such factors as source of funding, government procurement procedures, and whether local manufacturers exist in-country. (Note that while this section presents

Figure 1: Logistics and Procurement Cycles



Source: Family Planning Logistics Management (FPLM)/John Snow, Inc. *The logistics handbook: A practical guide for supply chain managers in family planning and health programs.* Arlington, VA, FPLM/John Snow, Inc., 2000.

[i] Center for Disease Control and Prevention (CDC), Crown Agents, Family Health International (FHI), John Snow International (JSI), Population Services International (PSI), Program for Appropriate Technology in Health (PATH), UNFPA, USAID, World Bank.

the procurement steps in a sequential format, it is often *necessary* to implement several steps at the same time).

2 Step-by-Step Procurement Process

Procurement steps may vary from country to country, but to be undertaken effectively, each step requires:

- Leadership
- Timely decision-making
- A willingness to collaborate and communicate with different parties involved in each step of the procurement process
- Attention to detail
- Time

The figure on page 58 summarizes these steps.

Step 1: Assess Programme Requirements

The procurement process begins with an assessment of the overall needs of the condom programme. Assessing programme requirements depends on several factors that should be discussed with the different parties involved in condom usage, promotion, distribution and procurement.

Before forecasting condom requirements, it is important to understand the history of procurement, condom use in your country and the trends in condom use. This information can be obtained through a desk search of available information and by meeting with all parties involved in the procurement, distribution and promotion of condoms.

There is a need to determine:

a) 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?
   - -- 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?
   - -- Who is the intended consumer?
   - -- Where and under what conditions are condoms stored?
   - -- How are condoms distributed and what is the annual consumption?

b) What is the current stock of condoms, where is the stock located, when is the product due to reach the expiry date and what is the projected time-scale for distribution?

c) What research, if any, has been undertaken to determine the current population needs and unmet need?

d) What are the trends in condom use?

e) What is the storage capacity for receiving a bulk consignment of condoms, and what is the storage and distribution system? Limited storage capacity would require that the procurement of condoms be phased over time rather than arriving as one consignment.

f) What are the systems to monitor the distribution of stocks?

g) What are the requirements of the national regulatory body (or bodies) regarding the procurement and importation of condoms?

h) How are condoms imported into the country? Airfreight is generally very expensive, so condoms are usually shipped by sea to the nearest port of entry into the country. What is the history of previous shipments?

i) What problems, if any, have been encountered with the procurement and distribution of condoms over the last two years?

j) 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.

Combining several programme procurement requirements can offer potential savings through price discounts and reduces the purchaser's administrative costs associated with having to process multiple orders.

Information gathered through the described assessment process allows the purchaser to:

- Create a broader picture of what is happening in the field of condom procurement and programming in the country
- Identify key stakeholders who need to be involved in the process
- Identify the total quantity of condoms required to support program needs

The quantity requirements allow for an estimated budget to be prepared, which is required for the next step: securing funding.

Step 2: Identify and Secure Funding

In developing countries, the majority of funding for condom procurement (and most contraceptives) for public-sector programmes is provided through international lending organizations (World Bank), bi-lateral donor aid (USAID, Department for International Development, Deutsche Gesellschaft für Technische Zusammenarbeit, etc.), and national government budgets. Allowance should be made for the length of time it will take to secure funding. The current trend is for national governments and the private sector to absorb the procurement funding for condoms.

Bi-lateral donor funding for condom procurement is traditionally initiated by senior ministry personnel contacting the country mission with a request for support. However, many countries may already have arrangements in place that are renewed on an annual basis. For international agency and bi-lateral donor funding requests, the purchaser'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 for government approval accurate estimates of the condom procurement budget.

When funds for the provision of condoms are negotiated between a donor and recipient country, the donor will state what conditions, if any, are to be attached to the procurement of these condoms. It is advisable to ask for and follow the guidelines of each donor agency.

Step 3: Select a Procurement Method

Once programme requirements have been assessed, the quantity has been determined, and the funding source has been identified, a decision must be made regarding the method of procurement to be used.

The method used to procure condoms will depend on:

- Size of the order
- How specialized the condom design and packaging requirements are
- Urgency of the need
- Funding source
- Capacity to undertake the procurement process

In principle there are four commonly applied methods:

a) **Buy 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 to have the technical capacity to follow the procedure detailed in these guidelines.

Competitive bidding, including international competitive bidding, is the most complex of the procurement methods used and is the method preferred by some international lending organizations, such as the World Bank. The purchaser must develop the specification and procurement documents, implement the bidding process and pre-qualification of potential suppliers, select the manufacturer, and arrange for compliance testing and shipping. If an organization does not have existing procurement capacity with competitive bidding experience, this method can be challenging.

The approximate 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.

b) **Buy through a procurement agency**
Procurement agencies undertake buying for organizations and national programmes that do not have their own procurement department or

staff. Although independent procurement agencies exist in most cities worldwide, very few of them have any knowledge of the special requirements for buying condoms.

It is therefore very important to select a procurement agent with a track record of procuring quality condoms. For example, UNFPA, USAID, Crown Agents, and Population Services International (PSI) will act as procurement agents.

The agent takes responsibility for procurement and quality checking. In this case the purchaser has to develop the specification and make a suitable contract with the purchasing agent. The agent will be responsible for handling the pre-qualification of potential suppliers, selecting the supplier, and arranging compliance testing and shipping.

WHO recommends that the source of the condoms be either a primary condom manufacturer or experienced agent.

Procurement should not be through a non-specialized commercial agent, or importer. The condoms may not be traceable to their manufacturer, and quality issues will prove much more difficult to resolve.

This option can be considered by organizations and national programmes that do not have the procurement capacity required to implement a competitive bidding process.

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.

c) **Buy from an international organization that already purchases condoms in large quantities**
UNFPA and other international agencies like USAID, PSI, John Snow, Inc. (JSI) and International Planned Parenthood Federation (IPPF) buy condoms using the *Model Specification* and undertake both the pre-qualification of manufacturers and LOT-by-LOT compliance testing. Some agencies, such as UNFPA, maintain a list of pre-qualified suppliers, thus reducing the lead-time to respond to requests for supply. The packaging for these condoms is generally plain foil with no consumer packs. However, unique programme requirements can be considered if the quantity ordered is significant and there is sufficient time for a manufacture to process the order.

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 buying directly from a condom manufacturer through a competitive bidding process. Depending on the quantity of condoms needed, this option can also offer a delivery time less than that required by a competitive bidding process.

Certain international organizations, for example UNFPA, JSI, PSI and USAID, maintain stocks of condoms to respond quickly to 'stock out' and emergency situations. UNFPA can draw upon moderate supplies either held in stock or from manufacturers, based on its pre-existing supply contracts, and will sell to programmes for distribution in-country.

d) **Buy from a social marketing organization**
Social marketing organizations operate like commercial retail companies. They buy the products and promote and sell them in the market at subsidized prices. Sometimes, the social marketing company is supplied with condoms by the donor and may then add consumer packaging before marketing them.

Table 7 (see page 47) compares the advantages and disadvantages of the four basic procurement methods, as

(continued on page 48)

Table 7: 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. 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. 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. 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. Important to select a procurement agent with a reputation for following quality assurance measures in a timely fashion. 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. 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.

(continued from page 46)

adapted from the *World Bank Condom Procurement Guide*, published November 2001[ii].

Step 4: Prepare for Procurement — Customize the Specification

Review the *Model 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 Model Specification can be copied from this document or the web site (http://www.WHO.int/reproductive-health).*

General Requirements
The general requirements section of the *Model Specification* covers those qualities of the condom that should be assessed by the manufacturer before the product is put on the market. They define 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 requirements relating to shelf-life claims and stability.

Do not change requirements

Performance Requirements
The performance requirements specified in the *Model Specification* are based on the requirements of *ISO 4074:2002*. They include 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 compliance testing of the product.

Do not change requirements

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 *Model Specification* and determine what alternative requirements might better fit 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.

Can change per buyer's requirements

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.

Verification of compliance with the design requirements is to be done as part of the LOT-by-LOT compliance testing of the product.

Packaging Requirements
The *Model Specification* specifies stringent requirements for condom packaging to protect the condom during transportation, storage and distribution.

Do not change requirements

Consumer Packs or Additional Requirements
Other packaging, such as consumer packs for delivery, will depend on individual requirements of the programme and are not specified. For example:

[ii] *Condom Procurement Guide, Health Nutrition and Population.* Washington, World Bank, November 2001. *Standard Bidding Documents, Procurement of Health Sector Goods, (Pharmaceuticals, Vaccines and Condoms).* Washington, World Bank, May 2002. *Technical Note: Procurement of Health Sector Goods*, Washington, World Bank, May 2000.

- If the buyer wants a particular consumer package, such as condoms produced in strips, 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 or coloured condoms, it is important to discuss and agree upon the colours and flavouring 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 font, size, style and colour (by Pantone number).

Step 5: Identify Country Rules and Regulations

Since condoms are medical devices, many countries have special regulations covering importation and distribution. Any individual involved in the procurement of condoms for a particular country must be aware of these rules and regulations. Examples of specific requirements may include one or more of the following:

- Is there a mandatory quality standard with which all condoms must conform?
- How are the standards applied?
- Is there a requirement to test all LOTS 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 or a recognized local laboratory?
- Is it possible to work with this laboratory to undertake the compliance testing?
- What other entry requirements are there, such as import duties and certification?
- Is there a registration requirement prior to importation?

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

Familiarity with these regulations will help to smooth the passage of the condoms through customs, ensure compliance with local requirements, and reduce frustrating delays that can hold up delivery even when the products have arrived in-country.

Step 6: Preparation and Release of Bidding Documents

a) Decide on the method of procurement

As discussed in Step 3, a specific method of procurement needs to be selected prior to release of Bidding Documents. It is also important at this stage to identify any national regulatory procedures and specific donor agency requirements that should be incorporated into the Bidding Documents.

b) Prepare a set of Bidding Documents

The purchaser or implementing agency prepares a set of Bidding Documents that 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:

- Request for documentary evidence of manufacturing quality assurance measures
- Specification and compliance procedure
- Package design and packing of the condoms
- National registration requirements
- Delivery schedule and delay clauses
- Shipping arrangements
- Pre-qualification and compliance testing procedures
- Procedure for resolution of disputes
- Payment arrangements
- Terms and conditions that will be part of any purchase contract that is issued

- Bidding forms
- Funding arrangements

c) **Decide on the pre-qualification procedures**
The purchaser decides on the pre-qualification procedures that will be used for procurement. One of the components of the pre-qualification process is examination of documentary evidence presented by the supplier. 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, products currently manufactured
- At least two references with addresses, e-mail, 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 Good Manufacturing Practice (GMP) and quality management certifications
- Data to support claimed shelf-life at tropical temperatures (e.g., real-time ageing studies at (30_{-2}^{+5}) °C[iii] for the claimed shelf-life of the product or results from accelerated stability studies)
- Any available information on toxicity, allergenicity and antioxidants
- Statement of the ability to comply with the specification attached (this statement may be incorporated into the bid form)
- Explanation of the manufacturers' codes and markings

d) **Seek information about potential suppliers**
The purchaser should request information on the potential supplier's financial situation. 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.

e) **Select an independent testing laboratory and choose a sampling agent**
The purchaser must select an accredited testing laboratory for testing the condom samples and 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 results of the testing laboratory chosen for the pre-qualification and compliance testing will be accepted by the supplier. Refer to Annex VII or contact the Help-Line for information on testing laboratories and sampling agencies.

f) **Prepare the Bidding Document package**
The information and documents discussed above are assembled into a Bidding Document package, which usually includes the following documents:

- Invitation to bid
- Bid summary label (to affix to the outside of submitted package)
- Schedule of requirements and delivery dates
- Instruction to bidders
- Bid form*
- Price schedule*
- Certificate of conformity
- Bid security form*
- General conditions of contract
- Special conditions of contract
- Specification
- Performance security form
- Bidder evaluation form
- Bid summary

[iii] That is, in the temperature range 28 °C to 35 °C.

The reason for preparing formal bid forms (marked with an *) is that they and other documents in the list will become part of the contract if a bid is ultimately successful.

Step 7: Advertise the Bid

The purchaser arranges to advertise the Invitation to Bid as widely as possible among potential suppliers. This invitation should include a brief outline of the requirements (quantities and timing of delivery) and should invite interested suppliers to apply for the package of bidding documents.

It can be distributed by using one or more of the following routes:

- Advertisements in suitable media
- Lists of known suppliers (one such list appears as Annex VII to this document)
- Recommendations from other purchasers
- The trade representative of any countries known to have condom manufacturers

A list of suppliers in Annex VII is based on the best information available to WHO at the time of publication. For more information, contact the Help-Line.

Inclusion in this list does not imply approval or accreditation by WHO, UNAIDS, or UNFPA.

The letter or advertisement will invite suppliers to apply for a set of bidding documents and ask them to confirm that they:

- Are capable of providing the quantities required within the desired time-frame
- Have a proven record of manufacturing products that conform to the *Model Specification*
- Will accept the procedure for the resolution of disputes
- Will permit:
  - -- Pre-qualification and compliance testing
  - -- A sampling agency to perform random sampling of condoms at the site of the manufacturing facility
  - -- An independent testing laboratory to test samples of their condoms

It is normally not necessary to include a copy of the specification with the advertisement. It is sufficient to state that the specification will be based on the *Model Specification*.

Some purchasers charge a nominal fee for these documents to discourage people who do not have the ability to supply from asking for the documents out of curiosity.

Step 8: Evaluate the Bids

Potential suppliers will submit Bidding Documents in response to the advertisement. The purchaser opens the 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 evaluation of the suppliers' Bidding Documents is traditionally conducted by a committee, which should include personnel with technical expertise to help evaluate the documentation and certification submitted by suppliers. In addition to reviewing the documentation and certification, the evaluation committee should also check to see that the suppliers have confirmed that they:

- Are capable of providing the quantities required within the desired time-frame
- Have a proven record of manufacturing products that conform to the WHO specification, the purchaser's specification, or similar requirements

- Will permit a sampling agency to perform random sampling of condoms at the site of the manufacturing facility
- Will accept the test results of the independent laboratory
- Will accept the procedure for the resolution of disputes
- Accept the general and specific conditions of the contract

The supplier is chosen on the basis of:

- Quality of the product
- Capacity to supply
- Price

It is important to consider all three factors — selection should not be based on price alone.

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.

Non-specialized procurement agents and importers should be eliminated from the list.

Suppliers that meet the purchaser's selection criteria are considered for placement on a short-list for pre-qualification evaluation. Any number of suppliers can be included in the short-list at the discretion of the buyer as long as they conform to the selection criteria. A minimum of three suppliers should be selected for pre-qualification since the lowest bid may not necessarily yield the quality of product required by the tender.

Step 9: Pre-qualification of Suppliers

Pre-qualification is a procedure designed to assess the quality management systems of the manufacturer and confirm that the manufacturer can produce condoms capable of meeting the performance requirements of the *Model Specification*. Pre-qualification protects both the buyer and the consumer (see Section 1, Chapter 1, Part 3.3).

There are several approaches that can be used to pre-qualify suppliers:

- Pre-qualified suppliers accepted through the bidding process.
- Purchasers who place large and frequent orders for condoms may carry out pre-qualification in advance of any tender. This generates a list of qualified manufacturers who are invited to tender for an order. This method is useful in situations where purchasers must wait for funds from donors before they can place the order.
- Where orders are placed less frequently, pre-qualification can be combined with the tendering process. The tendering documents can be reviewed, and manufacturers that can demonstrate the capability to meet the requirements of the tender will be requested to participate in the pre-qualification process.

Although any number of suppliers can be selected for pre-qualification, it is advisable to limit the number because of cost and time implications. It is recommended that at least three suppliers be selected for pre-qualification since the lowest bid may not necessarily yield the quality of product required by the tender. When the order is for a very large quantity, it may be necessary to include more suppliers in the pre-qualification process to ensure requirements can be met without lengthy schedule delays.

For large and frequent orders, the manufacturer may be requested to cover the costs of the pre-qualification process. For orders placed less frequently, the purchaser may have to absorb these costs. The cost is minimal when compared to the costs involved in dealing with products that have not been manufactured to the required level of quality and supplied in a timely manner.

Table 8: Pre-qualification Requirements (copy of Table 2)

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
General Requirements			
Constituent materials	3.1		Manufacturers' documentation
Shelf-life (minimum stability) (ISO 4074: 2002, Section 7.2)	3.1	*ISO 2859-1*, Level G-I, minimum Code Letter M	Manufacturers' documentation Laboratory testing AQL 1.5
Performance Requirements			
Burst volume before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 1.5
Burst pressure before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 1.5
Freedom from holes	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter N	Laboratory testing AQL 0.25
Visible defects	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter N	Laboratory testing AQL 0.4
Package integrity	3.2	*ISO 2859-1*, Level S-3, minimum Code Letter H	Laboratory testing AQL 2.5

Pre-qualification involves:

a) **The examination of documentary evidence presented by the supplier**
This is provided to verify the quality management systems, the integrity of the product manufactured and the capacity of the factory. Someone who is experienced in the manufacture of condoms must review documentary evidence. An individual who has not been exposed to manufacturing procedures and quality management systems will have difficulty assessing the value and validity of the documentation supplied by manufacturers.

b) **Testing of condoms manufactured by the supplier**
Tests required for pre-qualification are given in Section 1, Chapter 2 and summarized in Table 2 (see page 25) and repeated in Table 8 (see above). Instructions are given to a sampling agency to draw random samples of 1,200 condoms for each of three LOTS at each manufacturer on the list. The LOTS should be no more than 90 days old (since original manufacturing date) and should be sent by airfreight or courier to the testing laboratory.

The testing laboratory should be an independent laboratory chosen by the buyer. A single laboratory should be used for testing the samples from all manufacturers. The samples should be tested according to the *Model Specification* (Section 1, Chapter 2, Table 1).

It is important to recognize that the manufacturer will be producing for existing clients according to their own requirements, so the stocks drawn at random from the manufacturer may not comply with all requirements of the *Model Specification*. However:

- The manufacturer must be asked to indicate the specifications to which the product has been produced.
- The air inflation and freedom from holes requirement must be complied with.
- At the time of sampling, the manufacturer may be given the opportunity to exclude a small portion of stock from sampling if that stock was produced for markets where *ISO 4074:2002* does not apply.

Only individuals with extensive knowledge, understanding and experience of manufacturing processes and procedures should undertake factory visits.

Contact the Help-Line for assistance.

Condoms should have a shelf-life of not less than three and not more than five years. To support shelf-life claims, the manufacturer must be able to provide evidence that real-time stability studies are in progress and provide information to date from these studies and any data from accelerated studies.

c) Factory inspection

In some cases, particularly for large bulk purchases, it may be desirable to visit the supplier's facilities to assess their quality management system and capacity to produce the required order.

For small orders (of less than 10 million condoms) a factory visit is neither practical nor cost-effective. A factory visit is only worthwhile if the individual visiting the factory has extensive knowledge, understanding and experience of manufacturing processes and procedures.

A guideline on auditing factories will have limited value unless an individual is familiar with factory processes and is trained, mentored and tutored in the assessment process. Practical experience is the only way to learn how to audit a factory effectively.

Step 10: Selection of the Supplier and Contract Award

The manufacturer whose samples meet all the test requirements, submits a reasonable price and provides the most valid documentation is judged to be the successful bidder and is awarded the contract.

Step 11: LOT-by-LOT Compliance Testing

Provided the pre-qualification procedures have been followed correctly when selecting the supplier, there is a reasonable assurance that the delivered condoms will be of consistently high quality.

It is a fact that even the most conscientious manufacturer can sometimes suffer quality lapses, possibly due to variations in characteristics of raw materials or a temporary malfunction of the quality control systems. For this reason it is important to verify that every LOT manufactured complies with the requirements of the *Specification* before it is accepted for shipment. This is called LOT-by-LOT compliance testing.

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

LOT-by-LOT compliance testing protects the purchaser from receiving a product of questionable quality.

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*. Table 9 (see page 55) lists the tests and gives the sample sizes and acceptance limits for compliance testing.

WHO recommends that every LOT be tested for compliance with the specification before it is accepted for shipment to the purchaser.

The sampling agency sends the samples directly to the testing laboratory chosen by the purchaser, where they are subjected to the quality tests detailed in Section 1, Chapter 1 — Essential Elements of Condom Quality Assurance and Section 1, Chapter 2 — Model Specification for Male Latex Condoms.

If the purchase order is relatively small or split between several suppliers, LOT-by-LOT testing should be done throughout the contract.

If the purchase order with any one supplier is large enough to utilize a substantial portion of one or more dipping machines for an extended period, LOT-by-LOT testing should be done until the supplier's process variation has been verified. At this stage it would be possible to consider reducing costs using one of the options detailed in Annex V.

The use of options detailed in Annex V requires expert advice, which should be sought from either an experienced testing laboratory or quality control expert (contact the Help-Line for assistance). In all cases the supplier should provide the results of the production line and pre-release testing for each LOT, preferably in the form of control charts.

If the condoms do not pass 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 9: Compliance Test Requirements (copy of Table 3)

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
Performance Requirements			
Burst volume before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I	Laboratory testing AQL 1.5
Burst pressure before and after oven conditioning	3.2	*ISO 2859-1*, Level G-I	Laboratory testing AQL 1.5
Freedom from holes	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 0.25
Visible defects	3.2	*ISO 2859-1*, Level G-I, minimum Code Letter M	Laboratory testing AQL 0.4
Package integrity	3.2	*ISO 2859-1*, Level S-3	Laboratory testing AQL 2.5
Design Requirements			
Shape and texture	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Integral bead	3.3	Agreed upon between manufacturer and buyer	Visual inspection

Table 9: Compliance Test Requirements (continued)

REQUIREMENTS	SECTION	SAMPLING	VERIFICATION
Design Requirements			
Colour	3.3	Agreed upon between manufacturer and buyer	Visual inspection
Scents and flavouring	3.3	Agreed upon between manufacturer and buyer	Sensory inspection
Width	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Length	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Thickness	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 1.0
Lubricant quality (including powder)	3.3	*ISO 2859-1*, Level S-2	Laboratory testing AQL 4.0
Packaging Requirements			
Individual package	3.3	*ISO 2859-1*, Level S-3	Visual inspection AQL 2.5
Inner boxes and exterior shipping cartons	3.4	*ISO 2859-1*, Level S-3	Visual inspection

Step 12: Receipt of Shipment

Purchasers should be aware of the national regulatory and customs clearance requirements prior to issuing a contract (see Step 5, page 49).

If a local regulatory board has the technical expertise and appropriate laboratory equipment, arrangements can be made for it to undertake the compliance testing of condoms before shipping.

Before the contract with the supplier is issued, it must be decided who will undertake the compliance testing. In many countries, national regulatory bodies confine their role to reviewing the data and conclusions reached by independent laboratories. Occasionally they may undertake confirmatory testing if they have valid concerns regarding the possible deterioration of the product during transportation.

Confirmatory testing

On receipt of the shipment, some local regulatory boards may insist on undertaking confirmatory testing to ensure that the condoms have not been damaged during shipping. Confirmatory testing should be restricted to selected LOTS, determined at random from a shipment or consignment. It is recommended that priority be given to critical performance parameters — for freedom from holes, airburst properties and pack integrity.

The risk of statistical LOT failures due to sampling error should be considered when interpreting such

tests. 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 or contact the Help-Line.

It is not advisable for both an independent laboratory and the local regulatory boards to undertake compliance testing, because this doubles the cost of testing and may produce conflicting results.

Regulatory boards may waive their right to test condoms and be willing to accept the results of the testing laboratory.

Step 13: Customs Clearance

It is advisable to know the procedures for custom clearance before a contract is awarded to the supplier. The purchase contract should identify all customs documentation requirements the supplier needs to provide for the shipment to clear customs and avoid leaving condoms sitting on the dock. Dock delays not only incur demurrage charges, but also can damage the condoms if they are not stored properly.

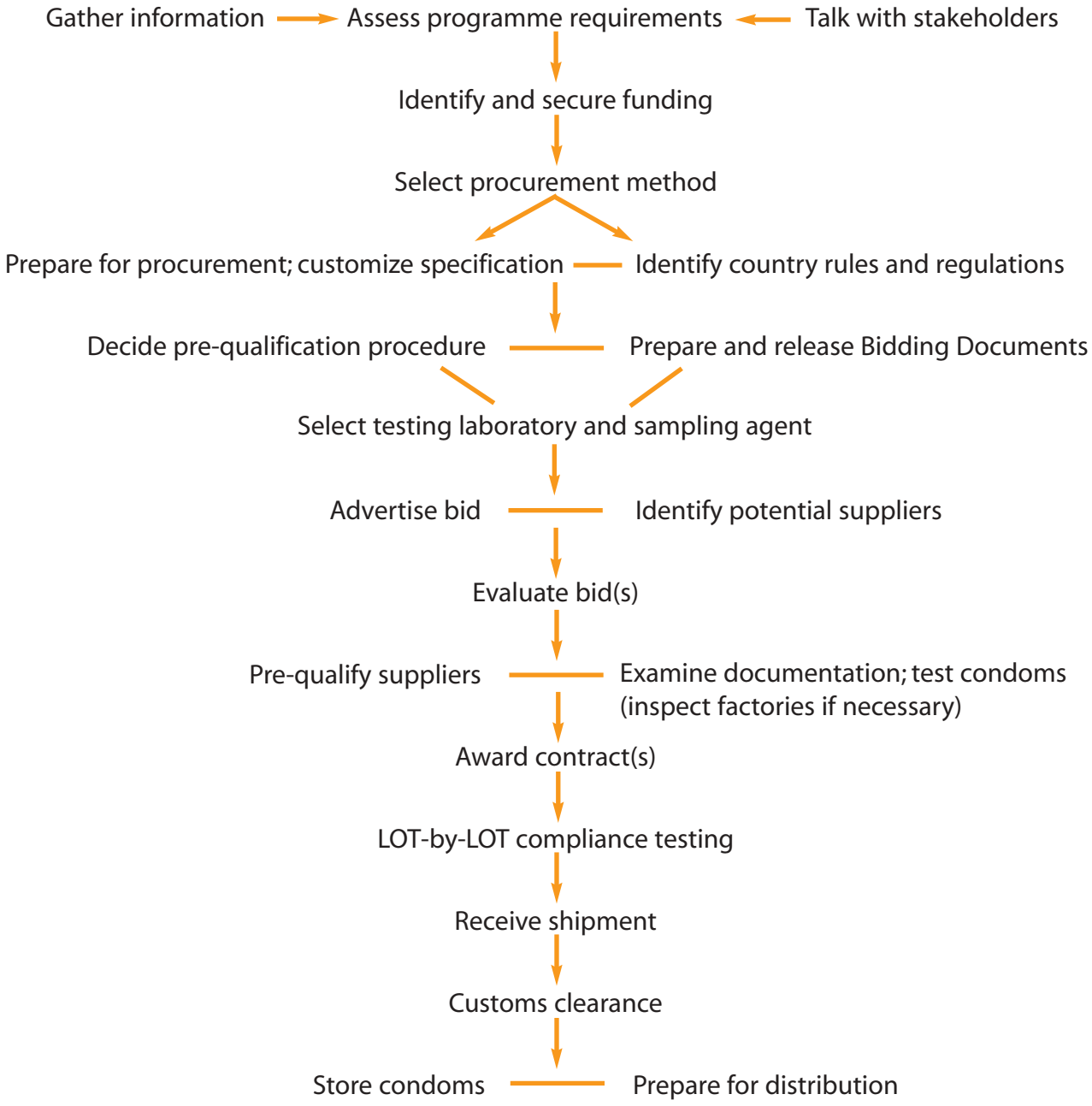
Step 14: Storage

Research has demonstrated that properly packaged, good-quality condoms do not deteriorate when stored at average temperatures found in tropical climates. Air conditioning is not necessary if the condoms are properly packaged and stored in a clean, dry, well-ventilated environment. They must not come into contact with oil, petrol, water or ultraviolet light.

If quality assurance measures have been followed during the procurement process, conditions of warehousing and storage play a major role in ensuring that quality condoms received reach the user in good condition. Condoms are protected with individual packaging, inner boxes and outer cartons. They should be left in their original packaging while in storage. The LOT number and marking on the cartons should be recorded to ensure that every LOT is traceable and distributed on a first in–first expiry basis (FI–FE).

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*.

Figure 2: Condom Procurement Steps



CHAPTER SIX
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: Assess programme requirements Do you know: History of 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?			
History of condom procurement over the last three years?			
History of previous shipments?			
Trends in condom procurement?			
Problems encountered in the procurement of condoms?			
Length of previous procurement cycles?			
Current stock levels and where condoms are stored?			
Projected time-scale for distribution?			
Your projected requirements?			
Time-scale for delivery?			
Storage and distribution system in place?			
Step 2: Identify and secure funding Do you know the procedures to secure funds?			
Record the procedures and tick off when completed:			
Step 3: Select procurement method Select one method: a) Directly from the manufacturer using a competitive bidding system			
b) Procurement agency			
c) International agency			
d) Social marketing organization			

Procurement Checklist

Step and Checklist	Yes	Date Completed	Comments/Notes
Step 4: Prepare for procurement; customize specification			
Refer to the *Model Specification* and specification checklist			
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			
Step 5: Identify country rules and regulations			
National regulatory authority visited			
Customs visited			
Regulations covering the national regulatory procedures, importation and distribution of condoms reviewed			
Step 6: Preparation and release of Bidding Documents			
Method of procurement agreed upon			
Set of Bidding Documents prepared			
Decisions on pre-qualification procedures made			
Information on potential suppliers collected			
Accredited testing laboratory selected			
Sampling agent selected			
Are pre-qualification procedures specified and costed?			
Are compliance testing procedures specified and costed?			
Is the procedure for the resolution of disputes specified?			
Prepare the Bidding Document package			
Step 7: Advertise bids			
Media for advertising bids known			
Bids advertised			

Procurement Checklist

Step and Checklist	Yes	Date Completed	Comments/Notes
Step 8: Evaluate bids Criteria for evaluating bids agreed upon			
Is assistance required to review and interpret documentary evidence supplied by manufacturers?			
Is the supplier evaluated on: -- Capacity to supply			
-- Quality of the product			
-- Price			
Do you have a short-list of suppliers?			
Have the suppliers agreed to allow the pre-qualification, sampling and compliance testing procedures?			
Have the suppliers agreed to the resolution of disputes procedures?			
Step 9: Pre-qualification of suppliers Is assistance required to examine documentary evidence? (Contact Help-Line).			
Has the sampling agency selected the samples of condoms?			
Have the laboratory reports been received?			
Is assistance required to interpret results? (Discuss with laboratories or contact Help-Line).			
Is a factory inspection required?			
Do you have an individual with extensive knowledge and practical experience of the manufacturing process to undertake the visit? (Contact Help-Line).			
Step 10: Selection of supplier; award of contract Is supplier selection based on: -- Capacity to supply			
-- Quality of the product			
-- Price			

Procurement Checklist

Step and Checklist	Yes	Date Completed	Comments/Notes
Step 11: LOT-by-LOT compliance testing Are arrangements made for every LOT manufactured to be sampled and tested for compliance with the specification prior to shipping?			
Are you conforming to your regulatory requirements?			
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?			
Step 12: Receipt of shipment Do you know the delivery schedule?			
Do you know the customs clearance procedures? Do you have all the appropriate information and forms required for customs clearance?			
Does the regulatory board require confirmatory testing?			
If yes, have sampling procedures and testing regime been agreed upon ?			
Is the regulatory board familiar with the process for resolving disputes?			
Step 13: Customs clearance and storage Has the delivery schedule been reconfirmed?			
Is the customs clearance procedure known?			
Has all 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?			
Step 14: Storage Clean, dry, well-ventilated environment?			
No contact with oil, petrol, water, ultraviolet light?			
Original packaging with manufacturing markings?			
Stored on the basis of first in – first expiry out?			

CHAPTER SEVEN
Specification Checklist

Refer to Section 1, Chapter 2 — Model Specification for Male Latex Condoms.

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

Specification Checklist

Step	Checklist	Action	Comments/Notes
1	Are the condoms for:		
	-- Social marketing programmes		
	-- Public sector		
	-- Both		
2	Target population:		
	-- Family planning programmes		
	-- STI/HIV/AIDS prevention programmes		
	-- Specific populations groups		
3	What are the regulatory requirements? (Refer to Procurement Checklist.)		
	What are the customs clearance requirements?		
	-- Clearance		
	-- Exemptions/waivers		
	-- Documentation required		
	What are the programmatic requirements?		
4	Where are stocks of condoms held?		
	How long will existing stocks last?		
	Are priority areas 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	Refer to procurement checklist		
	Sampling agency and testing laboratory selected		
	Testing regimes for pre-qualification and compliance testing established		

Specification Checklist

Step	Checklist	Action	Comments/Notes
6	Prepare specification		
	General requirements specified as detailed in *Model Specification*		
	Performance requirements specified as detailed in the *Model Specification*		
7	Prepare specification		
	Check design requirements: -- Colour — indicate pigment and discuss with manufacturer		
	-- Scent and flavouring — if fragrance is required add to specification and discuss with manufacturer		
	-- Shape and texture		
	-- State width (49 mm, 53 mm, 58 mm)		
	-- State length (160/180/190 mm)		
	--Thickness as recommended in the *Model Specification*		
	-- Lubricant as recommended in the *Model Specification*		
8	Prepare specification		
	Check packaging requirements		
	Individual packaging and markings packaging according to *Model Specification*		
	Language agreed to by manufacturer		
	Individual package foil markings: -- Manufacturer's name and address		
	-- Expiry date and date of manufacture		
	-- LOT number		
	-- Other references required by regulatory authority		
	-- Shelf-life (not less than 3 and not more than 5 years)		
	What additional foil markings are required? -- AIDS Help-Line		
	-- Licence number		
	-- Not for sale		
	-- Instructions for use and disposal		

Specification Checklist

Step	Checklist	Action	Comments/Notes
9	Prepare specification		
	Check packaging foil design: -- Colour (Pantone number)		
	-- Font		
	-- Logo		
	-- Style		
	-- Foil colour		
	-- Foil shape		
	Foil approval — what procedure to follow?		
10	Prepare specification		
	Check packaging requirements		
	Inner boxes and outer cartons according to *Model Specification*		
	Markings of inner boxes and cartons according to *Model Specification*		
	Inner pack quantity — 100/144		
	Any additional requirements: -- Logo?		
	-- Address of procuring agency?		
	-- Donor logo?		
11	Consumer packs specified by purchaser: -- Wallet size and design		
	-- Number per strip		

ANNEXES

ANNEX I TECHNICAL BASIS FOR THE MODEL SPECIFICATION

1 Introduction

The *Model Specification* is based on recommendations made during a WHO/UNFPA/UNAIDS/AFRO/FHI Informal Technical Consultation held in Johannesburg, South Africa, in May 2002. Thirty-two participants from 14 countries in Africa, Asia and South-East Asia attended the three-day meeting. The participants were selected because they represented a broad range of interested parties, donors, international agencies, non-governmental agencies, HIV/AIDS prevention programme managers, policy-makers, manufacturers, testing laboratories, sampling agencies, independent experts and research institutes.

During the meeting the participants reviewed the work of the ISO Technical Committee, ISO/TC/157, responsible for the revision of the recently published *ISO/4074: 2002 — Standard for the Male Latex Condom*. They also referred to three technical background documents prepared for the meeting. The first document, prepared by Dr. William Potter, focused on reviewing the evidence base for the *Specification and Guidelines for Condom Procurement*. References from these papers have been included in the bibliography of this annex.

A second paper, prepared by Dr. John Gerofi, reviewed the available information on whether two sizes of condoms meet the needs of all potential users. This topic has generated considerable debate, resulting in the conclusion that there is sufficient evidence to recommend a larger size of condom in the *Model Specification*. The third background paper was also prepared by Dr. Gerofi in conjunction with a number of experts. This paper reviewed the current literature on the safety and efficacy of condoms to prevent STIs. All papers will be published by WHO/RHR as technical reference papers and will be available on the WHO/RHR web site in 2004.

The Informal Technical Consultation was structured to ensure a series of frank discussions regarding:

- The technical basis for developing the *Model Specification*
- The quality assurance issues that should be understood by policy-makers and programme managers
- The development of practical procurement guidelines

A report of the Informal Technical Consultation is available from the WHO Department of Reproductive Health and Research.

This annex is designed to explain the technical basis for the *Model Specification*.

2 Requirements

2.1 General Requirements

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*. The safety assessment must include any dusting powder, colorant, lubricant and any other material that is added to the condom. A dossier containing the safety assessment shall be made available to prospective purchasers.

Manufacturers may rely upon regulatory clearance from internationally recognized regulatory bodies to substantiate the safety of their products. Examples of acceptable approvals include a 510(k) clearance to market the product from the 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.

Latex proteins have been implicated in type I allergic reactions in some individuals, although the incidence of allergic reactions associated with condom use is extremely rare. One report cites the incidence of latex protein allergy amongst condom users to be 0.08%[1]. Manufacturers shall take every precaution through effective leaching and washing of the product to maintain low levels of residual extractable proteins.

Shelf-life

Methods of assessing the shelf-life of latex condoms have been researched and considered in detail by ISO/TC/157 WG13. At present, there is no reliable method of predicting the shelf-life of condoms from accelerated ageing studies. For this reason ISO/TC/157 has recommended the following:

- Condoms shall meet the minimum stability requirements specified in *ISO 4074:2002*, Section 7.2.
- Manufacturers shall determine the shelf-life of the product by conducting real-time stability studies at (30-2+5) °C[i] to demonstrate that the condoms meet the airburst properties defined in Section 6.1 of *ISO 4074:2002* throughout the declared shelf-life of the product.
- Pending the outcome of the real-time studies, manufacturers may rely upon accelerated ageing studies conducted at elevated temperatures to estimate the shelf-life of the product.

Condoms shall comply with the performance requirements of this *Model Specification* throughout the stated shelf-life. Manufacturer shall stipulate a shelf-life based on the outcome of stability studies and measured from the date of manufacture. The stated shelf-life shall be not less than three years and not more than five years from the date of manufacture. The upper limit of five years has been set as a precaution, but manufacturers are encouraged to target shelf-lives in excess of this period.

Methods of conducting stability studies are given in Section 7 of *ISO 4074:2002*. Recent studies have shown that changes in the physical properties of condoms that occur at temperatures more than 50 °C to 60 °C may differ significantly from those observed in ageing studies conducted at 30 °C. In general a gradual decline in airburst volume is observed with many types of condoms when samples are aged at 30 °C, whereas at temperatures in excess of 50 °C to 60 °C the airburst volume remains relatively constant and the burst pressure falls. Caution should therefore be exercised when extrapolating shelf-life estimates from accelerated ageing studies conducted at elevated temperatures, particularly if these studies include results obtained at temperatures above 60 °C.

Shelf-life estimates based on accelerated studies shall be referenced to a storage temperature of 30 °C and real-time studies shall be conducted at (30-2+5) °C[i]. This temperature has been selected as the mean kinetic temperature of the most extreme climatic zone IV[2–3].

Minimum Stability Requirements

Given the lack of a reliable method of estimating the shelf-life from accelerated ageing data, ISO/TC/157 has determined that all condoms shall meet minimum stability requirements before being placed on the market. These requirements are specified in Section 7.2 of *ISO 4074:2002*. They include accelerated conditioning regimens at 50 °C and 70 °C. 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. The minimum stability test can be commenced as part of the pre-qualification stage of the procurement procedure and must be completed before any contract is confirmed. This test forms part of the normal pre-qualification procedure and is an *ISO 4074:2002* requirement.

2.2 Performance Requirements

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 test and requirements in this section are identical to those in ISO 4074:2002. The pass/fail criterion is based on constraining the number of condoms bursting below the limits stated. The relevance of the test to the performance of the condom in use has been explored in many articles[4–8].

Freedom from Holes and Visible Defects

A condom with a hole in it is clearly defective. The methods for testing for freedom from holes are identical to those in *ISO 4074:2002*, as are the requirements. These test methods have been in use for condoms for many years.

[i] That is, in the temperature range 28 °C to 35 °C.

There are two alternative tests, a visual test in which the condom is filled with water and inspected for leakage, and a conductivity test in which the condom is filled with a salt solution, is immersed in a tank containing salt solution and 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 European-funded study[9].

Several studies have investigated the viral barrier properties of condoms that pass the tests for freedom from holes[10–14]. These studies have demonstrated that intact condoms are, for all practical purposes, an effective barrier to the smallest viruses.

At the time that testing for freedom from holes is being done, *ISO 4074:2002* also requires that the condoms are examined visually for specified visible defects that may render the condom likely to fail in use. Such defects include broken, missing or severely distorted bead, or permanent creases with adhesion of the film (see Section 1, Chapter 3 — Workmanship and Visible Defects).

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, ultraviolet and visible light increases the risk of degradation of the condom.

The test adopted is identical to that in *ISO 4074:2002*. 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.

2.3 Design Requirements

The recommended design features are specified but some of them 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.

Shape and Texture
The traditional parallel-sided (cylindrical) condom shape has been in the WHO specification since its inception. 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[15–16] indicate that approximately equal proportions of people preferred the variants covered in the trials.

The parallel-sided condom is the easiest and cheapest to manufacture, but it is also possible to use some of the alternative shapes found in the commercial market. The design details of shaped condoms are specific to particular manufacturers who have the appropriate moulds. Selecting a particular non-parallel profile may thus reduce the range of possible suppliers.

There is no published data on the safety and efficacy of textured condoms. These may have dots, ribs, or other patterns on them. Anecdotal information from testing laboratories suggests that they are more likely than smooth condoms to fail critical test requirements and have therefore not been recommended in this specification.

Integral Bead
The integral bead (or rim) is a ring of rubber at the open end of the condom. It ensures the structural integrity of the open end.

Colour
Pigments may be added to the latex formulation. They need to be selected so 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.

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 of 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.

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.

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

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

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[ii]. Condoms of width 49 mm are readily available from many manufacturers, and this is therefore the preferred size for a smaller condom. There is no recognized "standard" size for larger condoms although some manufacturers produce condoms of 56 mm width.

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.

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[17] and are likely to be less acceptable to users.

The method of determining thickness follows *ISO 4074:2002* and involves weighing a known area of the condom, then dividing by the density.

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.

Lubricant
Silicone fluid is recommended as the preferred lubricant. It is inert, has minimal effect on the properties of the latex film and is the most commonly used lubricant for condoms. The quantity used has been selected to give as high a level of lubrication as practical without creating 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.

Lubricant quantity is determined 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.

Using an additional lubricant with a condom may be useful in some cases. Research suggests that this is especially true in anal intercourse[17].

It should be noted that many household products are used as sexual lubricants. Some have a highly damaging effect on latex and should not be used with condoms.

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

Household products that should not be used with condoms:

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

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.[18]

Individual Package Materials and Marking

Although some newer plastic materials are relatively impermeable to oxygen, aluminium foil is the most commonly used barrier material. It is combined with plastics to provide strength and sealing. It is important that the packaging protects the condom from oxygen, ozone, ultraviolet light and visible light, is easy to open, and does not leak lubricant.

Marking requirements are intended to provide the minimum essential information for the consumer. They also help 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.

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ANNEX II GLOSSARY OF TERMS AND ACRONYMS

AQL	Acceptable quality level. Defined in *ISO 2859-1* (q.v.) as, when a continuing series of LOTS is considered, the quality level which for the purposes of sampling inspection is the limit of a satisfactory process average.
Acceptance Number	The highest number of non-compliers (failures) allowed in a specific test from a selected sample.
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. The acceptance numbers (D) can be calculated from the equations (see Annex III) for any specific AQL and aggregated sample size (N).
AFRO	WHO Regional Office for Africa.
Batch	Sometimes used alternatively in place of LOT (q.v.). WHO recommends LOT to 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, used to describe a quantity of individual raw materials.
Bead	The thickened ring formed at the end of the condom.
Bid Security	A guarantee from a bank that the bidder will perform its obligations in regard to the bid.
CDC	Centers for Disease Control and Prevention.
CE Mark	A mark on product packaging certifying that the product conforms to the essential requirements of the European medical device directive 93/42/EEC.
Compliance Testing	A regime of testing to verify that a LOT complies with the specification.
Condom	Medical device used by consumers, which 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.
Consumer Pack	A wallet or carton into which one or more foil packages are inserted for marketing purposes.
Design Requirements	Characteristics of the condom, which are specified according to the buyer's requirements.
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.
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 which are verified before supply commences and that are not expected to vary from LOT to LOT.
GMP	Good Manufacturing Practice. A code of practice covering all aspects of the manufacturing process, including the supply of raw materials, record-keeping, and a quality management programme, which is generally recognized to be essential to the production of uniform, high-quality products.
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. The higher the inspection level, the more samples will be tested, and hence the lower the risk of faulty products reaching the consumer.
IPPF	International Planned Parenthood Federation.
ISO	International Organization for Standardization.
ISO 2859-1	A specification for sampling plans indexed by acceptable quality level (AQL) for LOT-by-LOT inspection.
ISO 4074	The standard for male latex condoms published by ISO (q.v.).
ISO 9000	A series of standards issued by ISO (q.v.) that is used for certifying that a manufacturer employs GMP (q.v.).
JSI	John Snow, Inc.
Length	The length of the condom measured from the open end to the tip, excluding any reservoir.
LOT	A quantity of condoms of a single grade, class, size and composition, manufactured under essentially the same conditions. With certain exceptions, all the condoms comprising a LOT will have identical formulation, the same dimension, colour, shape, and surface texture, be manufactured on the same production line, be vulcanized under the same conditions, and be manufactured within a period of 24 hours.
LOT Number or Code	A unique identifying alphanumeric code assigned to a LOT.
Manufacture Date	The date of production. For condoms, the manufacture date is the “dip date”.

National Regulatory Body	A regulatory body (q.v.) with authority in a specific country to control the importation and distribution of medical products.
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.
Performance Security	A guarantee by a bank that the supplier will perform its obligations in regard to the contract.
Process Average	The percentage of defects calculated for each requirement detailed in the *Model Specification* by dividing the total number of defective condoms found by the total number of condoms tested.
Pre-qualification	The steps taken by a buyer to verify a manufacturer's suitability to supply condoms of the required quality. Can consist of factory inspection, scrutiny of documentation and product testing.
Pre-shipment Test	A test, usually a regimen of compliance tests, carried out before a shipment leaves the supplier's factory.
PSI	Population Services International.
Random Sample	A sample of condoms drawn randomly from a LOT for testing purposes.
Regulatory Body	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.
Reservoir	The narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.
Sampling Plan	A specific plan that indicates the number of units (condoms) from each LOT that are to be inspected (sample size) and the associated criteria for determining the acceptability of the LOT (acceptance and rejection numbers).
Shelf-life	The period of time after manufacture that the product is considered acceptable for use.
Social Marketing	The use of commercial marketing techniques to promote and distribute products and services of social importance.
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 body.
UNFPA	United Nations Population Fund.
USAID	United States Agency for International Development.
USFDA	United States Food and Drug Administration.
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 III 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 the 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.

In general, it is most important to monitor the performance related to the quality 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 given as follows.

1. Process Average

The percentage of defects is calculated for each requirement detailed in the *Model Specification* by dividing the number of defective condoms by the total number of condoms tested. The percentage defects for each LOT can then be plotted against LOT number or any other appropriate parameter such as date of manufacture. Plotting has the advantage that any trends in quality can be easily seen and addressed.

More sophisticated methods of constructing charts to monitor process average are available. For example, warning and control limits can be added. Cumulative sum (cusum) control charts can also be used. In these charts the cumulative difference between the expected number of defective condoms found in each test and the expected number assuming that the process is in control 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. Refer to a standard textbook on quality control procedures or statistics for more information. Procedures for producing these charts are also given in a series of ISO standards: *ISO 7870:1993* is a general guide and introduction to control charts; *ISO 8245:1991* describes Shewart charts and includes techniques for charting attribute data; and *ISO 7966:1996* describes acceptance charts. Cusum charts are described in parts 1–4 of *BS 5703*.

2. Aggregate Analysis

Aggregate analysis is 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 the accept/reject numbers for the total sample size obtained by aggregating the results from a number of LOTS. 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 + 8N0.55)
AQL 1.0	D = 0.01(1.0N + 17N0.55)
AQL 1.5	D = 0.01(1.5N + 22N0.55)
AQL 2.5	D = 0.01(2.5N + 30N0.55)
AQL 4.0	D = 0.01(4.0N + 36N0.55)

For additional advice on calculating and using these acceptance numbers, please contact the Help-Line.

Exercise caution when using this method. The overall picture can be biased if a small number of LOTS with very poor quality are found within an otherwise acceptable series of LOTS. Remember that the aggregate analysis is still biased in favour of the manufacturer who retains at least a 95% probability of having marginal batches accepted. 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.

3. Number of LOTS Rejected

Another approach is to review the number of LOTS rejected in 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 highlight 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 past history. The switching rules are not generally used within 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.

ANNEX IV APPLICABLE DOCUMENTS

Various external documents form part of the *Model 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.

A 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
Case Postale 56
1211 Geneva 20
Switzerland

Testing Methods

ISO 4074, Annex C	Determination of Total Lubricant for Condoms in Individual Containers
ISO 4074, Annex D	Determination of Length
ISO 4074, Annex E	Determination of Width
ISO 4074, Annex F	Determination of Thickness
ISO 4074, Annex G	Determination of Bursting Volume and Pressure
ISO 4074, Annex H	Oven Treatment of Condoms
ISO 4074, Annex I	Determination of Force and Elongation at Break
ISO 4074, Annex J	Determination of Shelf-life by Real-time Stability Studies
ISO 4074, Annex K	Guidance on Conducting and Analysing Accelerated Ageing Studies
ISO 4074, Annex L	Testing for Holes
ISO 4074, Annex M	Tests for Package Integrity

Sampling

ISO 2859-1	Sampling Procedures and Tables for Inspection by Attributes

Labelling of Shipping Cartons

ISO 780	Packaging — Pictorial Marking for Handling of Goods

Good Manufacturing Practice

ISO 9000	Quality Management and Quality Assurance Standards
ISO 9001	Quality Systems — Model for Quality Assurance in Design/Development, Production, Installation and Servicing
ISO 9003	Quality Systems — Model for Quality Assurance in Final Inspection and Test
ISO 9004	Quality Management and Quality System, Elements and Guidelines

B Other Publications

The following additional documents form part of the *Model 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* USCFR 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

ANNEX V SELECTED METHODS FOR REDUCING TESTING COSTS

However stringent the testing, it is impossible to guarantee that a consumer will never receive a condom that does not comply with the specification. The purpose of the comprehensive testing regime recommended by WHO is to reduce to a very minimum the likelihood of defective condoms reaching the consumer.

Some buyers have remarked that testing adds a significant surcharge to the cost of condoms procured with scarce funds and have questioned whether this cost burden could not be mitigated by a less onerous testing procedure.

The answer is that some manufacturers, while capable of delivering good-quality condom LOTS, do not do so consistently, and the knowledge that their customers are carefully testing every LOT provides a powerful incentive to keep their production quality at the highest level.

On the other hand, there are other manufacturers who routinely deliver condoms well within the limits of the specification and, for these, LOT-by-LOT testing may seem an expensive way of confirming that their performance is meeting the buyer's expectations.

A number of alternative test regimes have been described in quality control reference books, and some have been used for condom testing. While it is possible that some of these methods may save money on testing costs, it is also possible that some of them, in certain circumstances, could add to testing costs.

Some of these methods are described here, with comments on the possible benefits and problems associated with them. Condom buyers considering implementing any of them should first consult an experienced condom testing laboratory, a reputable statistical quality control consultant or both.

Reduction in the total number of condoms tested is the source of the possible cost-savings. The other consequences of this reduction are a greater uncertainty of the test results, especially the process average, and increased complexity of procedures. This complexity gives rise to greater administrative costs and to greater risk of error in the operation of the scheme.

WHO advises that no reduced level of testing, or alternative procedure, be introduced until the buyer is completely satisfied that the manufacturer can normally be relied on to provide condoms consistently in compliance with the specification.

1 ISO Reduced Sampling

ISO 2859 provides for a system of reduced inspection levels that, in the case of a good-quality supplier, can theoretically reduce the cost of testing.

The problem with this method is that the work of the testing laboratory is continuously contingent on the results of the consignment so far and can require frequent switching of inspection levels during the testing of a consignment. This increases the need for communication among the buyer, sampling agency and testing laboratory; it can lead to long and costly delays, especially when the various parties to the procurement are in different countries.

Disputes can arise regarding the order of testing, especially if the laboratory tests more than one LOT in parallel, since the order of processing results can change the fate of LOTS. Inherent in the procedure is the provision of one seriously flawed batch to be accepted before normal sampling is resumed.

The method involves a greater administrative overhead on the part of the testing laboratory. Cost-savings may therefore be considerably less than expected.

2 Double or Multiple Sampling

Double and multiple sampling are techniques provided by *ISO 2859* for streamlining the burst and leakage tests in certain circumstances.

For double sampling, the sample is divided into two, and for multiple sampling, it is divided into seven. In total, the sample sizes are greater than in single sampling.

Each part of the divided sample is tested in turn and, at each stage but the last, the outcome can be pass, fail or no decision. In the last case, the next part of

the sample is tested, and so on until the test result is a clear pass or fail.

Double and multiple sampling are relatively simple schemes, which also retain a sample size sufficient to give a good estimate of process average for the performance tests.

3 Factory Monitoring

Factory monitoring consists of using the laboratory of the factory as the testing house and applying controls through audit testing, witnessing tests, reviewing in-process test data and verifying calibration.

The inspector must be an experienced independent testing expert. His or her arrival at the factory must always be unannounced, and he or she must always take a suitable sample for independent audit testing.

This method can be appropriate when large orders are placed with a single supplier and the supplier's factory is going to be fairly continuously occupied in producing the orders.

4 Skip-LOT Testing

This method involves testing only some LOTS (say, one in three) in a shipment, instead of every LOT. Sampling levels and test requirements are the same.

The assumption underlying skip-LOT testing is that the quality of the untested LOTS is equivalent to those that are tested.

Before skip-LOT testing is commenced, a complete shipment of not less than 10 LOTS must pass all tests.

At the same time, the entire shipment is subjected to the aggregate analysis described in Annex III, Part 2. Samples are drawn from every LOT and sent to the testing laboratory, which is instructed to test only the agreed proportion. The remainder of the samples are set aside in case it is necessary to resume more intensive testing due to failure.

If any LOT fails one of the performance tests, full LOT-by-LOT testing is resumed immediately for all LOTS making up the shipment. The procedure of validating for skip-LOT testing must then be repeated before going back to skip-LOT testing.

If a LOT fails a non-critical specification test, further action will be at the purchaser's discretion.

If it becomes necessary to make frequent switches between skip-LOT and full testing, it means that the supplier is not maintaining a consistent quality level and is not suitable for skip-LOT testing.

ISO 2859-3 provides an alternative approach to skip-LOT sampling. However, the implementation is relatively complex.

ANNEX VI 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.
Training Division
St. Nicolas House, St. Nicolas Road
Sutton, Surrey SM1 1EL
UK
enquiries@crownagents.co.uk

Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709
USA
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 rue de Varembé, Case postale 56
CH-1211 Geneva 20
Switzerland
central@iso.org
http://www.iso.org

John Snow, Inc.
Training Administrator, Family Planning
Logistics Management Project
1616 North Fort Myer Drive
Arlington, Virginia 22209
USA

Population Action International
1300 19th Street N.W., Second Floor
Washington, DC 20036
USA
pai@popact.org

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

Program for Appropriate Technology in Health (PATH)
Publications
1455 N.W. Leary Way
Seattle, WA 98107
USA
publications@path.org

UNAIDS
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
unaids@unaids.org

UNFPA
Technical and Evaluation Division
Reproductive Health Branch
220 East 42nd Street
New York, NY 10017
USA
http://www.unfpa.org/procurement7
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
lamberts@who.int
http://www.who.int/reproductive-health

ANNEX VII LIST OF MANUFACTURERS AND TESTING LABORATORIES

These lists are provided for the information of the reader and may not be comprehensive.

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Manufacturers

Ansell Healthcare
P.O. Box 1252
1500 Industrial Road
Dothan, Alabama 36303
USA

Ansell, Ltd. (Thailand)
Industrial Estate 110, M004
Chalongkrung Road
Bangkok
Thailand 10520

Ansell Shah Alam Sdn Bhd
Lot 16, Persiaran Perusahaan
Section 23, Shah Alam
Selangor Darul Ehsan
Malaysia 40000

Ansell/Suretex Prophylatics, Ltd.
Plot No. 74 to 91, Kiadb Industrial Estate
Jigani II, Phase Anekal Taluk
Bangalore 562 106
India

ARMKEL, Inc.
1851 Touchstone Road
Colonial Heights, Virginia 23834
USA

Beiersdorf (Malaysia) Sdn Bhd
Karung Berkunci No 786
80990 Johor Baru
Malaysia

Bimacom Perdana Rubber Industry
Wisma BCA, 5th Floor
Jalan Jend. Sudiman Kav
Jakarta 12920
Indonesia

Blowtex, Fabrica de Artefaos de Latex, Ltd.
Estrada do Briquituba
550-Caixa Postal 01
18125-000 Aluminio
Sao Paulo
Brazil

Carter-Wallace, SA
Calzada de las Armas 110 — Fracc.
Industrial Las Armas
Tlalneplantla, Edo. De Mexico
Mexico C.P. 54080

Chinteik Hygiene Products Co., Ltd.
60/50 Navanakorn Industrial Estate
Zone 2, Phaholyothin Road
Pathumthani
Thailand 12120

CPR Productions-Und Vertiebs GmbH
Im Kirchenfelde 8
31157 Sarstedt
Germany

Cupid Rubbers, Ltd.
A68, M.I.D.C.
Sinnar, Malegaon Nashik
India

Custom Services International
3111 West Post Road
Las Vegas, Nevada 89118
USA

Da Lian Latex Factory
188 Ma Lian Bei Jie
Sha He Kou District
Da Lian 116021
People's Republic of China

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Dongkuk Techno Rubber Industries Sbn Bhd
Lot 31, Bakar Arang Industrial Estate
Sungai Petani
Kedah
Malaysia 08000

Dongkuk Trading Co., Ltd.
Dongkuk Building 556-27
Sinsa-dong S1 Kangam
P.O. Box 270
Seoul
Korea

Eisai Company, Ltd.
Overseas Operations
6-01 Kolshikawa
4-Chome Bunkyo-ku
Japan

Everts Erfurt GmbH
Tiergartenstr.2
99089 Erfurt
Germany

Fuji Latex Co., Ltd.
Tochigi Plant
150 Kou-Machi
Tochigi-city Tochigi-Pref 328
Japan

G P Prophylactics SA Pty, Ltd.
P.O. Box 22665
Southgate Piertermaritzburg
South Africa

Greenmate Medical Supplies Corp.
1143-10 Seocho Dong
Seocho Ku
Seoul
Korea

Guang Zhou Latex Factory
90 Gong Ye Da Dao Bei
Hai Zhu District
Guang Zhou
Republic of China

Guilin Latex Factory
No. 6 Wushan Road
Guilin, Guangxi 541001
Republic of China

Hanarum Rubber Tech. Sdn Bhd
No 9-12 Jalan Makmur 2, Taman Makmur
Industrial Area, 09600 Lunas
Kedah
Malaysia

Hankook Latex Gongup Co., Ltd.
622-1 Hupyeong Dong
Chunchon, Kangwon Do
Republic of Korea 200

Hatu S.P.A.
Divisione Articoli Ingienico Sanitari
Via Agresti, 40123
Bologna
Italy

Hindustan Latex, Ltd.
Kanagala, Belgaum District
Karnataka
India 591225

Hindustan Latex, Ltd.
Latex Blavan Poojapura
Thiruvananthapuram
India 695012

INDUS Medicare, Ltd.
Suyodaya 1-10-60/3 Begumpet
500 016 Hyderabad
India

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Industria Nacional de Artefatos de Latex, Ltd.
Av. Piracicaba, 137, Caixa Postal 213
181300-000, Marmeleiro-Sao Roque
Sao Paulo
Brazil

Innolatex Sdn Bhd
Lot 7395, Bukit Cherakah
Shah Alam, Selangor
Malaysia 40150

J. K. Chemicals, Ltd.
Mahindra Towers, B-Wing, 2nd Floor
Pandurang Budhkar Marg, Worli
Bombay 400 018
India

Johnson and Johnson de Brasil
Industria e Comercio, Ltda.
Rod. Pres. Dutra, dm 157, Caixa Postal 184
12240-420 Sao Jose dos Campos-SP,
CEP 12237-350
Brazil

Karex Industries Sdn Bhd
PTD 7906 & 7907
Taman Pontian Jaya
Bt 34, Jalan Johor
82000 Pontian Johor
Malaysia

Laboraotorios Hispano-ICO SA
Puerto Principale 68, 08027
Barcelona
Spain

Latex Surgical Products (PTY), Ltd.
Pieterwessels Street
Stafford Ext, 4 Gauteng
P.O. Box 57037
Springfield 2137
South Africa

London Royal Consumer Products
Wellgrow Industrial Estate
100 Moo5
Bangna-Trad KM36
Bangpakong, Chachoengsao 24130
Thailand

Lord Hygiene-Curafam GmbH
Im Schlangengarten
76877 Offenbach/Landau
Germany

LS Rubber Sdn Bhd
PLO 22, Senai Industrial Estate
Phase 1 Senai
Johor Bahru
Malaysia 81400

MAPA GmbH
Postfach 1260
D27392 ZEVEN
Germany

Mayer Laboratories, Inc.
646 Kennedy Street
Building C
Oakland, California, 94606
USA

Medical Latex (DA) Sdn Bhd
PLO 8, Senia Industry State
81400 Senai Johor
Malaysia

Medtech Health Products
8 Park View Road
United India Colony, Kodambakkam
Madras
India

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Medtech Products, Ltd.
S-59 20th Street
Ana Nagar West
Chennai
India 600 040

Mercator Healthcare
83-87 Mittal Tower B Wing
Mumbai MH
India 400 021

MPA Darmstadt
Staatliche Materialprüfungsanstalt
Darmstadt, Grafenstr. 2
64283 Darmstadt
Germany

Okamota Industries, Inc.
1 Nishiyama
Itabashi-Cho Ryugaski, Ibaraki Pref
Japan

Pashupati Seohung
15/1A Loudon Street
Calcutta 700 017
India

Polar Pharma India, Ltd.
Plot No. 3, Somnathpur Industrial Estate
Remuna, Balasora
Orissa
India

Pleasure Latex Products Sdn Bhd
Lot 1365, 17th Miles, Jalan Sungai
Sembilang 45800 Jaram
Slangor Darul Ehsan
Malaysia

Profilatex, S.A. de C.V.
Febrero de 1917, No 4 Chalco
Estado DeMexico
Mexico C.P. 56600

Proteccion SICO, S.A. de C.V.
Av. san Antonio 429
Col. San Pedro De Los Pinos
Mexico D.F. — C.P. 01180

Qingdao Shaung Die Latex Production Co., Ltd.
No. 103 Taidong 1st Road
Qingdao 266022
Republic of China

Remed S.A.
Chaussée Alsemberg 1001
B-1180 Brussels
Belgium

RFSU
Bergvagen 8 A
S-186 41 Vallentuna
Sweden

Richter Rubber Technology
Plot 33, Kuala Ketil Industrial State
09300 Kedah
Malaysia

Ritex Gummiwarenfabrik GmBH
Postfach 180 182, 33691
Bielefeld
Germany

Sagami Industries (Malaysia) Sdn (Berhad)
Jalan Kilang Tiga Jelapang Light
Industrial Estate Box 387
30750 Ipoh
Malaysia

Sagami Rubber Industries Co., Ltd.
Rubber Product Manufacturing Dept.
2-1 Moto-Cho, Atsugi City
Kanagawa-Pref. 243-0002
Japan

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Songpa
P.O.Box 88
Seoul
Korea

Shang Hai Latex Factory
1700 Huang Xing Road
Shang Hai
Republic of China

Shangrila Latex Industries
Munshi Manor
20 Altamount Road
Mumbai 400 026
India

Shen Yang Latex Factory
67 He Ping Bei Da Jie
He Ping District
Shen Yang
Republic of China

Shinheng Corporation
Yeongdong
P.O. Box 371
Seoul
Korea

Sime Healthcare Sdn Bhd
Lot 64-66 Senawang Industrial Estate
Seremban
Malaysia 70300

SSL Corporation (Marketing and Sales)
P.O. Box 926090
3585 Engineering Drive, Suite 200
Norcross, GA 30092-9214
USA

SSN Medical Products Sdn Bhd
No. 1 Jalan 203, Off Jalan Tandang
46050 Petaling Jaya, Selangor
Malaysia

Suretex, Ltd.
71 Sap Road, Sipraya, Bangrak
Bangkok
Thailand

Suretex Prophilatex (India), Ltd.
No 1483, 40th Cross, 18th Main, 4th T Block
Jayanagar, Bangalore 560 041
India

Takaso Rubber Products Sdn Bhd
K55 Jalan Kesang, Kawasan
Perindustrian, Tg Asas
8400 Muar
Johor Bahru
Malaysia

Thai Nippon Rubber Industries
49 Laem Chabang Industrial Estate Export Zone 1
Thunsukla, 20230 Sriracha Chonburi
Thailand

The Female Condom Company (Chartex)
1 Sovereign Park Coronation Road
Park Royal
London NW10 7QP
UK

Tian Jin Latex Factory
240 Shan Mar Road
Hebei District, Tian Jin
Republic of China

TTK-LIG, Ltd.
6 Cathedral Road
Chennai 600 086
India

UNIDUS Corp.
Seokyung Building., 51 Bang-1 Dong
Songpa-Ku
Seoul
Korea

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UNIMIL Co., Ltd.
ul. Towarowa 8
32-410 Dobczyce
Poland

UNIMIL Co., Ltd.
ul. Gesia 8
31-535 Krakow
Poland

Vonix P.T.
Jl Balik Papan 21 E
Jakarta, Pusat
Indonesia

Vulkan Akciova Spolecnost
46334 Hrádek nad Nisou
Czech Republic

The mention of specific companies or products from certain manufacturers does not imply that they are endorsed or recommended by WHO, UNFPA and UNAIDS in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

If there are any inaccuracies in the names and address of companies, or if the name of your company has not been included in the list, please contact:

World Health Organization
Family Planning and Population
Division of Reproductive Health Technical Support
Avenue Appia
1211 Geneva 27
Switzerland

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Testing Laboratories and Other Services

Akron Rubber Development Laboratory
2887 Gilchrist Road
Akron, Ohio 44305
USA

Apoteket AB
Prismavagen 2
SE-141 75 Kungens Kurva
Sweden

Apoteksbolaget, AB
Centrallaboratorlet (ACL), 105 14
Stockholm
Sweden

Crown Agents Services, Ltd.
St Nicholas House, St. Nicholas Road
Sutton,Surrey SM1 1EL
UK

EMPA St. Gallen
Lerchenfeldstrasse 5
CH-9014 St. Gallen
Switzerland

Enersol Consulting Engineers
235 Nelson Street
Annandale, NSW 2038
Australia

Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709
USA

Instituto Nacional de Tecnologia
Avenida Venezuela nÏ82 sala 108
Rio de Janeiro RJ, CEP 20081-310
Brazil

Institut National de la Consommation
80 rue Lecourbe
75732 Paris Cedex 15
France

Interconform Testing Services
P.O. Box 8329
Bonaro Park 1622
South Africa

L.A. Falcao Bauer
Rue Aquinos 111, 05036-070
Sao Paulo SP
Brazil

Laboratoire National d™Essai (LNE)
1 rue Gaston Boissier
75724 Paris Cedex 15
France

Program for Appropriate Technology in Health (PATH)
1455 N.W. Leary Way
Seattle, Washington 98107
USA

PSB Corporation
Testing Group
1 Science Park Drive
Singapore, 118221
Singapore

Rubber Research Institute of Malaysia
Department of Chemistry & Technology
260 Jalan Ampang
50450 Kuala Lumpur
Malaysia

SGS India, Ltd.
General Laboratory
SGS Lab House
21 New Street, Kottur
Channai, 600 085
Madras
India

Smithers Scientific Service, Inc.
425 West Market Street
Akron, Ohio 44303
USA

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Appearance on these lists does not imply endorsement by WHO, UNAIDS or UNFPA.

Societe Generale de Surveillance
1 Place des Alpes
P.O. Box 2152
1211 Geneva
Switzerland

South African Bureau of Standards (SABS)
1 Dr Lategan Road, Groenkloof Private Bag X191
ZA — Pretoria 0001
South Africa

Swiss Federal Laboratories for Materials
Testing and Research (EMPA)
Unterstrasse 11, 9001
St. Gallen
Switzerland

Tanda Associates
P.O. Box 91091
Bayview Village Post Office, North York
Ontario M2K 2Y6
Canada

Thai Industrial Standards Institute
Standards Bureau 3
Rama VI Street
10400 Bangkok
Thailand

Valendor AB
Hjälmstavägen 8
SE-186 41 Vallentuna
Sweden

Vimta Labs, Ltd.
74 G N Chattv Road (Near Panagai Park)
600 017 Chennai
India

Zimbabwe Regional Drug Control Laboratory (ZRDCL)
106 Baines Avenue
P.O. Box UA
319 Union Avenue
Harare
Zimbabwe

The mention of specific companies or products from certain manufacturers does not imply that they are endorsed or recommended by WHO, UNFPA and UNAIDS in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

If there are any inaccuracies in the names and address of companies, or if the name of your company has not been included in the list, please contact:

World Health Organization
Family Planning and Population
Division of Reproductive Health Technical Support
Avenue Appia
1211 Geneva 27
Switzerland

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ANNEX VIII BIBLIOGRAPHY

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